

PRIX SOCIAL CHIESI 2021 pour la NEONATOLOGIE

1. APPLICANT INFORMATION

First Name	Aline
Last name	Vuckovic
Date of birth	May 13, 1980
Place of birth	Namur, Belgium
Degrees	MD, PhD
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2. PROJECT INFORMATION

2.1. PROJECT TITLE

Mindfulness to improve parental well-being and neurobehavior of preterm infants.

2.2. ABSTRACT

The neonatal intensive care unit (NICU) is an important source of stress for preterm infants and their parents.^{1,2} As key features of brain growth and establishment of neuronal networks occur during the NICU stay occur during the NICU stay, exposition to environmental stressors such as lightening, sounds, nociceptive procedures, and dystimulations related to caregiving activities can alter brain development.³ Besides, parents of preterm infants, far from the expected normal pregnancy, experience one of the most stressful times of their lives. Factors contributing to increase parental stress include high-tech equipment, prematurity-associated comorbidities, and altered parenting role.^{4,5} In the case of difficult coping, high levels of distress can impair the parent-infant attachment process, and further alter neonatal neurodevelopment.⁴

Family-centered care programs have been introduced to welcome parents and families in the NICU and involve them in the daily care of preterm infants.⁶ Such programs are based on individualized care promoting well-being, growth, and neurodevelopment through reinforcement of parent-infant interactions. As such, parents are implicated in decision processes for their child, while protecting sleep, providing skin-to-skin holding, minimizing stress and pain, and promoting nutrition via breastfeeding.⁷

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This implies that healthcare professionals become flexible in their activities and support the fundamental role of parents by bringing adequate information and individualized psychological assistance to attenuate stress.⁷ Among possible stress-relieving techniques, mindfulness meditation consists of relaxing the body and mind by focusing on the present moment with awareness, curiosity, and non-judgment.⁸ Through accepting every situation with detachment and openness, mindfulness can help develop adaptive ways of responding to stress in various clinical populations.⁹ It has been suggested that mindfulness-based interventions may improve early parent-infant interactions by increasing parents' ability to attend to their infants without becoming preoccupied by negative or self-critical thoughts.^{10,11} Because of potential risks associated with the use of psychotropic medication for breastfeeding women, nonpharmacological approaches might be important to attenuate psychological distress in mothers. There is some evidence that mothers who are more vulnerable to depression or anxiety may gain more benefit from mindfulness-based interventions than universal perinatal populations.¹² Based on this rationale, the MINDPI project aims at implementing mindfulness meditation for parents of very preterm infants throughout the NICU stay, to increase parental well-being, promote participation and parent-infant bonding, as well as improve early neurobehavior in infants after discharge. Because mindfulness is harmless, inexpensive, and growingly accepted in the public and all cultures, we expect that this meditation technique will be beneficial for most parents and their newborns and increase the quality of care that we offer in our NICU.

2.3. DETAILED PROJECT DESCRIPTION

2.3.1. Objectives

- Primary objective: to evaluate the effects of a mindfulness-based program on the level of participation of parents having a preterm infant hospitalized in the NICU.
- Secondary objectives: to evaluate the effects of a mindfulness program on the level of parental stress and neurobehavioral outcomes of preterm infants between discharge from the NICU and 6 months corrected age.

2.3.2. Design, eligibility and recruitment

As the intervention will target the whole unit staff, a randomized controlled study design is not applicable. Therefore, a prospective pre-/post-intervention design will be applied. Parents will be eligible if their infant is born ≤ 33 weeks gestational age, not transferred postnatally, and alive at discharge. This ensures a minimum NICU stay of 4 weeks. Infants receiving palliative care, being in a life-threatening state, or presenting major health issues impairing the quality of mother-infant interactions will not be considered for analyses. On a twice weekly basis, the eligibility of parents will be screened at the end of the NICU stay (around 37 weeks postmenstrual age). The study will be verbally explained to eligible parents, who will also be given a packet containing a study summary, a consent form, and contact information. Parents will have to give their consent within 3 days. After having signed the informed consent form, eligible parents and infants will be enrolled.

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2.3.3. Description of intervention

A first cohort, defined as the pre-intervention cohort, will receive the standard educational program as currently provided in our NICU. The second cohort, defined as the post-intervention cohort, will receive mindfulness-based coaching on the top of standard care, defined as the new standard of care. The standard education program includes: (1) information about breastfeeding, skin-to-skin contact, and sensorimotor development of the preterm infant; (2) bedside education related to the observation and recognition of preterm infant's behaviors and signs of infant self-regulation; (3) individualized support by a social worker, lactation consultant, intercultural mediator, or psychologist/psychiatrist; and (4) nursing support to help parents for bathing, feeding, diapering, and skin-to-skin holding.

The intervention program will consist of a flexible mindfulness program derived from the original mindfulness-based cognitive therapy (MBCT). All NICU healthcare providers (including neonatologists, nurses, and psychologists) will receive a formal MBCT training. Among them, a team of NICU volunteers will learn how to teach MBCT in a medical setting to identify parental needs, conduct exercises adapted for parent-infant interactions, and coach parents in their practice. At the end of the first week postpartum, the training of parents will start with a face-to face session (30-45 minutes), where the principles of mindfulness will be addressed, and two techniques will be demonstrated. Parents will be encouraged to practice while providing skin-to-skin contact and/or at home at their own rhythm. Audio and video recordings will be available on a secured web page designed for mindfulness practice (access via smartphone or touch-screen tablet provided in the NICU). Parents will meet the nursing staff every week of the stay to help adapt the practice.

2.3.4. Outcomes

Socio-demographic characteristics of parents as well as perinatal and neonatal comorbidities will be collected in the control and intervention groups. The primary outcome is the change in breastfeeding rate at discharge and duration of skin-to-skin contact per day of NICU stay, which is known to be inversely related to the level of maternal distress.¹⁸ Secondary outcomes will capture the change in the aspects of mindfulness using the Five Facet Mindfulness Questionnaire in parents at discharge; change in parenting and child attachment assessed by the Mother-to-Infant Bonding Scale at 1 month corrected age; change in maternal depression measured by the Edinburgh Postnatal Depression Scale at 4 months corrected age; and neurobehavioral outcomes assessed by the Neonatal Behavioral Assessment Scale at 1 month corrected age, the Ages and Stages Questionnaire at 4 months corrected age, and the Bayley-III Mental Developmental Index at 6 months corrected age. Except for the Five Facet Mindfulness Questionnaire, all the questionnaires and scales cited above are part of the regular follow-up of very preterm infants in our institution, and therefore, do not represent research tools.

2.3.5. Statistical plan

Considering two-sided tests with a power of 80% and α -value of 0.05, an estimated sample of 40 infants per group are required for an increase in $\geq 40\%$ in the primary outcome variable. We anticipate a high participation rate, as questionnaires and neurodevelopmental assessment are part of the regular follow-up for very preterm infants in our institution.

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Based on an expected participation rate of 90% and dropout rate of 10%, the expected number of infants will be 50 per group. Comparisons between pre-intervention and post-intervention cohorts will be performed using the Fisher's exact test (qualitative variables) and the Mann-Whitney U test or unpaired t-test (quantitative variables), completed by multivariate analysis.

2.3.6. References

1. Baía I, Amorim M, Silva S, Kelly-Irving M, de Freitas C, Alves E. Parenting very preterm infants and stress in Neonatal Intensive Care Units. *Early Hum Dev.* 2016;101:3-9.
2. Weber A, Harrison TM. Reducing toxic stress in the neonatal intensive care unit to improve infant outcomes. *Nurs Outlook.* 2019;67:169-189.
3. Altimier L, Phillips R. Neuroprotective care of extremely preterm infants in the first 72 Hours after birth. *Crit Care Nurs Clin North Am.* 2018;30:563-583.
4. Kim P. How stress can influence brain adaptations to motherhood. *Front Neuroendocrinol.* 2021;60:100875.
5. Busse M, Stromgren K, Thorngate L, Thomas KA. Parents' responses to stress in the neonatal intensive care unit. *Crit Care Nurse.* 2013;33:52-9.
6. Craig JW, Glick C, Phillips R, Hall SL, Smith J, Browne J. Recommendations for involving the family in developmental care of the NICU baby. *J Perinatol.* 2015;35 Suppl 1:S5-8.
7. Roué JM, Kuhn P, Lopez Maestro M et al. Eight principles for patient-centred and family-centred care for newborns in the neonatal intensive care unit. *Arch Dis Child Fetal Neonatal Ed.* 2017;102:F364-F368.
8. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. *Gen Hosp Psychiatry.* 1982;4:33-47.
9. Goyal M, Singh S, Sibinga EM et al. Meditation programs for psychological stress and well-being: a systematic review and meta-analysis. *JAMA Intern Med.* 2014;174:357-368.
10. Petteys AR, Adoumie D. Mindfulness-based neurodevelopmental care: Impact on NICU parent stress and infant length of stay; A Randomized Controlled Pilot Study. *Adv Neonatal Care.* 2018;18:E12-E22.
11. Mendelson T, McAfee C, Damian AJ, Brar A, Donohue P, Sibinga E. A mindfulness intervention to reduce maternal distress in neonatal intensive care: a mixed methods pilot study. *Arch Womens Ment Health.* 2018;21:791-799.
12. Lever Taylor B, Cavanagh K, Strauss C. The effectiveness of mindfulness-based interventions in the perinatal period: A systematic review and meta-analysis. *PLoS One.* 2016;11:e0155720.

2.4. FEASIBILITY, TIMETABLE & BUDGET

2.4.1. Feasibility

The feasibility of the implementation of mindfulness meditation in the NICU as well as its acceptance in the perinatal population have been previously demonstrated.^{10,11}

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Because the project team includes child psychiatrists and psychologists specialized in MBCT training and neurobehavioral assessment of preterm infants, successful teaching of MBCT to parents and regular follow-up will be ensured. The sample size of 50 infants per group will be achieved within 2,5 years, which is consistent with the number of admissions of very preterm infants in Belgian NICU's.

2.4.2. Timetable

	2021		2022												2023												2024													
	11	12	01	02	03	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06	07	08	09	10	11	12		
Ethics review & approval	◆																																							
Pre-intervention study																																								
Inclusion at NICU discharge																																								
First subject In		◆																																						
Follow-up visits until 6 months																																								
Mindfulness training provided to NICU professionals																																								
Intervention study																																								
Mindfulness coaching to parents																																								
Inclusion at NICU discharge																																								
Follow-up visits until 6 months																																								
Last subject out																																								◆
Data collection & monitoring																																								
Data analysis & dissemination of results																																								

2.4.3. Budget

Expense description	Amount
4 group classes of MBCT training for NICU health professionals (18 hours/cycle; 90€/hour) – Name of the instructor : Arnaud Boonen.	6480€
Design of a secured web page dedicated to parental mindfulness (including video and audio recordings)	2500€
2 touch-screen tablets for meditation practice, used by parents during their presence in the NICU	750€
TOTAL	9730€

3. TEAM COMPOSITION AND CURRICULUM VITAE OF EACH MEMBER

3.1. Aline VUCKOVIC

Professional training

- Academic degree: Ph.D. in Medical Science (ULB, 2016); Interuniversity Diploma in Neonatal Medicine and Resuscitation (Université Paris-Descartes, 2017); Master of Specialization in Pediatrics (ULB, 2012); Medical Doctor (ULB, 2005).
- Belgian professional title of neonatologist (2017).
- Other relevant trainings: Interuniversity Certificate in Medical Management (ULB, 2020); Developmental Care in Neonatology following A. Bullinger (in-hospital training provided by Geneva University Hospitals, 2017-2018); Training in intensive care and neonatal echocardiography (TINEC), CHUV Lausanne, Switzerland (2019).

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Professional career (medical & teaching)

- Head of Clinic, NICU, Queen Fabiola Children's University Hospital (since 2020).
- Co-chair for academic courses (clinical pediatric teaching in Master 2 & 3 in Medicine, ULB, since 2020).
- Deputy Head of Clinic, NICU, Queen Fabiola Children's University Hospital (2018–2020).
- Resident doctor, NICU, Queen Fabiola Children's University Hospital (2014–2018).
- Senior lecturer, Faculty of Medicine, ULB, Brussels (since 2018).
- Doctoral training in the Laboratory of Physiology and Pharmacology (ULB, 2008–2014).

Main publications

- Vuckovic A, Herber-Jonat S, Flemmer AW, Strizek B, Engels AC, Jani JC. Antenatal BAY 41-2272 reduces pulmonary hypertension in the rabbit model of congenital diaphragmatic hernia. *Am J Physiol Lung Cell Mol Physiol* 2016;310:L658-L669.
- Vuckovic A, Herber-Jonat S, Flemmer AW, Ruehl IM, Votino C, Segers V, Benachi A, Martinovic J, Nowakowska D, Dzieciecka M, Jani JC. Increased TGF- β : a drawback of tracheal occlusion in human and experimental congenital diaphragmatic hernia? *Am J Physiol Lung Cell Mol Physiol* 2016;310:L311-L327.
- Herber-Jonat S, Vuckovic A, Mittal R, Hilgendorff A, Jani JC, Flemmer AW. Intrapulmonary instillation of perflurooctylbromide improves lung growth, alveolarization, and lung mechanics in a fetal rabbit model of diaphragmatic hernia. *Pediatr Crit Care Med* 2014;15:e379-e338. Citations: 4.
- Vuckovic A, Herber-Jonat S, Flemmer AW, Roubliova XI, Jani JC. Alveolarization genes modulated by fetal tracheal occlusion in the rabbit model for congenital diaphragmatic hernia: a randomized study. *PLoS One* 2013;8:e69210.
- Makanga M, Dewachter C, Maruyama H, Vuckovic A, Rondelet B, Naeije R, Dewachter L. Downregulated bone morphogenetic protein signaling in nitrofen-induced congenital diaphragmatic hernia. *Pediatr Surg Int* 2013;29:823-834.
- Vuckovic A, Roubliova XI, Votino C, Naeije R, Jani JC. Signaling molecules in the fetal rabbit model for congenital diaphragmatic hernia. *Pediatr Pulmonol* 2012;47:1088-1096.
- Jani J, Valencia C, Cannie M, Vuckovic A, Sellars M, Nicolaidis KH. Tracheal diameter at birth in severe congenital diaphragmatic hernia treated by fetal endoscopic tracheal occlusion. *Prenat Diagn* 2011;31:699-704.
- Vuckovic A, Rondelet B, Brion JP, Naeije R. Expression of vasoactive intestinal peptide and related receptors in overcirculation-induced pulmonary hypertension in piglets. *Pediatr Res* 2009;66:395-399.
- Mathieu A, Saal I, Vuckovic A, Ransy V, Vereerstraten P, Kaltner H, Gabius HJ, Kiss R, Decaestecker C, Salmon I, Rummelink M. Nuclear versus cytoplasmic expression of galectin-3 in non-small cell lung cancer: a prognostic marker of recurrence. *Mod Pathol* 2005;18:1264–1271.

Grants / awards

- Medal of the Royal Academy of Medicine of Belgium (2016).
- Grant from the David and Alice van Buuren Foundation (2014).
- André Kahn Prize in Pediatrics and Pfizer Educational grant (ULB; 2012).
- Research grant, FNRS ("Aspirant" status; 2009–2013).
- Research grant, FNRS, ID 1900858 (2010).
- Research grant from The Belgium Kids' Fund (2008–2009).

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3.2. Annick LE BRUN

Professional training

- Training in sensory-motor development: Diploma in Bullinger's Sensory-Motor Assessment (2019); Interdisciplinary Diploma in infant Developmental Care (2014).
- Belgian professional title of neonatologist (2000).
- Academic degree, UCLouvain, Brussels: Advanced Master in Intensive Care (1997); Specialized Master in Pediatrics (1995); Medical Doctor (1990).

Professional career

- Deputy Head of clinic, NICU, Queen Fabiola Children's University Hospital (since 2012).
- Resident doctor, pediatric and maternity ward, Cliniques Saint-Pierre, Ottignies (2002–2012).
- Resident doctor, NICU and PICU, Cliniques Universitaires Saint-Luc, Brussels (1997–2001).

Publications/congress communications

- Le Brun A, Mortiaux J, Johansson AB. L'accompagnement des repas des bébés hospitalisés en soins intensifs néonataux. RMEF, Brussels, 2015.
- Aggujiaro C, Cooreman I, Le Brun A, Mortiaux J, Johansson AB. Protocole de soins et formation pratique du personnel pour améliorer la qualité du portage en peau à peau. RMEF, Brussels, 2015.
- Le Brun A. Outils pour évaluer les pratiques autour de l'alimentation en néonatalogie. Interhospital meeting in Developmental Care, Federal Public Service Health, Brussels, 2015.

3.3. Sandrine DEPLUS

Professional training

- Academic degree, UCLouvain, Brussels: Ph.D. in Psychology (2012); Master of Specialization in Psychotherapy (2002); Master's Degree in Psychology (1998).
- Cognitive therapy training: Mindfulness-Based Cognitive Therapy for Depression (2006); Cognitive Behavioral Therapy for children and adolescents (AFTCC, 2004).

Professional career

- Professor at the Psychological Sciences Research Institute (UCLouvain), involved in the Certificate in Mindfulness (UCL) and in the Master of Specialization in Psychology.

Publication/congress communications

- Deplus S, Lahaye M. La pleine conscience chez l'enfant et l'adolescent. Ed. Margada; 2015.

3.4. Julie MORTIAUX

Professional training

- Academic degree, ULB: Master in Public Health (MPH) with focus management of health care institutions and services, School of Public Health, ULB, Brussels (2012).
- University libre de Bruxelles (ULB), Belgium. Specialized Nurse in Pediatrics and Neonatology, Haute Ecole Libre de Bruxelles Ilya Prigogine (HELB), Brussels (2000).
- Bachelor of Science in Nursing (BSN), Haute Ecole Libre de Bruxelles Ilya Prigogine (HELB), Brussels (1999).
- Developmental Care in Neonatology following A. Bullinger (in-hospital training provided by Geneva University Hospitals (2017–2018).

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Professional career

- Head Nurse, Hematology Oncology, Queen Fabiola Children's University, Brussels (2017–2019).
- Deputy Head Nurse, NICU, Queen Fabiola Children's University, Brussels (2012–2017).
- Professional title of Advanced Practiced Registered Nurse (APRN) in Pediatrics and Neonatology (2012).
- Teaching activity, seminars and practical exercises (neonatal nursing teaching) for nursing students specialized in Pediatrics and Neonatology and Bachelor 4 of Midwifery (Haute Ecole Libre de Bruxelles Ilya Prigogine, HELB, Brussels (2008–2012).
- Pediatric Nurse, NICU, Queen Fabiola Children's University Hospital, Brussels (2001–2008).

Publications/congress communications

- Dewulf L, Mortiaux J, Aerden V, Chetti A, Mjahed Z, Johansson AB. "Lait de donneuse ou lait artificiel? Choix difficile lorsque les convictions religieuses s'en mêlent", RMEF, 2013, Marseille, France.

Grant

- Annick Marneff Grant to support a training in Sensory-Motor Developmental Care for nurses (2015).

3.5. Vildan GOBAN

Professional training

- Baby Distress Alarm (ADBB, 2013); Neonatal Behavioral Assessment Scale (2012).
- Academic degree, ULB, Brussels: Complementary Master in Psychiatry, orientation child psychiatry (2006–2011); Medical Doctor (1999–2006).

Professional career

- Pilot project "Born in Brussels" (support for vulnerable pregnant women; 2020); newborn observation and interaction at the National Children's Office (2019).
- Child psychiatrist at Queen Fabiola Children's University Hospital, Brussels (since 2011).

Publications/congress communications

- Goban V, Lambotte I, Rabinowitch J, Delvenne V. Expérience belge des dispositifs de soins en périnatalité projet collaboratif de deux hôpitaux bruxellois pour l'accompagnement des femmes enceintes en contexte de vulnérabilité. In: Soigner ensemble en psy-périnatalité. En acte(s); 2020.
- Zucca S, Lambotte I, Goban V, Fournieret P, Colin C, Kadji C, Delvenne V. Vulnérabilité en période périnatale: création d'un outil de dépistage. RMEF, Montréal, 2017. Prize of the best poster.

3.6. Audrey CAILLEAUX

Professional training

- Training in parent-infant interactions: Neonatal Behavioral Observation (2019); Neonatal Behavioral Assessment Scale (2016); Parent-baby psychotherapeutic training, Study Group in Early Childhood Psychoanalytic Family Clinic (GECFAPPE, 2015 –2017).
- Academic degree, ULB: Master in Psychological Sciences (2015).

Professional career

- Since 2017: Clinical children psychologist, perinatal prevention, Saint-Pierre Hospital, Brussels; Practical seminars about perinatality, Child and Adolescent Psychopathology, ULB.

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- Since 2016: Clinical psychologist, gynecology-obstetric consultation, Erasme Hospital, Brussels; Clinical psychologist, NICU, Queen Fabiola Children's University Hospital, Brussels.

Publications/congress communication

- Cailleaux A, Cordemans L, Delvenne V, Goban V, Moureau A, Lambotte I. Installation des liens précoces dans un contexte de vulnérabilité parentale. In: Enfants de parents en souffrance psychique, Enfances et adolescences; 2019.
- Cailleaux A. Création des liens précoces en cas de vulnérabilités parentales. AFPL; 2018.