# the FIT to Grow Old study - functionality of the immune system and healthy aging

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON54893

**Source**
ToetsingOnline

**Brief title**
FIT to Grow Old

### Condition

- Other condition

**Synonym**
Aging

**Health condition**

ouderdom

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Wageningen Universiteit
**Source(s) of monetary or material Support:** Hycult Biotech,Mead Johnson Nutrition,Ministerie van Landbouw;Natuur en Voedselkwaliteit; Hycult Biotec; Mead Johnson Nutrition

## Intervention

**Keyword:** Characterization, Elderly, Human monocytes, Immunometabolism

## Outcome measures

### Primary outcome

Cytokine and lactate production after ex-vivo exposure to pro-inflammatory

stimuli.

### Secondary outcome

ROS production, phagocytic capacity, glycolytic capacity, mitochondrial

capacity, metabolic response upon inflammation, immunophenotyping,

differentiation, transcriptomics, metabolomics, circulating metabolic and

immunological parameters in plasma or serum.

Other study parameters

- BMI

- Body composition

- CRP

- FFQ

- Questionnaires

# Study description

### Background summary

Aging is commonly associated with reduced functionality of the immune system, resulting in a higher prevalence of the infectious disease, auto-immune disease, cancer, and lower efficiency of vaccination. The reduction in immune functionality is called *immunosenescence* and is often observed in addition to a chronic state of systemic inflammation, referred to as *inflammaging*. It is commonly believed that strategies improving immune functionality can be applied to improve healthy aging. Nutritional strategies, in particular, receive increasing attention, as several foods and nutrients are shown to exert immunomodulatory properties. Nutritional strategies focussing on the intake of polyunsaturated fatty acids have indeed shown improvements in cytokine profile and inflammatory gene expression but suffer from large inter-individual variation, which might be caused by differences in immune functionality. Recent studies within the field of immunometabolism have shown that immune functionality is largely dependent on intracellular metabolism, leading to the introduction of the new term * immune cell fitness* which combines the metabolic and functional status of an immune cell. To improve the efficiency of immunomodulatory nutritional intervention strategies and work towards personalized approaches to support healthy aging, the identification of individuals with reduced immune cell fitness will be crucial.

### Study objective

During recent years the elderly*s immune system has drawn much attention by researchers as a target to improve quality of life during aging. Most research has focussed on the adaptive immune system, but knowledge of the innate immune system is lacking. Furthermore, the phenomena of inflammaging and immunosenescence are often present in the elderly but the meaning of these on a functional and metabolic level is poorly understood. Increased understanding of immune cell fitness in elderly and differences between individuals would be highly valuable for the application of personalized nutritional strategies to improve healthy aging. Therefore, the primary aim of this study is to extensively characterize immune cell fitness in the elderly population in order to distinguish immunologically fit elderly from the unfit. Since immune cell fitness is a new concept, we will define a good immune cell fitness state using a young adult study population. Using a follow-up visit, we will evaluate whether our measure of immune cell fitness is robust and stable over time. Furthermore, to identify potential nutritional strategies to improve immune cell fitness and work towards personalized approaches, we will identify metabolites or nutrients with the ability to improve immune cell fitness in the elderly.

### Study design

The study will be a cross-sectional study in which we will compare the immune fitness state of elderly people using young people as a positive control to define an *immune fit* status. Blood samples will be drawn after an overnight fast. Subjects will be given a standardized meal in the evening before and are not allowed to eat or drink anything but water after 20.00 h in the evening. Before the start of blood sampling, a small blood sample is collected to measure CRP levels. CRP levels of >=10.0 mg/L are considered to indicate severe infection and will consequently exclude the subject from participating that specific day. The relevant subjects are asked to make a new appointment. If CRP levels are repeatedly >=10.0 mg/L, the participant is excluded from further participation. The medical investigator will inform both the participant and the corresponding general practitioner. If CRP levels are < 10 mg/L, blood sampling will continue.
After blood sampling, anthropometric measurements including body weight and body height will be performed with each subject. A DEXA-scan will be performed to get insight into fat distribution since different fat depots can have different effects on the immune system. After anthropometric measurements, subjects will receive breakfast. Additionally, during the visit all subjects will fill in an FFQ and questionnaires on general health and sleep quality. After the characterization of the immunological fitness of each subject, only the elderly subjects are invited for a second study visit, which is identical to the first study visit. This blood sample will be used for an ex-vivo screening of potential immunomodulatory nutrients and metabolites which requires knowledge on the immunological state of the blood cells. The elderly population will be invited for the second visit at least 6 months and the latest 18 months after the first visit.

### Study burden and risks

Burden and potential risks by study procedures are estimated to be minor. The subject could experience mild pain by the venipuncture, which occasionally leads to feeling light-headed and fainting. The subject will sit on a chair during blood collection. A venipuncture could occasion-ally also lead to local hematoma.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• Age 20 - 30y and 60 - 75y
• BMI 18.5 - 25 kg/m2 (young adults) 20 - 30 kg/m2 (elderly)
• Willing to fast overnight for 12 hours
• Willing to give a blood sample
• Having veins suitable for blood sampling (judged by study nurse/medical doctor)
• Having a general practitioner
• Signed informed consent

## Exclusion criteria

• Diagnosed with metabolic and/or inflammatory disease (e.g. diabetes, cardiovascular disease (with the exception of hypertension), arthritis, arthrosis, and auto-immune diseases)
• Current diagnosis of cancer
• Regular use of medication that interferes with immune function (e.g. corticosteroids, cytokine blockers)
• Regular use of medication that may interfere with metabolism (e.g. metabolic inhibitors or activators)

• Use of medication that interferes with immune function and metabolism at least one week preceding the study visit (e.g. NSAID, anti-histamines, corticosteroids)
• More than 4kg weight loss over the last 4 months
• Vaccination within 1 month preceding the study visit (e.g. immunization against influenza, pneumonia, and travel-related infections)
• Donated blood within 2 months preceding the study visit
• Pregnant, lactating or wishing to become pregnant in the period between the screening and study visit (self-reported)
• Regular use of hard drugs and soft drugs (i.e. weekly use) and at least no use within 2 months preceding the study visit
• Excessive alcohol use (i.e. >14 glasses per week)
• Use of cigarettes and other tobacco products
• Participation in another study that involves an intervention 3 months preceding the study visit
• Members of the research team
• Working, or doing an internship or thesis at the division *Human Nutrition and Health*, Wageningen University

# Study design

## Design

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| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 11-11-2020 |
| Enrollment: | 159 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 28-01-2020 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 27-10-2020 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 09-09-2021 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL70696.081.19 |
| Other | Zal zsm worden bijgevoegd |