

An Infant Carrier Intervention and Breastfeeding Duration: A Randomized Controlled Trial

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abstract

OBJECTIVES: Parent-infant skin-to-skin contact immediately after birth increases initiation and duration of bodyfeeding. We hypothesized that providing ergonomic carriers to parents during pregnancy would increase the likelihood of breastfeeding and expressed human milk feeding through the first 6 months of life.

METHODS: A randomized two-arm, parallel-group trial was conducted between February 2018 and June 2019 in collaboration with a home-visiting program in a low-income community. At 30 weeks' gestation, 50 parents were randomly assigned to receive an ergonomic infant carrier and instruction on proper use to facilitate increased physical contact with infants (intervention group), and 50 parents were assigned to a waitlist control group. Feeding outcomes were assessed with online surveys at 6 weeks, 3 months, and 6 months postpartum.

RESULTS: Parents in the intervention group were more likely to be breastfeeding or feeding expressed human milk at 6 months (68%) than control group parents (40%; $P = .02$). No significant differences were detected in feeding outcomes at 6 weeks (intervention: 78% versus control: 81%, $P = .76$) or 3 months (intervention: 66% versus control: 57%, $P = .34$). Exclusive human milk feeding did not differ between groups (intervention versus control at 6 weeks: 66% vs 49%, $P = .20$; 3 months: 45% vs 40%, $P = .59$; 6 months: 49% vs 26%, $P = .06$).

CONCLUSIONS: Infant carriers increased rates of breastfeeding and expressed human milk feeding at 6 months postpartum. Large-scale studies are warranted to further examine the efficacy and cost-effectiveness of providing carriers as an intervention to increase access to human milk.

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Dr Little led the study design, data collection, and manuscript preparation; Dr Cioffi conducted the analyses and reviewed and revised the manuscript; Ms Bain helped with intervention implementation plan, participant recruitment, and data collection efforts; Dr Legare helped to design the study and reviewed and revised the manuscript; Dr Hahn-Holbrook helped to design the study, devise a data-analysis strategy, and review and revise the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Deidentified individual participant data will not be made available because we did not obtain permission to share individual data.

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WHAT'S KNOWN ON THIS SUBJECT: Breastfeeding rates in the United States consistently fall below medical recommendations. Research with critically ill infants has revealed that increasing skin-to-skin contact increases breastfeeding, yet carrying interventions with healthy infants in the United States have not been systematically examined.

WHAT THIS STUDY ADDS: Our results suggest that providing expectant parents from low-resourced communities with an ergonomic infant carrier may be an economical and efficient intervention to increase breastfeeding duration.

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The American Academy of Pediatrics recommends that infants be exclusively fed human milk for the first 6 months of life, with continued breastfeeding until at least 12 months.¹ In the United States, however, rates of direct breastfeeding and expressed human milk feeding are consistently below medical recommendations.²

Universal exclusive breastfeeding could prevent an estimated 823 000 child deaths worldwide³ and save \$3 billion in medical costs and \$14.2 billion in costs related to premature infant deaths.⁴ Although it is well established that skin-to-skin contact immediately after birth has benefits for infant health^{5,6} and increases breastfeeding readiness and success,⁷ the effect of infant-caregiver physical contact through carrying (without direct skin-to-skin contact) on breastfeeding outcomes has not been directly tested with US infants. The aim of this study was to test the effect of an infant carrier intervention on the likelihood of breastfeeding (feeding human milk directly at the parent's breast or chest, or feeding expressed human milk) through 6 months among parents in the United States.

Randomized controlled trials reveal that skin-to-skin contact between infant and birth parent immediately after birth increases the likelihood of breastfeeding initiation in the hospital⁸ and breastfeeding at 1 month⁹ and 4 months¹⁰ postpartum. Less is known about the effect of physical contact on breastfeeding outcomes without direct skin-to-skin contact, although there are several mechanisms by which physical contact may increase breastfeeding. For example, observational data reveal that birth parents who spend more time in physical contact with infants are more likely to detect early hunger cues and breastfeed more frequently than birth parents who spend less time in physical

contact.¹¹ Thus, interventions that increase day-to-day parent-infant physical contact through carrying may improve breastfeeding outcomes. Italian mothers randomly assigned to receive an infant carrier were more likely to be breastfeeding at 5 months postpartum (48%) compared with mothers who did not receive an infant carrier (24%).¹² Additional research is needed to evaluate the feasibility and efficacy of infant carrier interventions to improve feeding outcomes with diverse populations in the United States.

To fill this gap, we recruited 100 pregnant parents from a home-visiting program for families from low-income zip codes in the United States. Pregnant parents were randomly assigned to receive a soft-structured ergonomic infant carrier to facilitate increased physical contact with infants (intervention group) or to a waitlist control group. We predicted that the infant-carrying intervention would facilitate increased likelihood of breastfeeding at 6 months. We also predicted a dose-response relationship between infant carrier use and human milk feeding duration, exclusivity, and frequency of direct breastfeeding.

METHODS

A randomized two-arm, parallel-group trial (clinicaltrials.gov identifier NCT04376021) was conducted between February 2018 and June 2019 in collaboration with a home-visiting program for pregnant parents in a primarily Latinx, income-constrained community in California. All materials and procedures were approved by the Institutional Review Board for Project Concern International (protocol 28).

Recruitment

One hundred participants were recruited during a routine prenatal home visit conducted by trained community health workers who provide perinatal education, health screenings, and referrals. The sample size of 100 was selected on the basis of budget. Post hoc power estimates revealed that this study's sample size (after accounting for attrition at 6 months) had a 67% power to detect a 28% difference in any breastfeeding and 52% power to detect a 23% difference in breastfeeding exclusivity. All participants of the home-visiting program who met the following 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) access to a smartphone with Internet access (to fill out surveys), and (5) a functioning e-mail address (to receive gift card incentives). Participants were compensated with a \$10 gift card for completing each of the 5 online assessments, equating to \$50 in total possible compensation, offered equally to all participants.

Intervention

After providing informed consent, participants were randomly assigned with a random number generator to one of two study groups: intervention or waitlist control. Intervention participants were provided an ergonomic infant carrier (Omni 360; Ergobaby, Los Angeles, CA; see Fig 1) during a prenatal home visit to facilitate increased physical contact from birth onward. The home-visiting team was trained to help participants with their carrier, and all participants had unlimited access to an instructional video. In the waitlist control group, parents received the same infant carrier and educational training at 6 months



FIGURE 1
Ergobaby Omni 360 carrier.

postpartum after completion of the study. As part of the consent process, all participants 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 6 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 at 2 weeks, 6 weeks, 3 months, and 6 months after birth to assess carrier use and breastfeeding outcomes. These time points were chosen on the basis of the 6-month exclusive breastfeeding clinical guidelines and

to allow us to compare our results with those of previous breastfeeding interventions.^{13,14} Any breastfeeding and exclusive breastfeeding were assessed with the following question: “What are you currently using to feed your baby?” Participants were instructed to select all that applied from the following options: “Breastmilk (directly from breast), expressed or pumped breastmilk from bottle, donor breast milk, baby formula, cow’s milk, juice, water, other liquids (soy milk, honey, atole), solids.” Participants were characterized as breastfeeding at each time point if they indicated feeding their infant any breastmilk (directly from breast or chest) or any expressed or pumped human milk from bottle. Participants were

characterized as exclusively breastfeeding at each time point if they indicated feeding their infant only breastmilk (directly from breast) and/or expressed or pumped breastmilk from bottle and did not indicate using any other foods to feed their infant. At each time point, participants were also asked, “In the last 24 hours, how many times have you breastfed your baby directly from the breast (excluding feeding expressed breastmilk from a bottle)?” Number of direct breastfeeds was converted into a continuous variable with a range of possible values from 0 to 14 (hereafter referred to as direct breastfeeding). Frequency of carrier use was assessed with the question, “How many hours per day do you usually use your carrier? (text box to input number of hours).”

Intentions to breastfeed were assessed at the prenatal time point by using the Infant Feeding Intentions Scale.¹⁵ Participants were asked to rate their intentions to breastfeed on a scale of 0 (very much disagree) to 4 (very much agree). The first item asked about intentions to formula feed and was reverse scored. Items were summed and possible scores ranged between 0 and 16, with higher scores indicating greater intentions to breastfeed.

Analytic Strategy

Following best practice Consolidated Standards of Reporting Trials guidelines for randomized controlled trials, we used an intention-to-treat analytic strategy in which all participants are included in the analyses, regardless of whether they used the carrier in the intervention group. Baseline characteristics were compared between groups to ensure that a failure of random assignment did not contribute to breastfeeding outcomes. To assess baseline

participant differences, continuous and categorical variables were reported as mean \pm SD or percentages with 95% confidence intervals and analyzed by a Pearson χ^2 test for categorical variables and an independent samples *t* test for continuous variables. Fisher's exact test was used when a cell count was <5 . Any demographic factor that differed between study conditions at baseline was included as a covariate in further analyses.

The primary analyses to assess the effect of study condition on breastfeeding status and exclusive breastfeeding rates at each time point were conducted with binomial logistic regression. Linear regression was used to test for a dose-dependent association between frequency of infant carrier use and direct breastfeeding frequency per day. Within the intervention group, we used binomial logistic regression and linear regression as appropriate to assess whether there was an association between hours per day of carrier use in the intervention group and breastfeeding status, exclusive breastfeeding, and direct feeds per day. All analyses were performed by using R 3.5.3 (R Foundation, Vienna, Austria).¹⁶ Results were determined to be statistically significant if *P* values were $<.05$.

RESULTS

Participant Characteristics

A total of 238 participants were assessed for eligibility, with 138 excluded and 100 randomly selected during pregnancy into the intervention ($n = 50$) or waitlist control ($n = 50$) conditions (see Consolidated Standards of Reporting Trials diagram in Fig 2). Demographic characteristics are presented in Table 1. Participants in the intervention and control groups had similar intentions to breastfeed

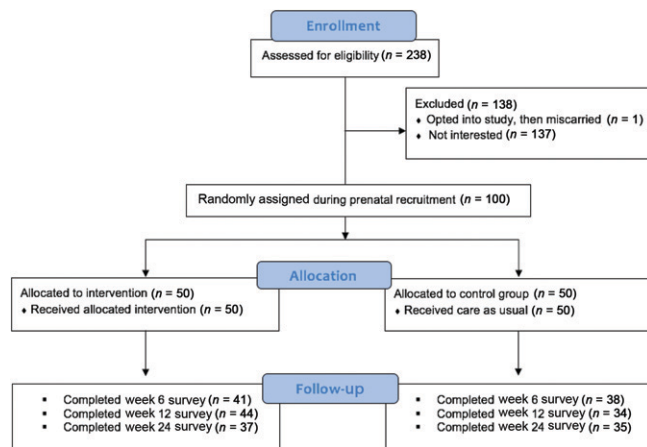


FIGURE 2 Consolidated Standards of Reporting Trials diagram.

and similar demographic and health characteristics except for maternal age (see Table 1); thus, age was included as a covariate in the primary analyses. A total of 2 infants in the intervention group and 4 infants in the control group were born preterm (no infant was more than 4 weeks premature).

Of the 50 participants randomly assigned to the intervention group, 41 completed the 6-week survey, 44 completed the 3-month survey, and 37 completed the 6-month survey. Of the 50 participants assigned to the control group, 38 participated in the survey at 3 months postpartum, and 35 participated in the survey at 6 months postpartum. There was no evidence of

heterogeneous attrition: participants who dropped out of the intervention and control conditions were similar in terms of demographic and health factors. There was some evidence of homogeneous attrition in that participants who dropped out of the study by 6 months tended to be younger (mean = 23.5) than the participants who completed the 6-month survey (mean = 26.9; $t = -2.69$, $P < .001$). No study-related adverse events were reported in either group.

Primary Analysis of Breastfeeding Outcomes

Breastfeeding status, exclusive breastfeeding, and direct breastfeeding were compared between study groups at 6 weeks, 3 months, and 6 months postpartum, controlling for participant

TABLE 1 Baseline Participant Characteristics Compared By Using a *t* Test for Age and χ^2 Analyses for Dichotomized Count Variables

	Intervention	Control	<i>P</i>
Age, y, mean (SD)	24.3 (6.0)	27.5 (6.1)	.010
Breastfeeding intentions, mean (SD)	10.7 (5.1)	9.9 (5.6)	.415
Latina, %	95	94	.999
Education greater than high school, %	69	63	.722
Born in the United States, %	50	45	.764
Married, %	50	72	.096
Currently employed, %	19	14	.713
Breastfed before, %	60	67	.673
Primiparous, %	35	23	.238
Mother breastfed, %	73	76	.953
Mother born outside the United States, %	80	93	.154

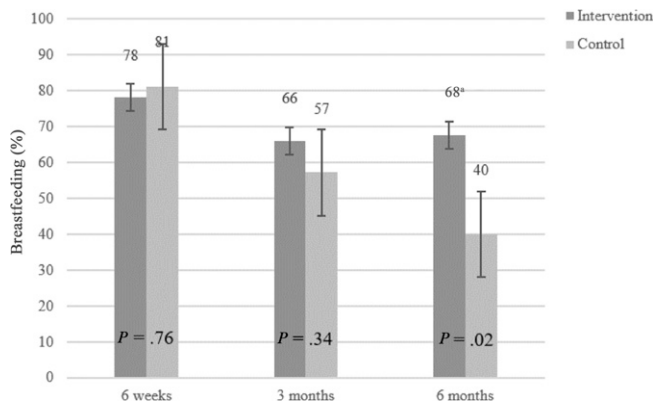


FIGURE 3 Breastfeeding status at 6 weeks, 3 months, and 6 months postpartum. ^aStatistically significant difference.

age (see Figs 3 and 4). There were no differences in breastfeeding status between study groups at 6 weeks (intervention = 78% versus control = 81%, $B = -.10$, $P = .75$) or 3 months postpartum (intervention = 66% versus control = 57%, $B = .24$, $P = .33$). At 6 months postpartum, a significantly higher percentage of participants in the intervention group (68%) were breastfeeding compared with participants in the control group (40%, $B = .60$, $P = .02$; see Fig 3). These percentages indicate that, on average, 3.6 patients would have to receive the infant carrier for 1 additional participant to breastfeed until 6 months of age, resulting in a number needed to treat of 4. There were no differences in rates of

exclusive breastfeeding at 6 weeks (intervention = 66%, control = 49%; $B = .33$, $P = .19$) or 3 months (intervention = 45%, control = 40%; $B = .14$, $P = .58$) between the intervention and the control groups. At 6 months, there was a nonsignificant trend in which more participants in the intervention group were exclusively breastfeeding (49%) than in the control group (26%, $B = .52$, $P = .06$; see Fig 4). There were no differences between study conditions in the frequency of direct breastfeeding at 6 weeks (intervention: mean [SD] = 6.20 [4.7]; control: mean [SD] = 6.50 [4.5]; $B = -.07$, $P = .61$) or 3 months (intervention: mean [SD] = 5.41 [4.9]; control: mean [SD] = 4.89 [4.5]; $B =$

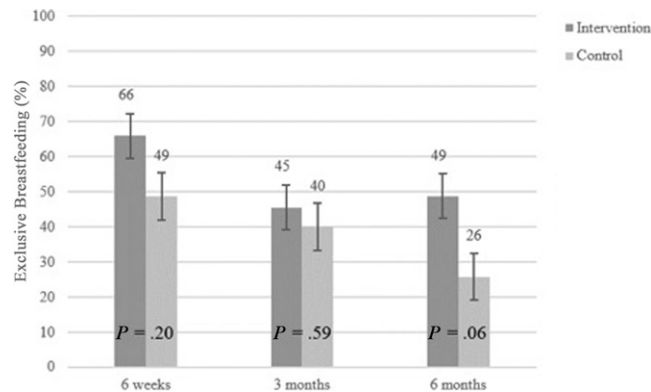


FIGURE 4 Exclusive breastfeeding at 6 weeks, 3 months, and 6 months postpartum. No statistically significant differences were detected after adjusting for age.

.03, $P = .84$). There was a nonsignificant trend at 6 months in which parents in the intervention group tended to feed their infants directly from the breast more frequently (mean [SD] = 5.68 times per day [5.0]) than parents in the control group (mean [SD] = 3.83 [4.8]; $B = .23$, $P = .09$). Breastfeeding rates did not differ by participant age. Excluding maternal age as a covariate from the analysis did not change our pattern of results.

Associations Between Infant Carrier Use and Breastfeeding Outcomes

At 6 months postpartum, participants in the intervention group used the infant carrier an average of 1.7 hours per day (SD = 1.2). See Table 2 for frequencies. There were no statistically significant associations between hours of carrier use per day and breastfeeding status at 6 months ($B = -.56$, $P = .45$), exclusive breastfeeding at 6 months ($B = -.49$, $P = .47$), or number of direct breastfeeds per day at 6 months ($B = -.18$, $P = .27$).

Sensitivity Analysis

A sensitivity analysis was conducted to examine whether significant differences between groups were visible if all of those who did not complete follow-up were assumed not to be breastfeeding. Sensitivity analyses yielded similar results. Specifically, participation in the intervention condition was associated with increased likelihood of breastfeeding at 6 months ($B = 1.23$, $P = .009$).

DISCUSSION

Carrying infants in close contact throughout the day is a ubiquitous component of childrearing in human cultures around the world (eg, reported by >90% of mothers in Guatemala),¹⁷ yet has been largely replaced by the use of strollers and car seat-style carriers in modern

TABLE 2 Hours Per Day Using the Carrier for Intervention Condition Participants (*n* = 35)

Hours per Day	%	Count
0	14	5
1	35	13
2	30	11
3	0	0
4	5	2
5	3	1

Western society. In this study, parents participating in a home-visiting program who were given infant carriers in pregnancy were more likely to sustain breastfeeding (feeding human milk directly at the parent's breast or chest, or feeding expressed human milk) through 6 months postpartum than parents not given carriers. Although many factors play a role in duration of breastfeeding, our use of a randomized control trial design limits the influence of confounding factors and provides strong evidence to support the use of infant carriers as a tool to increase breastfeeding. To our knowledge, this is the first study to test the efficacy of providing infant carriers to increase breastfeeding by using a randomized intervention in the United States. This study adds to the previous research conducted in Italy revealing that providing infant carriers increased breastfeeding at 5 months postpartum among Italian mothers.¹²

Intervention Explanations

Past research has highlighted several potential mechanisms that may underlie the relationship between carrying and likelihood of breastfeeding through the 6 months. More time in close physical proximity to infants may facilitate responsiveness to infants' early hunger cues. One study used self-report surveys to demonstrate an association between maternal-infant physical contact and initiating breastfeeding in response to early hunger cues,¹¹ which is a clinical recommendation for facilitating ease of breastfeeding. Increased physical

contact may also indirectly impact breastfeeding by facilitating bonding. Parents randomly assigned to receive an infant carrier versus a plastic car seat-style carrier were more likely to have infants who were securely attached.¹⁸ Similarly, carrier use may have an indirect effect on breastfeeding by decreasing crying,¹⁹ which could potentially make breastfeeding easier and more rewarding for the parent.

Limitations

Our study had important strengths, including a randomized controlled trial design and a well-characterized cohort; however, our results should be considered in the context of several limitations. First, our sample size was constrained by budget rather than being determined by a power analysis, leading to a lack of power to detect some of our primary outcomes. Second, we had relatively high attrition at the 6-month survey assessment, with younger participants dropping out of the study at a higher rate than older participants. Thus, results of this study may not generalize to younger breastfeeding parents, although attrition rates and characteristics were similar between the intervention and the control conditions. Lastly, in this intervention, we only tracked breastfeeding outcomes until 6 months postpartum. The American Academy of Pediatrics recommends breastfeeding until at least one year; therefore, lengthening the time frame of the intervention in future studies could answer the question of whether providing infant carriers promotes breastfeeding at 1 year and beyond.

Future Directions

Important considerations for future studies should focus on impact and scalability. Our sample was primarily Latinx parents from income-constrained households with overall high breastfeeding rates (from a US context), which is consistent with national breastfeeding rates in the Latinx community. Future research should assess whether a similar intervention would be effective and potentially more impactful in populations that have lower breastfeeding rates, such as Black and Indigenous communities.²⁰ Risk of harm from carrier use is low, making this program highly feasible as a public health intervention. Unintentional injuries resulting in fatalities have only been reported from infant carriers 14 times over the past 20 years. In comparison, every year there are on average 8 fatalities that result from plastic bucket carriers and 3 fatalities from bucket seat use.²¹ The carrier used in this study (Omni 360; Ergobaby; see Fig 1) was chosen because of the ability to be used safely with newborns and beyond (as small as 7 lb and up to 45 lb) and because it facilitates ergonomic infant hip alignment. Moving forward, it will also be important to test the implementation of this intervention in clinical pediatric settings.

CONCLUSIONS

Suboptimal breastfeeding rates in the United States are associated with an estimated \$3 billion in medical costs and \$14.2 billion in costs related to premature infant deaths. Our data reveal that providing birth parents with an ergonomic infant carrier may be an easy and effective intervention for increasing likelihood of feeding human milk directly at the parent's breast or chest, or feeding expressed human milk at 6 months. Additional research is warranted to test the feasibility and effectiveness of this type of breastfeeding promotion strategy on a broader scale.

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