



JUAN MORA PASTOR, President of the Ethics Committee and Vice-Rector for Research at the University of Alicante,

INFORMS:

That the Ethics Committee of the University of Alicante, in a meeting held on December 3, 2021, after reviewing the documentation submitted for the research project **"Predictive Models of the Morphological Evolution of the Human Body to Improve Adherence and Motivation in Dietary and Nutritional Treatments for Overweight and Obesity"**, File UA-2021-11-18, whose principal investigators are **Jorge Azorín López and Andrés Fuster Guillo**, approved the execution of the aforementioned project.

JUAN MORA PASTOR, President del Comitè de Ètica i Vicerector d'Investigació de la Universitat d'Alacant,

INFORMA:

Que el Comitè de Ètica de la Universitat d'Alacant, reunit amb data 3 de desembre de 2021, una vegada estudiada la documentació presentada del projecte de d'investigació **"Modelos predictivos de la evolución morfológica del cuerpo humano para mejorar la adherencia y motivación en tratamientos dietético-nutricionales del sobrepeso y la obesidad"** Expedient UA-2021-11-18 els investigadors principals del qual són **Jorge Azorín López y Andrés Fuster Guillo**, va donar el seu vistiplau per a la realització del citat projecte.

Signat/Signature

MORAPASTOR, JUAN

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Alicante, December 10, 2021

University of Alicante
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PATIENT INFORMATION SHEET

Reference:	PID2020-119144RB-100
Project title:	Predictive models of the morphological evolution of the human body to improve adherence and motivation in dietary-nutritional treatments for overweight and obesity
Principal investigator:	Jorge Azorín López
Service:	Information Technology and Computer Science Department
Center:	University of Alicante

We are writing to request your consent to participate in a research project on 4D Modeling and Visualization of the Human Body to Improve Adherence to Nutritional and Dietary Treatment of Obesity. This project has been funded by the MINISTRY OF SCIENCE AND INNOVATION AND UNIVERSITIES - MICIU/AEI/10.13039/501100011033 and by ERDF/UE. The project will be conducted in accordance with Good Clinical Practice guidelines and the international ethical principles applicable to medical research involving humans (Declaration of Helsinki and its latest revision).

In order for you to decide whether you wish to participate in this project, it is important that you understand why this research is necessary, what your participation will involve, how your information will be used, and the potential benefits, risks, and inconveniences. This document contains detailed information about the project. Please take the time to carefully read the information provided below, and we will clarify any questions you may have. Once you have understood the project, you will be asked to sign the informed consent if you wish to participate.

If you decide to participate in this study, you should know that you are doing so voluntarily and that you may also withdraw at any time. If you choose to suspend your participation, it will not result in any type of penalty, loss, or detriment to your rights or medical care.

WHY IS THIS PROJECT BEING CARRIED OUT?

Overweight and obesity are defined as an abnormal or excessive accumulation of fat that is harmful to health. The prevalence of overweight and obesity has increased worldwide, tripling over the past three decades in European Union countries. This rise in overweight and Body Mass Index (BMI) is a significant risk factor for cardiovascular diseases (mainly heart disease and strokes), diabetes, musculoskeletal disorders (especially osteoarthritis, a highly disabling degenerative joint disease), and certain types of cancer (including endometrial, breast, ovarian, prostate, liver, gallbladder, kidney, and colon cancer).

There is evidence that weight loss can reduce the risk of disease. Therefore, it is essential to implement prevention and intervention programs to improve dietary and nutritional habits. Currently, most intervention programs aimed at improving eating habits have focused on establishing dietary and nutritional recommendations and promoting physical exercise. Although, in general, these programs have proven effective in the short term, their effectiveness in maintaining behaviors over time has been limited.

Multicomponent interventions that include dietary modifications, exercise, and behavioral changes are more effective than those focusing on a single component, making their implementation crucial for improving long-term adherence to treatment and, consequently, overall health.

From a dietary and nutritional perspective, the Mediterranean diet, characteristic of countries like Spain and others in the Mediterranean basin, has been shown to provide numerous health benefits, including strengthening the immune system and reducing inflammatory processes in organs and body cells. Despite these preventive effects, Mediterranean countries are increasingly adopting a Westernized diet, high in fats, calorie-dense foods, and low in fruits and vegetables, leading to a rise in overweight, obesity, and other diet-related diseases.

WHAT IS THE OBJECTIVE OF THE PROJECT?

This project focuses on the development of computational methods for the study of the visual appearance change of the human body, using 3D/4D vision techniques to improve diagnosis and treatment techniques for obesity. As a result of the research, a complete system will be developed that is capable of providing the necessary data for the analysis of the morphological evolution of the body and its visualization in a realistic virtual form, based on a flexible and versatile acquisition system. In addition, the effect of diet and physical exercise on the psychological well-being and cognitive function of the participants will be studied.

WHAT BENEFITS CAN I GET FROM PARTICIPATING IN THIS STUDY?

You will receive an individual, personalized, and free dietary-nutritional intervention. The information you provide, along with the data obtained from the intervention, can be highly valuable for improving intervention programs aimed at promoting healthy lifestyle patterns in our population, emphasizing adherence to the Mediterranean diet and its positive impact on physical, psychological, and social health.

There will be no financial compensation for participating in the study.

WHAT RISKS COULD I FACE BY PARTICIPATING IN THE STUDY?

There are no risks involved. All exercises will be adapted to your needs. Protective measures against COVID-19 will be ensured.

WHAT DATA WILL BE COLLECTED?

We will collect personal data (such as sex, age, marital status, city of residence, education, employment, and economic status), physical data (such as weight, height, waist-to-hip ratio, body fat percentage, blood pressure, smoking and alcohol consumption), analytical data, medical conditions, pharmacological treatment, and overall cognitive function.

HOW WILL MY PERSONAL DATA BE TREATED AND HOW WILL CONFIDENTIALITY BE PRESERVED?

The collection, processing and use of the data required for this study will be done in accordance with the provisions of Law 15/1999 on the protection of personal data and its implementing regulations, if applicable (Royal Decree 1720/2007), and in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (RGPD).

Access to your personal information will be restricted to healthcare professionals and study investigators/collaborators always maintaining their confidentiality in accordance with current legislation. The Researcher, when processing and treating your data will take appropriate measures to protect them and prevent access to them by unauthorized third parties.

You may exercise the rights of access (request information about your data stored in the database), opposition (refuse to provide data), cancellation (request the deletion of your data), and rectification (if any data changes over time or an error is detected). You may revoke your consent for the processing of your personal data by contacting the researcher.

In addition to these rights, and in accordance with the GDPR, you may also limit the processing of incorrect data, request a copy, or have the data you have provided for the study transferred to a third party (portability). To exercise your rights, please contact the principal investigator of the study. We remind you that data cannot be deleted even if you withdraw from the study, to ensure the validity of the research and comply, if applicable, with legal obligations and drug authorization requirements. You also have the right to contact the Data Protection Agency if you are not satisfied.

Both the Center and the Sponsor are respectively responsible for processing your data and commit to complying with current data protection regulations. The data collected for the study will be identified by a code, so that no information that could identify you will be included, and only your study doctor/collaborators will be able to link this data to you and your medical history. Therefore, your identity will not be disclosed to any other person except to health authorities, when required, or in cases of medical emergency. The Research Ethics Committees, representatives of the Health Authority for inspection purposes, and personnel authorized by the Sponsor may only access personal data to verify clinical study data, procedures, and compliance with good clinical practice standards, always maintaining the confidentiality of the information.

WHO CAN I CONTACT IF I HAVE ANY QUESTIONS?

If you need more information about the study, please contact Jorge Azorín at jazorin@ua.es, Ana Zaragoza at ana.zaragoza@ua.es or Miriam Sánchez at miriam.sanchez@ua.es



INFORMED CONSENT

I, (Full name handwritten by the participant)

- ☐ I have read this information sheet and have had sufficient time to consider my decision.
- ☐ I have been given the opportunity to ask questions, and all of them have been answered satisfactorily.
- ☐ I have been informed by: _____
- ☐ I understand that my participation in this study will have no consequences for me and that my participation is voluntary.

I understand that I can withdraw from the study:

- At any time
- Without having to provide an explanation
- Without any consequences

I understand that if I decide to withdraw from the study, the results obtained up to that point may continue to be used.

I understand that, in accordance with the current legislation on data protection, I may exercise my rights regarding the processing of my personal data, including access, rectification, and deletion, among others, in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).

After reflecting on the information provided to me, I declare that my decision is as follows:

☐ I give ☐ I do not give

My consent to participate in the study and for the access and use of my data under the conditions detailed in the information sheet.



Adicionalmente, le invitamos a autorizar el tratamiento de sus datos en formato audiovisual:

☐ I give ☐ I do not give

My consent for the capture and recording of my image and sound (videos, photographs, or other media) for the purpose of participating in the study under the conditions detailed in the information sheet. The consenting person grants the right to reproduce, distribute, and disseminate their image and sound, in whole or in part, through any means and/or medium, tangible or intangible, online or offline.

I expressly authorize the University of Alicante to use the study for educational purposes as well.

Additionally, regardless of the primary objective, I accept that the data collected in the evaluation may be used for research purposes related to the scientific field in which the initial study is integrated by the research team. The data obtained will be processed in compliance with current data protection regulations, ensuring complete anonymity (pseudonymized). The legal basis for this processing is the consent of the interested person.

Within the framework of the aforementioned processing, your data will not be shared with third parties unless required by law. You may exercise your rights regarding the processing of your personal data, including access, rectification, and deletion, among others, by submitting a request to the person responsible for the research or to the Data Protection Officer of the University of Alicante (dpd@ua.es) at the General Registry of the University of Alicante, or through its Electronic Headquarters. (<http://sedeelectronica.ua.es>).

For all these reasons, I declare that I have received all relevant information and, through this document, I express my consent for the access and use of my data under the conditions detailed in the information sheet, as well as my agreement that the data will be processed as described.

PARTICIPANT'S SIGNATURE (1)	SIGNATURE OF THE PERSON RESPONSIBLE FOR THE INVESTIGATION (2)
NAME:	NAME:
DATE:	DATE:

In accordance with the provisions of current data protection legislation, you are informed that the University of Alicante will process the data provided in this form, as well as any accompanying documentation, and incorporate them into the data processing activity "0118-Online Questionnaires Research Projects" for the purpose of carrying out one or more research projects conducted by the University itself. The legal basis for this processing is the consent of the interested person. Within the framework of the aforementioned treatments, your data will not be shared with third parties unless required by law. We inform you that you may exercise your rights regarding the processing of your personal data, including access, rectification, and deletion, among others, by submitting a request to the Management of the University at the General Registry of the University of Alicante, or through its Electronic Headquarters (<http://sedeelectronica.ua.es>). You can consult additional and detailed information on Data Protection, your rights, and the Privacy Policy of the University of Alicante at the following link: <https://seuelectronica.ua.es/es/privacidad.html>.