Theocharis Ispoglou

Fairfax Hall, Room 211

Leeds Beckett University

Headingley

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Dear Sir or Madam

I am writing to you to invite you to take part in a research project being undertaken by myself and colleagues at Leeds Beckett University which is investigating the benefits of essential amino acid based supplements in men and women aged 60-80 years. Please take your time to read through the information sheets enclosed with this letter prior to deciding on whether you would like to participate in this research. If after reading through this information you have any questions, or if anything is unclear, please do contact us as we would be most happy to provide further information.

If you are interested in taking part in this research please return the reply slip at the bottom of this letter using the pre-paid envelope enclosed. A member of the research team will then contact you to allow you to ask any further questions you have about the study and to ensure you are suitable to participate. The researcher will then be able to arrange with you convenient times for you to come into the university to participate in this research.

Regards,

Dr Theocharis Ispoglou (Principal Researcher)

Dr Theocharis Ispoglou: tel (0)113 8128603, email T.Ispoglou@leedsbeckett.ac.uk

Matthew Lees (Research Assistant): M.Lees@leedsbeckett.ac.uk

Research Team: Dr Theocharis Ispoglou, Professor Roderick King, Dr Kevin Deighton and Helen White.

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Name:…………………………………………………………………………………………….

Address:………………………………………………………………………………………..

Contact Tel No:……………………………………………………………………………….

I would like to take part in this study (tick box if agree) ❒

I would like to ask some questions before I decide (tick box if agree) ❒

I do not wish to take part (tick box if agree) ❒

**Please return to**

**Dr Theocharis Ispoglou, Fairfax Hall (Room 211), Leeds Beckett University, Headingley, LS6 3QS**

**Participant information sheet**

**TITLE OF STUDY**

Perspective of different forms of essential amino acid supplements and effects on appetite in older men and women

**Invitation**

We would like to invite you to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what would be involved if you choose to take part. Please take time to read the following information carefully, and talk to others about it if you wish.

**What is the purpose of the study**

The purpose of this study is to gain a better understanding of how protein supplements can affect appetite and to investigate whether people prefer taking supplements in a gel or as a bar. Conducting this research will help to optimise methods for protein supplementation in older adults without limiting the nutrients they consume from their daily meals.

Dietary protein is just one of the food groups that we include in our diets on a daily basis, and it is a complex substance made up of many smaller parts called amino acids. Some of these amino acids are essential because the human body cannot make them and so they need to be taken through the diet. Leucine is one of these essential amino acids which we believe is required in greater amounts with as we get older. Since the body cannot make it itself, we obtain it from foods such as milk and meat. We all vary in the amounts we have in our diet and it remains unclear how much is required for the greatest benefit.

Loss of muscle and strength is a natural part of ageing which can lead to a number of health consequences including osteoporosis and a greater risk of falls. These risks increase greatly in those aged 80 years and over. Previous studies have shown that a protein supplement containing essential amino acids can help to preserve muscle mass in adults in their early retirement years and so may be able to decrease the risk of these negative health events. However, more research is required to ensure that such supplements can be designed to meet the needs and tastes of older adults.

**Why have I been chosen?**

You have been chosen for this study because you are aged between 60 and 80 years, you are healthy and are living in your own home without support. It is important that participants do not suffer from any health conditions that may affect the results of the study. Therefore, to be eligible for selection, you will be asked to complete a health screening questionnaire. You also need to meet the criteria listed below.

1. You must not have vascular disease, hypertension, diabetes, cardiac abnormalities
2. You must have not used estrogens (for women) within the previous 3 months
3. You must not suffer from any metabolic disorders
4. You must be a non-smoker
5. You must not be lactose (milk sugar) intolerant since the breakfast provided will involve ingestion of semi-skimmed milk.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show that you have agreed to take part. You are free to withdraw at any time, without giving a reason.

**What do I have to do if I take part?**

There are two arms to this study. It is up to you to decide if you would like to take part in one or both arms of the study.

**First arm of the study**

This will require you to attend three assessment sessions which will take place on three separate mornings at the Carnegie Research Institute at Leeds Beckett University, Headingley campus. The assessment sessions will be arranged at times convenient for you. Prior to attending the first assessment you will be sent a list of pre-test guidelines, which you will be asked to follow. You will then be asked to follow the same guidelines before subsequent sessions.

When you arrive for the first session, the details of all the procedures will be explained to you and you will be able to ask any questions before being asked to sign the consent form. You will also be asked to complete medical screening before taking part in the study. This will include completing a medical screening form, having your blood pressure taken and getting weighed and measured.

After completing the health screening the first assessment can be started. This assessment will be conducted under one of three different conditions, with the other conditions being completed on subsequent visits. The order in which these testing conditions are carried out will be randomised and so you will only find out on the day of the assessment.

There will be three testing conditions for this arm of the study which will mean consuming one of two protein supplements followed by an ad-lib breakfast, and a control condition. By having 1 trial where you consume just the breakfast with no supplement this will act as a control against which the responses to the supplements can be compared.

After consumption of the supplements (either protein supplement or control condition) or the control condition (nothing) you will be asked to rest for one hour prior to being given a standardised breakfast of porridge. During this hour you will be asked to complete a number of questionnaires about your feelings of hunger and your opinion of the supplement consumed.

In addition, at the start of each of the three assessment sessions a trained phlebotomist will insert a cannulla into one of the veins in your arm. A small amount of blood will then be taken at a number of occasions throughout the testing session which we will be able to analyse for your hormonal response to the different conditions.

**Second arm of the study**

This will require you to attend three assessment sessions. These sessions will be held in the same venue as described above and will follow the same pattern of attending on separate mornings having followed pre-test guidelines.

The two testing conditions will both require you to consume supplements containing a mixture of essential amino acids, either in the form of a bar which can be eaten, or as a gel which can be drunk; the 3rd condition will require that you consume only breakfast. The supplements will be taken at the same time as standardised breakfast of porridge. You will be asked to complete a couple of questionnaires prior to taking the supplement and at the end of your breakfast. No blood samples will be collected for this arm of the study

**How much rest will I need before undertaking each testing session?**

It is important that you do not take part in intense physical activities for 24 hours before each of the assessment sessions. During the rest of the period between assessments you will be free to maintain your normal exercise habits.

**WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?**

It is unlikely you will experience any long-term physiological benefits from taking part in these assessments. However, it is hoped that the information you help us to collect can be used to create dietary supplements suitable for use by older adults which can help to maintain muscle mass and so reduce the incidence of falls and other associated disabilities.

All participants completing the study will be offered an M&S git voucher as a small incentive for their participation and for covering travel expenses. Participants will be given either a £70 or £50 vouchers for completing the second or third arm of the study respectively.

**WHAT ARE THE POSSIBLE RISKS OF TAKING PART IN THE STUDY?**

**Blood Sampling**

Blood sampling will only be performed in the first arm of the study. Blood sampling will be conducted using aseptic techniques and in accordance with local and national guidelines to minimise any risks. Blood sampling will be carried out by researchers trained in phlebotomy and with a number of years experience in this area. Should the cannulla provide any lasting discomfort after insertion you will be asked to inform the researcher who will be able to act accordingly, removing the cannulla if necessary. Blood sample preparation will be separated from the testing area and participants to prevent cross-contamination and reduce the potential of any accidents.

**Supplements**

Ingestion of high volumes of protein and amino acid is not associated with renal (kidney) function decline in healthy individuals. There is also strong evidence to suggest that older individuals require more protein in their diets compared to younger ones. Deterioration of renal function as result of high protein intakes can occur over a number of years, however only in the presence of renal insufficiency. Due to the acute nature of the supplementation in this study even if you had suffered from renal insufficiency the risk of deterioration of kidney function would be minimal.

**WHAT HAPPENS IF SOMETHING GOES WRONG?**

All of the experimental procedures used in this study have been rigorously tested to ensure that they meet health and safety standards. Furthermore, all members of the research team have been trained in the use of these techniques and have years of experience working on similar studies. In the unlikely case of an accident their will always be a first aider in the building and direct access to a mobile phone if needed. In the unlikely event of you experiencing any problems that may be caused by this study, you must tell us immediately and we will do our utmost to address these. Should you be harmed in any way whilst participating in this study, the University maintains clinical trial Indemnity insurance. The clinical trial indemnity insurance will only respond in the event that the University is deemed to be legally liable for incidents that occur, as a direct result of the study

**What rights do I have if I start partiCipating in the study and I do not want to continue?**

Participation in this study is entirely voluntary. You may withdraw from this study at any time and for any reason without penalty. All information relating to you will be removed from the study and destroyed if you wish. Even when you have signed the informed consent form this does not mean you are bound to this study.Therefore you may still drop out at anytime without notification or explanation**.**

**What will we do with the results?**

As a participant you will have access to all the data we will collect on you, however, you will not have access to any other participant’s information. All data will be anonymised and will remain confidential, and as such, extra care will be taken when handling this information The results will be used in the publishing of scientific papers and presentations and to inform further studies in this area. No identifiable information will appear in any outputs generated from this study.

**How will you keep my information confidential?**

Your personal data will be coded at the start of the study by the researchers who will be the only persons able to trace data back to any participant. All material will be stored securely by the principal researcher (Dr Theocharis Ispoglou) and identities of participants removed from any data published. Any information that leaves Leeds Beckett University will have your name and address removed so that you cannot be recognised from it. Paper files will be destroyed after the completion of the data analysis. Electronic data may be stored for longer; however participants’ identities will not be included.

Thank you for considering participation in this study.

**CONTACTS FOR FURTHER INFORMATION**

If you have any questions or further information please contact one of the following researchers:

* Dr Theocharis Ispoglou

**Senior Lecturer in Exercise Physiology & Nutrition**

Carnegie Faculty, Headingley Campus, Leeds Becket University, Room 211 Fairfax Hall, Leeds LS6 3QS, **Tel: (+44) (0)113 81 28603**, T.Ispoglou@leedsbeckett.ac.uk

* Matthew Lees (Research Assistant): M.Lees@leedsbeckett.ac.uk

If you wish to speak to an independent researcher please contact:

Dr John O’Hara

Research Ethics Co-ordinator

Carnegie Faculty, [107 CRI centre](http://phonebook.leedsbeckett.ac.uk/main/result.htm?search=107%2C+Cri+Facility&searchby=Location&exact=true), Leeds Beckett University, Headingley Campus

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