Trial Description

Title

Prevention network Western Pomerania: Mental and neurobiological health in pregnant women and young mothers

Trial Acronym

PriVileG-M

URL of the trial

https://www.uni-greifswald.de/universitaet/information/aktuelles/detail/n/praeventionsstudie-zu-stress-und-sorgen-waehrend-der-schwangerschaft-und-nach-der-geburt-43743/

Brief Summary in Lay Language

PriVileG-M is a scientific pilot study conducted in Western Pomerania and it is designed to focus on pregnant women. We want to support the expectant mothers in reducing their own and their infants stress level. Furthermore we want to assist the participants in building a stable relationship with their child, reacting more self-confindent in conflicts and strengthen their self-competence.
The duration of the study is approximately 16 months. A total of five study assessments are planned with consultation/psychological support, filling in questionnaires, extraction of biological samples (for example blood and saliva), video recording, internet survey of the partners.

Brief Summary in Scientific Language

Background: As early as pregnancy, maternal mental stress impinge on the child development and health. Thus, this may cause an enhanced risk for premature birth, lowered fetal growth, and lower fetal birth weight as well as enhanced levels of the stress hormone cortisol and lowered levels of the bonding hormone oxytocin. Maternal stress further reduces maternal sensitivity for the child's needs which impairs the mother-child-interaction and bonding. Therefore, prevention and intervention studies are necessary that focus on mentally stressed parents begin in prepartum and apply rigorous research methodology, such as randomized controlled trials, to ensure high validity.
Methods: A sequentially randomized controlled trial is used to assess the impact of psychotherapy and telemedicine on maternal mental stress and the child's mental and physical health. Mentally stressed pregnant women are randomized to an intervention (IG) and a not intervened control group (CG). The IG receives an individualized psychotherapy starting prepartum and lasting for 10 months. Afterwards, a second randomization is used to investigate whether the use of telemedicine can stabilize the therapeutic effects. Using ambulatory assessments and video recording, the transfer into daily life, the maternal sensitivity and the mother-child-bonding are assessed. Psycho-biologically, the synchronicity of

cortisol and oxytocin levels between mother and child are assessed. The peptidome of the colostrum and breast milk, which are assumed to be essential for the adaptation of the child to the extra-uterine environment, is investigated. Moreover, an internet survey of the partners will be implemented (baseline, 8 weeks, 26 weeks, 52 weeks) to assess their influence on child development und maternal health.
All assessments made are compared with the assessments of healthy women. Finally, the results of the study will lead to the development of a qualification measure for health professionals who will be trained to detect mental stress, to treat it with low-level interventions and to refer those women with high stress levels to professional institutions
Discussion: The study aims to prevent the transgenerational transfer of psychiatric and somatic disorders from the mother to her child. The effects of the psychotherapy will be stabilized through telemedicine and long-term impacts on the child's and mothers' mental health are enhanced. The combination of psychotherapy, telemedicine and the methodologies of ambulatory assessment, video recording and biobanking are new in content-related and methodological manner.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

The study results will be released to the scientific public by conferences and international peer-reviewed impact journals as well as to the general public by presentations in health care organizations and national congresses. The study results will also contribute to the development of a qualification measure informing nurses, midwifes, pediatricians and mental healthcare practitioners about low-level interventions for stressed pregnant and postpartum women.
The datasets generated during the current study are available from the corresponding author on reasonable request.

Organizational Data

- DRKS-ID: **DRKS00017065**
- Date of Registration in DRKS: **2019/05/02**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **BB 012/19 , Ethikkommission an der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1230-9826**

Health condition or Problem studied

- Free text: **prenatal und postnatal maternal mental and physical health**
- Free text: **prenatal und postnatal mental and physical health of the offspring**

Interventions/Observational Groups

- Arm 1: **1. control group: mentally stable women**
- Arm 2: **2. control group: mentally stressed women without intervention**
- Arm 3: **Mentally stressed women with psychotherapeutic intervention and following telemedical intervention (psychotherapeutic Intervention from the end of the 2nd trimester until 26 weeks postpartal; telemedical intervention from week 26 postpartal until 52 weeks postpartal)**
- Arm 4: **Mentally stressed women with psychotherapeutic intervention without subsequent telemedical intervention**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Concerning the women, interventions are expected to reduce mental stress (assessed by the BSI-18 to screening, baseline and 8-week, 26-week and 52-week follow-ups)

Secondary Outcome

(1) concerning the women
i. to improve quality of life
ii. to enhance resilience
iii. to increase rates of breastfeeding mothers

(2) Concerning the children, interventions are expected

i. to reduce rates of preterm birth as well as complications during childbirth
ii. to reduce regulation disorders
iii. to reduce developmental retardations
iv. to strengthen physical health

(3) Concerning women and children, interventions are expected
i. to improve mother-child-interaction and to strengthen bonding (MAAS, PBQ, CARE Index)
ii. to lower cortisol levels and to increase oxytocin levels in both mother and child
The outcomes (1) to (3) are expected to converge to those of healthy mothers and children in the control group. In contrast, it is assumed that these outcomes depart in the group of stressed women without intervention from those of the intervention group.

(4) In addition, the results of the study will lead to the development of a qualification measure for health professionals who will be trained to detect mental stress, and in turn to refer those women to professional institutions.

The study aims to examine by explorative analysis hormonal transmissions between mother and child. Therefore, a biobank will be built up to analyse DNS-sequences, RNA-expression, miRNA as well as DNA methylation and other metabolomics. In particular, the study scrutinizes how the development of the HPA-axis in infants is shaped by depressive symptoms of the mother and how the HPA-axis in mother and infants is influenced by the different interventions of the study. Moreover, the constituents of breast milk will be analyzed, as well as hormonal responses of mother and child to stress.
Quantitative and qualitative analysis of the subjective satisfaction of the woman as well as of the efficacy and feasability of the intervention study.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Greifswald**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/05/19**
- Target Sample Size: **240**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**

Gender: **Female**

- Minimum Age: **17 Years**
- Maximum Age: **45 Years**

Additional Inclusion Criteria

Pregnant women are included if they are between 18 and 45 years of age and at the end of the second pregnancy trimester (25th to 29th week of pregnancy).

Exclusion criteria

Women with multiple pregnancies or foreseeable developmental disabilities of the fetus, as well as women requiring withdrawal, exhibiting low motivation for therapy, suffering alcohol or drug addiction (DIPS), having severe psychosis or reporting suicidality (DIPS) need to be excluded. In addition, women being submitted to a recent psychiatric or psychotherapeutic treatment (or another study including such treatments) have to be excluded in order to impede confounding of therapeutic effects. Women who are 17 years old at the screenings, can be included, but will be excluded if they won't reach the age of 18 at delivery.

Addresses

- **Primary Sponsor**

Universitätsmedizin Greifswald, Klinik und Poliklinik für Psychiatrie und Psychotherapie
Mr. Prof. Dr. Hans Grabe
Ellernholtzstraße 1-2
17489 Greifswald
Germany

Telephone: **03834 86 6842**
Fax: **[---]***
E-mail: **grabeh at uni-greifswald.de**
URL: **[---]***

- **Contact for Scientific Queries**

Universitätsmedizin Greifswald, Klinik und Poliklinik für Psychiatrie und Psychotherapie
Ms. Juliane Corleis
Walther-Rathenau-Str. 43-45
17489 Greifswald
Germany

Telephone: **01522 2406323**
Fax: **[---]***

Contact for Scientific Queries

Universitätsmedizin Greifswald, Klinik und Poliklinik für Psychiatrie und Psychotherapie
Ms. Juliane Corleis
Walther-Rathenau-Str. 43-45
17489 Greifswald
Germany

Telephone: **01522 2406323**
Fax: **[---]***
E-mail: **juliane.corleis at uni-greifswald.de**
URL: **[---]***

■ **Contact for Public Queries**

Universitätsmedizin Greifswald, Klinik und Poliklinik für Psychiatrie und Psychotherapie
Ms. Juliane Corleis
Walther-Rathenau-Str. 43-45
17489 Greifswald
Germany

Telephone: **01522 2406323**
Fax: **[---]***
E-mail: **privileg at uni-greifswald.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universitätsmedizin Greifswald, Klinik und Poliklinik für Psychiatrie und Psychotherapie
Mr. Prof. Dr. Hans Grabe
Ellernholzstraße 1-2
17489 Greifswald
Germany

Telephone: **03834 86 6842**
Fax: **[---]***
E-mail: **grabeh at uni-greifswald.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universität Greifswald, Institut für Psychologie Lehrstuhl Gesundheit und Prävention
Ms. Prof. Dr. Silke Schmidt
Robert-Blum-Straße 13
17489 Greifswald
Germany

Collaborator, Other Address

Universität Greifswald, Institut für Psychologie Lehrstuhl Gesundheit und Prävention
Ms. Prof. Dr. Silke Schmidt
Robert-Blum-Straße 13
17489 Greifswald
Germany

Telephone: **03834 420 3800**
Fax: **[---]***
E-mail: **Silke.schmidt at uni-greifswald.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universitätsmedizin Greifswald, Neonatologie und Pädiatrische Intensivmedizin
Mr. Prof. Dr. Matthias Heckmann
Ferdinand-Sauerbruch-Straße
17489 Greifswald
Germany

Telephone: **03834 86 6421**
Fax: **03834 86 6422**
E-mail: **matthias.heckmann at uni-greifswald.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universitätsmedizin Greifswald, Klinik und Poliklinik für Frauenheilkunde und Geburtshilfe
Mr. Prof. Dr. Marek Zygmunt
Ferdinand-Sauerbruch-Straße
17489 Greifswald
Germany

Telephone: **03834 86-6500 / 866503**
Fax: **[---]***
E-mail: **zygmunt at uni-greifswald.de**
URL: **[---]***

■ **Collaborator, Other Address**

Universitätsmedizin Greifswald, Institut für Community Medicine / Abt. Versorgungsepidemiologie und Community Health
Ms. PD Dr. Neeltje Van den Berg
Ellernholzstr. 1-2
17489 Greifswald
Germany

Collaborator, Other Address

Universitätsmedizin Greifswald, Institut für Community Medicine / Abt. Versorgungsepidemiologie und Community Health
Ms. PD Dr. Neeltje Van den Berg
Ellernholzstr. 1-2
17489 Greifswald
Germany

Telephone: **(0)3834 86 77 71**
Fax: **[---]***
E-mail: **neeltje.vandenberg at uni-greifswald.de**
URL: **[---]***

■ **Collaborator, Other Address**

Hochschule Neubrandenburg, Pflegewissenschaft/Ambulante Dienste
Ms. Prof. Dr. Bedriska Bethke
Brodaer Straße 2
17033 Neubrandenburg
Germany

Telephone: **0395 5693 - 3100**
Fax: **[---]***
E-mail: **bethke at hs-nb.de**
URL: **[---]***

Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Landesamt für Gesundheit und Soziales M-V
E.-Schlesinger-Straße 35
18059 Rostock
Germany

Telephone: **0381**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Ministerium für Arbeit, Gleichstellung und Soziales M-VReferat 540 "ESF-Fondsverwaltung/-steuerung"
Mr. Eberhard Messmann
Werderstraße 124
19055 Schwerin

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Ministerium für Arbeit, Gleichstellung und Soziales M-VReferat 540 "ESF-Fondsverwaltung/-steuerung"
Mr. Eberhard Messmann
Werderstraße 124
19055 Schwerin
Germany

Telephone: **0385 5889540**
Fax: **eberhard.messmann@sm.mv-regierung.de**
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*