

# Effects of Social Needs Screening and In-Person Service Navigation on Child Health

## A Randomized Clinical Trial

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**IMPORTANCE** Social determinants of health shape both children's immediate health and their lifetime risk for disease. Increasingly, pediatric health care organizations are intervening to address family social adversity. However, little evidence is available on the effectiveness of related interventions.

**OBJECTIVE** To evaluate the effects of social needs screening and in-person resource navigation services on social needs and child health.

**DESIGN, SETTING, AND PARTICIPANTS** Patients were randomized to intervention or active control conditions by the day of the week. Primary outcomes observed at 4 months after enrollment included caregivers' reports of social needs and child health status. Recruitment occurred between October 13, 2013, and August 27, 2015, in pediatric primary and urgent care clinics in 2 safety-net hospitals. Participants were English-speaking or Spanish-speaking caregivers accompanying minor children to nonacute medical visits.

**INTERVENTIONS** After standardized screening, caregivers either received written information on relevant community services (active control) or received in-person help to access services with follow-up telephone calls for further assistance if needed (navigation intervention).

**MAIN OUTCOMES AND MEASURES** Change in reported social needs and in caregiver assessment of child's overall health reported 4 months later.

**RESULTS** Among 1809 patients enrolled in the study, evenly split between the 2 sites, 31.6% (n = 572) were enrolled in a primary care clinic and 68.4% (n = 1237) were enrolled in an urgent care setting. The children were primarily Hispanic white individuals (50.9% [n = 921]) and non-Hispanic black individuals (26.2% [n = 473]) and had a mean (SD) age of 5.1 (4.8) years; 50.5% (n = 913) were female. The reported number of social needs at baseline ranged from 0 to 11 of 14 total possible items, with a mean (SD) of 2.7 (2.2). At 4 months after enrollment, the number of social needs reported by the intervention arm decreased more than that reported by the control arm, with a mean (SE) change of -0.39 (0.13) vs 0.22 (0.13) ( $P < .001$ ). In addition, caregivers in the intervention arm reported significantly greater improvement in their child's health, with a mean (SE) change of -0.36 (0.05) vs -0.12 (0.05) ( $P < .001$ ).

**CONCLUSIONS AND RELEVANCE** To our knowledge, this investigation is the first randomized clinical trial to evaluate health outcomes of a pediatric social needs navigation program. Compared with an active control at 4 months after enrollment, the intervention significantly decreased families' reports of social needs and significantly improved children's overall health status as reported by caregivers. These findings support the feasibility and potential effect of addressing social needs in pediatric health care settings.

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Childhood social adversities disproportionately affect low-income and racial minority populations and impose significant health burdens.<sup>1</sup> Childhood exposures like family financial stress, food insecurity, and residential instability have been linked with increased risk of socioemotional behavior problems, cognitive deficits, and short-term and long-term diseases of childhood, as well as earlier mortality later in life.<sup>2-16</sup> Negative health outcomes are more likely as the number of adverse exposures increases independent of specific types of adversity.<sup>9,17</sup>

Growing recognition of adversity's contribution to biological processes, health, and development has spurred calls for interventions addressing social factors as part of routine child health care.<sup>3</sup> In 2013, the American Academy of Pediatrics' Task Force on Childhood Poverty endorsed the promotion of evidence-based strategies for low-income children, including payment and health delivery system reforms to reduce negative health effects of poverty.<sup>18</sup> Similarly, the American Academy of Pediatrics recommended that pediatricians should increase interventions addressing social risks.<sup>19,20</sup>

In line with these recommendations, a number of social interventions have emerged in pediatric clinical settings.<sup>21-25</sup> Research on these efforts has primarily focused on assessing intervention processes or reductions in social needs. Such studies<sup>21-24,26,27</sup> have demonstrated that social screening and referrals can increase connections with community resources and decrease social needs. However, no studies have examined whether social interventions influence children's health, to our knowledge.

We address this gap by evaluating the effect on family social needs and parent-reported child global health status of an in-person screening and case management intervention targeting pediatric social needs vs an active control condition providing written resource information. We hypothesized that the in-person intervention would reduce social needs and improve child health more than the provision of written information.

## Methods

### Setting, Participants, and Eligibility Criteria

Study protocols and materials were approved by the University of California, San Francisco, Committee on Human Research and the Children's Hospital and Research Center Oakland Institutional Review Board. All adult caregivers completed written informed consents, and assents for participation were obtained for children 7 years or older. Study recruitment and follow-up took place on a predetermined timeline between October 13, 2013, and August 27, 2015, in 2 safety-net hospitals (Zuckerberg San Francisco General Hospital and Trauma Center and University of California, San Francisco, Benioff Children's Hospital Oakland), where most patients are enrolled in Medicaid or lack health insurance coverage. Study participants were drawn from families seen for children's medical services in primary care or urgent care departments located in those hospital settings. Eligible participants were English-speaking or Spanish-speaking caregivers 18 years or older who were familiar with the child's household environment and were

### Key Points

**Question** Can addressing social issues during pediatric primary and urgent health care visits decrease families' social needs and improve children's health?

**Findings** In this randomized clinical trial, the provision of in-person resource navigation services significantly decreased families' reports of social needs and significantly improved children's overall health status compared with an active control condition.

**Meaning** These findings suggest that addressing social needs in pediatric health care settings can affect both family circumstances and child health.

living in the county where enrollment took place. Families seeking health care for a child with severe illness were excluded. Only 1 child and 1 caregiver were enrolled per household regardless of the number of visits, number of children seeking care, or number of adults accompanying those children.

Volunteers drawn from local universities were trained to recruit patients, conduct social screening, and serve as patient navigators for caregivers in the navigation intervention arm. They received 8 hours of training covering intervention procedures, cultural accountability, and community, hospital, and government social service resources, as well as motivational interviewing. They also received ongoing, on-site training from supervisors (A.A., C.S., and other nonauthors), including observed volunteer-patient interactions, with feedback for quality improvement.

### Study Procedures

A computer program determined the study randomization schedule within each clinic setting, with day as the unit of randomization and each calendar month as the randomization block. Navigators were not masked to study arm because of this randomization method. They approached families between 9 AM and 8 PM and administered a 10-minute baseline survey with eligible, consenting participants. The survey included questions about household demographics and perceived social, legal, and mental health needs, as well as current benefits program enrollment and child global health. To avoid interference with clinical activities, medical staff (D.L., E.L., and other nonauthors) could interrupt survey administration, as needed, for clinical care; if interrupted, the caregiver could resume the survey immediately after the clinical encounter. Families identifying mental health needs for adult household members who experienced violence were referred to social work or other appropriate behavioral health professionals.

### Active Control Arm

Because of ethical concerns about identifying social needs and then not addressing them, we decided to provide control caregivers with written community resource information without the benefit of an in-person navigator or follow-up. After survey completion, participants in the active control arm who endorsed any social needs were provided with preprinted information about relevant resources available in their communities. County-specific resource guides were developed by lo-

cal social service agencies and downloaded from the internet to distribute to participating families.

#### Navigation Intervention Arm

After completing the baseline survey, intervention caregivers were offered a meeting with the navigator immediately after the child's clinic visit or by telephone if the caregiver needed to leave. Navigators used algorithms to provide targeted information related to community, hospital, or government resources addressing needs that participants had prioritized. Resources ranged from providing information about child care providers, transportation services, utility bill assistance, or legal services to making shelter arrangements or medical or tax preparation appointments to helping caregivers complete benefits forms or other program applications. Information about algorithms for program referrals is available online (<http://www.bayareahelpdesks.org>). Follow-up meetings were offered every 2 weeks for up to 3 months, until identified needs were met, or when caregivers declined further assistance.

#### Follow-up

Participants in both arms were telephoned not by the navigator but by a study research assistant (A.A., P.S., and other nonauthors) at 4 months after enrollment for a follow-up survey; those completing the survey received a small gift certificate for their time. The original trial protocol called for contacting patients twice (at 6 weeks and 4 months); however, because of participant burden, the study team changed this protocol early in data collection to a single follow-up at approximately 4 months (Supplement). The research assistant was aware of group assignment because survey questions included items about the intervention.

#### Measures

##### Demographics (Baseline)

At baseline, caregivers reported caregiver and child age, caregiver and child sex, child race/ethnicity, family income, and caregiver education level and relationship to the child. They also reported the number of individuals living in the household, which was used to calculate the federal poverty level.

##### Social Needs (Baseline and Follow-up)

At baseline and follow-up, caregivers endorsed (yes or no) any needs that their family was currently experiencing using a standardized 14-item social and mental health needs screening questionnaire.<sup>28</sup> Items included housing stability and habitability, food and income security, child care and transportation needs, employment, legal concerns, medical insurance and other public benefits enrollment, and concerns about any adult household member's mental health.

##### Child Global Health (Baseline and Follow-up)

Caregiver's report of child global health was assessed at baseline and follow-up with the single item from the 2011/2012 National Survey of Children's Health that measured child mental and physical health status.<sup>29</sup> This item asked the following question: "In general, would you say your child's health is..." on a 5-point scale, which ranged from 1 ("excellent") to 5 ("poor"), with lower values or decreases in global health over

time representing better or improved health. Parental reports of child health have been shown to serve as an acceptable proxy of actual child health status and to be associated with health services use.<sup>30,31</sup>

#### Sample Size

Our sample of 1809 caregiver participants provided 80% power in 2-sided tests with a type I error rate of 5% to detect standardized small effect sizes (Cohen *d* range, 0.17-0.20). Sample size estimates conservatively accounted for 40% to 50% loss to follow-up.

#### Data Analytic Plan

Although the original analysis plan involved examining primary and urgent care subgroups separately, data were combined for all analyses because of lower than anticipated enrollment. Differences between navigation intervention and active control arms were compared using generalized estimating equation analyses to account for clustering by enrollment date. Change in continuous outcomes was compared between the study arms using mixed linear regression models, also accounting for clustering by enrollment date in a stepwise, additive fashion. Model 1 included no covariates. Model 2 controlled for baseline levels of the outcome. Model 3 also included family demographic measures, clinic site, and setting.

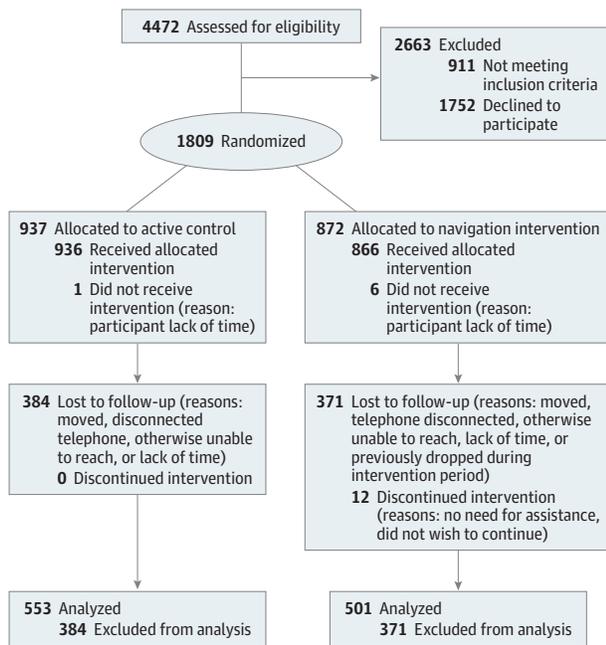
All analyses were conducted based on an intent-to-treat principle using all available data with the exception of a subgroup analysis, which examined navigation intervention arm effects only for families with at least 1 social need, because no intervention procedures were provided to families without reported needs. This method is in accord with the Consolidated Standards of Reporting Trials guidelines for reporting results from clinical trials.<sup>32</sup> A sensitivity analysis examined patterns of missing values using multiple imputation procedures.<sup>33</sup> Statistical analyses were performed using a software program (SPSS, version 22.0; SPSS Inc).

## Results

### Sample Characteristics

Of 4472 caregivers approached to participate, 911 were ineligible, 1752 refused, and the remaining 1809 agreed to participate. Caregiver lack of time or lack of interest were the most frequent reasons for nonparticipation. In total, 937 families were randomized to the active control arm and 872 families were randomized to the navigation intervention arm (Figure). Follow-up data were obtained from 1054 participants (58.3%), similar to other studies<sup>34-36</sup> in safety-net settings. At baseline, active control arm participants reported fewer social needs than navigation intervention arm participants but did not show statistically significant differences on any other baseline variable (Table 1) or in rates of follow-up. There also was no statistically significant differential retention between arms. Using multiple imputation models to estimate missing follow-up data, we found no differences in the number of social needs or child global health between caregivers who had and had not reported follow-up data.

Figure. CONSORT Diagram



CONSORT indicates Consolidated Standards of Reporting Trials.

The final sample was evenly split between sites (50.8% [919 of 1809] for Zuckerberg San Francisco General Hospital and Trauma Center and 49.2% [890 of 1809] for University of California, San Francisco, Benioff Children’s Hospital Oakland), with 68.4% of 1809 participants (n = 1237) recruited from urgent care and 31.6% (n = 572) recruited from primary care within each site. The children were primarily Hispanic white individuals (50.9% [n = 921]) and non-Hispanic black individuals (26.2% [n = 473]) and had a mean (SD) age of 5.1 (4.8) years; 50.5% (n = 913) were female. The mean (SD) age of caregivers was 33.2 (9.3) years, and they were predominantly female and had family incomes below the federal poverty level.

The reported number of social needs at baseline ranged from 0 to 11 out of 14 total possible items (mean [SD], 2.7 [2.2]). Of 1809 families, 17% (n = 307) did not endorse any needs, while 20% (n = 362) reported 4 or more needs. The most frequently endorsed social needs are listed in Table 2. For the total sample, these needs included running out of food before having money or food stamps to buy more (41.2% [n = 746]), not having enough money to pay utility bills (41.1% [n = 744]), having trouble finding a job (31.0% [n = 561]), not having a place to live (29.2% [n = 528]), living in an unhealthy environment (22.7% [n = 411]), and paying medical bills (21% [n = 379]). At baseline, most of the 1806 caregivers reported child global health as “excellent” (34.8% [n = 628]) or “very good” (26% [n = 470]), with 31% (n = 560) identifying the child’s health as “good,” 7.3% (n = 131) as “fair,” and 0.9% (n = 17) as “poor.” Caregivers in the navigation intervention arm who indicated social needs participated in a mean (SD) of 1.4 (1.6) (range, 0-13) follow-up meetings with navigators during the 3 months after enrollment.

Table 1. Characteristics of Participants by Study Arm at Baseline

Variable	Active Control Arm (n = 937) <sup>a</sup>	Navigation Intervention Arm (n = 872) <sup>a</sup>
Site, No. (%)		
Zuckerberg San Francisco General Hospital and Trauma Center	470 (50.2)	449 (51.5)
UCSF Benioff Children’s Hospital Oakland	467 (49.8)	423 (48.5)
Clinic, No. (%)		
Urgent care	649 (69.3)	588 (67.4)
Primary care	288 (30.7)	284 (32.6)
Child age, mean (SD), y	5.2 (4.7)	5.1 (4.8)
Child female sex, No. (%)	487 (52.0)	426 (48.9)
Child race/ethnicity, No. (%)		
Non-Hispanic white	41 (4.4)	33 (3.8)
Hispanic white	477 (50.9)	444 (50.9)
Non-Hispanic black	242 (25.8)	231 (26.5)
Hispanic black	64 (6.8)	48 (5.5)
Asian	41 (4.4)	45 (5.2)
Other or mixed race/ethnicity	71 (7.6)	71 (8.1)
Caregiver language, No. (%)		
English	611 (65.2)	551 (63.2)
Spanish	326 (34.8)	321 (36.8)
Caregiver age, mean (SD), y	33.2 (9.3)	33.1 (9.3)
Caregiver female sex, No. (%)	802 (85.6)	732 (83.9)
Caregiver relationship to the child, No./total No. (%)		
Parent	880/914 (96.3)	828/857 (96.6)
Legal foster parent or guardian	2/914 (0.2)	3/857 (0.4)
Other adult family member	32/914 (3.5)	26/857 (3.0)
≤100% Federal poverty level, No./total No. (%)	567/783 (72.4)	548/857 (62.8)
Family income, No./total No. (%), \$		
<10 000	242/784 (30.9)	225/724 (31.1)
10 000 to <20 000	232/784 (29.6)	229/724 (31.6)
20 000 to <30 000	157/784 (20.0)	146/724 (20.2)
≥30 000	153/784 (19.5)	124/724 (17.1)
Caregiver education level, No./total No. (%)		
Less than eighth grade	150/902 (16.6)	157/837 (18.8)
Some high school	163/902 (18.1)	140/837 (16.7)
High school graduate or general equivalency diploma	219/902 (24.3)	241/837 (28.8)
Some college	219/902 (24.3)	202/837 (24.1)
College graduate	151/902 (16.7)	97/837 (11.6)

(continued)

**Table 1. Characteristics of Participants by Study Arm at Baseline (continued)**

Variable	Active Control Arm (n = 937) <sup>a</sup>	Navigation Intervention Arm (n = 872) <sup>a</sup>
No. of social needs, mean (SD)	2.6 (2.0)	2.9 (2.1)
Parental report of child global health, No./total No. (%)		
Excellent	347/934 (37.2)	281/872 (32.2)
Very good	231/934 (24.7)	239/872 (27.4)
Good	285/934 (30.5)	275/872 (31.5)
Fair	66/934 (7.1)	65/872 (7.5)
Poor	5/934 (0.5)	12/872 (1.4)
Asked about nonmedical needs in the past year, No. (%)	156 (16.6)	163 (18.7)

Abbreviation: UCSF, University of California, San Francisco.

<sup>a</sup> The denominator is as listed except where indicated.

### Change in Social Needs Reported by Navigation Intervention and Active Control Arms

Our hypothesis that navigation intervention arm caregivers would have fewer social needs at follow-up than active control arm caregivers was confirmed. We found a significant difference between arms in the change in social needs from intake to follow-up (Table 3). Caregivers in the navigation intervention arm reported a decrease in their number of social needs by a mean (SE) of  $-0.39$  (0.13) needs, while caregivers in the active control arm reported a small increase in the number of social needs by a mean (SE) of  $0.22$  (0.13) more needs, for a mean (SE) cumulative between-group difference of  $0.61$  (0.18) needs ( $P < .001$ ). Adjusting for baseline number of social needs and clinic and family demographic variables yielded a similar pattern of results. Pooled estimates of mixed models using multiple imputation for missing follow-up data resulted in similar group differences.

### Change in Child Global Health

Our second hypothesis, that child health would improve more in the navigation intervention arm than in the active control arm, was also supported. Caregiver report of child global health (in which lower scores represent better health) improved a mean (SE) of  $-0.36$  (0.05) in the navigation intervention arm and a mean (SE) of  $-0.12$  (0.05) in the active control arm, resulting in a mean (SE) significant difference of  $-0.24$  (0.07) between arms ( $P < .001$ ). Adjusting for baseline child global health and family demographic variables continued to yield significant intervention group differences (Table 3). Pooled estimates of mixed models using multiple imputation for missing follow-up data yielded similar group differences. A subanalysis removing families referred to a social worker resulted in the same pattern of findings for both change in social needs ( $\beta = 0.62$ ; 95% CI,  $\beta = 0.28$  to  $0.89$ ;  $P < .001$ ) and child global health ( $\beta = 0.25$ ; 95% CI,  $\beta = 0.08$  to  $0.39$ ;  $P < .001$ ), suggesting that the referrals to social workers did not account for the greater improvements found in the navigation intervention arm. Exploratory analysis of whether reductions in social needs accounted for intervention effects did not show mediation. Although the effect of group on child global

**Table 2. Social Needs at Baseline From a Standardized 14-Item Social and Mental Health Needs Screening Questionnaire Among the Total Sample of 1809 Participants**

Item	No. (%) Endorsing Need	
	Active Control Arm (n = 937)	Navigation Intervention Arm (n = 872)
Running out of food before you had money or food stamps to buy more	357 (38.1)	389 (44.6)
Not having enough money to pay your utility bills	361 (38.5)	383 (43.9)
Trouble finding a job	271 (28.9)	290 (33.2)
Not having a place to live	248 (26.5)	280 (32.1)
Unhealthy living environment	195 (20.8)	216 (24.8)
Medical bills	208 (22.2)	171 (19.6)
No health insurance	149 (15.9)	170 (19.5)
Other concerns with housing	137 (14.6)	161 (18.5)
Cut off or denied from programs that provide income support	128 (13.7)	130 (14.9)
No primary care or regular general doctor	130 (13.9)	119 (13.7)
Disability-related impairment interfering with ability to work	86 (9.2)	90 (10.3)
Accessing mental health care for yourself/caregiver in household	60 (6.4)	72 (8.3)
Problems with a current or former job	55 (5.9)	56 (6.4)
Concerns about pregnancy-related work benefits	25 (2.7)	20 (2.3)

health was reduced, it continued to be a significant predictor after adding change in social needs into the model ( $\beta = 0.26$ ; 95% CI,  $\beta = 0.07$  to  $0.44$ ;  $P = .006$ ).

## Discussion

Demand is growing for interventions that bridge social and medical care in pediatric clinical settings, including screening for and addressing unmet social, legal, and mental health needs of families seen for primary or urgent care.<sup>21,22</sup> Evidence that these interventions affect health care quality and outcomes will accelerate efforts to incorporate them into care delivery. To our knowledge, this study is the first randomized clinical trial that includes child health outcomes in an evaluation of pediatric-based interventions designed to link families facing unmet social, legal, and mental health needs with community services.

The prevalence of families' unmet needs identified in the 2 study recruitment hospitals, each of which serves a majority of low-income families, is consistent with work from other safety-net settings,<sup>22,24,28,37</sup> as is the association we found between baseline social, legal, and mental health needs and parent-reported child global health.<sup>9,17,38-41</sup> As the number of social adversities experienced increased, so did the odds of poor child health.

Despite the association between social needs and child health, only 17.8% (322 of 1809) of families recruited for our study reported being asked about nonmedical needs in a health care setting within the past year. We evaluated 2 approaches to lessening the burden of these adversities, namely, a navigation intervention arm in which caregivers had assistance from a navigator to access social services and an active control arm in which they received written information. Families

Table 3. Predictors of Change in the Number of Social Needs and Poor Child Global Health From Baseline to Follow-up by Study Arm<sup>a</sup>

Variable	$\beta$ (SE) [95% CI]		
	Model 1	Model 2	Model 3
No. of social needs <sup>b</sup>	0.61 (0.17) [0.26-0.92]	0.43 (0.16) [0.11-0.74]	0.62 (0.18) [0.27-0.99]
Poor child global health <sup>b</sup>	0.24 (0.07) [0.10-0.38]	0.17 (0.06) [0.05-0.28]	0.17 (0.06) [0.04-0.29]

<sup>a</sup> Model 1 includes no covariates. Model 2 includes the covariate of baseline levels of the outcome. Model 3 includes the following additional covariates: site, clinic, child age, child sex (reference is female), child race/ethnicity (reference is Hispanic white), caregiver age, caregiver sex (reference is

female), and 100% or less of the federal poverty level.

<sup>b</sup> Reference is navigation intervention arm.

randomized to the navigation intervention arm experienced significantly greater decreases in the number of needs and improvements in parent-reported child health scores compared with families randomized to the active control arm. Given that the active controls were screened and received relevant information on community resources, this work is a conservative test of the effect; an even greater difference might be expected with a no-treatment control.

Prior research on social screening and interventions in pediatric clinical settings has predominantly assessed process outcomes. This work has shown that screening and electronic or written referral interventions are acceptable to patients, meet patient desires for discussion, and increase family contact with and receipt of community resources.<sup>21,22,26,27,42</sup>

The present study extends this literature by demonstrating an effect not only on degree of social need but also on child health in a brief time frame. In-person navigation was shown to be more effective than written resources given to caregivers. The intervention relied on a volunteer workforce that is low cost and potentially scalable to other pediatric health care settings, although dependent on the availability of volunteers. Navigators averaged fewer than 2 follow-up contacts with patients, which was enough to yield a significantly greater positive effect on child health. Future work could examine dose response in social interventions, including whether higher intervention doses have differential effects on specific social needs or child health outcomes. In addition, overall reductions in social needs did not mediate the effects of the navigation intervention on child health. Future work will also be needed to better characterize the associations between changes in specific social needs and health outcomes.

Four limitations of the study should be noted. First is the use of a single item to assess child health status. While widely used as an indicator of child health and well-being,<sup>30,31,40</sup> a single-item instrument does not provide a comprehensive or nuanced assessment. Second, despite randomization, the navigation intervention arm participants reported more social needs on average at baseline, which could be a chance occurrence or could reflect differential recruitment by navigators on the days when patients were randomized into the navigation intervention arm rather

than to the active control arm. Whatever the reason, statistical adjustment for these baseline differences yielded comparable results. Third, both the low rate of enrollment and study attrition may have resulted in bias. We did not find differential attrition by study arm on any key variable. Because the American Academy of Pediatrics' recommendations about social screening are incorporated into care, we anticipate that families will be more likely to accept these services as part of standard care delivery. Fourth, although the randomization of participants was an overall strength of this study, randomization by day and the lack of masking of navigators and research assistants could have biased both enrollment and survey results. The lack of evidence of differential attrition, along with finding no difference in the number of follow-up calls needed to obtain follow-up surveys or in the rates of survey completion, suggests that systematic biases between the 2 study arms were unlikely.

## Conclusions

This large randomized clinical trial of pediatric primary and urgent care-based social determinants of health interventions found a significantly greater decrease in social needs and improvement in parent-reported child health in families in an in-person navigation intervention arm compared with the active control arm providing written resource information. These findings extend previous work documenting the associations between social adversities experienced in childhood and health outcomes, as well as on process outcomes related to social interventions.

National pediatrics organizations have called for new delivery models that incorporate social interventions. Few pediatric patient caregivers and families are now screened for social risks in health care systems or receive help in addressing identified social needs.<sup>21</sup> While more work documenting health and health care use effects of social determinants of health interventions is needed to guide investments in this area, the finding that the low-intensity interventions undertaken in this study can affect child health outcomes underlines the value of such programs.

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responsibility for the integrity of the data and the accuracy of the data analysis.

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