

Invitation

You are being invited to take part in a research study. Before you decide, it is important you understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of this study?

We are interested in ways to help people manage their weight using a natural dietary fibre called alginate. In this study we are investigating whether consuming alginate in capsules will reduce people's weight. To achieve this we will be looking at weight, waist circumference and body composition.

Why have I been asked to take part?

We are looking for men and women who are generally healthy, non-pregnant, non-lactating non-smoking, aged over 18 years, and do not have any known food allergies.

Do I have to take part?

It is up to you to decide whether or not to take part. If you are interested in taking part, you will first be asked to sign a consent form (we will give you a copy to keep). You can withdraw from the study without giving a reason at any time.

What will happen to me if I take part?

The study will last 12 weeks depending on your availability.

On each visit we will ask you to come to the research facility in Newcastle University, before you have had any breakfast. You must not eat or drink anything (except water) after 8 pm the evening before you come in. This includes not drinking any alcohol (for 24 hours before), tea or coffee.

Each time you come in we will measure your height (first assessment only), weight, waist circumference and body composition. Your body composition is measured using scales which can determine the percentage of your body is fat or bone or muscle. This is done using a small harmless electrical current passing through your body, you will not detect or feel this at all. Your cholesterol, triglyceride and glucose levels in your blood will also be measured at each visit. This will be done through a single finger prick blood sample.

You will be given enough capsules to last you four weeks at the first three visits. The capsules will be filled with either alginate or another dietary fibre we believe has no effect on weight management.

You will be asked to take six of these capsules with your three main meals per day over the 12 week study.

After each visit you will be asked to complete a food diary for three days. The food diary uses an online program. You will be asked to recall all the foods you

consumed the day before. The food diaries should be completed on two weekdays and one weekend day.

What will happen to the samples I provide?

No samples will be retained, the droplet of blood you provide will be used to instantly measure cholesterol, triglyceride and glucose on a portable meter and discarded. Your measurement will be coded and kept anonymous so they cannot be traced back to you.

Are there any risks to taking part?

There are no known risks involved in this trial. The finger pricks may cause slight discomfort and potentially mild bruising. Consuming a higher than your normal amount of dietary fibre may lead to a bloated or gassy feeling initially but this would be expected to pass within the first week. If you feel ill or these symptoms persist please stop taking the capsules and contact the study team.

What are the possible benefits of taking part?

Although you may not derive any individual benefit, the knowledge gained from this study will help research into identifying food supplements that can help manage people weight. You will also have accurate measurements for weight, body composition and waist circumference as well as fasting levels of glucose, triglyceride and cholesterol.

What will happen if anything goes wrong?

Any complaints you have about this study should be made to Prof. Jeff Pearson, Newcastle University (jeffrey.pearson@ncl.ac.uk or 0191-2086996) and will be fully investigated.

Will my taking part in this study be kept confidential?

Any information which is collected about you during the course of the research will be kept strictly confidential. It will not be possible to identify you from the study results.

Who is organising and funding the study?

This study is being organised by Newcastle University and funded by the EU Northern Accelerator Proof of Concept Fund. In recognition of your time commitment, you will be given an honorarium in the form of a £80 voucher, upon completion of the study.

Contact for further information

If you would like any further information about this study, please do not hesitate to contact Matthew Wilcox on 0191 208 5013 or email matthew.wilcox@ncl.ac.uk

And finally...

Thank you for having taken the time to read this information sheet and for your interest in the study.



The effect of alginate supplementation
on weight management – A randomised
double blind placebo controlled pilot
trial

Information Sheet for Volunteers

Newcastle University Biosciences Institute
Medical School
Newcastle University

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