Lifestyle as a Family Event

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON26277

Source

Nationaal Trial Register

Brief title

LIFE

Health condition

Non-communicable disease (NCD)

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: Jeroen Bosch Ziekenhuis

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Gaining insight for future intervention studies of what will again be the subject of separate study applications

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

not applicable

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

unwillingness to provide informed consent for the LIFE study

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non controlled trial

Masking: Open (masking not used)

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 03-08-2021

Enrollment: 10000

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 03-08-2021

Application type: First submission

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

NTR-new NL9760

Other METC BRABANT : METC Brabant/21.084

Study results