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Community Health Workers in Early Childhood Well-Child Care for Medicaid-Insured Children
A Randomized Clinical Trial

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➕ **Visual Abstract**

➕ **Supplemental content**

IMPORTANCE An intervention model (the Parent-focused Redesign for Encounters, Newborns to Toddlers; the PARENT intervention) for well-child care that integrates a community health worker into preventive care services may enhance early childhood well-child care.

OBJECTIVE To examine the effectiveness of the PARENT intervention vs usual care for parents with children younger than 2 years of age.

DESIGN, SETTING, AND PARTICIPANTS A cluster randomized clinical trial was conducted between March 2019 and July 2022. Of the 1283 parents with a child younger than 2 years of age presenting for a well-child visit at 1 of the 10 clinic sites (2 federally qualified health centers in California and Washington) approached for trial participation, 937 were enrolled.

INTERVENTION Five clinics implemented the PARENT intervention, which is a team-based approach to care that uses a community health worker in the role of a coach (ie, health educator) as part of the well-child care team to provide comprehensive preventive services, and 5 clinics provided usual care.

MAIN OUTCOMES AND MEASURES There were 2 primary outcomes: score for parent-reported receipt of recommended anticipatory guidance during well-child visits (score range, 0-100) and emergency department (ED) use (proportion with ≥2 ED visits). The secondary outcomes included psychosocial screening, developmental screening, health care use, and parent-reported experiences of care.

RESULTS Of the 937 parents who were enrolled, 914 remained eligible to participate (n = 438 in the intervention group and n = 476 in the usual care group; 95% were mothers, 73% reported Latino ethnicity, and 63% reported an annual income <$30 000). The majority (855/914; 94%) of the children (mean age, 4.4 months at parental enrollment) were insured by Medicaid. Of the 914 parents who remained eligible and enrolled, 785 (86%) completed the 12-month follow-up interview. Parents of children treated at the intervention clinics (n = 375) reported receiving more anticipatory guidance than the parents of children treated at the usual care clinics (n = 407) (mean score, 73.9 [SD, 23.4] vs 63.3 [SD, 27.8], respectively; adjusted absolute difference, 11.01 [95% CI, 6.44 to 15.59]). There was no difference in ED use (proportion with ≥2 ED visits) between the intervention group (n = 376) and the usual care group (n = 407) (37.2% vs 36.1%, respectively; adjusted absolute difference, 1.2% [95% CI, −5.5% to 8.0%]). The effects of the intervention on the secondary outcomes included a higher amount of psychosocial assessments performed, a greater number of parents who had developmental or behavioral concerns elicited and addressed, increased attendance at well-child visits, and greater parental experiences with the care received (helpfulness of care).

CONCLUSIONS AND RELEVANCE The intervention resulted in improvements in the receipt of preventive care services vs usual care for children insured by Medicaid by incorporating community health workers in a team-based approach to early childhood well-child care.

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Well-child care visits during early childhood present a critical and time-limited opportunity to provide families with supportive, relationship-based preventive care services that can have an effect on child and family well-being.[1] For many families, particularly for racial and ethnic minoritized families and those with low incomes, well-child care visits do not provide adequate preventive care services. Many parents leave the visit with unaddressed social, developmental, and behavioral concerns.[2-4] There is preliminary evidence, however, that implementing team-based care during early childhood increases the quality of well-child care visits, the receipt of preventive care services, and child and family health outcomes.[1,5-7]

A *community health worker* (defined as "a frontline public health worker who is a trusted member of a community"[8]) can serve as an important part of team-based care for early childhood preventive care visits. At least 21 states allow Medicaid payment for community health worker services. Some states have enacted state plan amendments to allow provision of community health worker services within primary care settings.[9] Evidence is needed to inform the integration of community health workers into the clinical workflows at safety net practices.

The Parent-focused Redesign for Encounters, Newborns to Toddlers (PARENT) intervention is a model for well-child care. The intervention incorporates a community health worker as a coach and member of the early childhood well-child care team to provide clinic-based preventive care services designed to address concerns related to family psychosocial needs, and to help decrease reliance on the clinician as the sole provider of preventive care.[7,10,11] The intervention was designed, implemented, and tested in a community-partnered process that engaged parents, clinicians, and payers[7,10-15] for children living at the intersection of racism and poverty. The intervention aims to change the structure of well-child care by adding the community health worker to the team, thus changing the process or provision of care, which might improve receipt of preventive care and subsequent health outcomes.[4]

The PARENT intervention was tested in a pilot randomized clinical trial (RCT)[7] comprising 251 families across 2 clinics serving populations largely insured by Medicaid. The trial noted improved receipt of well-child care services and reduced emergency department (ED) use with the PARENT intervention vs usual care.[7] However, the intervention has not been tested in a large-scale pragmatic trial.

To further examine the effectiveness of the PARENT intervention, a cluster RCT including parents of children younger than 2 years of age was conducted.

Methods

Setting

The current RCT included clinical partners from 2 multisite federally qualified health centers in California and Washington State, with 6 and 4 participating practices each. The clinics serve children primarily insured by Medicaid in Los Angeles County, California, and Pierce County, Washington. The study was approved by the Seattle Children's institutional review board. The trial protocol was published[16] and appears in Supplement 1.

The California federally qualified health center serves more than 80 000 patients (children and adults) annually at 12 health centers, 9 of which serve pediatric patients. The Washington federally qualified health center serves more than 45 000 patients (children and adults) annually across 7 clinics. More than 80% of patients at both federally qualified health centers are insured by Medicaid, Medicare, or are uninsured.

Description of the Intervention

The PARENT intervention is a team-based approach that uses a community health worker as part of the well-child care team to provide comprehensive and family-centered preventive care, address concerns related to family psychosocial and social needs, and decrease reliance on the clinician as the sole provider of well-child care services (the elements of the intervention appear in eTable 1 in Supplement 2). The intervention was designed so that the coach and pediatric clinician have coordinated, distinct roles during the well-child visit.

The coach provides anticipatory guidance, psychosocial and social needs screening and referral, and developmental or behavioral surveillance, screening, and guidance at each well-child visit. A screening prior to the well-child visit is used to customize the visit to the parent's needs. Each well-child visit includes time with the pediatric clinician that is focused on topics requiring clinical expertise. Typically, the coach meets individually with the family at the start of the well-child visit for 10 to 20 minutes, depending on family need. Because this RCT was conducted throughout the COVID-19 pandemic, the coach could also conduct their portion of the well-child visit via phone or telemedicine, usually within 24 hours to 48 hours of the in-person or telemedicine well-child visit.

The 2 federally qualified health centers in California and Washington State formed a project working group composed of clinicians, staff, parents, and clinical and administrative leaders to determine adaptations in the process of implementing the intervention.[17] Over 12 months, the project

Key Points

Question What is the effectiveness of the Parent-focused Redesign for Encounters, Newborns to Toddlers intervention, a model for well-child care that integrates a community health worker into preventive care services at well-child care visits?

Findings In this cluster randomized clinical trial including 914 parents with a child younger than 2 years of age, those in the intervention group had a higher score for parent-reported receipt of recommended anticipatory guidance during well-child visits vs the usual care group (mean score, 73.9 vs 63.3, respectively); however, emergency department use was similar in the intervention and usual care groups (37.2% vs 36.1%, respectively).

Meaning Integrating a community health worker into well-child care visits to provide early childhood preventive care services can improve the care that children receive.

working groups and clinic teams defined intervention modifications necessary to respond to clinic priorities, workflow, staffing, space, and population need. By design, any modification (eg, use of federally qualified health center–specific templates for the coach's documentation of the previsit screening in the electronic health record) maintained the core elements of the intervention.[17,18]

The coaches were bilingual, native Spanish speakers with previous experience in clinic-based medical visits (language interpretation, care coordination activities). The coaches participated in a 4- to 6-week training that included didactics and observed mock and precepted visits with real-time feedback from a trainer or member of the clinic's well-child care team. The training of the coaches also broadly covered core community health worker competencies[19] (eg, communication, knowledge base) and topics such as community resource building, trauma-informed care, motivational interviewing, social needs, child development, and the Bright Futures preventive care guidelines.[20]

Study Procedures

Using computer-generated random allocation and location-stratified block randomization, the 10 clinic sites were randomized to provide the PARENT intervention with a coach and pediatric clinician (n = 5 clinics) or usual care with clinician-directed care only (n = 5 clinics). Of 1283 parents (or legal guardians) approached and assessed for study eligibility by a research assistant, 937 (73%) were enrolled (n = 452 in the PARENT intervention group and n = 485 in the usual care group; **Figure**).

Adult parents or legal guardians of a child younger than 12 months of age who were scheduled for a well-child care visit or follow-up visit at 1 of the 10 clinical sites were invited by research staff to enroll in the study. Eligibility included no plans to change clinic providers for the next 12 months and ability to speak English or Spanish. A trained research associate obtained written informed consent from the parent and administered surveys at baseline (enrollment) and at 6 and 12 months after enrollment either in-person at the clinic or by phone. Baseline surveys were completed within 1 month of enrollment, and the intervention or usual care exposure began for the current or next well-child visit and continued for a 12-month period.

Baseline demographics were collected for the parent or caregiver, infant, and household along with information regarding the infant's overall health since birth or 3 months prior to the enrollment. The race and ethnicity of the parent were included as a proxy for the family's experiences of racism, and were determined by the parent using a list of fixed categories that included "Other (please specify)."

Parents completed phone surveys at 6 months after enrollment on health care use and at 12 months after enrollment on the primary, secondary, and exploratory outcomes. A chart review was conducted at study end for attendance of the well-child care visits during the 12-month study period.

Parents in the intervention group (except 4) met with the coach at least once during the 12-month study period; 61% met with the coach 2 to 4 times and 35% met with the 5 to 7 times.

Figure. Flow of Parents Through the PARENT Randomized Clinical Trial
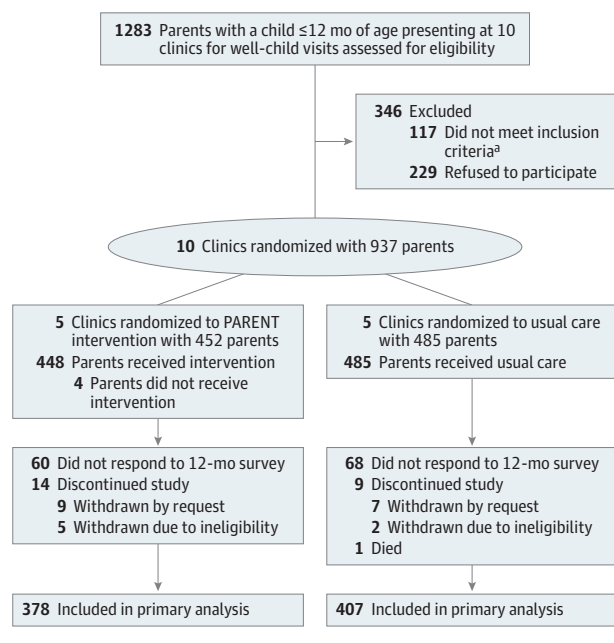
PARENT, Parent-focused Redesign for Encounters, Newborns to Toddlers.

[a] The reasons included (1) the parent was not planning to stay at the clinic (n = 50), had already seen a coach (n = 15), was not the legal guardian (n = 10), was not at the clinic for a well-child visit (n = 10), did not speak English or Spanish (n = 9), was younger than 18 years of age (n = 4), was already enrolled in the study with another child (n = 3), or was an employee of the clinic (n = 3); (2) the child was older than 12 months of age (n = 1); or (3) other (reason not documented) (n = 12).

Throughout the study, monthly fidelity checks were conducted by examining 4 randomly selected charts per coach to assess whether the coaches provided anticipatory guidance, social needs assessment, and elicitation or discussion of development or behavioral concerns; 94% of charts (384 of 407 of charts reviewed) documented all 3 services completed by the coaches.

Primary and Secondary Outcomes

There were 2 primary outcomes: score for parent-reported receipt of recommended anticipatory guidance during well-child visits (score range, 0-100) and ED use (proportion with ≥2 ED visits). The secondary outcomes included psychosocial screening, developmental screening, health care use, and parent-reported experiences of care.

To assess measures for the receipt of nationally recommended well-child care services (anticipatory guidance, developmental screening, and psychosocial assessment), health care use (ED and hospitalizations), and parental experiences of care (helpfulness of care), items from the Promoting Healthy Development Survey (PHDS-PLUS)[21] were used. The PHDS-PLUS is a survey given to parents that assesses the receipt of nationally recommended well-child care services. The PHDS-PLUS is endorsed by the National Quality Forum, is used by Medicaid agencies and health plans, and is available in English or Spanish at an eighth-grade reading level. The

PHDS-PLUS has strong construct validity (mean factor loading: 0.69) and internal consistency (mean Cronbach α = .80).[22]

The PHDS-PLUS was used to assess the score for the parent-reported receipt of recommended anticipatory guidance during well-child visits (one of the primary outcomes) with 17 topic-related and age-specific items (eg, "Did your health care team talk with you about things you can do to help your child grow and learn?"). Parents could respond with the following answers: "yes, and my questions were answered," "yes, but my questions were not answered completely," "no, but I wish we had talked about that," or "no, but I already had information about this topic and did not need to talk about it anymore." We calculated a summary score for the anticipatory guidance topics according to the child's age group (17 topic items for those aged 10-18 months and 14 topic items for those aged ≥19 months). The score was the proportion of items which the parent reported were both discussed and their questions were answered.[21] We also created an alternative version of the PHDS-PLUS score, which was the proportion of items either discussed and answered, or not discussed and for which the parent did not need or want information.

For the other primary outcome of ED use (proportion with ≥2 ED visits), parents were asked at 6 months and at 12 months how many ED visits they had made during each 6-month period and about hospitalizations over 12 months. The data on ED use were combined over 12 months.

The PHDS-PLUS also was used to assess the secondary outcomes (other measures of well-child care services and parental experience) over the previous 12 months: (1) psychosocial assessment (whether the team talked with them about 7 different topics; eg, whether they feel safe at home), (2) developmental screening (whether parents completed a developmental screening), (3) whether clinicians asked about and addressed any developmental or behavioral concerns, and (4) parental experiences of care (4-item PHDS-PLUS scale assesses how helpful the team was in providing preventive care guidance and the 5-item family-centered care measure from the National Survey of Children's Health[23]). One item from the Consumer Assessment of Healthcare Providers and Systems[24] was used as a global measure for the overall rating of care. To define up-to-date well-child care, the American Academy of Pediatrics Periodicity Schedule[25] was used. All visits between enrollment and 12-month follow-up were considered in this study.

Sample Size

From the pilot RCT,[7] we estimated that to detect a 12-point difference for the anticipatory guidance score (one of the primary outcomes), and a difference of 10% in the proportion of children with 2 or more ED visits (another primary outcome), we needed a final sample of 75 participants per site (10 sites) or 750 participants (after participant dropout and loss to follow-up), assuming a 1:1 randomization of 10 sites, an intraclass correlation of 0.01 based on previous delivery systems design for cluster RCTs among similar populations,[26,27] and 2-sided tests with a type I error rate of .05. The intraclass correlations observed in the current study were 0.008 for anticipatory guidance and 0.043 for ED use.

Statistical Analysis

The baseline characteristics and 12-month outcomes were summarized descriptively by study group, and the standardized mean differences were calculated. The baseline characteristics of participants missing 12-month primary outcome data were compared with those without missing data (eTable 2 in Supplement 2), and the study groups were compared among those missing primary outcome data. To assess the intervention effect, between-group adjusted absolute differences (AADs) for the 12-month outcomes (with 95% CIs) were estimated using mixed-effects linear regression for continuous outcomes and mixed-effects logistic regression for binary outcomes.

All models included random effects to account for clustering by clinic and were also adjusted post hoc for the child's age due to observed baseline differences. Additional post hoc stability analyses for the 2 primary outcomes were conducted to correct for the small number of clusters using adjustments for Satterthwaite denominator degrees of freedom.[28,29] Other post hoc analyses included an exploration of whether intervention effects were greater when there was a match between the community health worker and parent on primary language and race and ethnicity, in which the analyses for the 2 primary outcomes were stratified by Spanish as the parent's preferred language and Latino ethnicity.

Outcomes of ED use were also stratified by lower levels of child health (ie, less than "very good" health).[30] To handle missing data, a complete case analysis for the main analysis was conducted, and multiple imputation was used in the sensitivity analyses for the primary outcomes. The analyses assume that data are missing at random. However, if missingness is not random, the results may be biased.[31] All tests were 2-sided and P<.05 is considered statistically significant. All analyses were performed using Stata version 17.0 (StataCorp).

Results

In this cluster RCT, which was conducted between March 5, 2019, and July 1, 2021, 10 clinics were randomized with 937 parents who were enrolled and who completed a baseline survey. Twenty-three parents requested study withdrawal or became ineligible (1 died but the death was not related to study participation), leaving 914, of which, 785 (85.9%) completed the 12-month survey through July 15, 2022 (Figure). Baseline data for the 14.1% without primary outcome data were compared with those with primary outcome data (eTable 2 in Supplement 2).

The baseline characteristics were similar between the intervention and usual care groups (**Table 1**). However, there was a 0.7-month difference in age at enrollment. These data are shown with standardized mean differences in eTable 3 in Supplement 2.

The mean age at enrollment was 4.4 months for the children. The majority of parents participating in the trial were mothers (95.4%) and Latino (72.6%); most infants were insured by Medicaid (93.3%). Of those reporting income, 63% had an annual income less than $30 000. Forty-eight percent of enrolled parents were born outside the US, and 50% reported English as the primary language spoken at home (Table 1).

Table 1. Baseline Characteristics

	Intervention (n = 438)	Usual care (n = 476)
No. of participating clinics	5	5
Location of clinics	Los Angeles County, CA, and Pierce County, WA	
Populations served at clinics	Adults and children	
Child age, mo	(n = 435)	
Mean (SD)	4.0 (4.0)	4.7 (4.0)
Median (IQR)	2.0 (0-6.0)	4.0 (1.0-8.0)
Parent relationship to child, No. (%)	(n = 435)	
Mother	414 (94.5)	454 (95.4)
Father	20 (4.6)	22 (4.6)
Grandmother	1 (0.2)	0
Parent race and ethnicity, No. (%)	(n = 437)	
Latino	321 (73.5)	343 (72.1)
Non-Latino		
Asian	14 (3.2)	13 (2.7)
Black	24 (5.5)	22 (4.6)
White	52 (11.9)	56 (11.8)
Multiple races	16 (3.7)	15 (3.2)
Other[a]	10 (2.3)	25 (5.3)
Primary language spoken in the family's home, No. (%)	(n = 437)	
English	212 (48.5)	243 (51.1)
Spanish	197 (45.1)	199 (41.8)
Other[b]	28 (6.4)	34 (7.1)
Parent country of birth, No. (%)	(n = 436)	
US	218 (50.0)	249 (52.3)
Other country[c]	218 (50.0)	227 (47.7)
Parent marital status, No. (%)	(n = 437)	
Married	164 (37.5)	181 (38.0)
Divorced	6 (1.4)	8 (1.7)
Living with a partner	165 (37.8)	189 (39.7)
Separated	13 (3.0)	12 (2.5)
Single (never married and currently not living with a partner)	89 (20.4)	86 (18.1)
No. of adults in home, No. (%)	(n = 437)	
1	21 (4.8)	23 (4.8)
2	232 (53.1)	257 (54.0)
3	67 (15.3)	82 (17.2)
≥4	117 (26.8)	114 (23.9)
No. of children that parent has, No. (%)[d]	(n = 437)	
1	144 (33.0)	169 (35.5)
2	130 (29.7)	126 (26.5)
3	82 (18.8)	105 (22.1)
≥4	81 (18.5)	76 (16.0)
Type of health insurance for child, No. (%)		
Medicaid (Medi-Cal or Apple Health)	405 (92.5)	450 (94.5)
Uninsured	17 (3.9)	15 (3.2)
Private insurance plan	7 (1.6)	7 (1.5)
>1 Type of insurance	4 (0.9)	3 (0.6)
Military	1 (0.2)	0
Unknown[e]	2 (0.5)	1 (0.2)
Child has chronic medical problems, No./total (%)	10/436 (2.3)	6/476 (1.3)

(continued)

Table 1. Baseline Characteristics (continued)

	Intervention (n = 438)	Usual care (n = 476)
Trouble paying for any household expenses within past 12 mo, No./total (%)	238/432 (55.1)	289/475 (60.8)
Highest level of education completed, No. (%)	(n = 436)	
Less than high school	111 (25.5)	120 (25.2)
High school graduate or GED	159 (36.5)	166 (34.9)
2-y college or some college	127 (29.1)	152 (31.9)
≥4-y college degree	39 (8.9)	38 (8.0)
Annual household income, No. (%)	(n = 370)	(n = 398)
<$30 000	246 (66.5)	236 (59.3)
$30 000-$49 999	83 (22.4)	111 (27.9)
$50 000-$69 999	25 (6.8)	29 (7.3)
≥$70 000	16 (4.3)	22 (5.5)
Child's current overall health, No. (%)	(n = 433)	(n = 475)
Excellent	293 (67.7)	325 (68.4)
Very good	89 (20.6)	105 (22.1)
Good	43 (9.9)	44 (9.3)
Fair	8 (1.8)	1 (0.2)
Where child sleeps, No. (%)	(n = 433)	(n = 475)
Crib or bassinet	316 (73.0)	350 (73.7)
In bed with a parent	90 (20.8)	106 (22.3)
In own bed	13 (3.0)	10 (2.1)
In a co-sleeper	11 (2.5)	8 (1.7)
Other location[f]	3 (0.7)	1 (0.2)
Has childcare help ≥2 times/wk, No. (%)	393 (89.7)	428 (89.9)
Has person who helps with childcare, No. (%)	(n = 393)	(n = 428)
Family (eg, spouse or partner, other parent)	306 (77.9)	341 (79.7)
Extended family (eg, grandmother, aunt, or uncle)	197 (50.1)	215 (50.2)
Friend	14 (3.6)	9 (2.1)
Day care	8 (2.0)	7 (1.6)
Babysitter or nanny	7 (1.8)	10 (2.3)
Older sibling	6 (1.5)	7 (1.6)
Neighbor	1 (0.3)	6 (1.4)
PROMIS score, mean (SD)		
Global Mental Health[g]	54.7 (8.5) [n = 432]	53.9 (8.2) [n = 474]
Global Physical Health[g]	51.1 (8.4) [n = 432]	50.6 (7.9) [n = 475]
Emotional Support[h]	57.6 (7.0) [n = 430]	57.2 (7.6) [n = 475]

Abbreviation: GED, general equivalency diploma.

[a] Included 32 who selected Native Hawaiian or Other Pacific Islander and 1 each for American Indian or Alaska Native, Middle Eastern, and Filipino.

[b] Not specified by participant.

[c] Included Mexico (n = 248), El Salvador (n = 55), and Guatemala (n = 43). Countries in smaller numbers included American Samoa, Honduras, India, Kenya, Nigeria, and the Philippines.

[d] Parent was asked "Including [name of enrolled child], how many children do you have"? This number included children living in and out of the home and did not specify whether children were stepchildren or not.

[e] Three parents could not specify whether their insurance plan was through a commercial insurer or Medicaid.

[f] Included a swing (n = 1) or equal time in crib and parent bed (n = 2).

[g] Calculated by summing responses to 2 questions using a 5-point Likert scale. The total possible score was between 2 and 10 (9 values). Converting those 9 values to corresponding Patient-Reported Outcomes Measurement Information System (PROMIS) T-scores allows for a score range of 25.8 to 64.6 for Mental Health and 23.4 to 63.3 for Physical Health.

[h] Calculated by summing responses to 4 questions using a 5-point Likert scale. The total possible score was between 4 and 20 (17 values). Converting those 17 values to corresponding PROMIS T-scores allows for a score range of 25.7 to 62.0.

Primary Outcomes

Parents of children treated at the intervention clinics (n = 375) reported receiving more anticipatory guidance than the parents of children treated at the usual care clinics (n = 407) (mean score, 73.9 [SD, 23.4] vs 63.3 [SD, 27.8], respectively; AAD, 11.01 [95% CI, 6.44 to 15.59]) (Table 2). There was no statistically significant between-group difference in ED use (proportion with ≥2 ED visits) between the intervention group (n = 376) and the

Table 2. Primary and Secondary Outcomes

	Intervention	Usual care	Adjusted absolute difference, % (95% CI)[a]
Primary outcomes			
Score for parent-reported receipt of recommended anticipatory guidance during well-child visits, mean (SD)[b]	73.9 (23.4) [n = 375]	63.3 (27.8) [n = 407]	11.01 (6.44 to 15.59)[c]
Emergency department use (proportion with ≥2 emergency department visits), No./total (%)[d]	140/376 (37.2)	147/407 (36.1)	1.2 (−5.5 to 8.0)
Secondary outcomes, No./total (%)			
Psychosocial assessment performed	253/378 (66.9)	203/407 (49.9)	16.2 (9.4 to 23.0)
Individual items for psychosocial assessment[e]			
Do you or someone in your household smoke tobacco or marijuana?	341/378 (90.2)	343/405 (84.7)	5.2 (0.5 to 9.8)
Do you or someone in your household drink alcohol or use other substances?	324/377 (85.9)	333/406 (82.0)	3.3 (−2.3 to 8.9)
Do you feel safe at home?	358/378 (94.7)	368/407 (90.4)	4.0 (−0.9 to 9.0)
Do you ever feel depressed, sad, or have crying spells?	329/378 (87.0)	319/407 (78.4)	8.0 (1.2 to 14.9)
Do you have someone to turn to for emotional support?	337/378 (89.2)	306/407 (75.2)	12.3 (1.9 to 22.6)
Are there any changes or stressors in your family or home?	314/377 (83.3)	260/406 (64.0)	18.2 (10.3 to 26.2)
Do you have any firearms in your home?	318/378 (84.1)	313/407 (76.9)	7.0 (0.9 to 13.0)
Behavioral concerns elicited and addressed	305/342 (89.2)	292/356 (82.0)	7.4 (1.6 to 13.2)
Developmental screening performed	310/363 (85.4)	332/394 (84.3)	1.9 (−8.6 to 12.3)
Reported any inpatient hospitalizations	12/376 (3.2)	9/406 (2.2)	1.0 (−1.3 to 3.4)
Considered up-to-date on well-child care visits[f]	309/419 (73.7)	295/465 (63.4)	9.9 (1.1 to 18.8)

[a] From a post hoc stability analysis. Calculated with the child's age at baseline adjusted for as a continuous variable due to between-group differences.

[b] Based on the proportion of items that the parent reported were both discussed and their questions were answered. The score range was 0 to 100.

[c] Data are expressed as mean (95% CI).

[d] The included clinics were federally qualified health centers and their electronic health records are specific for the clinic and do not contain data on emergency department use.

[e] Parent reported that all 7 items (questions) were asked within the past 12 months.

[f] Based on electronic health record review. Child had completed all recommended well-child visits by age per the American Academy of Pediatrics Periodicity Schedule (recommendations for preventive pediatric health care).

usual care group (n = 407) (37.2% vs 36.1%, respectively; AAD, 1.2% [95% CI, −5.5% to 8.0%]).

The intervention effect remained after using alternative anticipatory guidance scoring. In the adjusted regression analysis (adjusted for unbalanced age for children at baseline), the anticipatory guidance score at 12 months was 11 points higher (95% CI, 6.5 to 15.6) in the intervention group vs the usual care group. For ED use, the results were similar in the main analyses (Table 2) and in the sensitivity analyses using multiple imputation. Stratification by Spanish language, Latino ethnicity, or worse child health did not change the findings.

Secondary Outcomes

Parents in the intervention group (n = 378) were more likely to receive a psychosocial and social needs assessment for all 7 items (66.9%) compared with the usual care group (n = 407) (49.9%) (AAD, 16.2% [95% CI, 9.4% to 23.0%]) (Table 2). The intervention group (n = 342) more often reported being asked about behavioral concerns and having them addressed (89.2%) compared with the usual care group (n = 356) (82.0%) (AAD, 7.4% [95% CI, 1.6% to 13.2%]). There was no difference between the intervention group and the usual care group for receipt of developmental screening; there were high screening levels reported in both groups. More children in the intervention group (n = 419) were up-to-date on well-child care by the 12-month follow-up (73.7% vs 63.4% in the usual care group [n = 465; AAD, 9.9% [95% CI, 1.1% to 18.8%]) (Table 2).

In the adjusted regression analyses, there was a positive intervention effect for the helpfulness of care score (mean, 77.8 [SD, 25.2] in the intervention group [n = 378] vs 69.8 [SD, 30.7] in the usual care group [n = 407]; AAD, 7.89 [95% CI, 1.61 to 14.18]), but not for family-centeredness of care (mean, 89.0 [SD, 22.5] vs 85.5 [SD, 27.1], respectively; AAD, 3.42 [95% CI, −2.74 to 9.58]) (Table 3). Because these 95% CIs were wide, the individual items for these outcomes were also examined. In the adjusted logistic regression analysis, there were positive intervention effects for 1 of the 5 family-centeredness items (82.2% for the intervention group [n = 377] vs 69.5% for the usual care group [n = 406]; AAD, 12.3% [95% CI, 5.9% to 18.7%] for "provided the specific information you needed concerning your child") and for all 4 helpfulness items (AAD range, 7.1% to 10.7%) (Table 3).

For the exploratory outcome of overall rating of care at 12 months, the mean score was slightly but statistically significantly higher in the intervention group (mean, 9.0 [SD, 1.4] [n = 378]) compared with the usual care group (mean, 8.8 [SD, 1.5] [n = 406]) on a scale from 0 to 10 (AAD, 0.22 [95% CI, 0.01 to 0.43]) (Table 3).

Sensitivity Analysis

The sensitivity analysis with multiple imputation yielded similar results to the main analysis (11.2-point difference [95% CI, 6.6 to 15.8]) as did the stability analysis correcting for a small number of clusters (11.0-point difference [95% CI, 5.0 to 17.1]). Stratification by preferred language of Spanish yielded a similar effect size of 11.1 (95% CI, 5.9 to 16.2) vs the effect size of 10.9 (95% CI, 5.2 to 16.7) for preferred language not Spanish.

Latino ethnicity was associated with a greater intervention effect (13.2 [95% CI, 7.9 to 18.5]) compared with non-Latino ethnicity (4.6 [95% CI, 3.0 to 12.1]).

Adverse Events

One parent died during the study period, but this death was not related to study participation. There were no reported adverse events or harms from study participation.

Discussion

This cluster RCT provides evidence on the effectiveness of incorporating community health workers without advanced degrees or licensure into early childhood well-child care visits to provide comprehensive preventive care services, improving the receipt of anticipatory guidance, other preventive care services, parent experiences of care, and attendance at well-child care visits.

Parents in the intervention group received more preventive care services, including anticipatory guidance and psychosocial assessment. By incorporating a community health worker as part of the well-child care team, the services provided to parents at well-child visits were expanded. Longer visits have been associated with greater receipt of preventive care services[32]; and it is possible that just extended clinician time in a visit could have resulted in similar improvements in care. However, by using a community health worker to extend that well-care visit time, rather than a clinician, clinics may be able to more efficiently use the expertise of their clinicians.

The intervention used in this study is unique from other well-child care interventions because of its use of a community health worker to provide comprehensive, clinic-based, well-child care services universally to all families receiving early childhood well-child care. Previous studies[33-36] examined nonphysician professionals and other team members as part of well-child care to enhance developmental and behavioral services and reported improved outcomes. In a clinical trial of the Healthy Steps program,[33] a licensed developmental specialist (eg, social worker, nurse) was incorporated into well-child care to improve developmental and behavioral services; the findings indicated improvements in the quality of well-child care across 4 domains. The PARENT intervention expands this prior well-child care redesign by (1) adding an unlicensed community health worker to the well-child care team, and (2) expanding the breadth of well-child care anticipatory guidance services to complement clinician well-child care.

The PARENT intervention is also distinct from evidence-based home visitation interventions[37,38] that do not change the delivery of well-child care. In addition, other well-child care interventions have used nonmedical professional personnel for outreach purposes to improve adherence to immunization schedules and attendance at well-child care visits without altering the structure, process, or content of the visit itself.[39-41] The PARENT intervention is unique in altering the fundamental structure of well-child care visits.

Table 3. Additional Secondary Outcomes and Exploratory Outcome

	Intervention	Usual care	Adjusted absolute difference, % (95% CI)[a]
Additional secondary outcomes			
Helpfulness of care score, mean (SD)[b]	77.8 (25.2) [n = 378]	69.8 (30.7) [n = 407]	7.89 (1.61 to 14.18)[c]
Individual items for helpfulness of care score, No./total (%)[d]			
Helped you understand your child's behavior	329/378 (87.0)	323/407 (79.4)	7.1 (1.9 to 12.4)
Learned how to protect your child from injuries	293/378 (77.5)	272/407 (66.8)	10.7 (4.2 to 17.3)
Gave you the information you needed, when you needed it	344/378 (91.0)	337/407 (82.8)	8.1 (3.2 to 13.0)
Helped you learn how to meet own needs while caring for your child	308/378 (81.5)	285/405 (70.4)	10.7 (1.0 to 20.5)
Family-centeredness of care score, mean (SD)[e]	89.0 (22.5) [n = 378]	85.5 (27.1) [n = 407]	3.42 (−2.74 to 9.58)[c]
Individual items for family-centeredness of care score, No./total (%)[f]			
Spent enough time with your child	235/378 (62.2)	217/407 (53.3)	8.2 (−1.5 to 18.0)
Listened carefully to you	295/378 (78.0)	287/407 (70.5)	6.9 (−0.1 to 14.0)
Showed sensitivity to your family's values and customs	286/378 (75.7)	283/405 (69.9)	6.0 (−2.0 to 13.9)
Provided the specific information you needed concerning your child	310/377 (82.2)	282/406 (69.5)	12.3 (5.9 to 18.7)
Helped you feel like a partner in your child's care	301/377 (79.8)	301/407 (74.0)	5.6 (−0.3 to 11.6)
Exploratory outcome			
Overall rating of care score, mean (SD)[g]	9.0 (1.4) [n = 378]	8.8 (1.5) [n = 406]	0.22 (0.01 to 0.43)[c]

a From a post hoc stability analysis. Calculated with the child's age at baseline adjusted for as a continuous variable due to between-group differences.

b Range, 0 to 100; a score of 100 represents the highest level of helpfulness of care and 0 represents the lowest level. See additional information in footnote d.

c Data are expressed as mean (95% CI).

d Each item had the following 4 response options: very helpful, helpful, somewhat helpful, or not at all helpful or did not discuss. These response options were assigned a value between 0 and 100 as follows: 100 for very helpful, 75 for helpful, 25 for somewhat helpful, and 0 for not at all helpful or did not discuss. The mean value of these 4 items was then calculated to determine the score. Scoring was based on Promoting Healthy Development Survey (PHDS-PLUS) scoring instructions.

e Range, 0 to 100; a score of 100 represents the highest level of family centeredness of care and 0 represents the lowest level. See additional information in footnote f.

f Each item had the following 4 response options: always, usually, sometimes, or never. These response options were assigned a value between 0 and 100 as follows: 100 for always or usually and 0 for sometimes or never. The mean value of these 5 items constituted the score. Scoring was based on PHDS-PLUS scoring instructions.

g Scale of 0 to 10; a score of 10 indicates the best care.

The pilot RCT[7] of the PARENT intervention noted a 50% reduction in 2 or more ED visits during a 12-month follow-up period; and we speculated that the mechanism might have been greater parental confidence in handling infant-related issues and reducing discretionary ED visits. In the current trial, we did not find a reduction in ED use. During the COVID-19 pandemic, and particularly during the early phase of the pandemic, ED visits generally plummeted to record lows, and the acuity of ED visits increased.[42,43] It is likely that we were unable to detect any difference in ED visits because ED use, particularly for low-acuity use, was lower during the current study for both the intervention and usual care families than would have been expected based on estimates from before the COVID-19 pandemic.[44,45]

We observed greater adherence to the well-child care visit schedule for the intervention group compared with the usual care group. For the clinics using fee-for-service arrangements or per-visit rates (at federally qualified health centers), fewer missed well-child care visits could enhance the financial sustainability of the PARENT intervention.

Although the current study was not powered to examine an intervention effect by cultural concordance of the coach and parent, we observed a greater effect with concordance between a Latino coach and a Latino parent compared with parents without racial or ethnic concordance with the coach. Additional research is needed to understand the effect of cultural concordance on the intervention effect.

For clinics to implement the PARENT intervention that integrates community health workers into well-child care, amendments to state Medicaid plans by allowing payment for community health worker services will be critical, but not sufficient. Clinics will require implementation and start-up support, a workforce of community health workers that has adequate training and equitable pay, and clinicians well trained in team-based care.

Limitations

Our study has limitations. First, the 12-month follow-up period did not include assessment of longer-term outcomes (eg, preschool readiness). Second, most of data were reported by the parents, and these data are potentially susceptible to social desirability bias.

Third, because of the COVID-19 pandemic, the visits with the coach were shifted to virtual and phone visits; this was an unplanned adaptation of the intervention, but also a critical element of a pragmatic trial. Fourth, we did not collect objective measures of time spent in the well-child visits after the intervention, limiting the conclusions on efficiency.

Fifth, there are no detailed data on clinic-level implementation provided in this article, but we have previously published data[17] to help practices understand the clinic-level adaptations that were required during implementation of the intervention. Rigorous evaluation of implementation will be important in future research.

Conclusions

The intervention resulted in improvements in the receipt of preventive care services vs usual care for children insured by Medicaid by incorporating community health workers in a team-based approach to early childhood well-child care.

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