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Bridging mothers with their children

Submission date 24/02/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/02/2026	**Overall study status** Ongoing	
Last Edited 26/02/2026	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

APVV
18-0283

Study information

Scientific Title

Bridging maternal and child psychological and neuroendocrine functions: underlying mechanisms

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/11/2019, Ethics Committee of the University Hospital with Polyclinic Bratislava (St. Cyril and Methodius Hospital Antolska 11, Bratislava, 85107, Slovakia; +421 268672507; stefan.simko@pe.unb.sk), ref: 11282019

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
The study focuses on the relationship between maternal and child psychological states, with a focus on postpartum blues and the mechanisms that play a key role in mediating this connection.

Interventions
The dyads (mothers and simultaneously their neonates) are being investigated twice, namely 3–4 days (72–96 h) postpartum and 7–9 months postpartum. The first examinations are done at the maternity hospital on the day of the discharge in the afternoon (13.00–16.00 h) to avoid the influence of daily rhythms on endocrine parameters. The mothers are administered psychometric questionnaires (EPDS, BDI, STAI, CISS, ZUNG). Saliva samples are collected from both the mother and her neonate under resting, non-stress conditions as well as in response to compulsory heel blood sampling in the form of the heel-prick test and in response to Still face test Paradigm. A 3 cm long strip of hair (starting from the scalp) is obtained from the mother at the time of both visits.

Intervention Type
Mixed

Primary outcome(s)
1. Maternal depressive symptoms measured using Edinburgh Postnatal Depression Scale EPDS, STAI, BDI, ZUNG, CISS at 3rd or 4th post partum day, at 7th - 9th months of infant age

2. Mother and infant salivary cortisol and alfa-amylase reactivity measured using ELISA, kinetic enzyme assay at sampling in the afternoon (13.00–16.00h), before stressor application and 20 minutes after

3. Hair cortisol measured using ELISA at in the end testing at 3rd or 4th post partum day, at the 7–9 month postpartum, in the end of a follow-up visit at the Research Clinic

Key secondary outcome(s))

1. FACS Facial action unit activity measured using automated computational analysis at during Still face test

Completion date
30/08/2030

Eligibility

Key inclusion criteria
1. A physiological course of gravidity, term birth (37 weeks 0 days to 41 weeks 6 days of gestation),
2. Eutrophic neonate with good post-delivery adaptation (Apgar score 7 or more in the first minute, pH in umbilical cord blood above 7.2)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
3 days

Upper age limit
45 years

Sex
All

Total final enrolment
84

Key exclusion criteria
1. The chronic somatic diseases of the mother before or during gravidity
2. A psychiatric disorder of the mother
3. Occurrence of gestosis, gestational diabetes or liver disease in pregnancy
4. BMI above 30 kg/m² at the beginning of pregnancy
5. Surgical conductance of the labor (forceps, vacuum extractor)
6. Drug abuse
7. Asphyxia of the neonate (Apgar score <6 in the 5th minute and/or pH in umbilical cord blood in the first minute below 7.2)

Date of first enrolment
01/11/2020

Date of final enrolment
06/02/2024

Locations

Countries of recruitment
Slovakia

Sponsor information

Organisation
The Slovak Research and Development Agency

Funder(s)

Funder type

Funder Name
Biomedical Research Center of the SAS, The Slovak Research and Development Agency

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Informed consent		26/02/2026	No	No
Other files	Informed consent in Slovak		26/02/2026	No	No
Participant information sheet			26/02/2026	No	Yes
Participant information sheet	in Slovak		26/02/2026	No	Yes
Protocol file			26/02/2026	No	No