INFORMATION TO PARTICIPANTS INVOLVED IN RESEARCH

You are invited to participate in

The Kyolic garlic & aerobic fitness trial

Effect of Kyolic aged garlic extract on arterial stiffness and aerobic fitness in middle-aged recreational endurance athletes: a dose-response trial

The study will be conducted by the research team at the National Institute of Integrative Medicine (NIIM) in Hawthorn, led by Chief Investigators A/Prof Karin Ried (Director of Research, NIIM), Nikolaj Travica and Prof Avni Sali (Director, NIIM).

Ethics Approval

This research project has been approved by the National Institute of Integrative Medicine Human Research Ethics Committee on 3 March 2020. The HREC Approval no. is [0062N_2020].

Project explanation and objectives

Arterial stiffness is a cardiovascular risk factor, which increases naturally with age. Kyolic garlic has been shown to improve the flexibility of arteries, and slows down blood flow, which may improve oxygen uptake, associated with aerobic fitness.

In this randomised double-blind placebo-controlled 12-week trial we aim to assess the effect and dose-response of Kyolic garlic on arterial stiffness and aerobic fitness in middle-aged endurance athletes with elevated arterial stiffness.

Aims: In this study, we want to find out, whether Kyolic garlic has an effect on

1. Arterial stiffness, assessed by measuring how fast your blood travels through your blood vessels (pulse wave analysis)
2. Aerobic fitness, assessed by high intensity exercise VO_2max test on a cycle ergometer
3. Lactate threshold, assessed by lactate levels during VO_2max testing
4. Muscular soreness and recovery, assessed by questionnaire
5. Cardiovascular proteomic biomarkers, assessed by urine spot test (subgroup)
6. Microcirculation, assessed by video microcapillary microscopy

Who can participate in this study?

1. We are seeking middle-aged (40-65 years) recreational endurance athletes with elevated arterial stiffness*
2. You regularly undertake a minimum of 3x30min/week moderate to high intensity exercise (e.g. triathlon, cycling, running, swimming)
3. You are not planning to change your diet and exercise routine during the 3-month trial.
4. You are not pregnant, or diagnosed with a cardiovascular condition, or chronic illness, e.g. cancer.
5. You have not had recent surgery and are not planning any surgery, or change of medication during the 3 month study.
6. You are not currently taking any garlic supplements, or have an intolerance to garlic.

What will I be asked to do?

0. *To assess eligibility, you will attend a screening visit at NIIM, where we will test your arterial stiffness with a hand-held gold-standard blood pressure tonometer SphygMoCor.

1. If you are eligible, you will undergo 1 hour of testing at NIIM and 1 hour of testing at METS Performance Consulting in Mulgrave at the start and the end of the study. Appointments can be made on different days. Additional test appointments of 30-60 min are required at NIIM at 4 weeks and 8 weeks.

2. In total, at NIIM, there will be 4x monthly appointments of 30-60 min over 12 weeks.
   Testing at NIIM will include arterial stiffness, microcapillary testing, and questionnaires at each appointment, and urine testing for cardiovascular proteomics at 0 and 12 weeks (subgroup).

3. The VO_2max cycle ergometer and lactate threshold testing will be done twice at baseline and 12 weeks at METS Performance Consulting, Mulgrave (https://metsperformance.com). Please allow at least 1 hour for testing.

What is the trial treatment?

The trial treatment will be odourless aged garlic extract (Kyolic®) or matching capsules that contain no active ingredients, that look exactly the same as the garlic capsules (known as placebo capsules). We advise all capsules to be taken in the evening with food. You will continue taking your prescribed medication as usual. The first half of the participants (IDs 1-40) will receive the lower dose of 2 capsules of Kyolic or placebo daily, and the second half (IDs 41-80) will receive the higher dose of 4 capsules daily. As this is a randomised double-blind placebo-controlled clinical trial, you will have a 50/50 chance of receiving the active capsules. Our study will be what is called 'double blind', which means that during the trial neither you, your doctor, nor the research assistants will know whether you are receiving any garlic capsules. We will be able to tell you and your doctor after the end of the trial whether you received garlic or placebo capsules.

Could the trial capsules have any side effects?

Minor side effects:

A quarter of the participants in our previous study reported belching with some garlic odour. The likelihood of this can be reduced if the trial medication is taken with food (main meal) as advised above.
In previous studies, 1 person in 16 (6%) experienced gastrointestinal discomfort when taking garlic. This can be minor such as bloating and flatulence. Please tell your doctor if you experience any nausea, vomiting or diarrhoea.

Serious side effects:

Allergic reactions to garlic are very rare. However, if you experience symptoms of a serious allergic reaction including difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives, stop taking the study treatment and immediately seek emergency medical attention.

What will I gain from participating?

There may be no direct benefits to you, or your arterial stiffness and aerobic fitness may improve.
After the study when all data has been collected and analysed, you will be sent a summary of the de-identified study results. We will also provide you with a summary of your personal test results, for your personal information at the end of the study, which you are encouraged to share with your doctor. At completion of the trial, all participants will have the opportunity to purchase Kyolic garlic for a discounted price.

How will the information I give be used?

The findings will be used for further scientific research. Results will be written up for submission to a peer reviewed journal and presented at conferences.

What are the potential risks of participating in this project?

All forms of exercise have a risk of injury. These range from fatigue and minor musculoskeletal injuries to risk of cardiovascular events, including heart attack, during maximal exercise testing.
Please note that VO2max testing on a cycle ergometer is a high intensity exercise to exhaustion. The VO2max test will be done at a professional lab (METS Performance), which is knowledgable and equipped with the necessary tools needed in case of emergency, e.g. heart problems. All participants will undergo a thorough eligibility assessment and have to provide consent before undertaking the VO2max test, as per METS Performance protocol (attachment q3).
Mild discomfort may arise from fingerprick testing for lactate levels. The fingerprick testing site will be treated with a topical germicide and a sterile lancet will be used to pierce the skin.

Management of Risk re intense exercise:

METS's staff are qualified in level 2 First Aid and CPR. All participants are made aware of the voluntary nature of the test, and reminded that they are free to stop whenever they want to; whether they feel sick, nauseous, dizzy, very uncomfortable, or we tell them to. Participant heart rate will be monitored throughout to detect any obvious abnormalities. Participants will not, however, be monitored via ECG. All participants have successfully passed stage 1 & 2 of the PAR-Q, and are therefore at 'low-risk' and cleared to exercise to volitional exhaustion. An AeD defibrillator is on site as an added safety precaution.

- All persons volunteering to perform maximal exercise tests are required to complete the PAR-Q form (Physical Activity Readiness Form, Q5 attached) to identify any possible health issues. Anyone not passing this assessment will not be able to perform the test.

- Written permission must be given by the participant before any maximal testing takes place.
- Testing will stop immediately if the volunteer becomes distressed in any way.
- Mets staff hold current first aid training and carry all necessary first aid supplied & equipment, including an automated external defibrillator.
- Mets Performance Consulting has performed more than 2,000 VO2 max tests with no serious or lasting negative outcomes, and can provide reference contact details on request.
- Volunteers will be given detailed instructions to help prevent any injuries from occurring.

Privacy and confidentiality

Your personal data will be known only to the study team. All data collected will be de-identified before analysis and stored securely in locked files at the NIIM clinic. No personal data will be divulged in publication.

Who is conducting the study and who should I contact if I have any questions about participating?

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Queries or complaints

If you wish to discuss with an independent person matters related to making a complaint, or your rights as a participants, contact the Human Research Ethics Committee's Secretary on hrec@niim.com.au.