

BMJ Open Effect of skin-to-skin contact on parents' sleep quality, mood, parent-infant interaction and cortisol concentrations in neonatal care units: study protocol of a randomised controlled trial

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ABSTRACT

Introduction Separation after preterm birth is a major stressor for infants and parents. Skin-to-skin contact (SSC) is a method of care suitable to use in the neonatal intensive care unit (NICU) to minimise separation between parents and infants. Less separation leads to increased possibilities for parent-infant interaction, provided that the parents' sleep quality is satisfactory. We aimed to evaluate the effect of continuous SSC on sleep quality and mood in parents of preterm infants born <33 weeks of gestation as well as the quality of parent-infant interaction and salivary cortisol concentrations at the time of discharge.

Methods and analysis A randomised intervention study with two arms—intervention versus standard care. Data will be collected from 50 families. Eligible families will be randomly allocated to intervention or standard care when transferred from the intensive care room to the family-room in the NICU. The intervention consists of continuous SSC for four consecutive days and nights in the family-room. Data will be collected every day during the intervention and again at the time of discharge from the hospital. Outcome measures comprise activity tracker (Actigraph); validated self-rated questionnaires concerning sleep, mood and bonding; observed scorings of parental sensitivity and emotional availability and salivary cortisol. Data will be analysed with pairwise, repeated measures, Mann Whitney U-test will be used to compare groups and analysis of variance will be used to adjust for different hospitals and parents' gender.

Ethics and dissemination The study is approved by the Regional Research Ethics Board at an appropriate university (2016/89–31). The results will be published in scientific journals. We will also use conferences and social media to disseminate our findings.

Trial registration number NCT03004677.

INTRODUCTION

Considerable effort has been put into improving the professional care of preterm infants. Nowadays, several care methods aimed at decreasing the amount of stress for the infant (ie, pain relief, fewer procedures

Strengths and limitations of this study

- The intervention will last for four consecutive days starting after at least one nights' sleep together as a family in a single family room, when the infant no longer is in need of intensive care in the intensive care room in the neonatal intensive care unit (NICU).
- Outcomes will be measured by both subjective and objective measurements such as sleep diary, questionnaires, actigraphy, observations and saliva for cortisol analysis.
- This study is not designed to evaluate the long-term consequences or benefits of continuous skin-to-skin contact in the NICU.

and increased respect for the infants' sensitivity) are routine in many neonatal intensive care units (NICUs). Despite this, preterm birth is associated with poorer school performance and developmental and cognitive problems.^{1 2} This could be a consequence of excessive levels of the stress hormone cortisol acting on the prefrontal cortex and the hippocampus region of the brain.³ As one of the most potent stressors in early life is separation from the parent, it is important to actively focus on early proactive parental involvement, that is, continuous skin-to-skin contact (SSC). Worldwide, we know that there is an underuse of continuous SSC in NICUs, especially when the infant is discharged from the intensive care room to the family room. The nurses' support, knowledge and attitudes affect the parents' choice and opportunities to perform SSC.^{4 5} NICU nurses, in a recent study, have expressed beliefs that mothers could feel trapped when practicing continuous SSC and that sleeping with the infant during SSC will hinder good

parental sleep and thus increase the risk of depressive symptoms.⁴

Poor sleep quality affect the parents' mood and quality of care provided to the infant.⁶ Mothers and fathers in the NICU have previously described that they were more able to relax when they cared for their preterm infant with SSC.⁶ On the other hand, fathers in another study found it difficult to eat and sleep with the infant while giving SSC, as they tried to lie absolutely still and semireclining in the same position, to ensure the infant's comfort.⁷ If the parents share the responsibility of SSC for the preterm infant, it might improve their quality of sleep. By encouraging each other to take turns and assist each other with practical support, the opportunities to provide SSC may be facilitated and manifold.^{5,8}

To our best knowledge, the effects of continuous SSC, after transfer to the family-room, on extremely and very preterm infants' hypothalamic-pituitary-adrenal (HPA) axis and the quality of the parent-infant interaction and parental sleep have not been studied previously. The results of this interventional study will provide further information about parents' sleep and mood during continuous SSC and whether a late and relatively short intervention, such as SSC for 4 days in the family-room, can improve parent-infant interaction and salivary cortisol coregulation.

BACKGROUND

Being a parent of a preterm infant

Every year around 15 million infants worldwide are born preterm. Being a parent of a preterm infant affects parenthood in a more negative way than being a parent to a healthy, full-term infant. Parents of preterm infants are exposed to more stressors related to the infants' health condition and need of intensive care than parents of full-term infants.⁹ Therefore, parents of preterm infants are at greater risk of postpartum depression, post-traumatic stress disorder and other mood swings that affect the quality of parent-infant interaction.¹⁰⁻¹³ Anxiety due to the preterm infants' medical conditions can result in less interaction and increased distance between the parents and infant.¹⁰ Mothers of preterm infants who are experiencing stress while the infants are in hospital tend to be less responsive towards their infants' communicative signals.¹² Parents with preterm infants often feel powerless and incapable of providing the care their infants need because they are separated from their infant. This may lead to inactive parenting that can negatively affect the parent-infant interaction.¹¹

Parent-infant interaction

Loss of parental proximity and stimulation are two of the most potent stressors in early life. Infants experiencing long-standing early life stress such as deprivation or neglect show atypical patterns of diurnal HPA activity, with lower morning cortisol levels. A reorganisation of the stress response system (the HPA-axis) requires that the

infant experience safeness, that is, a relationship with a consistently sensitive and responsive caregiver.¹⁴ Maternal sensitivity, defined as the mother's ability to read and respond in a sensitive and adequate way to their infant's communicative signals, is associated with the development of secure attachment. Sensitive mothers tend to have securely attached infants while less sensitive mothers are more likely to have infants classified as insecurely attached.¹⁵ Infants with less sensitive mothers have higher levels of cortisol in response to handling than infants with sensitive mothers.¹⁶ As the mother-to-infant bonding behaviours include touch, skin contact, eye-to-eye contact and soothing, it is important that mother and infant are close together after delivery to strengthen this bonding.¹⁷ However, extremely and very preterm infants are often transferred to intensive care immediately after birth. The infants are placed in an incubator, which decrease the parents' possibility to bond with their infant.

Preterm infants are, owing to their immature neurological system, less capable than full-term infants in showing their needs through communicative signals. Consequently, parents of preterm infants have more difficulties reading and responding accurately to their infant.¹⁸ The NICU environment in itself (eg, with incubators and ventilators) creates a barrier to parenting,¹⁹ which may negatively influence parent-infant interaction and thus the infant's long-term cognitive and physical developmental outcome.

Skin-to-skin contact

SSC is a method of care aiming to minimise separation of mothers and infants.²⁰ In SSC, parents carry the infant in an upright position placed skin-to-skin on the chest. Today SSC is used, more or less, all over the world, even for extremely preterm infants.²¹ In the beginning, infants are mostly taken out from their incubators a few hours per day to be cared for in *intermittent* SSC with the parents. Along with the infant's maturation, the time spent in SSC/day increases successively and eventually parents may care for their preterm infant via *continuous* SSC (ie, around the clock). Continuous SSC has so far been insufficiently evaluated in level III NICUs.²⁰ One earlier study performed in Sweden found that the median daily duration of SSC was <7 hours for infants born at GA 28+0 to 33+6.²² There are no studies investigating the effects of an intervention comprising continuous SSC with extremely and very preterm infants after the transfer to a family-room (level II NICU) from the intensive care room (level III NICU).

Benefits of SSC

SSC is beneficial for preterm infants, as it contributes to cardiorespiratory stabilisation, fewer signs of stress and a more organised sleep-wake cycle.²³⁻²⁵ In mothers, SSC improves mood, reduces stress and postpartum depression symptoms, encourages them to create a stimulating and care giving environment and promotes breastfeeding.^{23, 26-29} Few studies of SSC include fathers.³⁰ Yet, fathers participating in SSC have rated lesser spousal

relationship problems when their preterm infants were 4 months corrected age than fathers who did not practice SSC.³¹ Fathers' opportunities to be a part of the SSC may improve their paternal role⁷ and help them transition into a more equal parenthood.³²

Sleep quality

Sleep quality is subjective and described as the duration of sleep followed by spontaneous awakening and alertness throughout the day.³³ Poor sleep quality leads to increased negative emotions that in turn disrupt sleep, which further impairs emotional well-being.³⁴ For instance, several awakenings during night hinder deep sleep, which lead to sleepiness and insufficient recovery from a stressful day.³⁵ Poor sleep quality may result in sleep-related daytime dysfunctions such as maintaining enthusiasm to complete daily tasks and parental ability as well as motivation to adequately care for their child³⁶ and negative moods such as frustration, impatience and irritability against the child.³⁷ Worries and uncertainty about the infant's medical situation may also negatively influence parents' sleep quality. In two recent qualitative studies, parents of sick children have described that they avoid falling into deep sleep in case something untoward should happen to the child.^{6 38}

Cortisol

Stress response is a necessary physiological and biological response aimed at maintaining homeostasis when the individual is exposed to a stressor. Stress reactivity is when a stressor triggers the HPA-axis to release the stress hormone cortisol into the blood stream.³⁹ When there is adequate cortisol to handle the situation, the levels decline to baseline (recovery). Cortisol is also released in a diurnal circadian rhythm with the highest levels in the morning, a steady decrease throughout the day and the lowest levels at night. The circadian rhythm develops during the infants' first year of life.^{40 41} It has been suggested that genetic as well as environmental factors can affect the development of the cortisol circadian rhythm and coregulation between the mother's and infant's cortisol levels. For instance, a coregulation in salivary cortisol levels has been shown between preterm infants and their parents at discharge from the NICU if the parent had slept in the NICU compared with when the parent slept at home⁴² and between 3-month-old full-term infants and their parents prior to vaccination.⁴³ A coregulation in salivary cortisol levels has also been shown between 6-month-old full-term infants and their mothers, but not the fathers. This was explained by the fact that infants spent most of their time in the same environment as their mothers, who were the primary caregivers.⁴⁴ Moreover, a coregulation in salivary cortisol levels has been described for twins sharing the same environment but not for twins living in different environments.^{42 45 46} For mothers practicing continuous SSC with their preterm infant in the NICU, a coregulation in salivary cortisol was shown between the mother and the infant at 4 months corrected age but not in the control group.³²

Aim

The aim of the study is to evaluate the effect of continuous SSC on sleep quality and mood in parents of preterm infants born <33 weeks of gestation as well as parent-infant interaction and salivary cortisol concentrations at the time of discharge.

Our hypothesis is that SSC for four consecutive days during the first time they are given the opportunity to sleep together as a family will function as a restart for bonding and therefore improve the parents' mood, interaction behaviour and coregulation of salivary cortisol between parent and infant. Furthermore, our hypothesis is that the parents' possibility to take turns and assist each other with practical support during SSC will facilitate parents' sleep quality.

Research questions

Is there a statistically significant difference in the effect of continuous SSC compared with standard care on the parents' sleep quality and mood?

Is there a statistically significant difference in the effect of continuous SSC compared with standard care on the quality of interaction between the parent and preterm infant at the time of discharge?

Is there a statistically significant difference in the effect of continuous SSC compared with standard care on salivary cortisol reactivity, recovery and coregulation between parents and preterm infants at the time of discharge?

METHODS AND ANALYSIS

Design

This study is a randomised controlled trial.

Statistics

Calculation of power indicates that 48 parents are needed in each group for an effect size of 0.7 ($\alpha=0.01$; $\beta=0.80$) in the variable sleep quality. Because of the risk of dropout, the goal is to include 25 families (50 parents) in each group. Data will be analysed within the family dyads as well as individually to control for lack of independence. Sleep variables and mood will be analysed with pairwise, repeated measures. Parent-infant interaction will be analysed with descriptive statistics. Saliva cortisol will be analysed with pairwise, repeated measures and correlation analyses. Mann Whitney U-test will be used to compare groups and analysis of variance will be used to adjust for different hospitals, parents' gender and time in SSC. The statistical software program SPSS will be used for analyses.

Intervention

Parents will receive written and oral information about the study by a research coordinator before randomisation. The families who accept participation will be randomised to receive either continuous SSC (intervention group=IG) or standard care (control group=CG). Sequentially numbered envelopes generated by a statistical randomisation programme operated by the first author will be

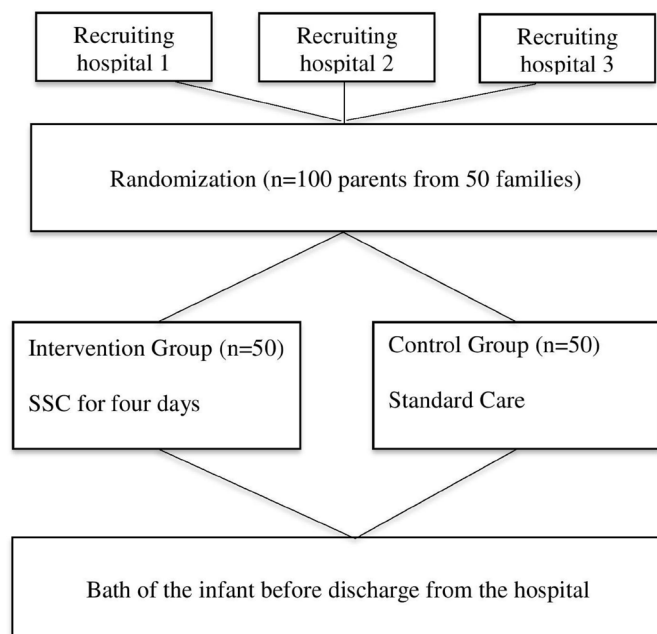


Figure 1 The CONSORT diagram of this study. SSC, skin-to-skin contact.

used for randomisation. The randomisation sequence is described in a Consort flowchart (figure 1). The intervention will last for four consecutive days starting after at least one nights' sleep together as a family in a single family room, when the infant no longer is in need of intensive care in the intensive care room in the NICU. Four days were chosen to study if a short intervention is feasible to affect parents' sleep, mood and parent-infant interaction, but also to avoid the risk of overload the families and of dropouts due to early discharge. In families assigned to the IG, the infants will be cared for by SSC on parents' chest 24 hours a day, alternating between the parents. The parents will note who provides the SSC, and if and for how long they are off SSC for any reason.

Families randomised to CG are free to practice intermittent SSC as much as they want. The parents will note with whom, when and for how long they provide SSC.

In the present study, standard care (CG) is defined as NICU care when the infant stay with its parents around the clock and is cared for skin-to-skin with its parents as much as the parents wish. NICU care for the infants in IG and CG are the same, but may partly differ between the NICUs. Because of ethical reasons, we cannot refrain the parents from using SSC. The only thing that separates the groups is the time the infant is cared for SSC during the four study days.

Settings

Family-centred NICUs (level II-III), in three university hospitals and two general hospitals in Sweden, with single family rooms where the family stay together with their infant around the clock when intensive care is no longer required.

The parents' presence at NICUs in Sweden are facilitated through the Swedish national insurance system, which

allows both parents to share parental benefit for 480 days per child. In addition, both parents of an infant requiring care at a NICU are entitled to 'temporary parental benefit' until the infant is discharged. This means that during the infant's entire NICU stay, both parents have the legal right to be together with their infant at the NICU. Further, in Sweden, hospital care for all children is free of charge.

Inclusion criteria

Parents (mother and father/partner) of single preterm infants born <33 weeks of gestation will be included. The infant should have moved out from the intensive care room and into a single family room where both parents can stay and care for their infant 24 hours a day. Parents need to be able to read and understand the questionnaires. Exclusion criteria are parents with sleeping disorders, psychiatric problems or drug abuse and infants with major congenital malformation, grade III-IV intraventricular haemorrhage or a chromosomal defect that could affect the infant's ability to interact.

How old the infants should be, as well as infant criteria, to be cared for in a single family room varies between the NICUs. Most often, this happens as soon as the infant no longer need ventilator therapy (except for oxygen cannula). The time the infants are cared for in a family room before discharge varies greatly, partly depending on the infant's and parent's well-being, the NICUs routines and access to further care at home.

Procedure

Figure 2 shows the study sequence. A pilot test has been performed to test the feasibility of the study in two families. Because of the parents' experience of the time it took to complete the questionnaires, minor changes were made. Two questionnaires (Sense of coherence and SF-36) were removed from the study. Moreover, data collection in the evening (Mood Adjective Checklist, MACL) was removed during the intervention.

Outcome measurements

Parents' sleep quality

The primary outcome of this study is sleep quality. A study-specific sleep diary for four consecutive days will be used to provide data on perceived sleep quality on a five-point scale (1=bad, 5=good). The diary includes the variables time going to bed, sleep onset latency, morning awakening time, sleep duration, nocturnal awakenings, daytime napping and sleep efficiency. The diary also consists of open-ended questions about potential variables affecting sleep.

A validated actigraph—Actigraph Link GT9X activity monitor—will be used to measure physical activity and sleep continuously during the 4-day intervention period. The actigraph will be placed around the waist to suit hygiene recommendations in the NICU.

Parents' mood

Parents will fill out the MACL at baseline, in the mornings during the intervention and at discharge. The MACL is

Primary outcome			Secondary outcome	
Informed written and verbal consent Randomisation		Baseline/Pre-test Day 1, 8.00 PM	Intervention Day 2-5, 8.00 AM	Post-test At discharge
Intervention group (IG)	Control group (CG)	IG + CG	IG + CG	IG + CG
Parents will provide continuous skin to skin-care 24 hours a day alternating between the parents with start 8.00 pm, day 1 Parents will be provided with clothes, i.e. tube tops, scarves, and blouses to facilitate the care	Conventional care. Parents will be free to practice intermittent skin to skin-care	Demographic data Uppsala Sleep Inventory (USI) Mother to Infant Bonding Scale (MIBS) The Edinburgh Postnatal Depression Scale (EPDS) State Trait Anxiety Inventory (STAI)	Sleep-log Mood Adjective Checklist (MACL)	Uppsala Sleep Inventory (USI) Mother to Infant Bonding Scale (MIBS) The Edinburgh Postnatal Depression Scale (EPDS) State Trait Anxiety Inventory (STAI) The parents will be performing a bath of the infant, which will be filmed and analysed later (Emotional Availability and Ainsworth Sensitivity Scale). Saliva cortisol samples from both parents and the infant before a bath and 30 min after the beginning of the bath
		Activity tracker Skin to skin-log		

Figure 2 Study schedule.

a self-administered, validated instrument measuring the bipolar dimensions of mood. The instrument consists of 71 adjectives (eg, ‘secure’, ‘relaxed’, ‘attached’, ‘happy’, ‘energetic’ and ‘sociable’) measured on a four-point scale (1=it definitely disagrees with what I feel right now, 4=it definitely agrees with what I feel right now), divided into six dimensions: control, calmness, social orientation, pleasantness, activation and extraversion. The instrument refers to how the responder feels at the moment.⁴⁷

Parents will fill out Spielberger’s State Trait Anxiety Inventory (STAI) at baseline and at discharge. The STAI is a self-administrated questionnaire measuring state and trait anxiety. The short version of STAI is a valid and reliable questionnaire consisting of six statements measured on a four-point scale. The questionnaire refers to how the responder feels at the moment.^{48 49}

Parents will fill out Edinburgh Postnatal Depression Scale (EPDS) at baseline and at discharge. The EPDS is a validated, self-administrated questionnaire developed to discover depression in new mothers. The scale consists of 10 statements measured on a four-point scale. The scale refers to how the responder has felt in the last 7 days.⁵⁰

Parent-infant interaction

Parent-infant interaction will be measured at time for discharge using the Mother-Infant Bonding Scale (MIBS), Emotional availability (EA) scale and Ainsworth’s sensitivity scale.

The MIBS is a reliability tested, self-rating mother-to-infant bonding questionnaire designed to assess the early feelings of a mother towards her infant. The MIBS includes eight items measured on a four-point scale. The scale refers to how the responder has felt in the last 7 days.⁵¹

The EA scale measures the parent-infant relationship. Five scales focus on the parent and two scales on the infant.⁵² A certified objective rater assesses the parent-infant dyad from a video recording of an interplay activity, in this study this is a bath of the infant, performed by the parents.

Ainsworth’s sensitivity scale consists of four nine-point scales, with five anchor points on each scale, measuring sensitivity, cooperation, availability and acceptance.¹⁵ A trained objective rater assesses the parent-infant dyad from a video recording of an interplay activity (bath).

Salivary cortisol reactivity, recovery and coregulation

Saliva for cortisol analysis will be collected from both parents and the infant before (baseline) and 30 (reactivity) and 40 (recovery) min after starting a bath for the infant (stressor).⁵³ The coregulation will be calculated as a paired correlation between the parents’ and infant’s cortisol levels. Saliva will be collected with Salimetrics oral swabs (Salimetrics, Pennsylvania, USA). The saliva samples will be centrifuged and stored at –80 C, until further analysis at the University hospital.^{54–56}

Measurements of possible confounding factors

Sleep quality

Thirteen items will be used from The Uppsala Sleep Inventory, measuring perceived sleep quality and consequences of sleep loss. The questionnaire evaluates perceived sleep retrospectively referring to the past 4 weeks. In this study, it will reflect the time since the infant was born. The questionnaire has been validated against polysomnography and actigraphy and is reliability tested.⁵⁷

Background data

Demographic and medical data, for infants and parents, will be collected to include age; education; marital and health status; information about birth (weight, APGAR score, birth condition); breastfeeding and the time in SSC and/or other activities performed in the NICU during the intervention period.

Stressor

The parents will give the infant a bath on the day of, or before, hospital discharge. The bath situation will be video recorded with a handy camera for later interpretation of parent-infant interaction.

Patient and public involvement

The development of research questions is based on previous qualitative studies describing patients' and NICU staff's experiences and preferences. The families have not been involved in the design and will not be involved in recruitment or conduct of the study. The results will be disseminated to study participants through media and information at the NICU wards.

ETHICS AND DISSEMINATION

The study is registered at ClinicalTrials.gov (NCT03004677).

The parents will receive oral and written information about the study before they give written, informed consent. They will be informed that they can decline to participate or can withdraw from the study at any time without explanation or consequences for their infant's future care. All collected data will be coded and are stored in separate, secure locations. Saliva samples will be collected and stored according to the Swedish law SFS 2002:297 on biobanks in healthcare with approval from the Regional Biobank Center. All saliva samples will be destroyed after analysis. The primary investigator is responsible for communicating important protocol modifications to relevant parties.

There is no physical or psychological harm related to the study. Families randomised to the CG are welcome to care for their infant in SSC for as much as they want. The amount of SSC these infants experience is recorded and when necessary, controlled for in the statistical analyses. The interpretation of the results will be adjusted accordingly.

Salivary cortisol sampling is painless and does not include any risks. As questionnaires can violate personal integrity, all questionnaires to be used in this study are well established, and participation in the study is voluntary and can be withdrawn at any time. The stressor used in this study, that is, bath, is performed by the parents and is part of the infants' normal care.

Normally, extremely and very preterm infants face the greatest risk of impaired development. Considering that 15 million infants are born preterm every year, it makes a great impact on the society at large. The risk of impaired cognitive development is further affected by high levels of cortisol and the quality of parent-infant interaction. For the individual infant that was born preterm, an improved cognitive development is certainly a tremendous gain, providing a healthier life with less cognitive disabilities and associated consequences. Each child that gains a healthier cognitive development also has great economic impact on the societal level, including reduced need for medical care during the entire childhood because of (1) less cognitive impairments such as visual and hearing problems, attention disorders and motor difficulties as well as (2) less psychosocial ill health such as socio-emotional problems, aggressions and depressions. An improved cognitive and socioemotional functioning, with less concentration and learning difficulties is also a great gain when it comes to school achievement and working life. As the bonding process and parent-infant interaction start right after birth, they are both affected negatively by parent-infant separation. If the transfer to family-room, including continuous SSC, can be used to rekindle the bonding process, it will facilitate parent-infant interaction. Moreover, if the NICU staff can support the family by providing methods with potential to hinder separation, it may have a tremendous impact on the individual child's life, family and society. Parker and Anderson have described positive outcomes of SSC in adoptive parents and suggest that biological parents of a critically ill preterm infant feel somewhat like adoptive parents after the prolonged period of time in NICU, customarily unable to hold their infant.⁵⁸ Moreover, SSC seems to work as a restart of breastfeeding in full-term infants after having latch-on problems.⁵⁹ In order to provide evidence-based methods, continuous SSC needs to be evaluated concerning parents' sleep quality, because poor sleep quality may affect parents' mood and the ability to interact with, and care for, the fragile preterm infant.

The results of this study will be published in scientific journals, international and national conferences.

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Ethics approval The study has been approved by the Regional Research Ethics Board at an appropriate university (2016/89–31).

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