ORIGINAL RESEARCH

Medical-Legal Partnership Effects on Mental Health, Health Care Use, and Quality of Life in Primary Care: A Randomized Clinical Trial

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Purpose: **To determine whether an immediate referral to a medical-legal partnership (MLP), compared with a 6-month waitlist control, improved mental health, health care use, and quality of life.**

Methods: **This trial randomly assigned individuals to an immediate referral or a wait-list control. The MLP involved a collaboration between the primary care clinic and a legal services organization. The primary outcome was stress (6 months) as measured by the Perceived Stress Scale (PSS). Secondary measures included the Center for Epidemiologic Studies Depression Scale; Generalized Anxiety Disorder scale (GAD-7); Patient-Reported Outcomes Measurement Information System (PROMIS); and emergency department (ED), urgent care, and hospital visits. Assessments were at baseline and 3-, 6-, and 9-month follow-ups. Bayesian statistical inference and a 75% posterior probability threshold were used to identify noteworthy differences.**

Results: **Immediate referral was associated with lower PSS scores and higher GAD-7 scores. PROMIS scores were higher for the immediate referral group with respect to several subdomains. At 6 months, the immediate referral group demonstrated 21% fewer ED visits and 75.6% more hospital visits.**

Conclusion: **Immediate referral to the MLP was associated with lower stress and a lower rate of ED visits but higher anxiety and a higher rate of hospital visits.**

Trial Registration: **ClinicalTrials.gov Identifier: NCT03805126. (J Am Board Fam Med 2023;00:000–000.)**

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Introduction

Social risk factors contribute to undesirable health outcomes,[1–7] leading to calls to connect social and medical care.[8,9] Spurred by programs such as Accountable Health Communities, primary care clinics are redesigning clinical workflows to identify individuals with social needs and refer them to community service providers.[9–11] One promising intervention is the medical-legal partnership (MLP), which coordinates services between medical and legal organizations to address health-harming legal

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needs (HHLNs).[12,13] The evidence base to support MLPs is growing,[12,14] with studies demonstrating that MLPs stabilize housing, enhance finances, and reduce stress.[15–18] Unfortunately, this body of work has been limited by the absence of randomized-controlled trials (RCTs).[17] Thus far, 2 studies, in pediatric populations, randomized participants to legal services and concluded that MLPs increased preventive services, reduced emergency department (ED) visits, and improved diabetes control.[17,19]

In 1967, an attorney worked at the nation's first community health center,[20] and nearly 30 years later, medical and legal professionals in Boston collaborated to help children with asthma. As this model expands, there is a need to evaluate MLPs nationwide.[21] Seeking to address social needs, a legal services organization and academic partner launched an MLP in 2018. The objective of this trial, the first of its kind in adults, was to assess whether referrals to the MLP were associated with improvements in stress (primary outcome), anxiety, depression, health care use, and quality of life and to identify the services provided by the MLP.

Methods

Study Settings and Participant Eligibility

The study took place from February 14, 2019, until September 30, 2020, in an urban primary care clinic. Eligible participants were low income (earning less than 200% of the federal poverty level), 18 years of age or older, spoke English or Spanish, and screened positive for HHLNs.

Study Procedures, Randomization, and Follow-Up

Individuals were screened using an instrument developed by the authors (Appendix). Those who identified as being at significant and immediate risk were excluded from randomization, directly referred to the MLP, and not included in analyses. To identify these individuals, we asked this question: "In your opinion, do your legal needs pose a significant and immediate (which means in the next several days) risk of serious personal harm to you or your close family members? For example: an eviction warning or a court date." Randomization was achieved using a computer-generated algorithm, with variable block sizes of 4 and 6, and 1:1 allocation to immediate referral to the MLP or placement on a 6-month waitlist control. The randomization sequence was generated by the study's statistician and implemented through REDCap by a research assistant. Three research assistants conducted in-person, baseline assessments and in-person, online, or telephonic 3-month, 6-month, and 9-month assessments (English or Spanish). Participants were entered into 2 $100 gift card drawings if they completed the 6-month and 9-month assessments, respectively.

Intervention

Those randomized to immediate referral were referred on the same day, whereas those on the waitlist were referred 6 months after randomization. The legal services organization made multiple attempts via telephone (typically 5) and mail. If successful, they conducted intake for eligibility and identification of HHLNs. Due to funding restrictions, the legal services organization could not accept cases that were out of state; involved conflicts of interest; or pertained to immigration, personal injury, or medical malpractice. In these situations, a list of resources was provided. For accepted cases, an attorney and paralegal delivered advice and counsel (both in person and over the phone), drafted documents, and provided legal representation at no cost. The paralegal was physically at the clinic 1 to 2 times per month. All had access to therapists, a social worker, and a community health worker at the clinic.

Measures

The Perceived Stress Scale (PSS) assessed the extent to which respondents found their lives to be unpredictable, uncontrollable, or overloading. The PSS at 6 months served as our primary outcome and primary endpoint. Higher scores (0 to 40) indicate greater psychological stress and correlate with mental and physical exhaustion.[22,23] The Center for Epidemiologic Studies Depression Scale (CES-D) measured depressive symptoms.[25] Higher scores (0 to 60) indicate more depressive symptoms and correlate with other measures of depression.[26,27] The Generalized Anxiety Disorder scale (GAD-7) assessed anxiety. Higher scores (0 to 21) correlate with lower functional status and disability.[28]

To assess quality of life, we administered the 29-item Patient-Reported Outcomes Measurement Information System (PROMIS) instrument (Profile version 2.1).[29] This instrument assesses physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain

interference, and pain intensity. Raw scores were transformed to T-scores (0 to 100; mean of 50 and SD of 10 for the US general population).[30] The T-score rescales raw scores into standardized scores with a mean equal to 50 and SD equal to 10 in reference to a population. Higher scores represent more of the domain being measured.[31,32] Thus, higher fatigue scores indicate more severe symptoms of fatigue.

To assess health care use, participants reported the number of urgent care, ED, and hospital visits over the prior 6 months (at baseline) and during the time since the previous assessment. Demographic data (age, sex, race, ethnicity, and language) were extracted from the electronic health record.

Given the lack of a universally accepted HHLN screening tool, we collaborated with researchers and legal professionals to develop one[33–35] and obtained permission when needed.[36,37] The screening tool (Appendix) is 25 items and encompasses legal issues, including income, insurance, safety, guardianship, housing, and food. We screened all eligible participants because no optimal screening strategy for HHLNs exists, and patients may not know they have HHLNs. We summed HHLNs via the screening instrument, by adding the positive responses for each subdomain. Since respondents could select multiple answer choices on paper, positive responses to the questions regarding housing instability, utilities, and food insecurity (separately for low and very low) were only counted once.

Receipt of Legal Services

Because of attorney-client privilege, the legal services organization could only share data for those participants who chose to sign a release. Among those who did, we tracked the HHLNs identified and addressed by the legal services organization. After completing an intake form and interview, legal professionals recorded whether they accepted or rejected (eg, they failed to respond or meet eligibility criteria) cases and the subsequent outcomes of those cases.[38]

To determine whether participants received legal services (a step needed for the per-protocol analysis below), we first categorized those whose cases were accepted as receiving legal services and those whose cases were rejected as not receiving legal services. Then, among the remaining participants, we categorized participants as not receiving legal services if they reported that they had not communicated with the MLP (a question asked during the 3-, 6-, and 9-month assessments) or if they did not have a record in the data management system of the legal services organization. We also report the categories of legal services provided.

Sample Size

Prior interventions using the PSS have reported mean differences of approximately 3 (scale range: 0-to 40; SD = 6).[23,24,39,40] Given a 2-sided α of 0.05 and β of 0.2, a priori power estimates determined we needed to recruit at least 64 people per group (128) to detect this difference. Accounting for loss to follow-up (20%), we needed to randomize 80 per group (or 160 total).

Blinding

Participants were not blind to their group. The research assistants completed the assessments and were blind to the group assignment with notable exceptions. For example, participants, on occasion, discussed their interactions with the MLP, revealing their group to the research assistants. In these cases, the research assistants were unblinded when conducting subsequent assessments. Furthermore, 1 research assistant sent the referrals and therefore was also not blinded. This individual primarily conducted the baseline and 9-month assessments (after all had received referrals). We conducted analyses blind to treatment group.

Statistical Analyses

Descriptive statistics were used to evaluate characteristics. Analyses were performed on an intention-to-treat sample of eligible participants. Generalized linear modeling was used to model the outcomes (6 months), controlling for baseline levels of the outcome. Before testing each outcome, characteristics were screened as potential confounders of the relationship between outcome and group (primary analyses: randomized groups; per-protocol analyses: received intervention groups). To test whether variables demonstrated a relationship with the group and outcome,[41,42] Chi-square and Mann-Whitney-Wilcoxon tests were used to screen for confounding (see Table 1 for *P* values). No variables met criteria for confounding in either analysis (ethnicity demonstrated a relationship with the received intervention grouping variable, but none of the outcomes).

The analyses of health care use measures relied on the negative binomial distribution to handle

Table 1. Participant Characteristics of a Randomized Controlled Trial Testing a Medical-Legal Partnership Referral, by Total Sample, Randomized Condition, and Whether Participants Received Legal Services

Variable	Overall (n = 159) Mean (SD)	Waitlist Control (n = 80) Mean (SD)	Immediate Referral (n = 79) Mean (SD)	*P* value
Age	52.3 (16.0)	50.5 (15.8)	54.7 (16.0)	0.821
	n (%)	n (%)	n (%)	*P* value
Sex				0.140
Female	108 (68%)	50 (62%)	58 (73%)	
Male	51 (32%)	30 (38%)	21 (27%)	
Race				0.849
African American	85 (54%)	40 (51%)	45 (57%)	
Hispanic*	44 (28%)	24 (31%)	20 (25%)	
Other	11 (7%)	5 (6%)	6 (7%)	
White	17 (11%)	9 (12%)	8 (10%)	
Ethnicity				0.463
Hispanic	21 (13%)	9 (11%)	12 (15%)	
Not Hispanic	136 (87%)	70 (89%)	66 (85%)	
Language				0.650
English	153 (97%)	76 (96%)	77 (97%)	
Spanish	5 (3%)	3 (3%)	2 (2%)	

Variable	Overall (n = 141) Mean (SD)	No receipt (n = 115) Mean (SD)	Received services (n = 26) Mean (SD)	*P* value
Age	52.8 (16.2)	53.1 (16.8)	51.7 (13.3)	0.701
	N (%)	N (%)	N (%)	*P* value
Sex				0.614
Female	98 (70%)	81 (70%)	17 (65%)	
Male	43 (30%)	34 (30%)	9 (35%)	
Race				0.171
African American	76 (55%)	58 (51%)	18 (72%)	
Hispanic*	39 (28%)	35 (31%)	4 (16%)	
Other	8 (5%)	8 (7%)	0 (0%)	
White	16 (12%)	13 (11%)	3 (12%)	
Ethnicity				0.020
Hispanic	20 (14%)	20 (18%)	0 (0%)	
Not Hispanic	119 (86%)	93 (82%)	26 (100%)	
Language				0.333
English	136 (97%)	110 (96%)	26 (100%)	
Spanish	4 (3%)	4 (4%)	0 (0%)	

*Please note that the race categories were provided by the clinical partner.
Abbreviation: SD, standard deviation.

overdispersed count outcomes, and the resulting regression coefficients were exponentiated to provide rate ratios (RRs). The psychological measures' total scores were modeled as binomial proportions of maximum possible values. As a result, we calculated the estimated marginal mean (EMM) for each randomized group. The T-scores were measured via the Gaussian (normal) distribution, with a truncated minimum and maximum value identified to aid model convergence.

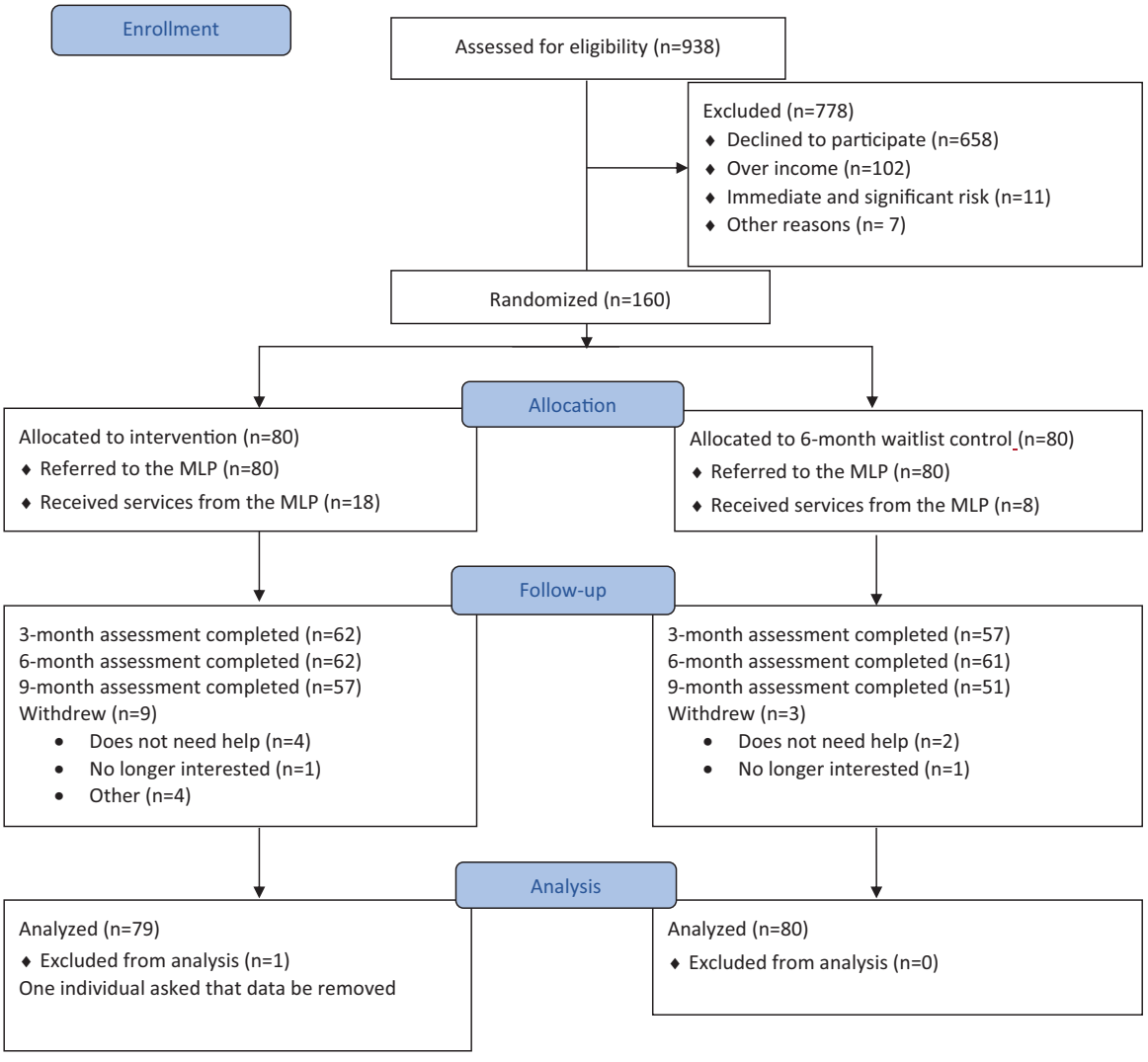
Bayesian statistical inference was used to quantify the probability that model effects exist, given the observed data and weakly informative priors (eg, $b \sim N(\mu = 0, \sigma = 10)$). Assumptions of Bayesian

inference were evaluated using scale convergence factors ("rhat"), effective sample size, and posterior predictive checking. These assumptions were satisfied. Model inferences relied on the posterior distribution for the regression coefficient for group. The median of the posterior distribution was taken as the most likely point estimate, and a credible interval was derived as the lower and upper limits including 95% of the posterior distribution. The posterior probability (PP) was taken as the proportion of values that were greater or less than the null effect value (eg, $b = 0$). The literature describes different thresholds of PP values: anecdotal (PP 50% to 74%), moderate (PP 75% to 90%), strong (PP 91% to 96%), very strong (97% to 99%), and extreme (>99%).[43–45] The current analyses stipulated that PP ≥ 75% provides a minimum threshold of evidence in favor of the alternative hypothesis to suggest that an effect of group is supported. The protocol was approved by the Committee for the Protection of Human Subjects at the University of Texas Health Science Center at Houston.

Results

We assessed 938 individuals for eligibility (Figure 1). Of these, 11 were excluded due to immediate risk. Participants were randomized to immediate referral (n = 80) or a waitlist (n = 80). Enrollment stopped when the target sample size was reached. While all were referred, only 18 (22.5%) immediate referral and 8 (10.0%) waitlist participants ultimately received services from the MLP. Twelve participants (9 immediate referral, 3 waitlist) withdrew

Figure 1. CONSORT flow diagram. Abbreviation: MLP, medical-legal partnership.



from the study because they no longer needed assistance or did not want to complete the assessments. Follow-up assessment completion (the percentage of participants completing the assessments) ranged from 71.3% to 77.5% in the immediate referral group and from 63.8% to 76.3% for the waitlist. One individual (immediate referral) requested for data to be removed; thus, 159 individuals were analyzed.

Baseline Characteristics

Characteristics between groups are reported in Table 1. Individuals averaged 1.3 ED, 0.5 urgent care, and 0.4 hospital visits over the 6-month period before enrollment. Except for the number of participants noting they had 2 or more hospital stays over the past year, the responses to the screening instrument were similar between the 2 groups (Table 2). On average, participants reported having nearly 7 of 25 possible needs. The mean baseline scores were 20.1 for PSS, 24.6 for CES-D, and 9.6 for GAD-7. Compared with the general population in the United States, participants had worse sleep (57.4), pain (61.6), depression (56.7), anxiety (58.9), and fatigue (57.7) and greater difficulty with physical functioning (37.4) and social roles and activities (46.7).

Primary Analysis (6 Months)

At 6 months, immediate referral was associated with lower PSS scores ($EMM_{IMMEDIATE} = 18.8$, $EMM_{WAITLIST} = 19.9$; PP = 74.8%) and higher GAD-7 scores ($EMM_{IMMEDIATE} = 10.3$, $EMM_{WAITLIST} = 6.7$; PP 89.8%). CES-D scores were not different between the 2 groups (PP = 52.7%). With respect to the PROMIS T-scores, immediate referral was related to worse pain ($b = 7.05$; PP = 86.9%), social function ($b = -6.26$; PP = 74.9%), fatigue ($b = 8.20$; PP = 82.5%), anxiety ($b = 6.15$; PP = 85.3%), sleep disturbance ($b = 4.06$; PP = 77.8%), and depression ($b = 4.55$; PP = 79.3%). Differences across the PROMIS T-scores were not supported for physical function ($b = -2.31$; PP = 72.7%). Those in the immediate referral group demonstrated a 21% lower rate of ED visits (RR = 0.79; PP = 79.7%), no difference in the rate of urgent care visits (RR = 0.86; PP = 62.0%), and a 75.6% higher rate of hospital visits (RR = 1.76; PP = 88.5%).

Per-Protocol Analysis (6 Months)

Per-protocol analyses evaluated each outcome with respect to receipt of MLP services, comparing receipt of MLP services (REC; n = 26) to nonreceipt (NON; n = 115). The total does not sum to 160 because not all participants completed the client release form (n = 113 completing), and we could not determine the outcome for 18 individuals. Those receiving services were slightly younger age (51.2 vs 53.1 years) and had higher baseline CES-D scores (29.6 vs 22.7). At 6 months, the group that received services demonstrated greater total scores for stress ($EMM_{REC} = 23.4$, $EMM_{NON} = 18.1$; PP = 99.2%), depression ($EMM_{REC} = 25.3$, $EMM_{NON} = 15.6$; PP = 98.9%), and anxiety ($EMM_{REC} = 15.5$, $EMM_{NON} = 7.5$; PP = 98.0%). The REC group demonstrated worse T-scores across all the PROMIS measures: pain ($b = 15.7$; PP = 97.3%), social function ($b = -25.2$, PP = 98.6%), physical function ($b = -11.3$; PP = 99.4%), fatigue ($b = 19.3$; PP = 95%), anxiety ($b = 5.6$; PP = 78.3%), sleep disturbance ($b = 14.1$; PP = 98.7%), and depression ($b = 11.4$; PP = 96.7%). These groups were not different with respect to health care use (ED visits: RR = 0.93; PP = 58.8%; urgent care visits: RR = 1.18; PP = 63.1%; and hospital visits: RR = 0.96; PP = 53.5%).

Legal Services Provided

Overall, the MLP provided 36 legal services to 30 unique individuals, which includes 4 individuals who were excluded from randomization due to immediate and significant HHLNs (Table 3). Nearly 30% of these benefits encompassed drafting wills, resolving probate issues, and establishing guardianship. In addition, the legal team helped clients to secure child support, seek housing repairs, fight evictions, address employment issues, and obtain Social Security. To address these issues, they provided advice and counsel and wrote letters on behalf of clients.

Discussion

Participants in the immediate referral group exhibited lower stress and a 21% lower rate of ED visits but also higher anxiety and a 76% higher rate of hospital visits. Although these results overlap with previous RCTs, unlike them, our findings were not uniformly positive, which, we suspect, is the result of differences in the interventions. First, the previous RCTs focused on pediatric populations; thus, caregivers were the recipients of the services and may have had greater motivation to create stable environments for their children. Second, the prior interventions included additional team members who bridged

Table 2. Responses to the Health-Harming Legal Needs Screening Instrument by Total Sample and Randomized Condition

	Total	Waitlist Control	Immediate Referral	
	N (%)	N (%)	N (%)	*P* value
Does anyone in your household have concerns about?				
Income issues (including disability, supplemental security income, Social Security, debt, medical bills, paying for medications, and Women, Infants, and Children benefits)	90 (56.6%)	46 (57.5%)	44 (55.7%)	0.819
Health insurance coverage or benefits	57 (35.8%)	27 (33.8%)	30 (38.0%)	0.579
Losing a job or being at risk for losing a job over the past 90 days	18 (11.3%)	9 (11.3%)	9 (11.4%)	0.977
Losing transportation or being at risk for losing transportation over the past 90 days	29 (18.2%)	20 (25.0%)	9 (11.4%)	0.026
Education needs that are not being met	13 (8.2%)	9 (11.3%)	4 (5.1%)	0.155
Immigration status	13 (8.2%)	10 (12.5%)	3 (3.8%)	0.045
Personal safety	22 (13.8%)	11 (13.8%)	11 (13.9%)	0.975
Personal injuries (including accidents)	20 (12.6%)	9 (11.3%)	11 (13.9%)	0.611
Custody, guardianship, or child support	38 (23.9%)	17 (21.3%)	21 (26.6%)	0.431
Wills, advance directives, power of attorney, or any other form of end-of-life planning	81 (50.9%)	41 (51.3%)	40 (50.6%)	0.938
What is your housing situation today?				
I do not have housing (I am staying with others, in a hotel, in a shelter, living outside on the street, on a beach, in a car, abandoned building, bus or train station, or in a park)	30 (18.9%)	16 (20.0%)	14 (17.7%)	0.714
I have housing today, but I am worried about losing housing in the future	45 (28.3%)	23 (28.8%)	22 (27.8%)	0.9
Utilities				
In the past 12 months, the electric, gas, or water company made threats to shut off services in your home	45 (28.3%)	21 (26.3%)	24 (30.4%)	0.563
In the past 12 months, the electric, gas, or water company made threats to shut off services in your home and the utilities are already shut off	1 (0.6%)	0 (0.0%)	1 (1.3%)	0.313
Think about the place you live. Do you have problems with any of the following? (Check all that apply)				
Bugs	37 (23.3%)	23 (28.8%)	14 (17.7%)	0.1
Mold	37 (23.3%)	23 (28.8%)	14 (17.7%)	0.1
Lead (or chipped) paint or pipes	16 (10.1%)	6 (7.5%)	10 (12.7%)	0.28
Water leaks or plumbing problems	45 (28.3%)	26 (32.5%)	19 (24.1%)	0.237
Neighborhood conditions that affect health	13 (8.2%)	9 (11.3%)	4 (5.1%)	0.155
Oven or stove not working	12 (7.5%)	7 (8.8%)	5 (6.3%)	0.563
No or not working smoke detectors	29 (18.2%)	17 (21.3%)	12 (15.2)	0.322
Inadequate heat or air conditioning	24 (15.1%)	12 (15.0%)	12 (15.2%)	0.973
Food				
Within the past 12 months, you worried that your food would run out before you got money to buy more (Often true)	28 (17.6%)	15 (18.8%)	13 (16.5%)	0.714
Within the past 12 months, you worried that your food would run out before you got money to buy more (Sometimes true)	45 (28.3%)	23 (28.8%)	22 (27.8%)	0.9
Within the past 12 months, the food you bought just didn't last and you didn't have money to get more (Often true)	26 (16.4%)	16 (20.0%)	10 (12.7%)	0.211
Within the past 12 months, the food you bought just didn't last and you didn't have money to get more (Sometimes true)	67 (42.1%)	35 (43.8%)	32 (40.5%)	0.679

Continued

Table 2. Continued

	Total	Waitlist Control	Immediate Referral	
	N (%)	N (%)	N (%)	*P* value
Over the past year, have you had…?				
3 or more emergency room visits	45 (28.3%)	21 (26.3%)	24 (30.4%)	0.563
2 or more hospital stays	21 (13.2%)	6 (7.5%)	15 (19.0%)	0.032
Additional concerns				
Would like to speak with a lawyer about other legal issues	102 (64.2%)	50 (62.5%)	52 (65.8%)	0.662
	Mean (SD)	Mean (SD)	Mean (SD)	*P* value
Number of issues	6.7 (3.5)	7.0 (3.5)	6.4 (3.5)	0.310

Abbreviation: SD, standard deviation.

the medical and social care systems. Of note, the per-protocol analysis demonstrated that receiving legal services was associated with worse outcomes. We hypothesize that participants may have realized that the MLP was unable to resolve their HHLNs causing distress or that new problems may have emerged after HHLNs were addressed. A third possibility is that patients do not want to be connected to legal services through primary care and that these referrals ultimately lead to greater net harms. These will need to be tested in future studies and will be explored during an accompanying qualitative study.

Of the 160 participants referred, only 16% (n = 26), at minimum, received services, highlighting the challenges of integration. This figure mirrors the Accountable Health Communities evaluation, which found that 14% had their health-related social needs resolved.[46] In a National Academies of Sciences, Engineering, and Medicine (NASEM) report on primary care and public health, the authors defined integration between the 2 as the linkage of programs to improve population health.[8] Our findings suggest that integration is elusive and potentially critical. Using the NASEM nomenclature, our project was a collaboration, because we worked together to plan and execute the program.[8] This included joint, biweekly meetings and providing the legal services organization with clinical space. Unfortunately, connecting with patients proved to be difficult, possibly because of a lack of trust and unstable housing, phone, Internet, and transportation. Our experience calls into question the effectiveness of programs that refer to community service providers without integration. Future efforts should aim for and test the effectiveness of partnerships, or "2 entities working so closely together that there is no separation from the end user's perspective."[8] This would require the legal services organization to be colocated at the clinic, with both sharing as much information as legally allowable when authorized by the patient.

Several limitations should be considered. First, our study randomized referrals rather than the receipt of services. We chose this design to isolate the effect of actions taken by clinics. Future studies should consider randomizing participants after legal services organizations accept them. Second, our results are affected by the lack of a validated screening tool for HHLNs, a problem that plagues social needs screening broadly.[47] Developing a screening instrument for HHLNs with acceptable psychometric properties is a critical need. Without such an instrument, efforts to identify individuals with HHLNs may result in high rates of false positives and false negatives. Third, for ethical reasons, we excluded individuals with immediate, serious risks, though their inclusion may have changed our results. Fourth, we were unable to determine the legal

Table 3. Legal Benefits Provided by the Medical Legal Partnership

Legal Benefit Provided*	# Participants Benefitted (%)
Wills & Guardianship	10 (27.8%)
Housing	9 (25.0%)
Social Security	6 (16.7%)
Employment & Education	4 (11.1%)
Insurance	3 (8.3%)
Food	2 (5.6%)
Income	1 (2.8%)
Other	1 (2.8%)

*Includes 4 individuals who were not randomized due to health-harming legal needs that represented an immediate and significant risk. All four had legal issues related to evictions. Furthermore, 6 individuals received more than 1 legal benefit.

outcomes for the nearly 30% that did not provide data-sharing authorization. Finally, we experienced workflow disruptions. Between November 2019 and February 2020, personnel changes at the legal services organization resulted in a coverage gap. The spring of 2020 coincided with the emergence of the COVID-19 pandemic. We highlight these because they reflect real-world challenges that may affect implementation in other settings.

Conclusions

The results of this RCT are mixed, as the MLP was associated with improvements in some outcomes (stress and ED visits) and worsening outcomes in other areas (anxiety and hospital visits). Despite these findings, some received important benefits, including assistance with housing, wills, Social Security, and food stamps. To achieve greater net benefit, practices should strive for tighter integration.

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To see this article online, please go to: http://jabfm.org/content/00/0/000.full.

References

1. WHO Commission on Social Determinants of Health, World Health Organization, eds. Closing the gap in a generation: health equity through action on the social determinants of health: Commission on Social Determinants of Health final report. World Health Organization, Commission on Social Determinants of Health; 2008.
2. Link BG, Phelan J. Social conditions as fundamental causes of disease. J Health Soc Behav 1995;35:80.
3. Berkman LF, Kawachi I. Social epidemiology. Oxford, UK: Oxford University Press; 2000.
4. Woolf S, Johnson R, Phillips R, Philipsen M. Giving everyone the health of the educated: an examination of whether social change would save more lives than medical advances. Am J Public Health 2007;97:679–83.
5. Zimmerman E, Woolf SH [Internet]. Understanding the relationship between education and health. National Academy of Medicine; 2014 [accessed 2017 Mar 10]. Available from: https://apha.confex.com/apha/142am/webprogram/Handout/Paper315693/Final%20BPH-UnderstandingTheRelationship.pdf.
6. Woolf SH, Jones RM, Johnson RE, et al. Avertable deaths associated with household income in Virginia. Am J Public Health 2010;100:750–5.
7. McGinnis JM, Foege WH. Actual causes of death in the United States. JAMA 1993;270:2207–12.
8. Committee on Integrating Primary Care and Public Health; Board on Population Health and Public Health Practice; Institute of Medicine. Primary care and public health: exploring integration to improve population health. Washington (DC): National Academies Press; 2012.
9. National Academy of Medicine. Integrating social care into the delivery of health care: moving upstream to improve the nation's health. Washington (DC): National Academies Press; 2019.
10. Center for Medicare and Medicaid Innovation [Internet]. Driving health system transformation—a strategy for the CMS Innovation Center's second decade; 2021 [accessed 2021 Dec 9]. Available from: tps://innovation.cms.gov/strategic-direction-whitepaper.
11. Gottlieb L, Colvin JD, Fleegler E, Hessler D, Garg A, Adler N. Evaluating the accountable health communities demonstration project. J Gen Intern Med 2017;32:345–9.
12. Martinez O, Boles J, Muñoz-Laboy M, et al. Bridging health disparity gaps through the use of medical legal partnerships in patient care: a systematic review. J Law Med Ethics 2017;45:260–73.
13. Legal Services Corporation [Internet]. The justice gap: measuring the unmet civil legal needs of low-income Americans; 2017 [accessed 2017 Sept 21]. Available from: https://www.lsc.gov/sites/default/files/images/TheJusticeGap-FullReport.pdf.
14. Klein MD, Beck AF, Henize AW, Parrish DS, Fink EE, Kahn RS. Doctors and lawyers collaborating to help children: outcomes from a successful partnership between professions. J Health Care Poor Underserved 2013;24:1063–73.
15. Rosen Valverde JN, Backstrand J, Hills L, Tanuos H. Medical-legal partnership impact on parents' perceived stress: a pilot study. Behav Med 2019;45:70–7.
16. Ryan AM, Kutob RM, Suther E, Hansen M, Sandel M. Pilot study of impact of medical-legal partnership services on patients' perceived stress and wellbeing. J Health Care Poor Underserved 2012;23:1536–46.
17. Malik FS, Yi-Frazier JP, Taplin CE, et al. Improving the care of youth with type 1 diabetes with a novel medical-legal community intervention: the Diabetes Community Care Ambassador Program. Diabetes Educ 2018;44:168–77.
18. Murphy C [Internet]. Making the case for medical-legal partnerships: an updated review of the evidence, 2013-2020; 2020 [accessed 2021 Dec 9]. Available from: https://medical-legalpartnership.org/wp-content/uploads/2020/10/MLP-Literature-Review-2013-2020.pdf.
19. Sege R, Preer G, Morton SJ, et al. Medical-legal strategies to improve infant health care: a randomized trial. Pediatrics 2015;136:97–106.
20. Lawton E [Internet]. A history of the medical-legal partnership movement; 2014 [accessed 2021 Dec 9].

Available from: https://medical-legalpartnership.org/wp-content/uploads/2015/01/NACHC-Magazine-A-History-of-the-Medical-Legal-Partnership-Movement.pdf.
21. National Center for Medical Legal Partnership [Internet]. Medical-legal partnerships across the U.S.; 2021 [accessed 2021 Dec 10]. Available from: https://medical-legalpartnership.org/partnerships/.
22. Nordin M, Nordin S. Psychometric evaluation and normative data of the Swedish version of the 10-item perceived stress scale. Scand J Psychol 2013;54:502–7.
23. Lee EH. Review of the psychometric evidence of the Perceived Stress Scale. Asian Nurs Res (Korean Soc Nurs Sci) 2012;6:121–7.
24. Cohen S, Janicki-Deverts D. Who's stressed? Distributions of psychological stress in the United States in probability samples from 1983, 2006, and 2009. J Appl Soc Psychol 2012;42:1320–34.
25. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Meas 1977;1:385–401.
26. Weissman MM, Sholomskas D, Pottenger M, Prusoff BA, Locke BZ. Assessing depressive symptoms in five psychiatric populations: a validation study. Am J Epidemiol 1977;106:203–14.
27. Cosco TD, Prina M, Stubbs B, Wu YT. Reliability and validity of the Center for Epidemiologic Studies depression scale in a population-based cohort of middle-aged U.S. adults. J Nurs Meas 2017;25:476–85.
28. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006;166:1092–7.
29. Bevans M, Ross A, Cella D. Patient-Reported Outcomes Measurement Information System (PROMIS): efficient, standardized tools to measure self-reported health and quality of life. Nurs Outlook 2014;62:339–45.
30. HealthMeasures [Internet]. HealthMeasures Scoring Service powered by Assessment Center; 2021 [accessed 2021 Mar 29]. Available from: https://www.assessmentcenter.net/ac_scoringservice.
31. HealthMeasures [Internet]. PROMIS score cut points; 2021 [accessed 2021 Mar 29]. Available from: https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis/promis-score-cut-points.
32. Bartlett SJ, Orbai AM, Duncan T, et al. Reliability and validity of selected PROMIS measures in people with rheumatoid arthritis. PLOS ONE 2015;10:e0138543.
33. National Center for Medical-Legal Partnership [Internet]. National Center for Medical-Legal Partnership; 2018 [accessed 2018 Feb 8]. Available from: http://medical-legalpartnership.org/.
34. Pettignano R, Bliss LR, Caley SB, McLaren S. Can access to a medical-legal partnership benefit patients with asthma who live in an urban community? Health Care Poor Underserved 2013;24:706–17.
35. Billioux A, Verlander K, Anthony S, Alley D. Standardized screening for health-related social needs in clinical settings. Accountable Health Communities Screen Tool Discuss Paper; 2017.
36. Hager ER, Quigg AM, Black MM, et al. Development and validity of a 2-item screen to identify families at risk for food insecurity. Pediatrics 2010;126:e26–e32.
37. National Association of Community Health Centers [Internet]. Protocol for responding to and assessing patients' assets, risks, and experiences; 2017 [accessed 2017 Oct 1]. Available from: http://www.nachc.org/research-and-data/prapare/.
38. National Center for Access to Justice [Internet]. Tracking outcomes: a guide for civil legal aid providers & funders; 2018. Available from: https://ncaj.org/tools-for-justice/outcomes-guide.
39. Ebert DD, Heber E, Berking M, et al. Self-guided Internet-based and mobile-based stress management for employees: results of a randomised controlled trial. Occup Environ Med 2016;73:315–23.
40. Woolhouse H, Mercuri K, Judd F, Brown SJ. Antenatal mindfulness intervention to reduce depression, anxiety and stress: a pilot randomised controlled trial of the MindBabyBody program in an Australian tertiary maternity hospital. BMC Pregnancy Childbirth 2014;14:369.
41. Pocock SJ, Assmann SE, Enos LE, Kasten LE. Subgroup analysis, covariate adjustment and baseline comparisons in clinical trial reporting: current practice and problems. Stat Med 2002;21:2917–30.
42. Assmann SF, Pocock SJ, Enos LE, Kasten LE. Subgroup analysis and other (mis)uses of baseline data in clinical trials. Lancet 2000;355:1064–9.
43. Andraszewicz S, Scheibehenne B, Rieskamp J, Grasman R, Verhagen J, Wagenmakers EJ. An introduction to Bayesian hypothesis testing for management research. J Manag 2015;41:521–43.
44. Jeffreys H. Theory of probability. 3rd ed. Oxford, UK: Oxford University Press; 1961.
45. Lee MD, Wagenmakers EJ. Bayesian cognitive modeling: a practical course. Cambridge, UK: Cambridge University Press; 2013.
46. International RTI [Internet]. Accountable Health Communities (AHC) model evaluation: first evaluation report; 2020 [accessed 2022 July 12]. Available from: https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.
47. Henrikson NB, Blasi PR, Dorsey CN, et al. Psychometric and pragmatic properties of social risk screening tools: a systematic review. Am J Prev Med 2019;57:S13–S24.

Appendix.

Study Screening Instrument–CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3-4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5
	11b	If relevant, description of the similarity of interventions	5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5-7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	5-7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1; 7
	13b	For each group, losses and exclusions after randomisation, together with reasons	7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	2
	14b	Why the trial ended or was stopped	7
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	8-9
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	8-9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	7-8
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8-10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8-10
Other information			
Registration	23	Registration number and name of trial registry	11
Protocol	24	Where the full trial protocol can be accessed, if available	Available on request
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	10

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.