

Nijmegen Exercise Study: the role of physical activity on the prevention of cardiovascular diseases

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The primary purpose of this study is to determine the relation between a physically active lifestyle and the primary and secondary prevention of diseases and death. Using an online questionnaire, we will approach all civilian participants of the...

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|------------------------------|---|
| Ethical review | Approved WMO |
| Status | Recruiting |
| Health condition type | Cardiac disorders, signs and symptoms NEC |
| Study type | Observational non invasive |

Summary

ID

NL-OMON36083

Source

ToetsingOnline

Brief title

Nijmegen Exercise Study

Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

cardiovascular diseases; cancer

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular risk factors, Cohort study, Physical activity

Outcome measures

Primary outcome

The primary study parameter is the development of cardiovascular and/or chronic diseases.

Secondary outcome

Blood determinations (glucose, lipid profile)

Anthropometric data

Blood pressure

Maximal handgrip exercise

Walking characteristics

Study description

Background summary

The relation between physical activity and health is well known and often described. Inactivity increases the risk to develop chronic illnesses like, cardiovascular disease, hypertension, stroke, osteoporosis and diabetes mellitus. To prevent the development of these chronic illnesses, physical activity is prescribed in all its ways: by physicians, radio, television, newspapers and patient information. However, only 52% of the Dutch population meets the guidelines for physical activity (the Nederlandse Norm Gezond Bewegen). This national average is in contrast with participants of the Nijmegen Four Days marches. Previous studies by the department of Physiology showed that 92% of this unique population meets the physical activity guidelines. Moreover, this group of subjects seems to be physically active during the whole year, and most of them during their whole life.

This unique population enables us to assess the effect of a physically active lifestyle on the prevention of cardiovascular and chronic diseases. Moreover, we can determine whether it is beneficial to change to an active lifestyle

later in life, and the relation between physical activity and quality of life. Whilst previous studies predominantly focused on a representative sample of the general population, it is difficult to include enough subjects with an active lifestyle. Alternatively, these studies compare the physical activity levels between patient (and/or control) groups, or include subject at their current activity level (while not correcting for their activity levels in the decades before participation in the study). These approaches have important limitations regarding their validity and extrapolation to the general population. Therefore we will include participants of the Nijmegen Four Days Marches in which we can obtain the intensity, frequency and type of physical activity. Furthermore we can obtain the physical activity levels for the past years, and the reasons why a subject changed their lifestyle from inactive to active (potential in combination with the diagnosis of a chronic disease).

Study objective

The primary purpose of this study is to determine the relation between a physically active lifestyle and the primary and secondary prevention of diseases and death.

Using an online questionnaire, we will approach all civilian participants of the Nijmegen Four Days Marches in 2011, which will be repeated annually during the next 15 years.

In addition to the questionnaire, additional measurements are performed in a subgroup of 9,600 subjects. These tests reveal important information regarding risk factors for cardiovascular and metabolic diseases.

Study design

Observational cohort study

Study burden and risks

The total cohort will receive an annual invitation to complete the online questionnaire (20 minutes). The additional measurements in the subgroup (anthropometric data, blood pressure, maximal handgrip exercise, walking characteristics, blood drawing - 25 mL) have a minimal burden, physically as well as in time, and provide important information which is necessary for the primary aim of this study.

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

- older than 18 years
- participant of the Nijmegen Four Days Marches 2011
- for the subgroup with additional measurements subjects must be younger than 80 years

Exclusion criteria

There are no exclusion criteria for participation in this observational cohort study.

Study design

Design

| | |
|---------------------|---------------------------------|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

Primary purpose: Prevention

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-07-2011 |
| Enrollment: | 24500 |
| Type: | Actual |

Ethics review

| | |
|--------------------|--------------------------------------|
| Approved WMO | |
| Date: | 03-06-2011 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO | |
| Date: | 14-04-2020 |
| 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

CCMO

ID

NL36743.091.11