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BRIEF REPORT

Daily Skin-to-Skin Contact and Crying and Sleeping in Healthy Full-Term Infants: A Randomized Controlled Trial

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This randomized controlled trial (NTR5697) examined the effects of a 5-week daily skin-to-skin contact (SSC) intervention, compared with care-as-usual, on full-term infant crying and sleeping duration during the first 12 weeks postnatally (secondary outcomes of this trial). This trial included 116 Dutch healthy mothers and their full-term infants. SSC mothers were instructed to provide 1 hr daily of SSC for the first 5 weeks postpartum. Intention-to-treat analyses revealed no group differences in infant crying (i.e., total duration and mean bout length) and sleeping (i.e., total duration and mean bout length). Per-protocol analyses, including only the SSC dyads who adhered to SSC guidelines, indicated that SSC reduced infant total crying duration and the crying bout length. Similarly, dose-response analyses indicated that more SSC minutes were associated with less infant crying (i.e., shorter total duration and bout length) and longer total sleeping duration, especially when the infant was younger. No group differences and associations were found with sleeping bout length. Mother-infant SSC, when performed regularly, may be a cost-effective intervention to reduce infant crying and potentially also extend infant sleep duration.

Keywords: full-term infants, infant crying, infant sleeping, skin-to-skin contact

Supplemental materials: https://doi.org/10.1037/dev0001392.supp

Infant crying and sleeping behaviors during the first weeks after birth are often a source of parental concern for which many parents seek advice from health care professionals (Cook et al., 2019; Sadeh et al., 2010; St. James-Roberts, 2007). Whereas normative infant development is characterized by large fluctuations in crying behavior (de Weerth et al., 1999) and a gradual consolidation of the sleep–wake cycle (Wolke, 2019), infant crying and/or short sleep durations are related to parental experience of exhaustion, depression, and anxiety (de Kruijff et al., 2021; Kurth et al., 2011; Petzoldt et al., 2016), and can even lead to maltreatment (Hemmi et al., 2011; Lee et al., 2007). Moreover, research indicates that excessive infant crying is a risk factor for later poor mental health outcomes, including socioemotional and inattention problems (Botha et al., 2019), and that shorter durations of infant sleep are a risk factor for the development of childhood obesity, impaired growth, and behavioral problems (Chaput et al., 2017; Gillman & Ludwig, 2013; Valla et al., 2021; Zhou et al., 2015). These findings highlight the fact that finding easily accessible ways for parents to reduce infant crying duration and extend infant sleeping duration during the first postnatal months may be beneficial for both parents and infants alike.

Skin-to-skin contact (SSC), placing the naked infant on the bare chest of the parent (World Health Organization, 2003), is a simple and relatively easy method which may help reduce crying and extend sleeping duration. Though the exact working mechanisms of SSC are unclear, SSC provides ample possibilities to expose the infant to so-called ‘hidden regulators’ (i.e., warmth, touch, smell) that are thought to regulate the infant and reduce stress (Hofer,

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The study was preregistered on March 13, 2016 (NTR5697; https://www.trialregister.nl/trial/5591), followed CONSORT guidelines, and the study protocol was previously published (Cooijmans et al., 2017). Preliminary results were previously presented by the authors as part of the online Dutch iLactation conference from May 15, 2021 to July 15, 2021 and the online English iLactation conference from September 15, 2021 to December 15, 2021.

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2005). Moreover, during SSC, due to the involvement of multiple senses including touch, the oxytocinergic system is activated and the hormone oxytocin is released in both mother and infant (Moberg et al., 2020; Uvnäs-Moberg et al., 2014). Elevated oxytocin levels have the ability to decrease HPA-axis and sympathetic nervous system activity, in turn reducing physiological and, potentially, behavioral stress reactions (Moberg et al., 2020). These stress-reducing effects may lead to less crying and more sleeping.

Indeed, in preterm infants daily SSC reduced the amount of crying and extended the amount of sleeping (Ludington-Hoe et al., 2008; Shattnawi & Al-Ali, 2019). In full-term infants, SSC immediately after birth reduced the crying duration during SSC (Moore et al., 2016). Additionally, one hour of SSC immediately after birth reduced the crying duration and extended the sleeping duration during a 1-hr observation period, starting 4 hr postnatally (Ferber & Makhoul, 2004). In full-term neonates, a one-time SSC session 2 days after birth, compared with sleeping in a crib, extended quiet sleep duration during SSC (Morgan et al., 2011). Moreover, SSC during a heel lance procedure in full-term newborns decreased crying duration, compared with being swaddled or placed in a crib (Johnston et al., 2017). However, not all studies on SSC in full-term infants found positive effects. In 5-to-6 week old full-term infants, a one-time SSC session did not reduce the crying duration during a mild stressor (i.e., a bathing session), when compared with resting alone in a crib or playpen (Beijers et al., 2016).

No studies examined the effects of SSC on full-term infant crying and sleeping duration beyond the first postnatal hours and days. Despite of this, there are reasons to believe that daily SSC over a longer time period may affect crying and sleeping in full-term infants. For example, a few studies in preterm infants examined long-term effects of prolonged daily SSC early in life. Feldman, Eidelman, et al. (2002; Feldman et al., 2014) reported that a daily hour of SSC during the first 2 weeks after birth was associated with improved cognitive and motor development, and better executive functioning from 6 months to 10 years of age. Also, daily SSC in preterm infants was related to higher thresholds to negative emotionality and more efficient arousal modulation at 3 months of age and better organized sleep at term age and at 10 years of age (Feldman, Weller, et al., 2002; Feldman et al., 2014). In addition to studies with SSC interventions, studies on daily carrying in mothers and full-term infants, which also includes close physical contact, found beneficial long-term effects on infants. Daily carrying was, for example, associated with reduced infant crying during the first 12 weeks after birth (Norholt, 2020).

The current randomized controlled trial (RCT) investigated the effects of a 5-week daily hour of SSC, compared with care-as-usual (CAU), in mothers and full-term infants on infant total crying and sleeping durations per day and mean bout lengths (secondary outcomes). The reason for including both total duration per day and mean bout length (i.e., of one crying/sleeping episode) as measures for crying and sleeping duration was based on the fact that these different characteristics of infant crying/sleeping are differentially related to, for example, infant colic (Barr et al., 2005), feeding modus (breastfeeding vs. formula feeding; Lee, 2000), and caregiver frustration (Fujiwara et al., 2011). We hypothesized that in SSC infants the total crying duration and bout length would be shorter, and the total sleeping duration and bout length longer, than in CAU infants.

Method

Design and Ethical Considerations

This RCT included two parallel groups. The study "Skin-to-Skin Contact to Improve Outcomes in Full-Term Infants and Their Mothers: A Randomized Controlled Trial" was approved by the Ethics Committee of the Social Science faculty of Radboud University, Nijmegen, the Netherlands (ECSW2015-2311-358). All procedures were in accordance with the 1964 Helsinki Declaration and its later amendments. No changes were made after the trial commenced except for additional analyses. Outcomes were secondary outcomes in this trial. Findings on the primary outcome indicated that daily SSC did not affect maternal depressive symptoms (Cooijmans et al., 2021). Recruitment started in April 2016 and finished in September 2017. Data collection for this study took place between April 2016 and January 2018.

Participants

Sample size calculations based on the primary outcome indicated that, accounting for attrition, 58 dyads in each group were needed to detect an effect size of Cohens $f = .24$, with a power of .80 and alpha .05 (Cooijmans et al., 2017).

Pregnant women in a community setting were recruited in Nijmegen and surrounding areas. Maternal eligibility criteria were as follows: singleton pregnancy, age ≥18, no drug/medication use, no severe health problems, sufficiently fluent in Dutch, and no participation in other studies. Infant inclusion criteria were as follows: born ≥37 weeks of pregnancy, birth weight ≥2,500 g, no congenital anomalies, and 5-min Apgar score ≥7.

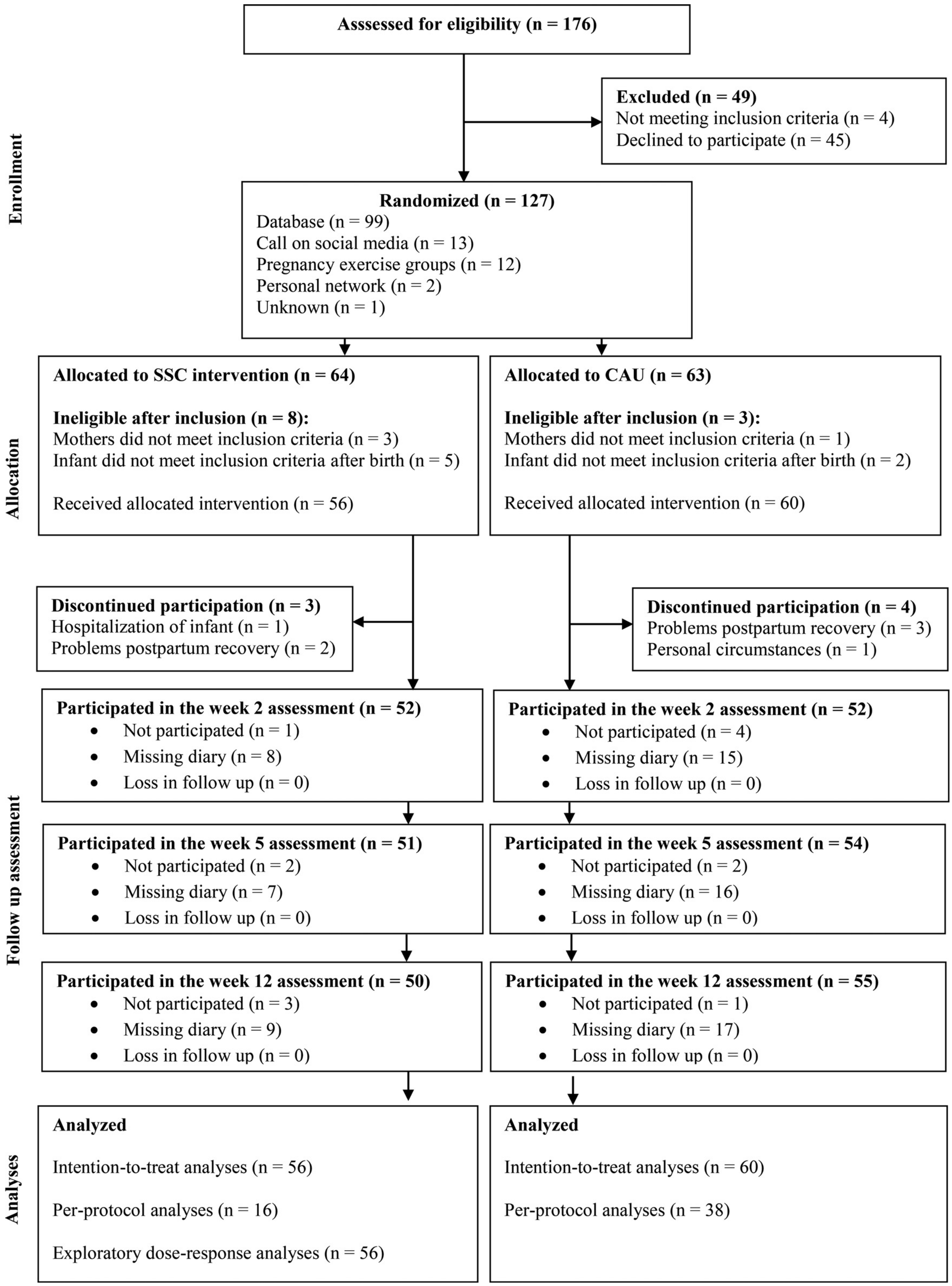
Figure 1 shows the participant flowchart. Initially, 116 dyads were recruited. Four women were excluded due to postenrollment medication use, and seven infants did not meet inclusion criteria. Consequently, 11 additional pregnant women were enrolled, resulting in 127 participants. During the intervention, seven mothers discontinued participation. No loss to follow-up was recorded. Baseline characteristics are presented in Table 1.

Procedure

Prenatal

Pregnant women were recruited via social media, flyers, and a database of pregnant women interested in research participation. The recruitment phase included a cover story to reduce potential self-selection biases for mothers in the SSC and CAU condition. Women were informed that the study was about mother-infant (mental) health, infant sleeping and feeding, mother-infant contact, and that some women would be asked to implement a 5-week daily mother-infant contact period. For eligible interested women, study details were explained during a home visit (pregnancy week 34 through week 36). After written consent, women were randomly allocated (1:1) with random blocks (four and six) stratified by parity (primiparae vs. multiparae) into a condition. The allocation sequence was computer-generated and concealed in envelopes by an independent researcher. After providing consent, SSC mothers were asked to provide their infant with at least 1 hr uninterrupted daily of SSC for the first 5 weeks postnatally. The SSC

Figure 1
Flow of Participants



Note. SSC = skin-to-skin contact; CAU = care-as-usual.

Table 1
Demographics and Descriptive Statistics

Variable	Intention-to-treat		Per-protocol	
	SSC (*n* = 56)	CAU (*n* = 60)	SSC (*n* = 16)	CAU (*n* = 38)
Maternal age (years)	32.36 (3.85)	32.48 (3.05)	32.39 (3.21)	32.48 (2.95)
Maternal education[a]	6.82 (1.55)	6.87 (1.79)	6.94 (1.39)	7.32 (1.30)
Smoking (% no)	54 (96%)	60 (100%)	15 (94%)	38 (100%)
Alcohol (% no)	55 (98%)	60 (100%)	15 (94%)	38 (100%)
C-section (% no)	51 (91%)	55 (92%)	15 (94%)	36 (95%)
Birth order				
First	27 (48%)	28 (47%)	5 (31%)	17 (45%)
Second	18 (32%)	23 (38%)	6 (38%)	14 (37%)
Third	11 (20%)	9 (15%)	5 (31%)	7 (18%)
Apgar score	9.84 (0.42)	9.70 (0.62)	9.75 (0.58)	9.82 (.39)
Child sex				
Male	23 (41%)	34 (57%)	6 (38%)	21 (55%)
Female	33 (59%)	26 (43%)	10 (62%)	17 (45%)
Gestational age at birth (weeks)	40.08 (1.01)	40.02 (1.10)	40.13 (1.09)	39.89 (.98)
Birthweight (grams)	3,650.05 (414.93)	3,567.47 (385.77)	3,762.50 (483.50)	3,543.92 (333.86)
Contact				
SSC by the mother (minutes)	2,082.64 (853.12)	420.48 (848.93)	2,821.33 (440.84)	456.60 (908.68)
SSC by other caregivers (minutes)	206.72 (321.21)	100.00 (172.05)	247.27 (451.28)	94.38 (174.16)
Holding by the mother (minutes)	14,289.34 (5,268.44)	16,272.59 (4,757.45)	13,982.81 (4,075.64)	15,701.35 (4,736.96)
Holding by other caregivers (minutes)	4,530.99 (1,987.98)	4,911.04 (2,366.88)	3,728.20 (1,634.43)	4,935.69 (2,439.06)
Breastfeeding				
Week 2 (% yes)	43 (77%)	44 (73%)	15 (94%)	32 (84%)
Week 5 (% yes)	41 (73%)	40 (67%)	15 (94%)	33 (87%)
Week 12 (% yes)	34 (61%)	36 (60%)	14 (88%)	30 (79%)
Outcome				
Week 2				
Total crying duration (minutes)	122.72 (68.10)	122.97 (57.01)	106.04 (52.74)	129.39 (53.87)
Total sleeping duration (minutes)	919.86 (112.70)	900.85 (110.15)	935.73 (94.41)	897.02 (111.90)
Crying bout length (minutes)	12.90 (6.89)	13.56 (7.87)	10.95 (3.68)	14.03 (7.95)
Sleeping bout length (minutes)	89.84 (18.77)	92.41 (26.97)	90.21 (15.09)	91.23 (25.44)
Week 5				
Total crying duration (minutes)	128.65 (64.27)	140.54 (59.37)	113.75 (42.21)	141.26 (62.36)
Total sleeping duration (minutes)	890.32 (92.27)	859.20 (123.86)	924.27 (74.22)	859.29 (117.79)
Crying bout length (minutes)	12.81 (6.53)	14.01 (6.83)	10.82 (4.12)	13.99 (7.09)
Sleeping bout length (minutes)	87.85 (20.40)	93.55 (35.08)	90.30 (20.55)	93.26 (36.26)
Week 12				
Total crying duration (minutes)	84.71 (53.87)	93.61 (58.48)	69.48 (40.22)	94.95 (59.08)
Total sleeping duration (minutes)	871.29 (84.74)	878.65 (87.16)	885.31 (78.94)	878.29 (89.99)
Crying bout length (minutes)	11.77 (6.15)	12.42 (6.17)	10.19 (4.95)	12.42 (6.27)
Sleeping bout length (minutes)	109.08 (26.81)	115.40 (36.33)	114.47 (30.37)	113.89 (36.51)

Note. SSC = skin-to-skin contact; CAU = care-as-usual.
[a] Maternal education: 1 = primary education, 2–6 = secondary education, 7–8 = higher education.

protocol was adapted from a prior study in which mothers were requested to provide their infants with at least 6 hr daily of SSC during the first postnatal week and continue with at least 2 hr daily of SSC until the infant was one month old (Bigelow et al., 2012). As daily SSC is not a routine part of care in our country, the requested daily hours of SSC were reduced and the requested weeks with daily SSC were slightly extended to optimally facilitate SSC adherence in the current study. This protocol was considered feasible due to the country's 10 to 12 weeks postpartum paid maternity leave. Group allocation was only masked for CAU mothers because they received no additional instructions. Other study procedures were the same for both conditions. Lastly, mothers filled out baseline questionnaires.

Postnatal

During the intervention period, mothers retrospectively filled out a daily contact logbook every 2 to 3 hr, for example, during natural breaks for feeding. All mothers, including CAU mothers, registered the following behavioral categories in 15-min intervals: (a) SSC by mother, (b) SSC by other caregiver, (c) holding by mother, (d) holding by other caregiver, and (e) no contact. Additionally, weekly contact by text message or phone with the researcher (first author) was arranged to remind mothers to complete the logbook and, only for SSC mothers, discuss SSC difficulties (e.g., problems with fitting SSC into their schedule, dealing with initial infant distress during SSC). At 2, 5, and 12 weeks postnatally, mothers completed the 3-day Baby's Day Diary (BDD; Barr et al., 1988).

Measures

Mothers filled out the BDD (uses lines and symbols with 5-min intervals), every 2 to 3 hr for 3 consecutive days reporting: fussing, crying, unsoothable crying, sleeping, feeding, and awake without crying (Barr et al., 1988). The diary is valid and has been extensively used before (e.g., Hechler et al., 2018; Korja et al., 2014).

To prepare data per measurement wave (2, 5, and 12 weeks postnatally), the frequency and the mean duration (bout length) of a fussing, crying, unsoothable crying, and sleep episode was defined for each day. Diary data was only accepted when all three days were completed for ≥80%. Fussing, crying, and unsoothable crying were summed (Wolke et al., 2017). Next, the mean frequency and mean bout length over 3 days were calculated. Four outcome measures were used: total crying duration (Frequency × Bout), total sleeping duration (Frequency × Bout), mean crying bout length, and mean sleeping bout length.

Analytic Strategy

Outliers were winsorized (replacing values with three standard deviations above or below the mean; Tukey, 1977). Missingness was examined by investigating the percentage and pattern of missingness. Correlations were investigated between total crying duration, total sleeping duration, crying bout length, and sleeping bout length at 2, 5, and 12 weeks postnatally. Conditions were compared on total SSC duration by the mother, total SSC duration by other caregivers, holding by the mother, and holding by other caregivers with independent samples *t* tests.

The following three analyses were performed: confirmatory intention-to-treat (ITT), exploratory per-protocol (PP), and exploratory dose-response (DR) analyses. The study protocol only included ITT analyses. Following current recommendations, PP and exploratory DR analyses were added (Hernán & Hernández-Díaz, 2012). For ITT analyses, conditions were compared regardless of withdrawal or compliance. For PP analyses, SSC mothers who adhered to the SSC protocol and without missing data were compared (n = 16) with CAU mothers without missing data. SSC adherence data, derived from the logbook, were used only when logbooks were completed for ≥80% of each day for ≥21 out of 35 days (i.e., 60% of the days; see Beijers et al., 2013 for a prior study). Data from invalid logbooks were not used. Of the total sample, 90 adequately filled out the logbook (27 = no missing days; 39 = 1 or 2 missing days; 16 = 3–7 missing days; 8 = 8–14 missing days). Missing days were imputed with the mean SSC duration 2 days before and after the missing day. After, days with ≥60 SSC min were determined. As only three dyads reported 35 out of 35 days with ≥60 SSC min, and based on Bigelow et al. (2012), we decided to include SSC dyads in PP analyses when 80% of the intervention days (≥28 out of 35) included ≥60 SSC min (n = 18). For exploratory DR analyses in the SSC group, total SSC duration during the intervention was used as the predictor.

Multilevel growth curve analyses were used for all analyses. First, intraclass correlation coefficients (ICC) were calculated. Then, time was introduced at Level 1 and nested within the dyad at Level 2. Intercept and time were considered random factors. Next, time and quadratic time (for crying models), and condition/total SSC were added one-by-one as fixed main effects, followed by the interactions of time by condition/total SSC interaction and, for crying models due to the expected crying peak (St. James-Roberts et al., 2013), quadratic time by condition/total SSC. Likelihood ratio tests were used to compare models. Normality of residuals in final models was checked. The main analyses were repeated including breastfeeding (yes/no) on Weeks 2, 5, and 12 as confounders. This was done because in an earlier study we found SSC to be associated to breastfeeding in the current trial (Cooijmans et al., 2021), and breastfeeding may, in turn, affect crying and sleeping (Moore et al., 2016; Schmid et al., 2011; Thomas, 2000; Wolke et al., 1998).

Transparency and Openness

The study was preregistered NTR5697, followed CONSORT guidelines (online supplemental materials), and the study protocol was published (Cooijmans et al., 2017). Data, analysis code, and research materials are available upon publication (no end date) to researchers with a methodologically sound proposal for re-use of the data, analysis code, or research materials. The proposal should be directed to the last author. Data were analyzed using SPSS Statistics for Mac OS, version 26.0.

Results

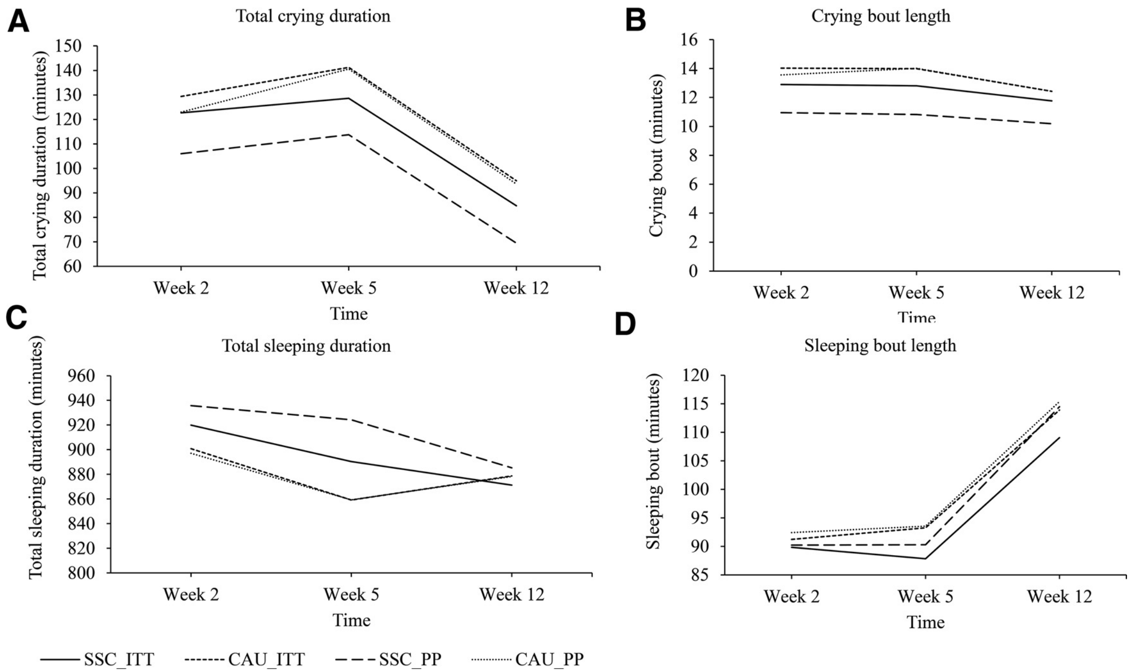
Preliminary Analyses

In total, 17.01% of the outcome values were missing and 13 outliers were winsorized. Missingness was not completely at random (Little's MCAR test: χ^2[176] = 223.23, p = .009). Missing data were handled using maximum likelihood estimation (the default for multilevel models). Figure 2 presents the mean scores of outcome measures over time. The correlations between the total crying duration and the crying bout length at infant age 2, 5 and 12 weeks ranged between .52 and .63. The correlations between the total sleeping duration and the sleeping bout length ranged between .15 and .35. Independent samples t tests indicated that SSC mothers provided significantly more total SSC minutes during the intervention than CAU mothers for both the ITT and PP selection, $t(88)_{ITT} = –9.24$, $p_{ITT} < .001$; $t(50)_{PP} = –9.87$, $p_{PP} < .001$. Also, SSC dyads in the ITT selection reported significantly more total SSC minutes provided by other caregivers, compared with CAU dyads, whereas no differences were found for the PP selection, $t(73.78)_{ITT} = –2.00$, $p_{ITT} = .05$; $t(17.02)_{PP} = –1.31$, $p_{PP} = .21$. Finally, holding by the mother, $t(88)_{ITT} = 1.86$, $p_{ITT} = .07$; $t(50)_{PP} = 1.26$, $p_{PP} = .21$, and holding by other caregivers, $t(88)_{ITT} = .83$, $p_{ITT} = .41$; $t(50)_{PP} = 1.80$, $p_{PP} = .08$, did not significantly differ in SSC and CAU dyads in the ITT and PP selection. Consequently, the main analyses were repeated while including SSC by other caregivers as a confounder. Only 16 out of 56 SSC mothers adhered to the SSC protocol and had no missing outcome data. Importantly, SSC mothers who did or did not adhere to SSC guidelines did not significantly differ on baseline characteristics. No adverse events were reported.

Primary Analyses

The ICCs (range = .21–.61) were appropriate to use multilevel growth curve models. Residuals for total crying duration and the crying and sleeping bout length were not normally distributed. A square root transformation for total crying duration and log transformations for the crying and sleeping bout length resulted in normally distributed residuals. In all analyses, including the random

Figure 2
Mean Scores for Infant Variables



Note. Variable means over time in the skin-to-skin contact (SSC) and care-as-usual (CAU) conditions for the intention-to-treat (ITT) and per-protocol (PP) selections. Winsorized data are presented for variables including outliers. Panel A: Total crying duration. Panel B: Crying bout length. Panel C: Total sleeping duration. Panel D: Sleeping bout length.

effect of time produced accuracy warnings; accordingly, time was entered as a fixed effect. Final models are presented in Table 2.

Infant Crying

All models for total crying duration showed a significant main effect of quadratic time; total crying duration increased from Week 2 to Week 5 and decreased thereafter. For the ITT analysis, condition did not improve the model fit. In the PP analysis, total crying duration was shorter in SSC than CAU infants. In the DR analysis, more total SSC minutes were associated with shorter total crying duration. Interaction effects did not improve any of the models' fit.

All models for the crying bout length showed a significant main effect of time; the crying bout decreased over time. In the ITT analysis, condition did not improve model fit. In the PP analysis, the crying bout length was shorter in SSC than CAU infants. In the DR analysis, more SSC minutes were associated with a shorter crying bout length. Interaction effects did not improve any of the models' fit.

Infant Sleeping

The total sleeping duration ITT and DR models showed a significant main effect of time; total sleeping duration decreased over time. In the ITT analysis, condition and interactions did not improve model fit. In the PP analysis, time, condition, and interactions did not improve model fit. In the DR analysis, a significant main effect of total SSC and a significant interaction effect of time by total SSC were found; more total SSC minutes were associated with longer total sleeping duration. For the interaction effect, simple slopes were computed with MODPROBE (Hayes & Matthes, 2009). SSC infants with more SSC minutes showed high initial levels of total sleeping duration that gradually decreased over time ($b = -8.07$, $SE = 2.86$, $t = -2.82$, $p = .006$; see Figure 3); note that at Week 12 they showed comparable levels of total sleeping duration to SSC infants with fewer SSC minutes. The slope for SSC infants with fewer SSC minutes was nonsignificant; total sleeping duration was stable over time ($b = -1.34$, $SE = 2.79$, $t = -.48$, $p = .63$).

All models for sleeping bout length showed a significant main effect of time; the sleeping bout length increased over time. Condition and interactions did not improve model fit.

Discussion

This RCT compared the effectiveness of 5 weeks of daily mother-infant SSC with CAU on full-term infants' crying and sleeping behavior during the first 12 weeks postnatally. In ITT analyses (i.e., also including noncompliant participants), there was no evidence that daily SSC affected crying and sleeping. However, PP analyses (i.e., including only SSC participants who adhered to the protocol), indicated that SSC reduced both the total duration and bout length of crying, compared with CAU. Total duration and bout length of sleeping were not extended. Exploratory DR analyses indicated that more minutes of total SSC were associated with a shorter total duration and bout length of crying, and a longer total sleeping duration, especially when the infant was younger. At 12

Table 2
Best-Fitting Multilevel Models Predicting Total Crying and Sleeping Duration and Crying and Sleeping Bout Length

	Intention-to-treat			Per-protocol			Exploratory dose response		
Final model	Estimate (*SE*)	*p*	95% CI	Estimate (*SE*)	*p*	95% CI	Estimate (*SE*)	*p*	95% CI
				Total crying duration					
Fixed effects									
Intercept	9.81 (.51)	.001	[8.80, 10.82]	9.09 (.75)	.001	[7.60, 10.58]	12.26 (1.14)	.001	[9.99, 14.52]
Time	.55 (.18)	.002	[.20, .89]	.52 (.22)	.021	[.08, .96]	.53 (.22)	.020	[.09, 1.00]
Time^2	−.05 (.01)	.001	[−.08, −.03]	−.05 (.02)	.001	[−.08, −.02]	−.05 (.02)	.001	[−.08, −.02]
Condition				−1.20 (.60)	.050	[.001, 2.41]	−.001 (.001)[a]	.005	[−.002, −.001]
Random effects									
Intercept	4.86 (.92)	.001	[3.36, 7.04]	2.92 (.80)	.001	[1.71, 4.98]	4.51 (1.16)	.001	[2.73, 7.46]
Deviance	1,219.16			726.94			602.44		
				Crying bout length					
Fixed effects									
Intercept	2.51 (.05)	.001	[2.42, 2.61]	2.37 (.09)	.001	[2.20, 2.55]	2.83 (.16)	.001	[2.50, 3.15]
Time	−.01 (.01)	.040	[−.02, −.001]	−.01 (.01)	.022	[−.02, −.002]	−.01 (.01)	.153	[−.02, 003]
Condition				−.20 (.10)	.044	[.01, .40]	−.001 (.001)[a]	.014	[−.001, −.001]
Random effects									
Intercept	.12 (.02)	.001	[.08, .18]	.08 (.02)	.001	[.05, .14]	.11 (.03)	.001	[.07, .19]
Deviance	257.64			125.54			120.39		
				Total sleeping duration					
Fixed effects									
Intercept	904.38 (11.09)	.001	[882.51, 926.24]	889.13 (11.28)	.001	[866.51, 911.76]	870.94 (16.62)	.001	[838.15, 903.74]
Time	−2.82 (1.06)	.009	[−4.92, −.73]				−.12 (1.61)	.942	[−3.29, 3.06]
Condition							.03 (.01)[a]	.00	[.01, .04]
Time × Condition							−.002 (.001)[a]	.027	[−.004, −.001]
Random effects									
Intercept	5,538.79 (1,101.71)	.001	[3,750.63, 8,179.48]	5,123.12 (1,344.45)	.001	[3,063.06, 8,568.68]	4,667.41 (972.22)	.001	[3,102.92, 7,020.72]
Deviance	3,119.53			1,921.45			2,875.06		
				Sleeping bout length					
Fixed effects									
Intercept	4.41 (.03)	.001	[4.35, 4.47]	4.41 (.04)	.001	[4.33, 4.49]	4.39 (.03)	.001	[4.32, 4.46]
Time	.02 (.01)	.001	[.02, .03]	.02 (.01)	.001	[.02, .03]	.02 (.004)	.001	[.01, .03]
Random effects									
Intercept	.03 (.01)	.001	[.02, .04]	.03 (.01)	.001	[.02, .05]	.02 (.01)	.006	[.01, .03]
Deviance	13.69			22.58			30.76		

Note. Comparable results were found while including breastfeeding and skin-to-skin contact (SSC) provided by other caregivers as confounders, except condition became marginally significant in per-protocol analyses for total crying duration when controlling for breastfeeding and SSC provided by other caregivers.
[a] Values are for dose variable rather than condition variable.

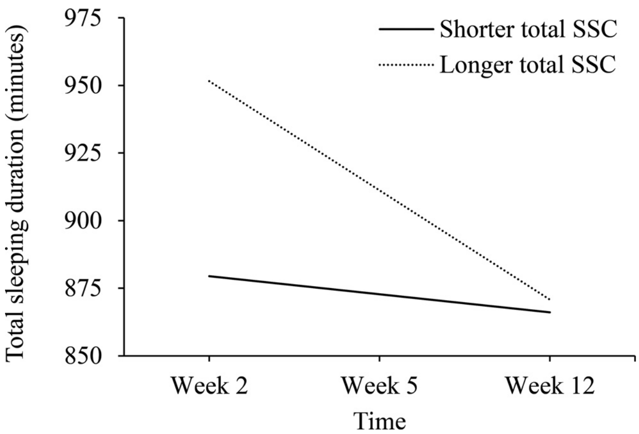
weeks, total sleeping duration was similar for SSC infants with longer and shorter total SSC. No associations were found with sleeping bout length. These findings provide first preliminary support that regular daily SSC may be effective in reducing infant crying, and that performing more SSC may extend infant sleeping duration.

Results from the PP analyses are consistent with prior studies on beneficial effects in full-term infants of one-time SSC during the first postnatal hours and days on infant crying duration (Ferber & Makhoul, 2004; Johnston et al., 2017; Moore et al., 2016). As SSC during the first postnatal hours is recommended worldwide (Unicef, 2017), mothers in the CAU group also performed some SSC, mainly during the first postnatal hours and days. If immediate or early postnatal SSC were sufficient to reduce crying duration and extend sleeping duration as much as was observed in the current study, then no group differences would have been found between the CAU and SSC group. Our findings hence suggest that extended SSC adds to the already beneficial effects of SSC during the first postnatal hours/days, at least regarding infant crying and sleeping. The promising findings from the PP analyses are also supported by the exploratory DR analyses, in which more minutes of SSC during the 5-week intervention period were related to shorter infant total duration and bout length of crying. Since these results derived from PP and exploratory DR analyses, and not ITT analyses, future replication trials are warranted to validate these findings.

Unlike previous studies in preterm infants and newborns that indicated improved infant sleep with the use of SSC (Ferber & Makhoul, 2004; Ludington-Hoe et al., 2008), we found limited evidence for such improvement. Our ITT and PP analyses did not reveal that daily SSC, beyond the first postnatal hours and days, increased the total duration and bout length of sleeping in full-term infants. Only exploratory SSC dose-response (DR) analyses indicated possible benefits: total sleeping duration increased with longer total SSC, especially during the first weeks postnatally. However, these findings should be interpreted with caution due to the exploratory nature of the analyses. As differences for total sleeping duration for the SSC and CAU groups were only found during and immediately after the SSC intervention period, the results may have been different if the daily SSC intervention period had been extended. However, as low SSC protocol adherence

Figure 3

Interaction Between Time and Skin-to-Skin Contact (SSC) Duration During the Intervention Period on Total Sleeping Duration



rates were observed with the current 5-week SSC protocol, and many mothers anecdotally reported that their infant moved more and became more restless during SSC near the end of the intervention period, it is important to investigate the optimal duration of the intervention period both for infant outcomes as well as for feasibility and protocol adherence.

Contrary to our expectations (based on prior research; Bigelow et al., 2012), low participant adherence to the SSC protocol was observed. This potentially interfered with being able to replicate PP and DR findings in the ITT analyses. Only 16 out of 56 SSC mother-infant dyads adhered in at least 28 out of 35 days to the daily hour of SSC, had complete outcome data and, subsequently, were included in the PP analyses. The only prior study on daily SSC in full-term infants (Bigelow et al., 2012) documented high adherence rates with a much stricter daily SSC protocol (Week 1: 6 hr daily SSC; Week 2–4: 2 hr daily SSC), but recruited a self-selected sample of mothers. Low adherence rates are a well-known concern in behavioral change interventions, including interventions during the postnatal period (Gilmore et al., 2017; Swift & Greenberg, 2012). Participants in the current study were not prepared for SSC when providing consent and were allocated to their condition irrespective of their motivation to perform SSC. Moreover, mothers were not informed about potential benefits of SSC, and SSC is not a normal part of the Dutch culture. Despite having paid maternity leave and being contacted weekly during the intervention period, it is therefore perhaps not surprising that many mothers were noncompliant to the protocol. Nonetheless, the lack of baseline differences between compliant and noncompliant SSC mothers gives weight to the PP and exploratory DR findings. Hence, and as a following step in this line of research and with the goal of increasing participant compliance, we recommend future RCTs in which SSC mothers are informed about potential benefits of SSC (e.g., similarly to medication RCTs), as well as the use of focus groups prior to designing the final SSC protocol to gather information on maternal preferences (e.g., on type and frequency of communication, SSC timing and duration). In the present study, we called mothers on days five and fifteen after birth, and in the remaining weeks communicated with them via text messages. From notes made during the telephone calls, we know that 68% of all mothers reported no SSC difficulties. The remaining mothers reported maternal mental or physical recovery problems (14%), problems with fitting SSC into their daily routine (10%), infant physical health problems (4%) or other problems (dealing with initial infant distress during SSC, not feeling comfortable performing SSC) as difficulties that interfered with their adherence to the protocol. For future studies, we recommend collecting information on SSC difficulties more systematically and throughout the intervention period, to shed more light on SSC feasibility and challenges to protocol adherence.

An alternative explanation for our findings is that SSC did not affect infant crying and sleeping, but rather maternal perception of infant crying and sleeping. Prior research showed that short daily mother-infant massages, which also include touch, during the first postnatal month improved the mother's perception of her newborn's sleep (Field et al., 2016). Despite our use of the valid and reliable BDD (Barr et al., 1988), maternal perception of crying rather than actual crying may have improved due to daily SSC. Future studies, with more objective measures, such as observations or wearables, are warranted to replicate our PP and DR findings.

This study had a number of strengths. First, this preregistered randomized controlled trial was designed and reported according to the SPIRIT and CONSORT guidelines to advance research quality and transparency. Second, the intervention is uncomplicated and low cost. Limitations of the study were the low SSC adherence rates, as described before. Second, mothers were mainly highly educated and recruited from a database of women interested in research which may affect the generalizability of our findings. Future studies in more heterogeneous samples are therefore required. Future research should also include the impact of time of day on SSC implementation and outcomes. Prior research indicates that prolonged, inconsolable and unpredictable episodes of crying often cluster in the late afternoon and evening hours during the first weeks postnatally (Barr et al., 2009). It is therefore relevant to study whether SSC has a differential impact on crying and sleeping as a function of time of day (e.g., by requesting mothers to perform SSC at different times of day). Last, future research is needed to reveal the underlying mechanisms of SSC, including the role "hidden regulators" (e.g., warmth, touch, smell; Hofer, 2005) and the oxytocinergic system (Moberg et al., 2020; Uvnäs-Moberg et al., 2014).

These preliminary findings on the potential benefits of daily SSC, especially on infant crying, are promising since the prevalence of parent-reported concerns related to crying and sleeping is high and can affect parental wellbeing, caregiving, and child development. However, before considering whether these findings justify recommending daily SSC to new parents, replication studies focusing on SSC protocol adherence are crucial to confirm the results of the subgroup and the exploratory dose-response findings.

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