Pregnancy and the human brain: a window of neuroplasticity

Published: 05-08-2022
Last updated: 27-04-2024

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

Summary

ID

NL-OMON51565

Source
ToetsingOnline

Brief title
PHB

Condition

- Other condition

Synonym
n.v.t.

Health condition

the effects of a healthy pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: EU - ERC Starting Grant

Intervention

Keyword: Brain, Hormones, Plasticity, Pregnancy

Outcome measures

Primary outcome

Changes in measures of brain structure and function relative to the

pre-pregnancy baseline session.

Secondary outcome

We will relate these changes in brain structure and function during pregnancy

to gestational hormone levels, genetic factors, biological and lifestyle

factors, contingent changes in cognitive and social-cognitive functioning and

behavioral and neural indices of postpartum maternal responsiveness.

Study description

Background summary

During mammalian pregnancy, the body and brain are exposed to unequaled levels of sex steroid hormones. In non-human animals, this period is known to involve substantial, long-lasting alterations in neural architecture. Surprisingly, very little is known on the effects of pregnancy on the human brain, although hormone surges on a much smaller scale have been shown to affect brain morphology. In a previous prospective MRI study, we found extensive and long-lasting alterations in gray matter volume after pregnancy, which were primarily located in a network of higher-order association areas subserving social cognition (Hoekzema et al., 2017). While our previous findings on the impact of pregnancy on neural gray matter structure point to the existence of a dramatic pregnancy-related neural plasticity in humans, these insights only begin to scratch the surface and pave the way for further exploration of this

topic.

Study objective

Beyond mapping the pregnancy-related neural plasticity in structure and function, this project is designed to reveal functional and behavioral implications of the transformations impacting a woman*s brain across this major transitional stage. The proposed study is designed to reveal a comprehensive map of the transformations manifesting in a women*s brain across the unique transition to motherhood, by investigating changes in gray matter anatomy, structural and functional networks and connectivity and neural activity related to reward, inhibition and empathy. Furthermore, this study aims to gain key insights into the neural changes and associated biological factors underlying specific adaptive and maladaptive changes in maternal functioning.

Study design

This topic will be investigated using a prospective within-subjects case-control setup. Women with the intention to get pregnant in the near future will participate in an experimental session before trying to achieve this, and, if successful, will be asked to participate in a pregnancy session during the third trimester, an early postpartum (as soon as feels good, preferably after 4 weeks) and a late postpartum session (around one year after giving birth). Participants with no intention to become pregnant within the following year will be recruited as controls and will also take part in longitudinal experimental sessions. During the experimental sessions, we will use structural MRI and Diffusion Tensor Imaging (DTI) to examine brain anatomy. Moreover, the participants will perform fMRI paradigms targeting the reward circuitry, inhibition, and empathy as well as a resting state fMRI paradigm. Performance on a battery of cognitive tests and questionnaire data will also be collected. In addition, hormone levels, genetic information and inflammation markers will be determined from saliva, blood, hair, feces, and breastmilk. Except for the blood samples, all measures are non-invasive.

Study burden and risks

There are no known risks associated with participating in an MRI study. This is a noninvasive technique involving no catheterizations or introduction of exogenous tracers. Numerous children and adults have undergone magnetic resonance studies without apparent harmful consequences. Some people become claustrophobic while inside the bore;magnet and in these cases the study will be terminated immediately at the subject's request. The only absolute contraindications to MRI studies are the presence of intracranial or intraocular metal, or a pacemaker. Subjects who may have metallic foreign bodies in the eyes or head, or have cardiac pacemakers, will be excluded. Relative contraindications include pregnancy and claustrophobia. The first

acquisition will be planned prior to the participant*s pregnancy, but the second session involves an MRI acquisition in the third trimester of pregnancy for those women who can still participate in such a session without experiencing discomfort (i.e. inability to lie on back or side). Pregnancy is considered a relative contraindication for MRI exposure. However, in contrast to early pregnancy, MRI in the third trimester is commonly used for clinical purposes to examine fetal health. In addition, magnetic resonance imaging in the third trimester of pregnancy is also increasingly used for scientific research of healthy fetal development. Moreover, a growing body of research has examined the short-term and long-term consequences of in utero MRI exposure during late pregnancy, and these have not observed any effects on child development or hearing capacity.
Although there is no direct benefit to the participants from this proposed research, there are greater benefits to society from the potential knowledge gained from this study. This knowledge is critical to increase our understanding of the way the human brain is modified during pregnancy, a topic of wide interest that affects many women. Moreover, this knowledge will pave the way for elucidating how these changes contribute to the development - and potential disruptions herein * ofadequate maternal responsiveness, to identify neural markers that signal a predisposition for peripartum mental disorders and to evaluate the gestational changes that precede their emergence.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Women of age between 20 and 45 years
2. The intention to become pregnant (pregnancy group) or not (control group) in the near future
3. No neurological disorder/disease
4. No contraindications to MRI
5. No previous pregnancy beyond the first trimester

Exclusion criteria

1. History of neurological disorder/disease
2. Contraindications to MRI, which include metal implants, heart arrhythmia, claustrophobia, and possible early pregnancy
3. A previous pregnancy beyond the first trimester

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2023

Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL80273.018.22