Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

Randomized Controlled Trial to Prevent Postpartum Depression: An Infant Carrier Intervention

Emily E. Little[1], Lisa Bain[2], and Jennifer Hahn-Holbrook[3]

[1]Nurturely 56 E 15th Ave Eugene OR 97401
[2]Global Communities
[3]University of California Merced

March 10, 2023

Abstract

Objective: To evaluate the effectiveness of an ergonomic infant carrier for increasing postpartum parent-infant physical contact and reducing postpartum depression risk. **Design:** A randomized two-arm, parallel-group trial. **Setting:** Study participants' homes from February 2018 to June 2019. **Population or Sample:** 100 participants in an income-constrained urban community in the United States. **Methods**: At 30-weeks gestation, 50 participants were randomly assigned to receive an ergonomic infant carrier and instruction on use (intervention), and 50 participants were assigned to a waitlist (control). Follow-up data were collected at 6-weeks postpartum from 78 participants (intervention n = 41; waitlist control n = 37). **Main Outcome Measures:** Edinburgh Postpartum Depression Scale (EPDS) score and extent of infant carrier utilization. **Results**: Participants in the carrier condition reported using their carriers for an average of 1.95 hours per day (SD = 1.59) with participants in the intervention condition using an infant carrier significantly more often at 6-weeks (β = 2.69, SE = .347, p < .001, 95% CI = 2.08-3.41). The intervention group reported significantly fewer depressive symptoms at 6-weeks postpartum than the waitlist control group (β = -.541, p = .042). Participants who used an infant carrier more hours per day reported significantly fewer depressive symptoms (β = -1.60, SE = .069, p = .019, 95% CI = -.30 to -.025). **Conclusions**: An infant carrier intervention reduced postpartum depression at 6-weeks postpartum, with a significant dose-response association where increased infant carrier use predicted decreased postpartum depression symptomology. **Funding:** ErgoBaby donated all infant carriers used in this study but did not participate in any part of the research.

Randomized Controlled Trial to Prevent Postpartum Depression: An Infant Carrier Intervention

Emily E. Little[a], PhD, Lisa Bain[b], MPH, Jennifer Hahn-Holbrook[c], PhD

Affiliations:

[a] Nurturely, 56 E 15th Ave, Eugene, OR 97401

[b]Global Communities, 5151 Murphy Canyon Rd, San Diego, CA 92123

[c] University of California Merced, Department of Psychological Sciences, 5200 North Lake Rd.

Merced, CA 95343

Corresponding Author: Emily Little; Executive Director; Nurturely,

56 E 15th Ave, Eugene, OR 97401; Phone: 707-391-7477; emily@nurturely.org

Short title: Infant Carriers and Postpartum Depression

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

Abstract

Objective : To evaluate the effectiveness of an ergonomic infant carrier for increasing postpartum parent-infant physical contact and reducing postpartum depression risk.

Design: A randomized two-arm, parallel-group trial.

Setting: Study participants' homes from February 2018 to June 2019.

Population or Sample: 100 participants in an income-constrained urban community in the United States.

Methods : At 30-weeks gestation, 50 participants were randomly assigned to receive an ergonomic infant carrier and instruction on use (intervention), and 50 participants were assigned to a waitlist (control). Follow-up data were collected at 6-weeks postpartum from 78 participants (intervention $n = 41$; waitlist control $n = 37$).

Main Outcome Measures: Edinburgh Postpartum Depression Scale (EPDS) score and extent of infant carrier utilization.

Results : Participants in the carrier condition reported using their carriers for an average of 1.95 hours per day ($SD = 1.59$) with participants in the intervention condition using an infant carrier significantly more often at 6-weeks ($\beta = 2.69$, $SE = .347$,$p < .001$, 95% $CI = 2.08$-3.41). The intervention group reported significantly fewer depressive symptoms at 6-weeks postpartum than the waitlist control group ($\beta = -.541$, $p = .042$). Participants who used an infant carrier more hours per day reported significantly fewer depressive symptoms ($\beta = -1.60$, $SE = .069$,$p = .019$, 95% $CI = -.30$ to $-.025$).

Conclusions : An infant carrier intervention reduced postpartum depression at 6-weeks postpartum, with a significant dose-response association where increased infant carrier use predicted decreased postpartum depression symptomology.

Funding: ErgoBaby donated all infant carriers used in this study but did not participate in any part of the research.

Keywords: postpartum depression; infant carriers; perinatal

Clinical Trial Registration Number: NCT0437602; https://beta.clinicaltrials.gov/study/NCT04376021

Introduction

Postpartum depression is the most common complication of childbirth, impacting approximately 17% of postpartum mothers globally.[1] Postpartum depression is a major public health problem because it raises the risk of parental suicide,[2, 3] and can impair parenting behavior, adversely impacting the cognitive and behavioral development of children.[4, 5] Given the widespread adverse consequences of postpartum depression, significant resources have been devoted to identifying interventions that may help to prevent postpartum depression.[6, 7] One previously identified target of prevention is parent-infant skin-to-skin contact directly after birth, which has been found to reduce postpartum depression symptoms in parents of preterm or low birthweight infants.[8] However, no research has examined the effect of infant carrying on postpartum depression risk in healthy parent-infant dyads.

Parent-infant skin-to-skin contact with preterm and low birthweight neonates is a well-established intervention that can improve parental mood by reducing stress,[9] enhancing anxiety regulation,[10] and reducing postpartum depression symptomatology.[11] Physiologically, skin-to-skin contact can trigger the release of the bonding hormone oxytocin,[12-14] and decreased levels of the stress hormone cortisol,[15] both of which have been implicated in reduced postpartum depression risk.[16] Behaviorally, skin-to-skin contact between parents and infants reduces infant crying,[17] supports breastfeeding,[18]and bolsters parent-infant bonding,[9] all of which may reduce postpartum depression risk.[1] The effects of immediate skin-to-skin contact after birth can be long-lasting, influencing infant sleep-wake cycles up to 10 years after birth.[11] However, research on the effects of parent-infant physical contact is largely limited to skin-to-skin interventions occurring within

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

a specific window of time (within the first hours after birth) and among specific populations (preterm or low birthweight infants).

Only a handful of studies have tested whether parent-infant physical contact has health benefits in healthy parent-infant dyads.[19, 20] Our group previously showed that low-income mothers randomly assigned to receive an ergonomic infant carrier in pregnancy were significantly more likely to be breastfeeding at 6-months compared to mothers in the wait-list control condition.[19] A similar experimental paradigm used in adolescent mothers found that infant-carrier use improved psychological metrics like infant attachment and parental responsiveness.[20] Taken together, these results suggest that infant carrying could have psychological and physiological benefits for healthy mother-infant dyads.

Thus, we sought to examine whether an infant carrier intervention would reduce the risk of developing postpartum depression symptomology in the first six weeks postpartum. We predicted that the infant carrying intervention would facilitate reduced risk of PPD symptomatology at 6-weeks postpartum. We also predicted a dose-response relationship between infant carrier use and PPD, with mothers who used infant carriers more often, regardless of study condition, fewer PPD symptoms.

Methods

A randomized two-arm, parallel group trial (clinicaltrials.gov id: NCT04376021) was conducted between February 2018 (first participant enrolled February 7, 2018) and June 2019 in collaboration with a home visiting program for perinatal parents in a primarily Latinx, income-constrained urban community to study the effects of an infant career intervention on postpartum depression symptomatology and breastfeeding rates (breastfeeding results reported previously by Little and colleagues.[19]All materials and procedures were approved by the Institutional Review Board for Project Concern International, now Global Communities (protocol # 28).

Recruitment

Participants were recruited during a routine prenatal home visit conducted by trained, culturally-matched Community Health Workers who provide perinatal education, health screenings, and referrals to other services as needed. All participants of the home visiting program who met the following study eligibility requirements were invited to take part in the informed consent process: 1) 18 years of age or older, 2) currently pregnant, 3) fluent in either Spanish or English, 4) consistent access to a smartphone with internet access (to fill out surveys), and 5) a functioning email address (to receive gift card incentives). Participants were compensated with a $10 gift card for completing each of the 3 online surveys equating to $30 in total possible compensation for this study (with an additional 2 surveys and gift cards available for those who chose to participate in the full 6-month intervention. All participants regardless of study condition assignment were offered the same monetary incentives.

Intervention

After receiving information about the study and providing informed consent, participants were randomly assigned with a random number generator to one of two study groups: intervention or waitlist control. The first author generated the random allocation sequence, the Community Health Workers enrolled participants, and research assistant assigned participants to interventions based on enrollment timeline. Participants assigned to the intervention group were provided with an ErgoBaby Omni 360 (ergonomic infant carrier) during a prenatal home visit to facilitate increased mother-infant physical contact from birth onward. The first author, who is an infant carrying educator, trained the home visiting team in carrier use to be able to support the study participants and study participants were also provided with ongoing virtual access to an instructional video to ensure proper, safe, and comfortable use of the carrier. In the waitlist control group, mothers received the same infant carrier and educational training at 6-months postpartum. As part of the consent process before choosing to take part in the study, all participants were informed of the differences

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

between the two groups and were told that if they chose to participate: "You will be given a baby carrier to use with your new baby. You may receive the carrier while you are still pregnant, or you may receive it six months after the birth of your baby."

Measures

Electronic surveys were sent via text message to participants' mobile phone during pregnancy (between 30- and 38-weeks gestation) and postpartum (at 6-weeks postpartum) to assess carrier use and depressive symptomology. We chose to measure postpartum depression at 6-weeks postpartum because previous research suggests that depressive symptomology peaks between 4- and 8-weeks postpartum.[16] Depressive symptomatology was measured using the 10-item Edinburgh Postpartum Depression Scale (EPDS).[21] Participants indicated how often they experienced 10 common symptoms of depression in the past week on a 4-point scale. The continuous EPDS score for each individual (values ranged from 0 to 30, hereafter referred to as *depressive symptomology*) was used in our analysis, with higher scores indicating increased depressive symptomology. Participants also reported their relationship status (married, living in union, single, divorced), intentions to breastfeed, education, age, English language proficiency, race/ethnicity, country of their birth, number of children, and whether their baby was born preterm.

Data Analytic Strategy

Following best practice CONSORT guidelines for randomized controlled trials, we used an "intention-to-treat" analytic strategy in which all participants were included in the analyses, regardless of whether they used the carrier in the intervention group. Baseline characteristics were compared between groups to ensure that failure of random assignment did not contribute to any observed differences in depressive symptomology. To assess baseline participant differences, binominal logistic regression was used to test for demographic differences across study conditions (0 = control condition; 1 = intervention condition). Any baseline demographic factor that differed between study conditions at $p < .10$ was included as a covariate in further analyses.

The primary analyses to assess the effect of study condition on postpartum depressive symptomatology were carried out with stepwise linear regression using a bootstrapping procedure with 5000 replications recommended for analyses with smaller sample sizes.[22]Condition alone was entered in Model 1 and any confounds that differed across conditions at baseline were included in Model 2, allowing for the comparison of the effect size as a function of study condition in unadjusted and adjusted models. Linear regression was used to test for a dose-response association between hours-per-day of reported infant carrier use and depressive symptomatology across both study conditions (given that participants in the control group could also have been using infant carriers) and within the intervention group. Results were determined to be statistically significant if p values were less than .05. Effect sizes are given in terms of odds ratios for analyses using binomial logistic regression (Table 1) and unstandardized Betas, standard errors, and 95% *CI* for analyses using linear regression (Table 2). All analyses were performed using SPSS version 27.

Results

Participant Characteristics

A total of 238 participants were assessed for eligibility, with 138 excluded and 100 randomized during pregnancy into the intervention ($n = 50$) or waitlist control ($n = 50$) conditions (see the Consort Diagram in Figure 1).

Demographic characteristics are presented in Table 1, with all participants identifying as female (hereafter referred to as mothers). Mothers in the intervention and control groups had similar intentions to breastfeed and had similar demographic and health characteristics except for maternal age, English language proficiency, married/living in union status and preterm birth (see Table 1). Specifically, by chance, mothers randomly

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

assigned to the control group were significantly older, had higher English proficiency (and so were more likely to take the survey in English), and were less likely to give birth preterm than mothers assigned in the intervention group. In addition, there was a marginally significant difference ($p = .051$) in partnership status across conditions, with mothers in the control condition more likely to be married/living in union than mothers in the intervention condition. A total of 4 infants in the intervention condition and 0 infants in the control condition were born preterm (no infant was more than 4 weeks premature). Thus, maternal age, language proficiency, preterm birth, and marital/living in union were included as covariates.

Of the 100 participants randomly assigned, 41 completed the 6-week survey in the intervention group and 37 completed the 6-week survey in the control group. There was no evidence of heterogeneous attrition: participants who dropped out of the intervention and control conditions were similar in terms of demographic factors. There was some evidence of homogeneous attrition in that mothers who dropped out of the study (in both conditions) tended to be younger ($M = 23.5$) than the mothers who did not ($M = 26.9$; $t = -2.69$, $p < .001$). No study-related adverse events were reported in either group.

Primary Results

Linear regression models showed that mothers in the carrier intervention had significantly lower levels of depressive symptomology at 6-weeks ($M = 2.04$; $SD = 3.48$; $n = 37$) than mothers in the waitlist control group ($M = 3.7$; $SD = 4.79$; $n = 41$, see Model 1 in Table 2). This difference in depressive symptomology between conditions remained statistically significant when covariates were included in the model (See Model 2 in Table 2).

Testing dose-response associations

There was good uptake of our carrier intervention: 79.5% of participants in the intervention condition reported using an infant carrier in the first 6-weeks postpartum, whereas only 1 participant in the control condition reported using an infant carrier within the first 6-weeks postpartum. Participants in the carrier condition reported using their carriers for an average of 1.95 hours per day ($SD = 1.59$). Participants in the intervention condition used an infant carrier significantly more often at 6-weeks than women in the control condition ($B = 2.69$, $SE = .347$, $p < .001$, 95%$CI = 2.08$-3.41), even after adjusting for potential confounds. Moreover, across the sample, participants who used the carrier more hours per day reported significantly fewer depressive symptoms (B= -1.60, $SE = .069$, $p = .019$, 95% CI = -.30 to -.025). When examining the effect just within the intervention group, there was not a significant dose-response relationship between hours of carrier use and depressive symptoms (B = -.10, $SE = .11$,$p = .354$, 95% CI = -.30 to .13).

Discussion

Main Findings

In experimentally testing the efficacy of an infant carrier intervention to reduce postpartum depression symptomatology, we found that participants randomly assigned to receive an infant carrier reported significantly fewer depressive symptoms at 6-weeks postpartum than participants in the waitlist control group. Further, there was good uptake of the carrier intervention (79.5% of participants in intervention groups used their carriers in the first 6-weeks postpartum). Across the sample, mothers who spent more time using an infant carrier reported reduced depressive symptoms at 6-weeks postpartum than women who used their carriers less often. Although many factors play a role in the etiology of postpartum depression, our use of a randomized controlled trial design limits the influence of confounding factors. Together, these results suggest that providing infant carriers in pregnancy may be an effective intervention to help protect mothers in low-income urban areas against developing postpartum depressive symptomology. Additional studies are warranted to examine whether this intervention could work in clinical settings (e.g., hospitals) and with additional high-priority populations (e.g., Black mothers).

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

Strengths and Limitations

Infant carriers may be a promising avenue to decrease postpartum depression symptomology in a safe and culturally-relevant manner. Infant carriers are safe: cloth slings and carriers are 6x safer than plastic car-seat style carriers during ambulatory-style transport.[23] Though parents and healthcare professionals in the US often view carriers simply as a transport method rather than a public health intervention or parenting tool,[20] infant carrying is an integral part of human childrearing strategies in populations around the world.[24, 25] These data add to the literature showing infant carriers to be a preventative postpartum health intervention that may have particular cultural relevance for global majority parents, adding psychological benefits to the growing body of research showing that infant carrying is associated with positive physical outcomes for both infant and adult.[26-29]

Although this study had notable strengths including the use of a randomized controlled trial design, these results should be considered in the context of several limitations. First, our sample size was relatively small and was determined by study budget rather than by power analysis. There was also significant participant drop-out by 6-weeks postpartum, especially amongst younger mothers. Although participant attrition is common in interventions in vulnerable populations and drop-out rates did not differ across study conditions (thus not undermining our experimental validity), our results may not be generalizable to samples of younger mothers. In addition, our small sample size made it more difficult to detect dose-dependent effects of infant carrier use on depressive symptoms when analyses were restricted to the intervention condition alone. Second, because our sample comprised primarily Latina mothers from a geographically-specific income-constrained community, it remains to be seen if this carrier intervention would be effective in other racial/ethnic populations or in communities with a different income status. Finally, because this research was conducted within a Community Health Worker-led home visiting program, it will also be important to test whether this intervention would work in clinical obstetric or pediatric settings.

Interpretation

There are several plausible *behavioral* and *biological*pathways through which infant carrying could reduce postpartum depression symptomology. Behaviorally, infant carrying increases breastfeeding,[19, 30] promotes parent-infant attachment,[9] and reduces infant crying,[31] all of which have been linked to reduced postpartum depression risk.[32-35] Neuroscience studies show that infant carrying enhances neural reactivity to infant crying in fathers,[36] which relates to our findings because depressed parents are less likely to have heightened neural responses to infant distress signals.[37, 38] Physiologically, the physical contact from infant carrying also increases oxytocin[12-14] and decreases cortisol,[15] both of which have been implicated in the etiology of postpartum depression.[16]

Conclusion

Postpartum depression is a serious public health issue, costing an estimated $14.2 billion per year in the US[33] with health implications for both the birthing parent and the child. Our research demonstrates that providing parents with an ergonomic infant carrier may be an easy and effective intervention to decrease postpartum depression symptomatology. To better understand the nature of this intervention, we encourage future research that examines the effect of infant carrying on key behavioral (e.g., breastfeeding, bonding, infant crying) and biological (e.g., oxytocin, stress physiology) factors implicated in the etiology of postpartum mood disorders.

Table 1 *Baseline Participant Characteristics*

Age, mean (*SD*)	
Breastfeeding intentions	
English Language Proficiency	
Latina	
High School Graduate	

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

US Born
Married or Living in Union
Currently Employed
Preterm
Primiparous
Note: Binomial logistic regression was used in all analyses to predict differences in demographics across study condition (0 =

Table 2

Step-Wise Linear Regression Model Testing for Differences in Postpartum Depressive Symptomology Between Study Condition

Model 1
Study Condition
Model 2
Study Condition
Maternal Age
English Language Proficiency
Preterm Delivery
Married or Living in Union
Note: Step-Wise linear regression model was used with bootstrapping across 5000 samples to improve estimate accuracy give

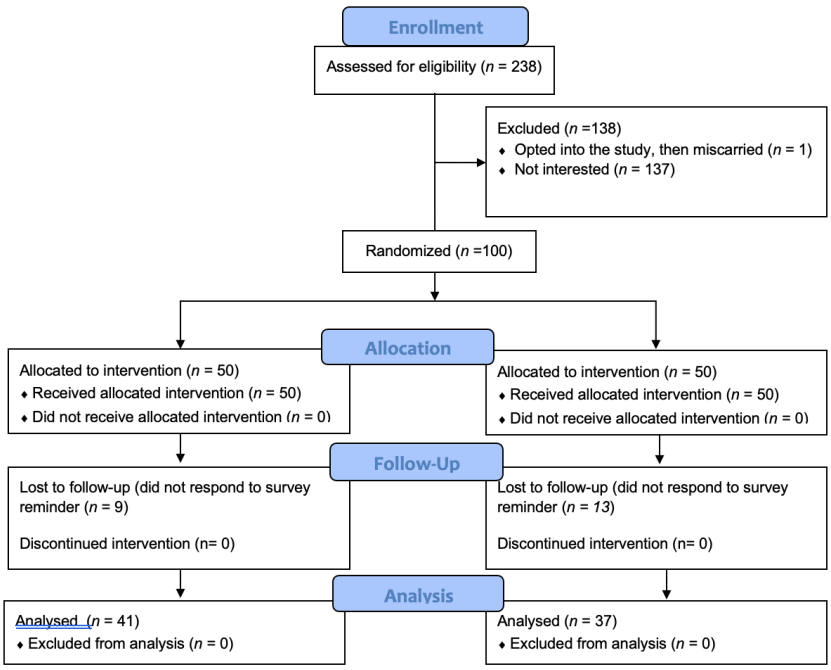


Figure 1: CONSORT Diagram

Acknowledgments: The study protocol was developed in partnership with California Border Healthy Start (CBHS), a program of Project Concern International (now Global Communities). The program began oper-

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

ation in 2007 and is funded through the National Healthy Start initiative, which aims to address disparities in birth outcomes. The authors appreciate the support of CBHS staff (especially Alejandra Leon) in helping with the protocol design; recruitment and retention of study participants; and the provision of infant carriers. Also, the help of Nurturely research assistants (especially Sarah Jarrell) who coordinated survey dispatch.

Disclosure of Interests: ErgoBaby donated all infant carriers used in this study but did not participate in any part of the research. The authors have no other financial, personal, political, intellectual, or religious relationships relevant to this article to disclose.

Contribution to Authorship: Dr Little led the study design, data collection, and manuscript preparation. Lisa Bain helped with intervention implementation plan, participant recruitment, and data collection efforts. Dr Hahn-Holbrook helped to design the study, conducted all analyses, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Details of Ethics Approval: All procedures received ethics approval from the relevant ethics committee responsible for human experimentation: Institutional Review Board for Project Concern International, now Global Communities (approved protocol # 28).

Funding: ErgoBaby donated all infant carriers used in this study but did not participate in any part of the research.

References

1. Hahn-Holbrook J, Cornwell-Hinrichs T, Anaya I. Economic and health predictors of national postpartum depression prevalence: A systematic review, meta-analysis, and meta-regression of 291 studies from 56 countries. Front Psychiatry. 2017;8:248.

2. Miranda JJ, Patel V. Achieving the Millennium Development Goals: Does mental health play a role? PLoS Med. 2005;2(10):e291.

3. Oates M. Perinatal psychiatric disorders: a leading cause of maternal morbidity and mortality. Br Med Bull. 2003;67:219-29.

4. Field T. Postpartum depression effects on early interactions, parenting, and safety practices: a review. Infant Behav Dev. 2010;33(1):1-6.

5. Paulson JF, Dauber S, Leiferman JA. Individual and combined effects of postpartum depression in mothers and fathers on parenting behavior. Pediatrics. 2006;118(2):659-68.

6. Dennis CL, Dowswell T. Psychosocial and psychological interventions for preventing postpartum depression. Cochrane Database Syst Rev. 2013(2):Cd001134.

7. Werner E, Miller M, Osborne LM, Kuzava S, Monk C. Preventing postpartum depression: review and recommendations. Arch Womens Ment Health. 2015;18(1):41-60.

8. Scime NV, Gavarkovs AG, Chaput KH. The effect of skin-to-skin care on postpartum depression among mothers of preterm or low birthweight infants: A systematic review and meta-analysis. J Affect Disord. 2019;253:376-84.

9. Tessier R, Cristo M, Velez S, Giron M, de Calume ZF, Ruiz-Palaez JG, et al. Kangaroo mother care and the bonding hypothesis. Pediatrics. 1998;102(2):e17.

10. Cong S, Wang R, Fan X, Song X, Sha L, Zhu Z, et al. Skin-to-skin contact to improve premature mothers' anxiety and stress state: A meta-analysis. Matern Child Nutr. 2021;17(4):e13245.

11. Feldman R, Gordon I, Schneiderman I, Weisman O, Zagoory-Sharon O. Natural variations in maternal and paternal care are associated with systematic changes in oxytocin following parent-infant contact. Psychoneuroendocrinology. 2010;35(8):1133-41.

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

12. Carter CS, Pournajafi-Nazarloo H, Kramer KM, Ziegler TE, White-Traut R, Bello D, et al. Oxytocin: behavioral associations and potential as a salivary biomarker. Ann N Y Acad Sci. 2007;1098:312-22.

13. Cong X, Ludington-Hoe SM, Hussain N, Cusson RM, Walsh S, Vazquez V, et al. Parental oxytocin responses during skin-to-skin contact in pre-term infants. Early Hum Dev. 2015;91(7):401-6.

14. Mörelius E, Örtenstrand A, Theodorsson E, Frostell A. A randomised trial of continuous skin-to-skin contact after preterm birth and the effects on salivary cortisol, parental stress, depression, and breastfeeding. Early Hum Dev. 2015;91(1):63-70.

15. Takahashi Y, Tamakoshi K, Matsushima M, Kawabe T. Comparison of salivary cortisol, heart rate, and oxygen saturation between early skin-to-skin contact with different initiation and duration times in healthy, full-term infants. Early Hum Dev. 2011;87(3):151-7.

16. Yim IS, Tanner Stapleton LR, Guardino CM, Hahn-Holbrook J, Dunkel Schetter C. Biological and psychosocial predictors of postpartum depression: systematic review and call for integration. Annu Rev Clin Psychol. 2015;11:99-137.

17. Erlandsson K, Dsilna A, Fagerberg I, Christensson K. Skin-to-skin care with the father after cesarean birth and its effect on newborn crying and prefeeding behavior. Birth. 2007;34(2):105-14.

18. Moore ER, Anderson GC. Randomized controlled trial of very early mother-infant skin-to-skin contact and breastfeeding status. J Midwifery Womens Health. 2007;52(2):116-25.

19. Little EE, Cioffi CC, Bain L, Legare CH, Hahn-Holbrook J. An infant carrier intervention and breastfeeding duration: A randomized controlled trial. Pediatrics. 2021;148(1).

20. Williams LR, Turner PR. Experiences with "Babywearing": Trendy parenting gear or a developmentally attuned parenting tool? Children and Youth Services Review. 2020;112:104918.

21. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry. 1987;150:782-6.

22. Preacher KJ, Hayes AF. Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models. Behav Res Methods. 2008;40(3):879-91.

23. Batra EK, Midgett JD, Moon RY. Hazards associated with sitting and carrying devices for children two years and younger. J Pediatr. 2015;167(1):183-7.

24. Little EE, Polanco MA, Baldizon SR, Wagner P, Shakya H. Breastfeeding knowledge and health behavior among Mayan women in rural Guatemala. Soc Sci Med. 2019;242:112565.

25. Mu'minah A, Nugraha A. Values of Traditional Baby Carrier in Indonesia. AESCIART: International Conference on Aesthetics and the Sciences of Art2020.

26. Havens KL, Severin AC, Bumpass DB, Mannen EM. Infant carrying method impacts caregiver posture and loading during gait and item retrieval. Gait Posture. 2020;80:117-23.

27. Mannen EM, Havens KL, Kahney A, Nelson-Wong E. Baby-carrying method impacts caregiver postural sway and pain during prolonged standing. Journal of Women's & Pelvic Health Physical Therapy. 2020;44(2):47-53.

28. Siddicky SF, Bumpass DB, Krishnan A, Tackett SA, McCarthy RE, Mannen EM. Positioning and baby devices impact infant spinal muscle activity. J Biomech. 2020;104:109741.

29. Vaidya S, Aroojis A, Mehta R. Developmental dysplasia of hip and post-natal positioning: Role of swaddling and baby-wearing. Indian J Orthop. 2021;55(6):1410-6.

30. Pisacane A, Continisio P, Filosa C, Tagliamonte V, Continisio GI. Use of baby carriers to increase breastfeeding duration among term infants: the effects of an educational intervention in Italy. Acta Paediatr.

2012;101(10):e434-8.

31. Hunziker UA, Barr RG. Increased carrying reduces infant crying: a randomized controlled trial. Pediatrics. 1986;77(5):641-8.

32. Alimi R, Azmoude E, Moradi M, Zamani M. The association of breastfeeding with a reduced risk of postpartum depression: A systematic review and meta-analysis. Breastfeed Med. 2022;17(4):290-6.

33. Hahn-Holbrook J, Haselton MG, Dunkel Schetter C, Glynn LM. Does breastfeeding offer protection against maternal depressive symptomatology?: A prospective study from pregnancy to 2 years after birth. Arch Womens Ment Health. 2013;16(5):411-22.

34. McNamara J, Townsend ML, Herbert JS. A systemic review of maternal wellbeing and its relationship with maternal fetal attachment and early postpartum bonding. PLoS One. 2019;14(7):e0220032.

35. Vik T, Grote V, Escribano J, Socha J, Verduci E, Fritsch M, et al. Infantile colic, prolonged crying and maternal postnatal depression. Acta Paediatr. 2009;98(8):1344-8.

36. Riem MME, Lotz AM, Horstman LI, Cima M, Verhees M, Alyousefi-van Dijk K, et al. A soft baby carrier intervention enhances amygdala responses to infant crying in fathers: A randomized controlled trial. Psychoneuroendocrinology. 2021;132:105380.

37. Laurent HK, Ablow JC. A face a mother could love: depression-related maternal neural responses to infant emotion faces. Soc Neurosci. 2013;8(3):228-39.

38. Rutherford HJ, Graber KM, Mayes LC. Depression symptomatology and the neural correlates of infant face and cry perception during pregnancy. Soc Neurosci. 2016;11(4):467-74.

Posted on 10 Mar 2023 — The copyright holder is the author/funder. All rights reserved. No reuse without permission. — https://doi.org/10.22541/au.167845088.87835810/v1 — This a preprint and has not been peer reviewed. Data may be preliminary.

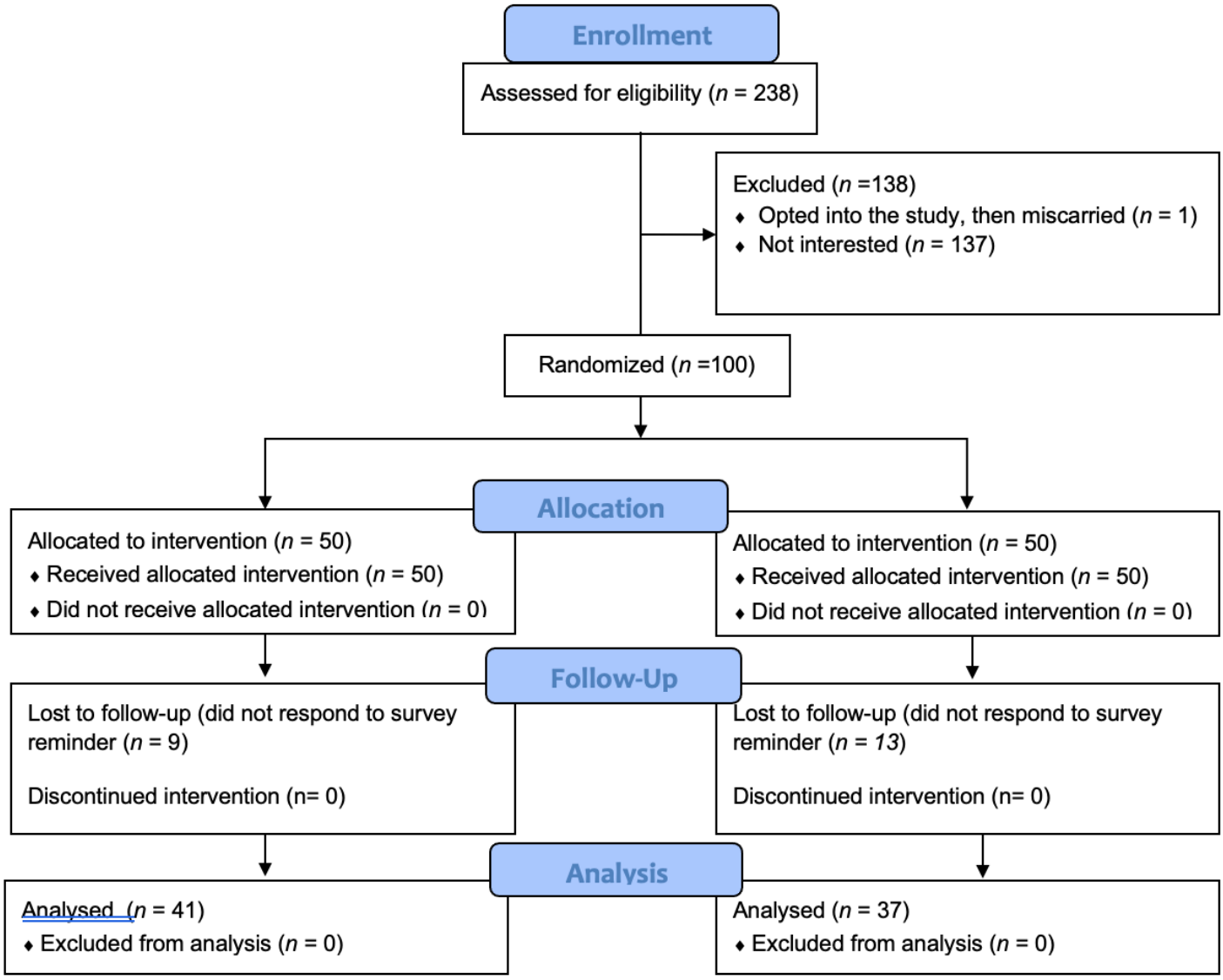
Print Form

Table. CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial[a]

Section and Topic	Item No.	Checklist Item	Reported on Page No.
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomization Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomization; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7-8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	8-9
	13b	For each group, losses and exclusions after randomization, together with reasons	8-9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10-11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10-11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	10-11
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	10-11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10
Comment			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12-13
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	12-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-13
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NA

[a]We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, noninferiority and equivalence trials, nonpharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see http://www.consort-statement.org.

©2010 American Medical Association. All rights reserved.


Enrollment
Assessed for eligibility (n = 238)
Excluded (n =138)
♦ Opted into the study, then miscarried (n = 1)
♦ Not interested (n = 137)
Randomized (n =100)
Allocation
Allocated to intervention (n = 50)
♦ Received allocated intervention (n = 50)
♦ Did not receive allocated intervention (n = 0)
Allocated to intervention (n = 50)
♦ Received allocated intervention (n = 50)
♦ Did not receive allocated intervention (n = 0)
Follow-Up
Lost to follow-up (did not respond to survey reminder (n = 9)
Discontinued intervention (n= 0)
Lost to follow-up (did not respond to survey reminder (n = 13)
Discontinued intervention (n= 0)
Analysis
Analysed (n = 41)
♦ Excluded from analysis (n = 0)
Analysed (n = 37)
♦ Excluded from analysis (n = 0)