Information notice – pre-registration phase (all) – V4 (15/10/2020)
ID No. – RCB: 2020-A00172-37

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

Trial sponsor: Côte d'Azur University
Head of research: Prof. Fabienne d'Arripe-Longueville, Laboratoire Motricité Humaine, Expertise, Sport Santé [*Laboratory of Human Motricity, Expertise, Sport, and Health*] (EA 6312), Côte d'Azur University
Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

Madam,
We would like to offer you the opportunity to participate in a clinical research study because you are undergoing a bariatric surgery procedure.
This information notice will tell you more about the study.
You have a 7-day reflection period during which you can take the time to read and understand this information, reflect on your participation, and ask the principal investigators of the study to explain what you did not understand.

PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.
Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up.
The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

You will be monitored through physical and psychological assessments. You will be included in a group at random. This random selection will be made by the person in charge of the study as soon as you return this information letter and the signed consent form. In order to guarantee the scientific validity of the study, you will then receive the information corresponding to the group in which you are assigned.

Assessments will take place upon inclusion in a group (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

The questionnaires to which you will be submitted can be filled in online on the *LimeSurvey* platform. You will receive an e-mail with the link to the questionnaire and a reminder of your anonymity number. If you have difficulty completing the questionnaires on the *LimeSurvey* platform, you can also complete them on paper during the physical assessments. The questionnaires will be used to evaluate:

- Self-reported physical activity level
- Observance and motivation:
  - The number, duration and type of physical activity sessions per week according to international recommendations.
  - Physical exercise habits and history
  - The stage of engagement in practice
  - Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.
- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

The risks that may arise during these assessments are those of possible and classic discomforts during the sessions (vaso-vagal episode, drop in blood pressure, shortness of breath, dizziness)

for which the assessors are trained and which are the same as those related to practising physical or sports activities of daily life.
However, the scientific committee reserves the right to terminate the experiment in case of poor adaptation or intolerance.

CONSTRAINTS

You are free to participate in another research protocol, provided it does not involve new technologies and does not have an impact on physical activity levels or fitness measurement.

FINANCIAL PARTICIPATION

Your collaboration in this research protocol will not involve any financial participation on your part.
All costs (medical, supervision, equipment, insurance, etc.) related to the study will be covered by the researchers.
Only an uncashed cheque used as a security deposit for the loan of the equipment will be requested from you and then destroyed upon the return of the equipment.

LEGISLATION - CONFIDENTIALITY

In accordance with Articles L. 1121-1 et seq. of the French Public Health Code, the Committee on Human Research studied this research project and issued a favourable opinion on 01/04/2020.
An insurance policy, number 146 177 524, was taken out by the sponsor of the trial, the Côte d'Azur University - 20 avenue Valrose - BP 2135 - 06103 Nice Cedex 2, with the company MMA Entreprise, to cover the risks linked to this research.
Any information about you collected during this trial will be treated confidentially.
Only those responsible for the study and possibly the health authorities will have access to this data. With the exception of these people - who will treat the information in the strictest respect of medical secrecy - your anonymity will be preserved. The publication of the results of the study will not include any individual results.
The data recorded over the course of this study will be subject to computerised processing by the sponsor. As this is personal data, you have the right of access, rectification, portability, deletion or limitation in the processing of data concerning you at any time by contacting the Data Protection Officer, Mr. Didier Martin at the Côte d'Azur University and those in charge of the study. As regards information of a medical nature, this right is exercised through the intermediary of Professor Nicolas Chevalier at the University Hospital of Nice, in accordance with France's law on Information Technology, Data Files and Civil Liberties, No. 78-17 of 6 January 1978, amended by law No. 94-548 of the 1st of July 1994, and Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). The project received a

notification of compliance with reference to methodology, and an analysis of the impact on privacy delivered by the Data Protection Officer of the Côte d'Azur University on 28/04/2020. In accordance with Article L. 1122-1, as amended, of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study can be communicated to you if you wish.

If you have any questions during your participation in this study, you may contact the principal investigators of this study:

- Prof. Nicolas Chevalier, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice
- Prof. Antonio Iannelli, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice

Or the scientific head of research:

- Prof. Fabienne d'Arripe-Longueville, phone: 04.89.15.39.55 at the LAMHESS of the Côte d'Azur University.

Or the Data Protection Officer:

- Mr. Didier Martin, phone: 04.89.15.11.99 at the Côte d'Azur University

You are free to accept or refuse to participate in this study. This will in no way affect the quality or the level of care you will receive, which will be the same as it has been thus far. During the course of the study, you may also decide to discontinue your participation without having to justify your decision.
Thank you for taking the time to read this newsletter. If you agree to participate in this research study, we invite you to sign the attached consent form.

Consent – Pre-registration phase (all) – V3 (04/03/2020)
ID No. – RCB: 2020-A00172-37

CONSENT FORM
FOR PARTICIPATION IN THE OCAPAS STUDY

Study on Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

I the undersigned …… (*Last name and first name of the volunteer*), accept to participate in the "**OCAPAS**" study.
The objectives and terms of the study were clearly explained to me by Prof. Nicolas Chevalier and Prof. Antonio Iannelli.
I have read and understood the information sheet given to me.
I accept that the documents in my medical file that relate to the study may be accessible to those responsible for the study and possibly to the health authorities. With the exception of these persons, who will treat the information in the strictest respect of medical confidentiality, my anonymity will be preserved.
I accept that my personal data collected during this study may be subject to automated processing by the research organisers. I may exercise my right of access, rectification, portability, deletion or limitation of the processing of data concerning me by contacting the data protection representative Mr. Didier Martin at the Côte d'Azur University, and as regards information of a medical nature by contacting Professor Nicolas Chevalier at the Nice University Hospital.
I understand that my participation in the study is voluntary.
I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.
My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.
Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator *Signature of the volunteer*

Information notice – ACTI-MOBIL Group – V4 (15/10/2020)
ID No. – RCB: 2020-A00172-37

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

Trial sponsor: Côte d'Azur University
Head of research: Prof. Fabienne d'Arripe-Longueville, Laboratoire Motricité Humaine, Expertise, Sport Santé [*Laboratory of Human Motricity, Expertise, Sport, and Health*] (EA 6312), Côte d'Azur University
Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

Madam,
We would like to offer you the opportunity to participate in a clinical research study because you are undergoing a bariatric surgery procedure.
This information notice will tell you more about the study.
You have a 7-day reflection period during which you can take the time to read and understand this information, reflect on your participation, and ask the principal investigators of the study to explain what you did not understand.

PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.
Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up. To support your commitment to physical activity, the *MyBody* mobile application proposed by *Be Patient* will be made available to you.
The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

To support your commitment to physical activity, you will benefit from the *MyBody* mobile application proposed by *Be Patient* and a connected watch that will allow you to view the number of steps you've taken each day, week and month. The mobile application is composed of advice sheets with quizzes, and a guided adapted physical activity program to be begun between the 3rd and 6th month following bariatric surgery. The adapted physical activity programme will respect international recommendations, i.e. it will accompany you in achieving 150 minutes per week with the goal of reaching 300 minutes per week. On the mobile application, you will be proposed two sessions per week, lasting from 30 to 50 minutes, consisting of endurance exercises and resistance strength-conditioning exercises in the form of a training circuit which will evolve progressively over the course of the programme. In addition, you will also be encouraged to walk regularly so as to reach the recommendations. After each session, you will record your participation on the application and evaluate your rating of perceived exertion on a scale from 0 to 10.

You will be monitored through physical and psychological assessments in the form of questionnaires. Assessments will take place at the beginning of inclusion (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

The questionnaires to which you will be submitted can be filled in online on the *LimeSurvey* platform. You will receive an e-mail with the link to the questionnaire and a reminder of your anonymity number. If you have difficulty completing the questionnaires on the *LimeSurvey* platform, you can also complete them on paper during the physical assessments. The questionnaires will be used to evaluate:

- Self-reported physical activity level
- Observance and motivation:
    - The number, duration and type of physical activity sessions per week according to international recommendations.
    - Physical exercise habits and history
    - The stage of engagement in practice
    - Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.

- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

The risks that may arise during these assessments are those of possible and classic discomforts during the sessions (vaso-vagal episode, drop in blood pressure, shortness of breath, dizziness) for which the assessors are trained and which are the same as those related to practising physical or sports activities of daily life.

When carrying out the physical activities guided by the mobile application, the recommended perceived intensity must be strictly respected so as to avoid any risk during the practice (vaso-vagal episode, drop in blood pressure, shortness of breath...). Even if the risk of occurrence is low, it is advisable to always have a trusted person nearby to be able to react in the event of an undesirable event.

However, the scientific committee reserves the right to terminate the experiment in case of poor adaptation or intolerance.

CONSTRAINTS

You are free to participate in another research protocol, provided it does not involve new technologies and does not have an impact on physical activity levels or fitness measurement.

FINANCIAL PARTICIPATION

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Any information about you collected during this trial will be treated confidentially.

Only those responsible for the study and possibly the health authorities will have access to this data. With the exception of these people - who will treat the information in the strictest

respect of medical secrecy - your anonymity will be preserved. The publication of the results of the study will not include any individual results.
The data recorded over the course of this study will be subject to computerised processing by the sponsor. As this is personal data, you have the right of access, rectification, portability, deletion or limitation in the processing of data concerning you at any time by contacting the Data Protection Officer, Mr. Didier Martin at the Côte d'Azur University and those in charge of the study. As regards information of a medical nature, this right is exercised through the intermediary of Professor Nicolas Chevalier at the University Hospital of Nice, in accordance with France's law on Information Technology, Data Files and Civil Liberties, No. 78-17 of 6 January 1978, amended by law No. 94-548 of the 1st of July 1994, and Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). The project received a notification of compliance with reference to methodology, and an analysis of the impact on privacy delivered by the Data Protection Officer of the Côte d'Azur University on 28/04/2020. In accordance with Article L. 1122-1, as amended, of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study can be communicated to you if you wish.

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Consent –ACTI-MOBIL Group – V3 (04/03/2020)
ID No. – RCB: 2020-A00172-37

CONSENT FORM
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Study on Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

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I understand that my participation in the study is voluntary.
I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.
My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.
Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator *Signature of the volunteer*

Information notice – ACTI-VISIO Group – V4 (15/10/2020)
ID No. – RCB: 2020-A00172-37

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

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Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

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PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.
Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up. To support your commitment to physical activity, adapted physical activity sessions by videoconference will be made available to you.
The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

To support your commitment to physical activity, following your bariatric surgery, you will benefit from an adapted physical activity program delivered via videoconferencing by a trained professional. Initially, you will have one-on-one videoconferences with an adapted physical activity professional, and then you will be given the opportunity to participate in group sessions with a group of young women included in this study like you. This group will be composed of a maximum of 4 people. The adapted physical activity program carried out by videoconference will comply with international recommendations, i.e. it will accompany you in achieving 150 minutes per week with the goal of reaching 300 minutes per week. You will be proposed two videoconference sessions per week, lasting from 30 to 50 minutes, consisting of endurance exercises and resistance strength-conditioning exercises in the form of a training circuit which will evolve progressively over the course of the programme. For each exercise, the professional will show you the exercise and explain it to you, and then you will carry out the number of repetitions planned together. As the sessions will be carried out live, the professional will be able to correct your posture and give you advice. In addition, he will encourage you to walk regularly so as to reach the recommendations. After each session, the professional will record your participation on a monitoring form and will ask you to evaluate your rating of perceived exertion on a scale from 0 to 10.

You will be monitored through physical and psychological assessments in the form of questionnaires. Assessments will take place at the beginning of inclusion (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

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    - The number, duration and type of physical activity sessions per week according to international recommendations.

- Physical exercise habits and history
- The stage of engagement in practice
- Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.

- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

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When carrying out the physical activities guided by the adapted physical activity professional by videoconference, the recommended perceived intensity must be strictly respected so as to avoid any risk during the session (vaso-vagal episode, drop in blood pressure, shortness of breath...). Even if the risk of occurrence is low, it is advisable to always have a trusted person nearby to be able to react in the event of an undesirable event.

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If you have any questions during your participation in this study, you may contact the principal investigators of this study:

- Prof. Nicolas Chevalier, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice
- Prof. Antonio Iannelli, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice

Or the scientific head of research:

- Prof. Fabienne d'Arripe-Longueville, phone: 04.89.15.39.55 at the LAMHESS of the Côte d'Azur University.

Or the Data Protection Officer:

- Mr. Didier Martin, phone: 04.89.15.11.99 at the Côte d'Azur University

You are free to accept or refuse to participate in this study. This will in no way affect the quality or the level of care you will receive, which will be the same as it has been thus far. During the

course of the study, you may also decide to discontinue your participation without having to justify your decision.

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Consent – ACTI-VISIO Group – V3 (04/03/2020)
ID No. – RCB: 2020-A00172-37

CONSENT FORM
FOR PARTICIPATION IN THE OCAPAS STUDY

Study on Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

I the undersigned …… (*Last name and first name of the volunteer*), accept to participate in the "**OCAPAS**" study.
The objectives and terms of the study were clearly explained to me by Prof. Nicolas Chevalier and Prof. Antonio Iannelli.
I have read and understood the information sheet given to me.
I accept that the documents in my medical file that relate to the study may be accessible to those responsible for the study and possibly to the health authorities. With the exception of these persons, who will treat the information in the strictest respect of medical confidentiality, my anonymity will be preserved.
I accept that my personal data collected during this study may be subject to automated processing by the research organisers. I may exercise my right of access, rectification, portability, deletion or limitation of the processing of data concerning me by contacting the data protection representative Mr. Didier Martin at the Côte d'Azur University, and as regards information of a medical nature by contacting Professor Nicolas Chevalier at the Nice University Hospital.
I understand that my participation in the study is voluntary.
I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.
My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.
Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator *Signature of the volunteer*

Information notice – Group C – V4 (15/10/2020)
ID No. – RCB: 2020-A00172-37

INFORMATION NOTICE FOR PATIENTS FOR PARTICIPATION IN THE OCAPAS STUDY

Study of Physical Activity and Bariatric Surgery

Research title: "OCAPAS" Scientific study

Trial sponsor: Côte d'Azur University
Head of research: Prof. Fabienne d'Arripe-Longueville, Laboratoire Motricité Humaine, Expertise, Sport Santé [*Laboratory of Human Motricity, Expertise, Sport, and Health*] (EA 6312), Côte d'Azur University
Principal investigators: Prof. Nicolas Chevalier, University Professor – Hospital Practitioner at the Nice University Hospital; Prof. Antonio Iannelli, University Professor – Hospital Practitioner at the Nice University Hospital

Madam,
We would like to offer you the opportunity to participate in a clinical research study because you are undergoing a bariatric surgery procedure.
This information notice will tell you more about the study.
You have a 7-day reflection period during which you can take the time to read and understand this information, reflect on your participation, and ask the principal investigators of the study to explain what you did not understand.

PURPOSE OF THE STUDY

The "OCAPAS" scientific study is conducted in partnership with the Laboratoire Motricité Humaine, Expertise, Sport, Santé (LAMHESS) of Côte d'Azur University, the Specialised Obesity Center of the Provence Alpes Côte d'Azur East, the DARE [*Digestive-Anesthesia-Resuscitation-Endocrinology*] pole of the Nice University Hospital, the Public Health Department of the Nice University Hospital, Azur Sport Santé, the Laboratoire d'Anthropologie, Psychologie Cliniques, Cognitives et Sociales (LAPCOS) [*Laboratory of Anthropology, Clinical, Cognitive and Social Psychology*] of Côte d'Azur University, and the companies *Be Patient* and *Mooven*.
Its main objective is to study patient engagement in physical activity during bariatric surgery follow-up. To support your commitment to physical activity, you will be monitored and receive advice from the adapted physical activity professional from the bariatric surgery service.
The secondary objectives are to study the impact of your physical activity practice on different engagement and health indicators. Your perception of various mechanisms which could help to strengthen your commitment to physical activity will also be measured.

ANTICIPATED BENEFIT(S)

This study, through the physical activity that will be recommended to you, should help improve your health, quality of life and well-being.

CONDUCTING THE STUDY

To support your commitment to physical activity, you will be monitored and receive advice to help you achieve 150 minutes per week of physical activity with the goal of reaching 300 minutes per week. This advice and recommendations will be given to you by the adapted physical activity professional from the bariatric surgery service. You will be encouraged to walk regularly in order to reach the recommendations and to carry out two sessions per week dedicated to physical activity including muscle strengthening exercises adapted to the bariatric surgery course.

You will be monitored through physical and psychological assessments in the form of questionnaires. Assessments will take place at the beginning of inclusion (T0), then at 3 months (T3), and 6 months (T6) after inclusion. Only the physical assessments requiring a measurement will be required to take place at the Archet 2 University Hospital in Nice.

Physical assessments will be based on a 6-minute walking test (carried out under standardised conditions), a strength test, and the wearing of an accelerometer for 7 days positioned at the time of the assessments (and returned at the end of the 7-day period by post with a stamped envelope provided). Height, weight and impedance measurements will be carried out by a doctor or nurse as part of the standard monitoring.

The questionnaires to which you will be submitted can be filled in online on the *LimeSurvey* platform. You will receive an e-mail with the link to the questionnaire and a reminder of your anonymity number. If you have difficulty completing the questionnaires on the *LimeSurvey* platform, you can also complete them on paper during the physical assessments. The questionnaires will be used to evaluate:

- Self-reported physical activity level
- Observance and motivation:
    - The number, duration and type of physical activity sessions per week according to international recommendations.
    - Physical exercise habits and history
    - The stage of engagement in practice
    - Motivation for physical activity, how you feel during physical activity, and your reactions to various situations.
- Your perception of the solution to strengthen your commitment to physical activity
- Quality of life and health.

POTENTIAL RISKS

The respect of the protocol and contra-indications, the specific training of the adapted physical activity professional, as well as the carrying out of the evaluations at the Archet 2 Nice University Hospital, will guarantee your safety during the evaluations.

The risks that may arise during these assessments are those of possible and classic discomforts during the sessions (vaso-vagal episode, drop in blood pressure, shortness of breath, dizziness) for which the assessors are trained and which are the same as those related to practising physical or sports activities of daily life.

When carrying out the recommended physical activities, the recommended perceived intensity must be strictly respected so as to avoid any risk during the practice (vaso-vagal episode, drop in blood pressure, shortness of breath...).

However, the scientific committee reserves the right to terminate the experiment in case of poor adaptation or intolerance.

CONSTRAINTS

You are free to participate in another research protocol, provided it does not involve new technologies and does not have an impact on physical activity levels or fitness measurement.

FINANCIAL PARTICIPATION

Your collaboration in this research protocol will not involve any financial participation on your part.

All costs (medical, supervision, equipment, insurance, etc.) related to the study will be covered by the researchers.

Only an uncashed cheque used as a security deposit for the loan of the equipment will be requested from you and then destroyed upon the return of the equipment.

LEGISLATION - CONFIDENTIALITY

In accordance with Articles L. 1121-1 et seq. of the French Public Health Code, the Committee on Human Research studied this research project and issued a favourable opinion on 01/04/2020.

An insurance policy, number 146 177 524, was taken out by the sponsor of the trial, the Côte d'Azur University - 20 avenue Valrose - BP 2135 - 06103 Nice Cedex 2, with the company MMA Entreprise, to cover the risks linked to this research.

Any information about you collected during this trial will be treated confidentially.

Only those responsible for the study and possibly the health authorities will have access to this data. With the exception of these people - who will treat the information in the strictest respect of medical secrecy - your anonymity will be preserved. The publication of the results of the study will not include any individual results.

The data recorded over the course of this study will be subject to computerised processing by the sponsor. As this is personal data, you have the right of access, rectification, portability, deletion or limitation in the processing of data concerning you at any time by contacting the

Data Protection Officer, Mr. Didier Martin at the Côte d'Azur University and those in charge of the study. As regards information of a medical nature, this right is exercised through the intermediary of Professor Nicolas Chevalier at the University Hospital of Nice, in accordance with France's law on Information Technology, Data Files and Civil Liberties, No. 78-17 of 6 January 1978, amended by law No. 94-548 of the 1st of July 1994, and Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation). The project received a notification of compliance with reference to methodology, and an analysis of the impact on privacy delivered by the Data Protection Officer of the Côte d'Azur University on 28/04/2020. In accordance with Article L. 1122-1, as amended, of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study can be communicated to you if you wish.

If you have any questions during your participation in this study, you may contact the principal investigators of this study:

- Prof. Nicolas Chevalier, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice
- Prof. Antonio Iannelli, phone: 04.92.03.55.19 at the Archet 2 University Hospital of Nice

Or the scientific head of research:

- Prof. Fabienne d'Arripe-Longueville, phone: 04.89.15.39.55 at the LAMHESS of the Côte d'Azur University.

Or the Data Protection Officer:

- Mr. Didier Martin, phone: 04.89.15.11.99 at the Côte d'Azur University

You are free to accept or refuse to participate in this study. This will in no way affect the quality or the level of care you will receive, which will be the same as it has been thus far. During the course of the study, you may also decide to discontinue your participation without having to justify your decision.
Thank you for taking the time to read this newsletter. If you agree to participate in this research study, we invite you to sign the attached consent form.

Consent – Group C – V3 (04/03/2020)
ID No. – RCB: 2020-A00172-37

FORMULAIRE DE CONSENTEMENT POUR LA PARTICIPATION A L'ETUDE OCAPAS

Etude Activité Physique et Chirurgie Bariatrique

Research title: "OCAPAS" Scientific study

I the undersigned …… (*Last name and first name of the volunteer*), accept to participate in the "**OCAPAS**" study.

The objectives and terms of the study were clearly explained to me by Prof. Nicolas Chevalier and Prof. Antonio Iannelli.

I have read and understood the information sheet given to me.

I accept that the documents in my medical file that relate to the study may be accessible to those responsible for the study and possibly to the health authorities. With the exception of these persons, who will treat the information in the strictest respect of medical confidentiality, my anonymity will be preserved.

I accept that my personal data collected during this study may be subject to automated processing by the research organisers. I may exercise my right of access, rectification, portability, deletion or limitation of the processing of data concerning me by contacting the data protection representative Mr. Didier Martin at the Côte d'Azur University, and as regards information of a medical nature by contacting Professor Nicolas Chevalier at the Nice University Hospital.

I understand that my participation in the study is voluntary.

I am free to accept or refuse to participate, and I am free to stop my participation at any time during the course of the study. This will not affect the quality of care I will receive.

My consent does not relieve the organisers of this study of their responsibilities. I retain all my rights under the law.

Having discussed it and having obtained the answers to all my questions, I freely and voluntarily agree to participate in the research study proposed to me.

Prepared in Nice, on _ _ / _ _ / _ _ _ _

Name and signature of the investigator *Signature of the volunteer*