

Tied to mommy*s womb?: the effects of prenatal maternal thyroid function and emotional complaints on infants*, toddlers* and preschoolers* self-regulation and socio-emotional adjustment; Part I

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To gain insight in the relation between maternal thyroid function and maternal emotional complaints during pregnancy and the development of the child in relation to the self-regulation capacities of the child.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON29816

Source

ToetsingOnline

Brief title

The Kempen study I

Condition

- Thyroid gland disorders
- Maternal complications of pregnancy
- Anxiety disorders and symptoms

Synonym

Emotional complaints during pregnancy and child development

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

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

Intervention

Keyword: early child development, Emotional complaints during pregnancy, parent-child interaction, thyroxine levels in pregnancy

Outcome measures

Primary outcome

Degree of behavioral problems of the child and assessment of the mental and motor development of the child.

Secondary outcome

Current degree of depression and anxiety of the mothers and fathers; personality of the parents, as well as their inclination to give socially desirable answers.

Study description

Background summary

Maternal hypothyroxinemia (fT4 smaller or equal to the lowest tenth percentile with normal TSH) during early gestation increases the risk of subsequent developmental delay of infants at one and two years of age (Pop et al., 2003). High maternal anxiety during pregnancy is also related to a delay in infant development (Brouwers et al., 2002). More research regarding the consequences of these factors, in relation to each other and controlling for other important factors (confounders), is necessary, because of different theoretical viewpoints and practical consequences.

One of the theoretical viewpoints concerns the possibility that the endocrine regulation of the mother has a lasting influence on the development of the fetus: *fetal programming* (Godfrey & Barker, 2001). Abnormalities in this

regulation disturb fetal development or the fetus adapts in a way that his own regulation systems are not optimally attuned to further postnatal development (Zoeller, 2003). In particular, the functioning of the child's HPA axis is possibly negatively influenced (O'Connor et al., 2002 and 2003). The endocrine regulation of the mother can be mildly disturbed, for example when maternal hypothyroxinemia occurs, and directly affecting fetal development. Also indirect disturbance of maternal endocrine regulation systems can result of her emotional complaints. Subsequently the own regulation systems of the fetus may be affected with consequences for later development. Children of depressed and anxious mothers appear to have several developmental problems that are possibly influenced in this way (Elgar et al., 2004; Huizink et al., 2004). In all studies concerning the development of children after perinatal risk factors, not all children with the same degree of risk are found to display developmental problems. Possibly there are factors that play a protective role. As potential protective factors, the influence of the father and the self-regulation capacities of the child need further research.

Study objective

To gain insight in the relation between maternal thyroid function and maternal emotional complaints during pregnancy and the development of the child in relation to the self-regulation capacities of the child.

Study design

Parents who indicated they are willing to participate with future research will receive several questionnaires at home. Current depressive symptoms and complaints of anxiety of the parents will be measured with self-report questionnaires: the Edinburgh Depression Scale (EDS; Pop et al., 1992) and the anxiety subscale of the Symptom Checklist-90 of Derogatis (SCL-90; Arrindell & Ettema, 2005). Personality of the parents will be measured with the Type D questionnaire (Denollet et al., 1996); the parents also have to answer a questionnaire that measures the degree they are inclined to answer in a socially desirable way (Crowne & Marlowe, 1964).

The development of the child will be measured with a questionnaire answered by the mother, the Dutch translation of the Ages and Stages Questionnaire (Bricker & Squires, 1996; Van Baar, van Bakel, & Hunnius, 2006). Behavioral problems will be measured with the Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2001). The degree of behavioral problems reflects also problems with self regulation.

Study burden and risks

The burden for the parents will be to answer questionnaires and experience a possible confrontation with unpleasant characteristics of themselves or their

child. Because these characteristics will already be known to them, this is seen as a limited burden. When parents have questions or would like to get further advice they can contact the researchers or the independent general practitioner.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

All women who signed the informed consent letter and participated in the original study from 12 weeks pregnancy onwards and delivered a life born child.

All women, their partners and children who participated in the study by dr. Wijnen and who consented to participation in a further study.

Exclusion criteria

The original exclusion criteria:

- deviant thyroid function
- severe illness during pregnancy like diabetes, reumathoid arthritis, eclampsia
- women with a deviant uterus
- women carrying multiples
- obstetrical parameters like placenta praevia, dysmature foetus
- severe congenital malformations of the foetus like trisomie or spina bifida
- insufficient knowledge of dutch language in view of the questionnaires
- Parents that did not consent with further studies;-

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2006

Enrollment: 500

Type: Actual

Ethics review

Approved WMO

Date: 15-08-2006

Application type: First submission

Review commission: METC Brabant (Tilburg)

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	NL12707.008.06