

## Supplemental Online Content

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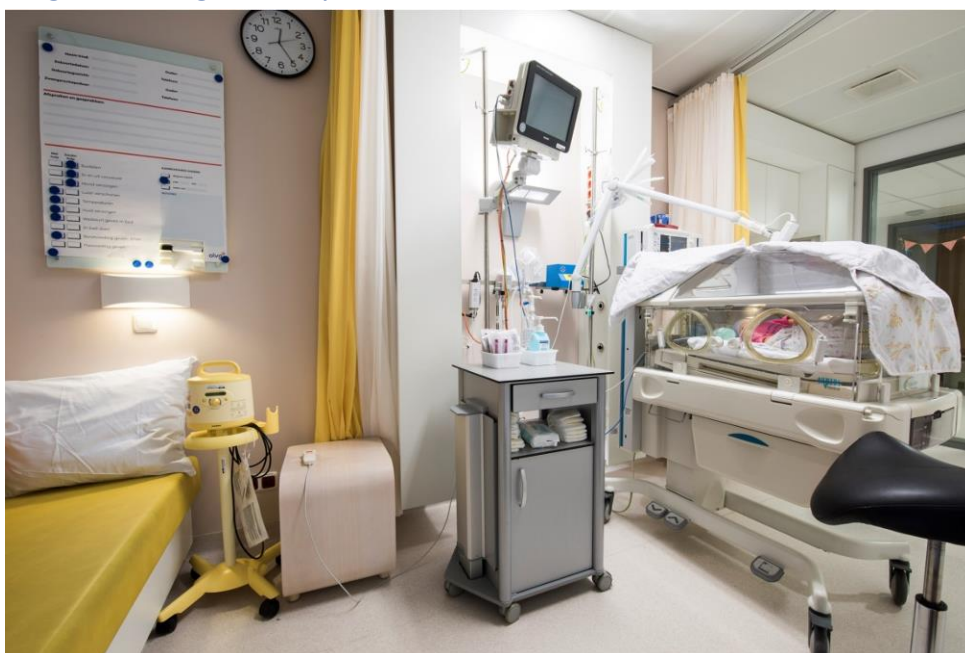
This supplemental material has been provided by the authors to give readers additional information about their work.

eFigure 1. Complete Couplet Care Setup



A Single-Family Room for highly complex maternity and neonatal Level 2 Care. Women and their newborns will remain in this suite for as long as both require specialized care, or at least for 7 days if the newborn requires specialized care. Fathers, too, can be present continuously. If after 7 days and one of them no longer needs specialized care, the woman and the newborn are transferred to a smaller single-family room, a room for highly complex maternity care and neonatal level 1 care or a room for neonatal level 2 care. All single-family rooms provide rooming-in facilities for one parent/partner. Printed with the permission of the audiovisual department OLVG Hospital, Amsterdam, the Netherlands, June 2020.

eFigure 2. Single Family Room for Neonatal Level 2 Care



eFigure 3. Family Participation in the Single Family Room



Depicted is a family with twin infants born at a gestational age of 32 weeks, together with a doctor and nurse specialized in neonatal care. The family stays continuously together in a single family room in our integrated neonatal-maternity ward. This enables both parents to participate, as equal partners in the medical team, in the care and medical decision making for their infants during hospital stay.

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eFigure 4. Standard Neonatal Care Setting With Open Bay Unit



## eAppendix 1. Supplemental Methods

### Scales Used in the Study

To measure stress, the Parental Stress Scale: Neonatal Intensive Care Unit (PSS-NICU) was used. This scale was developed by Miles in 1993 and measures the parental perception of stressors due to the physical, psychosocial and emotional environment of the neonatal intensive care unit<sup>1</sup>. This scale consists of 26 questions and was filled in both at admission and at discharge. The PSS-NICU scale has 3 subdomains and measures the degree of stress experienced by parents during hospitalization related to alterations in their parental role, the appearance and behavior of their infant, and sights and sounds of the unit. Parents rate their experiences on a 5-point rating scale ranging from "not at all stressful" to "extremely stressful." In an update of the tool in 2007, sights and sounds of the environment (5 items) were combined with infant's appearance subscale (14 items) and scored as one subscale and Parental Role Alteration as the second subscale (7 items).<sup>2</sup> If fathers did not experience the stressor, we transformed the score to "0".<sup>3</sup>

The Hospital Anxiety and Depression Scale was developed in 1983 and is used to measure the possible presence of anxiety and depressive complaints (Zigmond & Snaith, 1983). This scale has also been converted to Dutch, so that it is also available in this language (Spinhoven et al, 1997). Parents were asked to fill in this 14-item self-report at admission and at discharge.

#### *Parent- and infant bonding*

The Postpartum Bonding Questionnaire (PBQ), was devised by Brockington et al. (2001) as a screening instrument to detect bonding problems in obstetric and primary care services<sup>4,5</sup>. The PBQ is a 25-item scale reflecting a mother's feelings or attitudes towards her baby (e.g. "I feel close to my baby", "My baby irritates me"). Participants rate how often they agree with these statements on a 6-point Likert scale ranging from always (score=0) to never (score=5) with low scores denoting good bonding. The PBQ has four subscales which reflect impaired bonding (Scale 1) (12 items, ranging from 0 to 60), rejection and anger (Scale 2) (7 items, scores ranging from 0 to 35), anxiety about care (Scale 3) (4 items, scores ranging from 0 to 20) and risk of abuse (Scale 4) (2 items, scores ranging from 0 to 10). Scale 1 (impaired bonding) has a sensitivity of 0.93 and a specificity of 0.85 in detecting mothers with a bonding disorder.

#### *Parental empowerment and satisfaction*

Parent satisfaction was measured using the EMpowerment of PARENTS in THE Intensive Care - Neonatology questionnaire<sup>6</sup>. This scale was developed and tested in a single center in the Netherlands, and available in Dutch. The domains covered are: Information (14 statements); Care and Treatment (20 statements); Parental Participation (nine statements); Organization (11 statements); and Professional Attitude (13 statements). The 57 statements divided in five domains provide a conceptualization of parent satisfaction within the neonatal ward from a family-centred care perspective<sup>6</sup>.

#### *Parental Self Efficacy*

The Perceived (Maternal) Parenting Self-Efficacy (PMP-SE) tool, was used to measure perceived parental self-confidence when caring for the infant admitted to the Neonatal Ward<sup>7</sup>. The internal consistency reliability of the Perceived Maternal Parenting Self-Efficacy tool is 0.91, external/test-retest reliability is 0.96. A total of four conceptually unique subscales of parenting are: "Care taking procedures" (parents' perceptions of their ability to perform the activities and tasks related to the baby's basic needs like feeding). "Evoking behaviour(s)" (perceptions in their ability to elicit a change in the baby's behaviour, for example, soothing the baby). "Reading behaviour(s) or signalling" (perceptions in their ability to understand and identify changes in their baby's behaviour, for example, 'I can tell when my baby is sick'). "Situational beliefs" (parents' beliefs about their ability to judge their overall interaction with the baby). Responses to each item were recorded on a four point Likert scale ranging from 'strongly disagree' (score 1) to 'strongly agree' (score 4). A low score on this scale indicates a low parental self-efficacy.

We previously validated a measurement tool on parent participation in neonatal care (the CO-PARTNER tool), which includes 6 domains: 1) daily care 2) medical care 3) information gathering 4) advocacy and leadership 5) time spent with infant 6) closeness and comforting the infant.<sup>8</sup> Total scores per domain were obtained by summing scores. For Domain 1, 2 and 6 we calculated 0 for 'the nurse does this', 1 for 'the nurse and I do this together' and 2 for 'I do this independently' (minimum scores 0 to 22, 8 and 14 respectively). For domain 3 and 4 'yes' was scored as 1, and 'no' as 0 (minimum scores 0 to 3). Non-applicable items were transformed to 0 (no participation in this item). For the domain Time Spent with Infant (3 items) quartiles were calculated resulting in 0 to 4 score (total score in domain 5 minimum 0 maximum 12). A total participation score was obtained by summing all domain scores. Minimum total scores were 0 and maximum 62. Additionally, we aimed to analyze in multiple mediation models the extent to which domain of participation contributes to ameliorated outcomes in the FiCare model.

### Inclusion and exclusion criteria of the AMICA study.

In order to be eligible to participate in this study, a subject had to meet all of the following criteria:

- Born between 24 and 36 6/7 weeks gestational age, with a postconceptional age  $\leq$  44 weeks on admission
- At least 1 week of hospital stay on the Neonatal Ward. Infants <35 weeks gestational age were recruited in the first days after birth, as their hospital stay is usually more than 7 days. Infants with a gestational age between 35 and 37 weeks were recruited after consultation with the attending physician, and were recruited when a hospital stay of >7 days was expected.
- Would visit the Outpatient Clinic of the OLVG East, OLVG West or NWZA after discharge or consents to gather required information through infant health centers
- Written informed consent from the parents

A potential subject who met any of the following criteria was excluded from participation in this study:

- Metabolic or chromosomal/syndromal diseases
- Therapeutic hypothermia for perinatal asphyxia
- Severe psychiatric or psychosocial problems i.e. parents under supervision of youth care
- Transfer to another hospital before discharge
- Parents unable to answer the questionnaires in Dutch/English
- Death of an infant

### Sample size calculation

The primary outcome of the AMICA study is neurodevelopment in infants at 2 years of age. We pre-stratified the study population towards infants born <32 weeks of gestation with a previous admission to a level 3 NICU and infants that were born >32 weeks of gestation. Within each gestational age group, we did a power calculation for the primary outcome of neurodevelopment. We calculated to have 64 experimental subjects and 128 control subjects with power 0.90 ( $1-\beta$ ) at a significance level of 0.05 ( $\alpha$ ) with a true difference in the outcome of neurodevelopment at the age of 2 years of  $\frac{1}{2}$  SD. To allow for 30% withdrawal we aimed to include 91 patients in group A and 182 patients in group B per risk group (post-

intensive care versus inborn infants). A total of 546 infants who were hospitalised and their parents were expected to be included in this study.

For this study we calculated the power for the outcome on stress in fathers *post-hoc*.<sup>11</sup> The group sample sizes of 89 and 93 achieved 84% power to detect a difference of -8.6 between the null hypothesis that both group means are 40.8 and the alternative hypothesis that the mean of group 2 is 49.4 with known group standard deviations of 20.3 and 18.9 and with a significance level (alpha) of 0.05 using a two-sided two-sample t-test.

### Variables used in multiple imputation model

For the imputation model we used the following strategy<sup>12</sup>

1. Include all variables that are part of the analysis model, including the dependent (outcome) variable.
2. Include additional (auxiliary) variables that are related to nonresponse
3. Include additional variables that are related to variables with missing values.
4. Exclude variables with a high correlation (> 0.90) that cause multi-collinearity problems.
5. Exclude variables with high percentages of missing data (> 50%).

The following variables were used in the multiple imputation model:

- Gestational age in days
- Inborn
- Work hours per week
- FICare model
- Singleton status
- Work hours per week
- Identifies with Dutch cultural background
- University degree
- HADS at admission/discharge\*
- PBQ at admission/discharge\*
- PMP at admission/discharge\*
- PSS-NICU at admission/discharge\*
- Participation at admission/discharge\*
- Smoking
- Use of recreational drugs
- Alcohol use

### Collinear variables

- Gestational age < 32 weeks
- Length of stay in NICU (with total gestational age)
- Length of stay total (with total gestational age)
- Paid work (with work hours per week)
- GA admission (with total gestational age)

- Use of psychotropic drugs (n (%))

\*depending on parcel mean summary score and which database was imputed.

### Confounders and effect modifiers

Potential confounders and effect modifiers were identified from the literature and assessed using statistical analyses. We considered socio-economic class (including education and employment status), family composition (single parent vs co-parenting), older/other infants in the family, stress at birth, gestational age of infant, singleton status and mode of delivery. If the beta-regression coefficient differed at least 10% in regression analyses, this was used as an indication of statistical confounding, and the variable was included in the adjusted model. If collinearity was present, the strongest confounder (largest change in crude beta-coefficient) was used to adjust for.



eTable 1. Scale Properties

|   | Scales   | Minimum score | Maximum score | Internal consistency/ Cronbach's alpha (reference) |
|---|--|---------------|---------------|--|
| Stress  | PSS-NICU   | 0             | 130           | 0.89-0.94 <sup>1,2</sup>                           |
|   | Sights and sounds, behaviour of the infant           | 0             | 95            | 0.92 <sup>2</sup>                                  |
|   | Parental role alteration                             | 0             | 35            | 0.92 <sup>2</sup>                                  |
| Anxiety and depression                                | HADS   | 0             | 42            | 0.71-0.90 <sup>9</sup>                             |
| Self-efficacy   | PMP-SE   | 20            | 80            | 0.91 <sup>7</sup>                                  |
| Mother infant bonding                                 | PBQ  | 0             | 125           | 0.87-0.78 <sup>10</sup>                            |
| Satisfaction with care (median scores over all items) | EMPATHIC-N   | 1             | 6             | 0.82 -0.95 <sup>6</sup>                            |
| Collaboration and participation in neonatal care      | CO-PARTNER   | 0             | 62            | NA <sup>8</sup>                                    |
|   | <b>Domain 1</b> <i>Participation in daily care</i>   | 0             | 22            | 0.934 <sup>8</sup>                                 |
|   | <b>Domain 2</b> <i>Participation in medical care</i> | 0             | 8             | 0.558 <sup>8</sup>                                 |
|   | <b>Domain 3</b> <i>Information gathering</i>         | 0             | 3             | 0.745 <sup>8</sup>                                 |
|   | <b>Domain 4</b> <i>Advocacy and leadership</i>       | 0             | 3             | 0.855 <sup>8</sup>                                 |
|   | <b>Domain 5</b> <i>Time spent with infant</i>        | 0             | 12            | 0.839 <sup>8</sup>                                 |
|   | <b>Domain 6</b> <i>Comforting the child</i>          | 0             | 14            | 0.871 <sup>8</sup>                                 |

EMATHICN-N: EMpowerment of PArents in THe Intensive Care- Neonatology, HADS: hospital anxiety and depression score, PBQ: postpartum bonding questionnaire, PMP-SE: *The Perceived (Maternal) Parenting Self-Efficacy*, PSS-NICU: parental stress scale – neonatal intensive care unit

eTable 2: CO-PARTNER Tool

| Activity  | Response  |
|---|---|
| <b>Domain 1. Daily Care</b>                       |   |
| 1. Bath my child/clean my child with a washcloth. | <ul style="list-style-type: none"> <li><input type="radio"/> The nurse does this</li> <li><input type="radio"/> I do this together with the nurse</li> <li><input type="radio"/> I do this independently (without the help of the nurse)</li> <li><input type="radio"/> This is not applicable</li> </ul> |
| 2. Change my child's diaper.                      | <ul style="list-style-type: none"> <li><input type="radio"/> The nurse does this</li> <li><input type="radio"/> I do this together with the nurse</li> <li><input type="radio"/> I do this independently (without the help of the nurse)</li> <li><input type="radio"/> This is not applicable</li> </ul> |
| 3. Feed my child (breast or bottle).              | <ul style="list-style-type: none"> <li><input type="radio"/> The nurse does this</li> <li><input type="radio"/> I do this together with the nurse</li> <li><input type="radio"/> I do this independently (without the help of the nurse)</li> <li><input type="radio"/> This is not applicable</li> </ul> |
| 4. Change my child's clothing.                    | <ul style="list-style-type: none"> <li><input type="radio"/> The nurse does this</li> <li><input type="radio"/> I do this together with the nurse</li> <li><input type="radio"/> I do this independently (without the help of the nurse)</li> <li><input type="radio"/> This is not applicable</li> </ul> |
| 5. Get my child out of the incubator/cradle.      | <ul style="list-style-type: none"> <li><input type="radio"/> The nurse does this</li> <li><input type="radio"/> I do this together with the nurse</li> <li><input type="radio"/> I do this independently (without the help of the nurse)</li> <li><input type="radio"/> This is not applicable</li> </ul> |
| 6. Give my child medication.                      | <ul style="list-style-type: none"> <li><input type="radio"/> The nurse does this</li> <li><input type="radio"/> I do this together with the nurse</li> <li><input type="radio"/> I do this independently (without the help of the nurse)</li> <li><input type="radio"/> This is not applicable</li> </ul> |
| 7. Weigh my child.                                | <ul style="list-style-type: none"> <li><input type="radio"/> The nurse does this</li> <li><input type="radio"/> I do this together with the nurse</li> <li><input type="radio"/> I do this independently (without the help of the nurse)</li> </ul>   |

|  |   |
|--|---|
|  | <ul style="list-style-type: none"> <li>○ This is not applicable</li> </ul>  |
| 8. Keep track of output (urination and defecation) of my child                                   | <ul style="list-style-type: none"> <li>○ The nurse does this</li> <li>○ I do this together with the nurse</li> <li>○ I do this independently (without the help of the nurse)</li> <li>○ This is not applicable</li> </ul> |
| 9. Measure the temperature of my child.  | <ul style="list-style-type: none"> <li>○ The nurse does this</li> <li>○ I do this together with the nurse</li> <li>○ I do this independently (without the help of the nurse)</li> <li>○ This is not applicable</li> </ul> |
| 10. Keep track of my child's weight.   | <ul style="list-style-type: none"> <li>○ The nurse does this</li> <li>○ I do this together with the nurse</li> <li>○ I do this independently (without the help of the nurse)</li> <li>○ This is not applicable</li> </ul> |
| 11. Keep track of drinking and my child's feeds.   | <ul style="list-style-type: none"> <li>○ The nurse does this</li> <li>○ I do this together with the nurse</li> <li>○ I do this independently (without the help of the nurse)</li> <li>○ This is not applicable</li> </ul> |
| <b>Domain 2. Medical Care</b>  |   |
| 12. Give tube feeding to my child.   | <ul style="list-style-type: none"> <li>○ The nurse does this</li> <li>○ I do this together with the nurse</li> <li>○ I do this independently (without the help of the nurse)</li> <li>○ This is not applicable</li> </ul> |
| 13. Look at my child's monitor and handling accordingly (e.g. stimulating during a bradycardia). | <ul style="list-style-type: none"> <li>○ The nurse does this</li> <li>○ I do this together with the nurse</li> <li>○ I do this independently (without the help of the nurse)</li> <li>○ This is not applicable</li> </ul> |

|  |   |
|--|---|
| 14. Regulate the visiting of others to my child.   | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| 15. Participate in the daily rounds with the doctor.   | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| <b>Domain 3. Acquiring Information</b>   |   |
| 16. Did you ask healthcare professionals information on the health of your child?                                  | <input type="radio"/> Yes<br><input type="radio"/> No   |
| 17. Did you ask the healthcare professionals for information about your child for times when you were not present? | <input type="radio"/> Yes<br><input type="radio"/> No   |
| 18. Did you talk with another parent about your experiences?   | <input type="radio"/> Yes<br><input type="radio"/> No   |
| <b>Domain 4. Parent Advocacy</b>   |   |
| 19. I stood up for my child; I told somebody to do something in the care of my child.                              | <input type="radio"/> Yes<br><input type="radio"/> No   |
| 20. I stood up for my child; I told somebody NOT to do something in the care of my child; I gave boundaries        | <input type="radio"/> Yes<br><input type="radio"/> No   |
| 21. I gave an explanation on the daily routines of my child to a healthcare professional.                          | <input type="radio"/> Yes<br><input type="radio"/> No   |
| <b>Domain 5. Time Spent with Infant</b>  |   |
| 22. On average, how many hours were you present in the hospital with your child?                                   | Number of hours per day:  |

|  |   |
|--|---|
| 23. On average, how many hours a day do you have contact with your child?    | Number of hours per day:  |
| 24. On average, how many hours were you really close with your child?        | Number of hours per day:  |
| <b>Domain 6. Closeness and Comforting the Infant</b>                         |   |
| 25. Hold/rock/cuddle my child.   | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| 26. Comfort my child whenever he/she needs it.                               | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| 27. Kangaroo care / skin to skin contact.                                    | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| 28. Be together with my child, be close with my child. (intimate time).      | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| 29. Be together with my child (be present).                                  | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| 30. Soothe my child during a painful procedure (for instance drawing blood). | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse<br><input type="radio"/> I do this independently (without the help of the nurse)<br><input type="radio"/> This is not applicable |
| 31. Recognize my child's signals.  | <input type="radio"/> The nurse does this<br><input type="radio"/> I do this together with the nurse  |

|  |  |
|--|--|
|  | <ul style="list-style-type: none"><li>○ I do this independently (without the help of the nurse)</li><li>○ This is not applicable</li></ul> |
|--|--|

Based on van Veenendaal et al.<sup>8</sup>

## eAppendix 2. Supplemental Results

We included fathers of infants who filled out any questionnaires during infant hospital stay in the analyses. Fathers who did not fill out any questionnaires during infant hospital stay were not analyzed, as we did not have any data on their baseline characteristics, such as work status, identification with Dutch cultural background, (see eTable 3, n= 81) and therefore multiple imputation was not deemed fit to perform on this subsample, with too much missingness in characteristics.

Fathers who were non-responders, and thus not included, were not different in their baseline characteristics from responders (eTable 3), yet were still deemed unfit to be included in multiple imputation processes. Similar non-response rates were found in FICare (48.9% vs. 45.7%,  $p=0.727$ ), the gestational age of their infants was similar (  $33^{+1}$  ( $30^{+6} - 35^{+0}$ ) vs  $33^{+3}$  ( $31^{+3} - 34^{+6}$ ),  $p=0.682$ ) and length of stay in the neonatal unit. Thus 81 fathers were not analyzed for this study.

Of those fathers who filled out any questionnaires during hospital stay (n=182), 156 fathers filled out questionnaires at discharge (eTable 4). Thus, 26 fathers filled out questionnaires solely at admission. As we did have data on these fathers, we deemed it fit to include them in analysis and use their data for multiple imputation (see Methods) to generate imputed datasets.

eTable 3. Response Rates of Fathers

|                                  | Filled out any questionnaires (n= 182) |                  | p-value |
|----------------------------------|--|------------------|---------|
|                                  | FICare                                 | SNC              |         |
| Fathers <32<br>(No./Total (%))   | 42 / 59 (71.2%)                        | 23 / 28 (82.1%)  |         |
| Fathers >32<br>(No./Total (%))   | 47 / 67 (70.1%)                        | 70 / 109 (64.2%) |         |
| Fathers total<br>(No./Total (%)) | 89 / 126 (70.6%)                       | 93 / 137 (67.9%) | 0.727   |

\* at discharge and/or admission and/or 3 months of age

eTable 4. Baseline Characteristics of All Fathers Who Consented to Participate and Did or Did Not Fill Out Any Questionnaires During Infant Hospital Stay

|   | Responders (n=182)                                      | Non-responders (N=81)                                   | p-value |
|---|---|---|---------|
| FICare (No. (%))  | 89 (48.9)   | 37 (45.7)   | 0.727   |
| Gestational age (weeks, median (IQR))                                     | 33 <sup>+1</sup> (30 <sup>+6</sup> – 35 <sup>+0</sup> ) | 33 <sup>+3</sup> (31 <sup>+3</sup> - 34 <sup>+6</sup> ) | 0.682   |
| Inborn (No. (%))  | 101 (55.5)  | 48 (59.3)   | 0.664   |
| Gestational age <32 weeks (No (%))  | 65 (35.7)   | 22 (27.2)   | 0.223   |
| Non-singleton status (No. (%))  | 28 (15.4)   | 14 (17.3)   | 0.837   |
| Paid work (No. (%))   | 143 (78.6)  | Unknown   | NA      |
| Identifies with Dutch cultural background (No. (%))                       | 146 (80.2)  | Unknown   | NA      |
| University degree (No. (%))   | 149 (81.9)  | Unknown   | NA      |
| Total length of stay in hospital (birth to discharge, days, median (IQR)) | 26 (14 – 47)  | 22 (15 – 34)  | 0.163   |
| Length of stay in level 2 (admission to discharge, median (IQR))          | 25 (14 – 37)  | 20 (14 – 30)  | 0.125   |

IQR: interquartile range, No.: number



eTable 5. Baseline Characteristics of Included Fathers With or Without Filled Out Questionnaires at Discharge

|   | <b>Filled out questionnaires at discharge (n=156)</b> | <b>Did not fill out questionnaire at discharge (n=26)</b> |        |
|---|---|---|--------|
| FICare (No. (%))  | 78 (50.0)   | 11 (42.3)   | 0.607  |
| Gestational age (weeks, median (IQR))                                     | 33+4 (31+0 – 35+1)                                    | 32+1 (30+2 – 34+0)  | 0.048  |
| Inborn (No. (%))  | 90 (57.7)   | 11 (42.3)   | 0.212  |
| Singleton status (No. (%))  | 131 (84.0)  | 23 (88.5)   | 0.769  |
| Paid work (No. (%))   | 131 (84.0)  | 12 (46.2)   | 0.331  |
| Work hours per week (mean (SD))   | 40.6 (6.6)  | 37.5 (3.1)  | 0.0008 |
| Identifies with Dutch cultural background (No. (%))                       | 125 (80.1)  | 11 (42.3)   | 0.023  |
| Total length of stay in hospital (birth to discharge, days, median (IQR)) | 23 (14 – 46)  | 35.5 (22.8 – 55.5)  | 0.050  |
| Length of stay in level 2 (admission to discharge, median (IQR))          | 22 (13 – 36.5)  | 34.5 (22.8 – 43.5)  | 0.011  |
| Length of stay in level 3 (admission to discharge, median (IQR))          | 0 (0 – 6)   | 2 (0-13.3)  | 0.197  |
| Gestational age <32 weeks (No. (%))                                       | 52 (33.3)   | 13 (50.0)   | 0.155  |
| University degree (No. (%))   | 137 (87.8)  | 12 (46.2)   | 0.028  |
| Anxiety and depression score at admission (median (IQR))                  | 6.5 (3 – 11)  | 5 (3 – 14.5)  | 0.965  |
| Impaired parent-infant bonding score at admission (median (IQR))          | 9 (6 – 13)  | 7.5 (1 – 9.9)   | 0.204  |
| Self-efficacy score at admission (mean (SD))                              | 59.6 (6.5)  | 60.9 (6.8)  | 0.545  |
| Stress total score at admission (mean (SD))                               | 40.5 (16.6)   | 49.4 (23.0)   | 0.198  |
| Smoking (No. (%))   | 14 (9.0)  | 6 (23.1)  | 0.0006 |
| Use of drugs (No. (%))  | 6 (3.8)   | 0   | 1.000* |
| Use of psychotropic drugs (No. (%))                                       | 1 (0.6)   | 0   | 0.551* |
| Alcohol use (No. (%))   | 92 (59.0)   | 9 (34.6)  | 0.716  |

\*Fisher exact test, IQR: interquartile range, No.: number, SD: standard deviation

eTable 6. Missing Data in Baseline Characteristics of Fathers Included in the Analyses

| Characteristic                              | FiCare (n= 89)<br>Missing (No.<br>(%)) | SNC (n=93)<br>Missing (No.<br>(%)) |
|---|--|------------------------------------|
| Age   | 2 (2.2)                                | 13 (14.0)                          |
| Female                                      | 5 (5.6)                                | 7 (7.5)                            |
| University degree                           | 7 (7.9)                                | 8 (8.6)                            |
| Paid job                                    | 7 (7.9)                                | 9 (9.7)                            |
| Work hours per week                         | 18 (20.2)                              | 22 (23.7)                          |
| Identifies with dutch cultural background   | 5 (5.6)                                | 7 (7.5)                            |
| Stress of pregnancy                         | 5 (5.6)                                | 8 (8.6)                            |
| Stress of birth                             | 6 (6.7)                                | 9 (9.7)                            |
| Gestational age                             | 0                                      | 0                                  |
| Inborn infant                               | 0                                      | 0                                  |
| Singleton pregnancy                         | 0                                      | 0                                  |
| First child upbringing                      | 6 (6.7)                                | 8 (8.6)                            |
| Plan for upbringing Together with partner   | 6 (6.7)                                | 10 (10.8)                          |
| Smoking                                     | 11 (12.4)                              | 11 (11.8)                          |
| Use of drugs                                | 11 (12.4)                              | 13 (14.0)                          |
| Use of psychotropic drugs                   | 2 (2.2)                                | 3 (3.2)                            |
| Alcohol use                                 | 11 (12.4)                              | 12 (12.9)                          |
| Anxiety and depression at admission         | 54 (60.7)                              | 75 (80.6)                          |
| Impaired parent-infant bonding at admission | 55 (61.8)                              | 74 (79.6)                          |
| Parent self-efficacy at admission           | 51 (57.3)                              | 73 (78.5)                          |
| Stress at admission                         | 51 (57.3)                              | 73 (78.5)                          |

No.: number

### Baseline characteristics difference between FiCare model and two standard care groups.

After review, we tested for differences between the FiCare model and two standard care groups.

For comparison of multiple groups for normally distributed data we used the one-way analyses of variance (ANOVA) and for non-normally distributed data the Kruskal-Wallis test. If differences were significant within the normally distributed data we computed Tukey HSD (Tukey Honest Significant Differences) for performing multiple pairwise-comparison between the means of groups.

For non-parametric tests, we post-hoc performed multiple pairwise U-tests, with a Holm-Bonferroni correction, to test for differences in non-normally distributed data.

Chi-square ( $\chi^2$ ) tests were used to test for differences in binary outcomes. If expected cell-counts were 5 or lower, we calculated differences with the Fisher's exact test. If differences between all groups were significant we performed a pairwise Z-test with Bonferroni correction between proportions of groups.

Overall, groups were similar except for gestational age, length of hospital stay or being inborn, but this was not a difference found between the two standard care groups. A difference was present within the standard care group, concerning identifying with a Dutch cultural background(77.9% vs 100%).

eTable 7. Baseline Characteristics Difference Between FiCare Model and Two Standard Care Groups

| Characteristic   | FiCare group (n=89)  | SNC group 1 (n=75)   | SNC group 2 (n=18)   | P-value (overall)  | P-value (within SNC) |
|--|--|--|--|--------------------|----------------------|
| Age (mean (SD))  | 35.1 (4.8)   | 36.5 (5.6)   | 35.5 (4.3)   | 0.24               |                      |
| Female (No. (%))   | 2/84 (2%)  | 1/68 (1.5%)  | 0/18   | >0.99 <sup>a</sup> |                      |
| University degree (No. (%))                                | 74/82 (90%)  | 58/67 (86.6%)  | 17/18 (94.4%)  | 0.58               |                      |
| Paid job (No. (%))   | 71/82 (87%)  | 56/66 (84.8%)  | 16/18 (88.9%)  | 0.73               |                      |
| Work hours per week (mean (SD))                            | 39.7 (4.9)   | 41.2 (8.1)   | 39.8 (6.1)   | 0.40               |                      |
| Identifies with Dutch cultural background (No. (%))        | 75/84 (89%)  | 53/68 (77.9%)  | 18/18 (100%)   | 0.03 <sup>a</sup>  | <0.001               |
| Stress of pregnancy (mean (SD), max score 5)               | 2.1 (1.3)  | 2.2 (1.4)  | 2.1 (1.4)  | 0.75               |                      |
| Stress of birth (mean (SD), max score 5)                   | 3.2 (1.3)  | 2.8 (1.2)  | 2.6 (1.4)  | 0.07               |                      |
| Gestational age (median (IQR), range (min-max))            | 32 <sup>+1</sup><br>(30 <sup>+1</sup> – 35 <sup>+0</sup> )<br>(24 <sup>+5</sup> – 36 <sup>+6</sup> ) | 34 <sup>+1</sup><br>(32 <sup>+5</sup> – 35 <sup>+1</sup> )<br>(25 <sup>+4</sup> – 36 <sup>+6</sup> ) | 33 <sup>+1</sup><br>(31 <sup>+5</sup> – 34 <sup>+1</sup> )<br>(28 <sup>+2</sup> – 35 <sup>+6</sup> ) | 0.02               | 0.21                 |
| Inborn infant (No. (%))                                    | 40/89 (45%)  | 48/75 (64.0%)  | 13/18 (72.2%)  | 0.02               | 0.70                 |
| Singleton pregnancy (No. (%))                              | 74/89 (83%)  | 64/75 (85.3%)  | 16/18 (88.9%)  | 0.81               |                      |
| First child upbringing (No. (%))                           | 61/83 (73%)  | 45/67 (67.2%)  | 12/18 (66.7%)  | 0.66               |                      |
| Plan for upbringing Together with partner (No. (%))        | 83/83 (100%)   | 62/65 (95.3%)  | 18/18 (100%)   | 0.09               |                      |
| Smoking (No. (%))  | 8/78 (10%)   | 11/63 (17.5%)  | 1/18 (5.6%)  | 0.28               |                      |
| Use of drugs (No. (%))                                     | 4/78 (5%)  | 2/62 (3.2%)  | 0/18   | 0.85 <sup>a</sup>  |                      |
| Alcohol use (No. (%))                                      | 47/78 (60%)  | 43/63 (68.3%)  | 11/18 (61.1%)  | 0.60               |                      |
| Anxiety and depression at admission (median (IQR))         | 8 (3 – 14)<br>(n=35)   | 3.5 (1.8 – 5.5)<br>(n=12)  | 10 (7 – 13)<br>(n=6)   | 0.08               |                      |
| Impaired parent-infant bonding at admission (median (IQR)) | 9 (3 – 12.8)<br>(n= 33)  | 9 (5 – 12)<br>(n= 12)  | 10 (9 – 12)<br>(n=7)   | 0.53               |                      |
| Parent self-efficacy at admission (mean (SD))              | 60.4 (6.9)   | 59.4 (6.5)   | 58.4 (5.1)   | 0.71               |                      |
| Stress at admission (mean (SD))                            | 43.2 (20.1)  | 44.2 (17.9)  | 37.4 (11.1)  | 0.69               |                      |
| Length stay (days, birth – discharge, median (IQR))        | 39 (15 - 58)   | 19 (13.5 – 35)   | 23 (16 – 38)   | 0.01               | 0.59                 |

Data are n/N (%), mean (SD) or median (IQR). Denominators differ because of missing data. <sup>a</sup>: Fisher exact test, IQR: interquartile range, max: maximum, No: number, SD: standard deviation

eTable 8. Answers on the PSS-NICU

| Question   | NA / 0 (n) | 1 (n)<br>Not at all stressful | 2 (n) A little stressful | 3 (n) Moderately stressful | 4 (n) Very stressful | 5 (n) Extremely stressful | Total answers (n) |
|--|------------|-------------------------------|--------------------------|----------------------------|----------------------|---------------------------|-------------------|
| 1 The presence of monitors and equipment                                       | 12         | 52                            | 54                       | 22                         | 11                   | 0                         | 151               |
| 2 The constant noises of monitors and equipment                                | 24         | 32                            | 63                       | 20                         | 9                    | 1                         | 149               |
| 3 The sudden noises of monitor alarms  | 25         | 20                            | 31                       | 49                         | 23                   | 2                         | 150               |
| 4 The other sick babies in the room  | 59         | 46                            | 12                       | 21                         | 9                    | 2                         | 149               |
| 5 The large number of people working in the unit                               | 10         | 90                            | 23                       | 21                         | 5                    | 0                         | 149               |
| 6 Tubes and equipment on or near my baby                                       | 19         | 48                            | 51                       | 20                         | 8                    | 1                         | 147               |
| 7 Bruises, cuts or incisions on my baby  | 74         | 22                            | 22                       | 16                         | 12                   | 3                         | 149               |
| 8 The unusual color of my baby (for example looking pale or yellow jaundiced)  | 50         | 23                            | 41                       | 25                         | 6                    | 2                         | 147               |
| 9 My baby's unusual or abnormal breathing patterns                             | 35         | 14                            | 41                       | 31                         | 23                   | 2                         | 146               |
| 10 The small size of my baby   | 13         | 52                            | 39                       | 33                         | 8                    | 0                         | 145               |
| 11 The wrinkled appearance of my baby  | 64         | 57                            | 17                       | 6                          | 1                    | 0                         | 145               |
| 12 Having a machine (respirator) breathe for my baby                           | 77         | 15                            | 27                       | 13                         | 11                   | 2                         | 145               |
| 13 Seeing needles and tubes put in my baby                                     | 32         | 14                            | 42                       | 25                         | 23                   | 7                         | 143               |
| 14 My baby being fed by an intravenous line or tube                            | 16         | 65                            | 39                       | 16                         | 5                    | 1                         | 142               |
| 15 When my baby seemed to be in pain   | 16         | 9                             | 42                       | 32                         | 39                   | 4                         | 142               |
| 16 When my baby looked sad   | 16         | 19                            | 47                       | 36                         | 23                   | 1                         | 142               |
| 17 The limp and weak appearance of my baby                                     | 50         | 17                            | 31                       | 23                         | 17                   | 4                         | 142               |
| 18 Jerky or restless movements of my baby                                      | 19         | 23                            | 58                       | 30                         | 11                   | 1                         | 142               |
| 19 My baby not being able to cry like other babies                             | 89 2       | 25                            | 19                       | 7                          | 1                    | 1                         | 142               |
| 20 Being separated from my baby  | 24         | 24                            | 30                       | 34                         | 28                   | 5                         | 145               |
| 21 Not feeding my baby myself  | 48         | 33                            | 35                       | 19                         | 9                    | 2                         | 146               |
| 22 Not being able to care for my baby myself (for example, diapering, bathing) | 62         | 30                            | 25                       | 18                         | 10                   | 1                         | 145               |
| 23 Not being able to hold my baby when I want                                  | 49         | 22                            | 30                       | 27                         | 16                   | 2                         | 146               |
| 24 Feeling helpless and unable to protect my baby                              | 26         | 33                            | 36                       | 24                         | 23                   | 4                         | 146               |

|  |    |    |    |    |    |   |     |
|--|----|----|----|----|----|---|-----|
| from pain and painful procedures                               |    |    |    |    |    |   |     |
| 25 Feeling helpless about how to help my baby during this time | 20 | 33 | 49 | 23 | 19 | 2 | 146 |
| 26 Not having time alone with my baby                          | 38 | 37 | 30 | 26 | 12 | 3 | 146 |

n: number

eTable 9. Associations Between Fathers' Participation and Outcomes

| Outcome                        | Beta (95%CI)               | p-value | Adjusted beta (95%CI)*    | p-value | Indirect effect | 95%CI of indirect effect |
|--------------------------------|----------------------------|---------|---------------------------|---------|-----------------|--------------------------|
| Stress                         | 0.254 (-0.140; 0.649)      | 0.204   | 0.223 (-0.157; 0.602)     | 0.248   | 0.763           | -0.627; 2.517            |
| Depression/anxiety             | -0.016 (-0.029; -0.0002)** | 0.024   | -0.015 (-0.028; -0.002)** | 0.029   | -0.051          | -0.133; -0.003           |
| Self-efficacy                  | 0.147 (0.000; 0.294)       | 0.049   | 0.133 (-0.022; 0.289)     | 0.092   | 0.457           | -0.119; 1.357            |
| Impaired father-infant bonding | -0.024 (-0.039; -0.010)**  | 0.001   | -0.024 (-0.040; -0.009)   | 0.003   | -0.082          | -0.177; -0.015           |
| Satisfaction with care         | 0.004 (-0.007; 0.015)      | 0.479   | 0.005 (-0.007; 0.017)     | 0.387   | 0.018           | -0.022; 0.075            |

Outcomes are from multiple imputed datasets. \* adjusted for gestational age, education, cultural background, age, stress at birth, work hours per week, upbringing plan, paternal smoking and alcohol use; \*\*after log transformation, NA: not applicable

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