# Lifestyle as a Family Event

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**Ethische beoordeling** Positief advies **Status** Werving gestart

Type aandoening

**Onderzoekstype** Observationeel onderzoek, zonder invasieve metingen

## **Samenvatting**

#### ID

NL-OMON26277

**Bron** 

Nationaal Trial Register

Verkorte titel

LIFE

**Aandoening** 

Non-communicable disease (NCD)

## **Ondersteuning**

**Primaire sponsor:** Jeroen Bosch Ziekenhuis

Overige ondersteuning: Jeroen Bosch Ziekenhuis

### Onderzoeksproduct en/of interventie

#### **Uitkomstmaten**

#### Primaire uitkomstmaten

Mapping the clinical (e.g. medical and psychological) presentation of these patients, their level of physical activity and fitness level, their well-being, food preferences and taste development, their socio-economic background, the therapeutic approaches that are used, the course and the prognosis of patients with elevated risk for NCDs, with the aim of

improving our insight on recognition, diagnosis, treatment, counseling and prevention of the diseases that belong to the group of NCD's

## **Toelichting onderzoek**

#### Achtergrond van het onderzoek

Rationale: Non Communicable Diseases (NCDs), such as cardiovascular disease and diabetes, develop at early age. The basic approach both for prevention as for treatment purposes is a healthy lifestyle, e.g. a balanced diet, getting regular exercise and sufficient sleep. Unfortunately, not many people succeed in pursuing a healthy lifestyle. Furthermore, a lifestyle change for adults is very difficult and seldom successful. The greatest chance of success is achieved when learning a healthy lifestyle is started early. The question then is at what age should we start learning our children a healthy lifestyle? In elementary school, as a toddler or should we start as early as with the future parents in the preconception phase? Moreover, what exactly constitutes a healthy lifestyle at these age ranges? In any case, it is clear that the child is dependent on its parents. Learning to live a healthy lifestyle is most successful if the whole family adopts a healthy lifestyle. Healthy lifestyle becomes as it were, a permanent family event. In the preconception phase, generally, future parents are very eager to do the right thing for their coming child. Unfortunately, unexpected problems such as intrauterine growth retardation or premature birth can also arise during pregnancy, leading to increased risks for NCD's. In fact, throughout the full paediatric age range, conditions, diseases or disorders can arise that potentially increase the risk of chronic disease later on. In the Jeroen Bosch hospital, all these patient groups come for admission, treatment or regular check-ups. Measuring and monitoring these groups of patients provide invaluable information for understanding the development of NCDs and learning possible approaches towards better prevention or treatment of diseases.

Objective: Mapping the clinical (e.g. medical and psychological) presentation of these patients, their level of physical activity and fitness level, their well-being, food preferences and taste development, their socio-economic background, the therapeutic approaches that are used, the course and the prognosis of patients with elevated risk for NCDs, with the aim of improving our insight on recognition, diagnosis, treatment, counseling and prevention of the diseases that belong to the group of NCD's.

Study design: The LIFE study is a long term observational cohort study with an unlimited duration

Study population: potential patients coming to the reproductive medicine, obstetrics, neonatology and paediatric clinic of the hospital or collaborating centre, e.g. (future) parents and children with ages 0 months until 18 yr old

Intervention: not applicable

Main study parameters/endpoints: All data obtained from history, physical examination,

additional examination and data requested during the intake and follow-up contacts are used for the statistical analyzes regarding clinical presentation, recognition, diagnosis, therapeutic approaches used, course and prognosis

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: With the data obtained in the LIFE study, the care for patients with increased risks for NCDs can be improved in the future and prevention of NCDs can be organized more efficiently. Policy decisions may also be better substantiated with the help of data obtained. This can be beneficial for the test subject himself and for the group as a whole. Since it is an observational study, there is no risk of participation and no additional burden for the patient. All registered patients are eligible for inclusion, no distinction is made on any grounds.

#### Doel van het onderzoek

With the data obtained in the LIFE study, the care for patients with increased risks for NCDs can be improved in the future and prevention of NCDs can be organized more efficiently. Policy decisions may also be better substantiated with the help of data obtained. This can be beneficial for the test subject himself and for the group as a whole

#### Onderzoeksopzet

time points are related to the visits to the hospital, therefore measurements depend on the type of hospital visit with a minimal measurement of height en weight

#### Onderzoeksproduct en/of interventie

not applicable

## Contactpersonen

#### **Publiek**

Jeroen Bosch ziekenhuis Elma de Vaan

073-5532444

### Wetenschappelijk

Jeroen Bosch ziekenhuis Elma de Vaan

073-5532444

## **Deelname** eisen

# Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

referral to the department of reproductive medicine, obstetrics, neonatology and paediatrics of the Jeroen Bosch Hospital or collaborating centre and informed consent for the LIFE study.

# Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

unwillingness to provide informed consent for the LIFE study

## **Onderzoeksopzet**

#### **Opzet**

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel: Anders

Toewijzing: N.v.t. / één studie arm

Blindering: Open / niet geblindeerd

Controle: N.v.t. / onbekend

#### **Deelname**

Nederland

Status: Werving gestart

(Verwachte) startdatum: 03-08-2021

Aantal proefpersonen: 10000

Type: Verwachte startdatum

#### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

# **Ethische beoordeling**

Positief advies

Datum: 03-08-2021

Soort: Eerste indiening

# **Registraties**

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register ID

NTR-new NL9760

Ander register METC BRABANT : METC Brabant/21.084

## Resultaten