

Trial Description

Title

BLUES-Studie: Beyond Labour - Use and Effects of Singing on wellbeing

Trial Acronym

Blues

URL of the trial

[---]*

Brief Summary in Lay Language

The relationship between birth mode, wellbeing of the mother, breastfeeding and mother-infant bonding will be explored in the current study. Furthermore, the influence of a postnatal singing intervention as a preventive and interventional method is explored.

Brief Summary in Scientific Language

The study explores the relationship between birth mode, wellbeing, breast feeding and mother-infant bonding. Additionally it investigates whether a singing intervention influences wellbeing, postnatal depressive symptoms and mother-infant bonding.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015178**
- Date of Registration in DRKS: **2018/11/09**
- 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.: **2018-175 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

Health condition or Problem studied

- Free text: **pregnancy**

Interventions/Observational Groups

- Arm 1: **experimental group - singing intervention; the mothers are offered participation after birth. After inclusion they are asked to fill in the first questionnaires (including the childbirth experience questionnaire, questionnaire regarding well-being (EPDS, STAI-state, VAS), and mother infant bonding. They are then assigned (randomized) to one arm. Two weeks after birth they are asked to fill in questionnaires online (same questionnaires as T1). In the singing group, mothers are asked to join at least two singing intervention in the clinic with their baby between the 4th and 12th week of life. Before and after the intervention the mood of the mothers is evaluated as well as saliva samples are taken to examine Cortisol and oxytocin. In the singing intervention a music therapist will sing songs with the mothers and babies and will teach them nursery rhymes. Three months after birth the mothers are asked to fill in another inventory of questionnaires.**
- Arm 2: **control group - no intervention; the procedure is identical to the experimental group except that the control group does not receive an intervention**

Characteristics

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

Primary Outcome

Evaluation of the effect of a singing intervention on wellbeing of the mother

(evaluated with STAI-State, EPDS, VAS at T3 - 3 months after birth) ; evaluation of the effect of a singing intervention on mother-infant bonding (evaluated with the postnatal bonding questionnaire at T3); evaluation of the relationship between birth mode and wellbeing (evaluated with the STAI-State, EPDS and VAS at T1 - 24h after birth, T2 - 2 weeks after birth and T3 - 3 months postpartum) ; evaluation of the relationship between birth mode and mother-infant bonding (evaluated with the postnatal bonding questionnaire at T1, T2 and T3); evaluation of the influence of the birth experience on mother-infant bonding (evaluated with the Childbirth Experience Questionnaire and postnatal bonding questionnaire at T1, T2 and T3)

Secondary Outcome

Evaluation of the direct effect of a singing intervention on the mothers mood (pre and post measuring time point of the intervention using the SMA questionnaire and cortisol and oxytocin levels from saliva); evaluation of the influence of trait anxiety and personality on the effect of the intervention (by means of the STAI-Trait Questionnaire and the Big Five personality questionnaire); evaluation of the influence of trait anxiety and personality on birth mode (by means of the STAI-Trait Questionnaire and the Big Five personality questionnaire); evaluation of the satisfaction with the intervention (using a self-generated questionnaire); evaluation of the influence of birth mode on birth experience (Childbirth Experience Questionnaire); evaluation of the effect of birth mode on postnatal anxiety and stress level (using VAS and STAI-State); evaluation on the time course of several parameters (birth experience, anxiety, wellbeing, mother-infant bonding) taking into account birth mode at all measurement points (T1 - 24h after birth; T2 - 2 weeks after birth; T3 - 3 months after birth).

Countries of recruitment

- DE Germany

Locations of Recruitment

- University Medical Center **Frauenklinik, Düsseldorf**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/13**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**

Gender: **Female**

■ Minimum Age: **18 Years**

■ Maximum Age: **60 Years**

Additional Inclusion Criteria

informed written consent

Exclusion criteria

hearing deficits, serious complications during birth or serious comorbidities of the mother (according to the assessment of the principle physician), transfer of the mother into intensive care, known serious illnesses of the baby, transfer of the newborn into special care, anxiety disorder of the mother, insufficient German language level.

Addresses

■ **Primary Sponsor**

**Heinrich-Heine-Universität
Universitätsstr. 1
40225 Düsseldorf
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Contact for Scientific Queries**

**Institut für Experimentelle Psychologie
Heinrich-Heine-Universität
Ms. Dr. Nora K. Schaal
Universitätsstr. 1
40225 Düsseldorf
Germany**

Telephone: **0211 8113863**

Fax: **0211 8113490**

E-mail: **nora.schaal at hhu.de**

URL: [---]*

■ **Contact for Public Queries**

**Institut für Experimentelle Psychologie
Heinrich-Heine-Universität
Ms. Dr. Nora K. Schaal**

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Institut für Experimentelle Psychologie Heinrich-Heine-Universität

Ms. Dr. Nora K. Schaal

Universitätsstr. 1

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Germany

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URL: [---]*

Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Else-Kröner-Fresenius Stiftung

Am Pilgerrain 15

61352 Bad Homburg v. d. Höhe

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2019/10/10**

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.