

Preventing Muscle Wasting During Rheumatoid Arthritis Flares: A Randomised Controlled Trial

**335887
19.12.2023
Version 1**

Participant Identification Number:

INFORMED CONSENT FORM**Preventing Muscle Wasting During Rheumatoid Arthritis Flares: A Randomised Controlled Trial**Answer
'Yes' or 'No'

1. The purpose and details of the study have been explained to me. ☐
2. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that this research will contribute towards a PhD thesis and all procedures have been ethically approved by the NHS and Leeds Beckett University. ☐
4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
5. I understand that the information I provide is strictly confidential and will be kept anonymous to the researchers. ☐
6. I understand that the information I provide will be stored securely for a maximum of 10 years. ☐
7. I understand that I should notify the researcher for any changes to my medication. ☐
8. I agree to complete health and well-being questionnaires throughout each of the testing sessions. ☐
9. I understand who I can approach if I am not happy with how the study is being conducted or if I have any other questions regarding the research. ☐
10. I understand that my GP will be informed about my participation in this study. ☐
11. I agree to take an amino acid supplement twice per day for 28 days should I be randomised to the intervention arm of the trial. ☐
12. I understand that the supplements used are from a certified supplier** (See information about supplements overleaf). ☐

13. I agree to allow the researchers to take blood samples from me on each of the testing sessions.

☐

14. I confirm that I am not allergic to anything in the ingredient list for the supplements (see information about supplements overleaf).

☐

Name of Participant Date Signature

Name of Person Date Signature
taking consent

Further information on supplements

Non-batch tested products but from a certified manufacturer** - Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. Furthermore, the supplements provided during this experiment have been purchased from certified manufacturers who have passed appropriate quality control standards. This significantly reduces the risk of any contamination, but we cannot guarantee that the supplement is free of prohibited substances. Please consider this information if you are a competitive athlete subject to drug testing.

The supplement has been optimised and well received in adult populations and those who are suffering from disease. It is made up of amino acids which are considered to assist the body in building muscle. The supplements come in a gel form which you consume orally so please consider this if you have issues with this type of foodstuff. The supplement is an orange and passionfruit flavour and contains essential amino acids and vitamin D. If you are randomised to the intervention arm of the trial, you will be required to consume two of these supplements each day – one before breakfast and one before lunch. This intervention period will last for 4 weeks and you will be required to fill in a form each day simply ticking or crossing whether you consumed the gel or not. The ingredient list for the supplement is as follows:

Water, Glucose Liquid, L-Leucine, Sucrose, L-Lysine, L-Valine, Citric Acid, L-Isoleucine, L-Threonine, DL-Phenylalanine, L-Histidine (hcl), DL-Methionine, Cholecalciferol, Potassium Sorbate, Xanthan Gum, Orange and Passionfruit Flavourings.