Pragmatic Clinical Trial to Improve Patient Experience Among Adults During Transitions from Hospital to Home: the PArTNER study

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INTRODUCTION: Minority-serving hospitals (MSHs) need evidence-based strategies tailored to the populations they serve to improve patient-centered outcomes after hospitalization.

METHODS: We conducted a pragmatic randomized clinical trial (RCT) from October 2014 to January 2017 at a MSH comparing the effectiveness of a stakeholder-supported Navigator intervention vs. Usual care on post-hospital patient experience, outcomes, and healthcare utilization. Community health workers and peer coaches delivered the intervention which included (1) in-hospital visits to assess barriers to health/healthcare and to develop a personalized Discharge Patient Education Tool (DPET); (2) a home visit to review the DPET; and (3) telephone-based peer coaching. The co-primary outcomes were between-group comparisons of 30-day changes in Patient-Reported Outcomes Measurement Information System (PROMIS) measures of anxiety and informational support (minimum important difference is 2 to 5 units change); a p-value <0.025 was considered significant using intention-to-treat analysis. Secondary outcomes included death, ED visits, or readmissions and measures of emotional, social, and physical health at 30 and 60 days.

RESULTS: We enrolled 1029 adults hospitalized with heart failure (28%), pneumonia (22%), MI (10%), COPD (11%), or sickle cell disease (29%). Over 80% were non-Hispanic Black. Overall, there were no significant between-group differences in the 30-day change in anxiety (adjusted difference: −1.6, 97.5% CI −3.3 to 0.1, p=0.03), informational support (adjusted difference: −0.01, 97.5% CI −2.0 to 1.9, p=0.99), or any secondary outcomes. Exploratory analyses suggested the Navigator intervention improved anxiety among participants with COPD, a primary care provider, a hospitalization in the past 12 months, or higher baseline anxiety; among participants without health insurance, the intervention improved informational support (all p-values <0.05).

CONCLUSIONS: In this pragmatic RCT at a MSH, the Navigator intervention did not improve post-hospital anxiety, informational support, or other outcomes compared to Usual care. Benefits observed in participant subgroups should be confirmed in future studies.

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INTRODUCTION

Heart failure, pneumonia, myocardial infarction (MI), chronic obstructive pulmonary disease (COPD), and sickle cell disease are leading causes of re-hospitalization and adverse health outcomes at minority-serving hospitals (MSHs).[1–3] Now that high 30-day readmissions place hospitals at risk for financial penalties,[4] MSHs will benefit from evidence-based strategies tailored to the populations they serve.[5,6]

Historically, patients and their family caregivers played a minimal or no role in developing hospital-to-home transitional care programs. These programs largely evaluated interventions developed and delivered by clinicians to improve care quality and reduce post-hospital healthcare utilization.[7,8] During focus groups we conducted, patients and caregivers expressed concerns that such strategies do not adequately address their experience during care transitions, including

concerns regarding abandonment, lack of information and confidence in disease self-management and navigating the healthcare system, and increased anxiety due to insufficient readiness and resources to manage their condition after discharge.[9] Improving patient experience represents a priority in value-based models of reimbursement given its importance to patients and association with improvements in patient safety, effective processes of care, treatment adherence, and health outcomes.[10] MSHs generally perform worse on measures of patient experience compared to other hospitals,[11] highlighting the need for evidence-based approaches to improving patient experience during hospital-to-home care transitions in addition to health outcomes at MSHs.

Previous single-center clinical trials examining the roles of community health workers (CHWs) as patient navigators for hospitalized populations suggest the potential for increasing rates of outpatient follow-up after hospital discharge[12,13] and reducing 30-day readmissions.[12] However, these studies and others did not examine patient experience as a primary outcome.[14] In this report, we present the PArTNER study, a single-center pragmatic clinical trial at a MSH that compared the effectiveness of a multifaceted stakeholder-supported Navigator intervention versus Usual care on patient experience and other outcomes. We also describe the barriers and facilitators of successfully implementing the Navigator intervention in real-world settings.

METHODS

Study Design

A more detailed description of the methods is available in the Supplemental Appendix and in previous publications.[9,15] In brief, a multidisciplinary group of stakeholders provided input in defining the intervention and outcomes to ensure the study design addressed their expressed needs regarding the target population, importance of outcomes, and practicality of the intervention (Supplemental Appendix). The PArTNER study employed a pragmatic "real-world" randomized effectiveness trial design comparing the Navigator intervention to Usual care.[16] This trial design was selected to provide rigorous evidence of the effects of the intervention as it would be implemented in routine transitional care management services[17] when compared to Usual care, and to address the needs of stakeholders involved in healthcare decisions.

Participants were recruited from October 2014 to April 2016 in the hospital setting at a single MSH in Chicago, IL. Following baseline data collection, participants were randomized using block-stratified randomization with permuted blocks. To understand the feasibility and effects of the intervention in routine settings, and to minimize participant burden, enrollment and baseline visits occurred as participants received care in the hospital, while evaluation of post-hospital outcomes relied on patient-reported information collected by telephone and review of electronic health records. Research staff conducting recruitment and data collection were masked to the treatment allocation sequence. Staff delivering the intervention and study participants were not masked due to the nature of the intervention.

To understand the barriers and facilitators of successfully implementing the Navigator intervention, we used a mixed-methods approach to assess the completion of each component of the intervention and to conduct interviews with study staff and a convenience sample of participants.

All study participants provided written informed consent. Study procedures were approved by the University of Illinois Institutional Review Board.

Participants

Eligible patients were aged 18 years or older and were hospitalized with a physician diagnosis of heart failure, pneumonia, COPD, MI, or sickle cell disease. Key exclusion criteria included planned transfer to another acute care facility, discharge to a facility other than home, and hospice care.

Intervention and Comparator

All participants received usual healthcare as per their treating medical team. The Navigator intervention was delivered by CHWs and peer coaches during the index hospitalization and for 60 days post-discharge (Fig. 1). The CHWs interviewed participants to identify social barriers to health and healthcare and provided support to promote self-management skills during the index hospitalization and at a home visit within 3 days of discharge. The CHW created a tailored plan for solutions to each barrier that included community resources used by the hospital's social work department. The CHW also explained the discharge process and completed a personalized "Discharge Patient Education Tool" (DPET; Supplemental Appendix) using the patient's documented discharge instructions. The CHW discussed barrier solutions and reviewed the DPET with the participant to address post-discharge social needs, follow-up visits and tests, recommended lifestyle changes, medications, and, if needed, assisted scheduling follow-up appointments. Some elements of the self-management support were tailored to the enrollment condition (e.g., medication recommendations) whereas other elements were generalized (e.g., follow-up visits). Requests for medical advice were referred to the participant's clinicians. During the home visit, a CHW reviewed the personalized plan and helped to address newly identified barriers. Following the CHW-led intervention, Navigator group participants received telephone-based peer-coaching support to continue supports initiated by the CHW.

Outcomes

The two co-primary outcomes were between-group comparisons of the change in Patient-Reported Outcomes Measurement Information System (PROMIS)[18] measures of anxiety and informational support (ability to obtain advice or useful

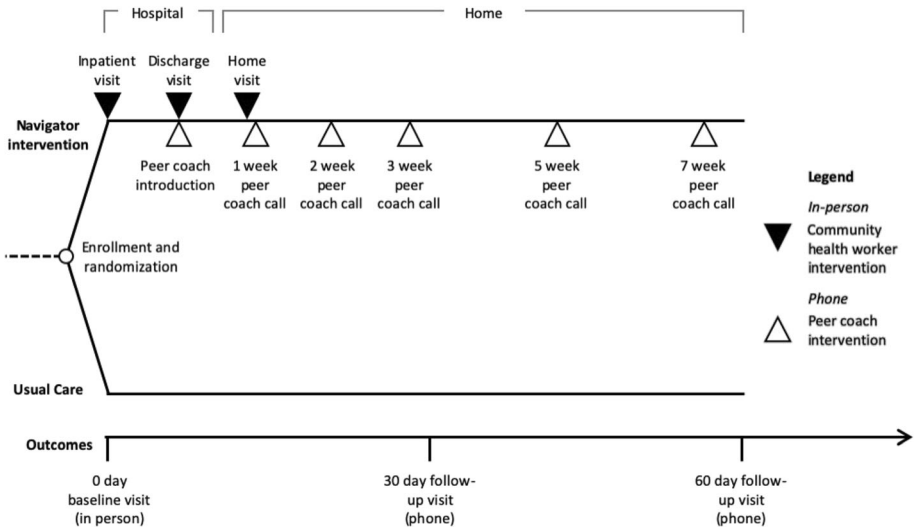

Figure 1 PArTNER study design. In the PArTNER study, participants hospitalized with a physician diagnosis of heart failure, pneumonia, chronic obstructive pulmonary disease (COPD), myocardial infarction, or sickle cell disease were randomly allocated to one of two groups: Navigator intervention or Usual care. The Navigator intervention was initiated during the index hospitalization and continued for 60 days post-discharge and included (1) community health workers (CHWs) who conducted in-person study visits in the hospital and a single home visit 1–3 days post-discharge to assess barriers to patient-centered transitions from hospital to home; and (2) peer coaches introduced on hospital discharge who contacted participants via telephone at approximately 1, 2, 3, 5, and 7 weeks post-discharge to continue supports initiated by CHWs. Following in-person baseline data collection prior to randomization, follow-up outcomes were assessed via telephone at 30 days and 60 days post-discharge.

information) from enrollment to 30 days post-discharge. The PROMIS emotional distress-anxiety short form (version 1.0 SF4a) was used to assess participant anxiety and the PROMIS informational support short form (version 2.0 SF4a) was used to assess informational support. PROMIS scores are standardized such that the US national population has a mean T-score of 50 units with a standard deviation (SD) of 10 units.[19,20] Higher PROMIS T-scores indicate more of the concept being measured (e.g., higher anxiety T-scores indicate more anxiety).[19] A 2 to 5 units difference is considered the minimum important difference.[19,21,22]

Secondary outcomes included between-group comparisons of 60-day changes in anxiety and informational support, as well as 30-day and 60-day changes in other PROMIS measures (instrumental support; emotional support; mental health; physical health). We also assessed attendance at an outpatient visit at 14 days in addition to 30-day and 60-day measures of death, death or hospitalization, and death or hospitalization or ED visit.

Statistical Analysis

We pre-specified the primary analysis as the results of multivariable linear regression models comparing the two co-primary outcomes in the Navigator and Usual care groups after adjusting for age, gender, race, enrollment condition, having a primary care provider, patient-reported usual source of healthcare, patient-reported hospitalization in the prior 12 months, education, and health insurance. We employed a 2-sided Bonferroni-corrected alpha of 0.025 (and 97.5% confidence intervals, CIs) for the two co-primary outcomes, and a 2-sided alpha of 0.05 (and 95% CIs) for all other hypothesis tests. Analyses used a modified intention-to-treat principle, in which we ignored individuals with missing data for the co-primary outcomes. Qualitatively similar results were obtained in sensitivity analyses that used multiple imputations under missing at random and missing not at random assumptions (Supplemental Appendix).

Exploratory analyses examined the potential for heterogeneity of treatment effects for the primary outcomes across pre-specified subgroups. We also conducted per-protocol analyses where we considered the Navigator intervention per protocol if the participant received all components of the CHW-led intervention (barrier assessment, discharge visit, and home visit) and the peer-coaching intervention (completed at least 3 of 5 peer-coaching calls). Post hoc analyses examined the potential for dose-response effects of the Navigator intervention on the primary and secondary outcomes.

Assuming 20% attrition and a Bonferroni correction for two co-primary outcomes, we estimated 1130 participants were needed for 95% or greater power to detect a 2.5-unit difference in T-score for each of the co-primary outcomes. This sample size also provided 80% power to detect a 7.5% absolute reduction in 30-day risk of death or re-hospitalization and 90% power to detect a 10% reduction.

RESULTS

Study Population

A total of 1029 eligible patients were randomized (Fig. 2) to the Navigator intervention (n=518) or Usual care (n=511). The final sample size was less than planned due to the inability to

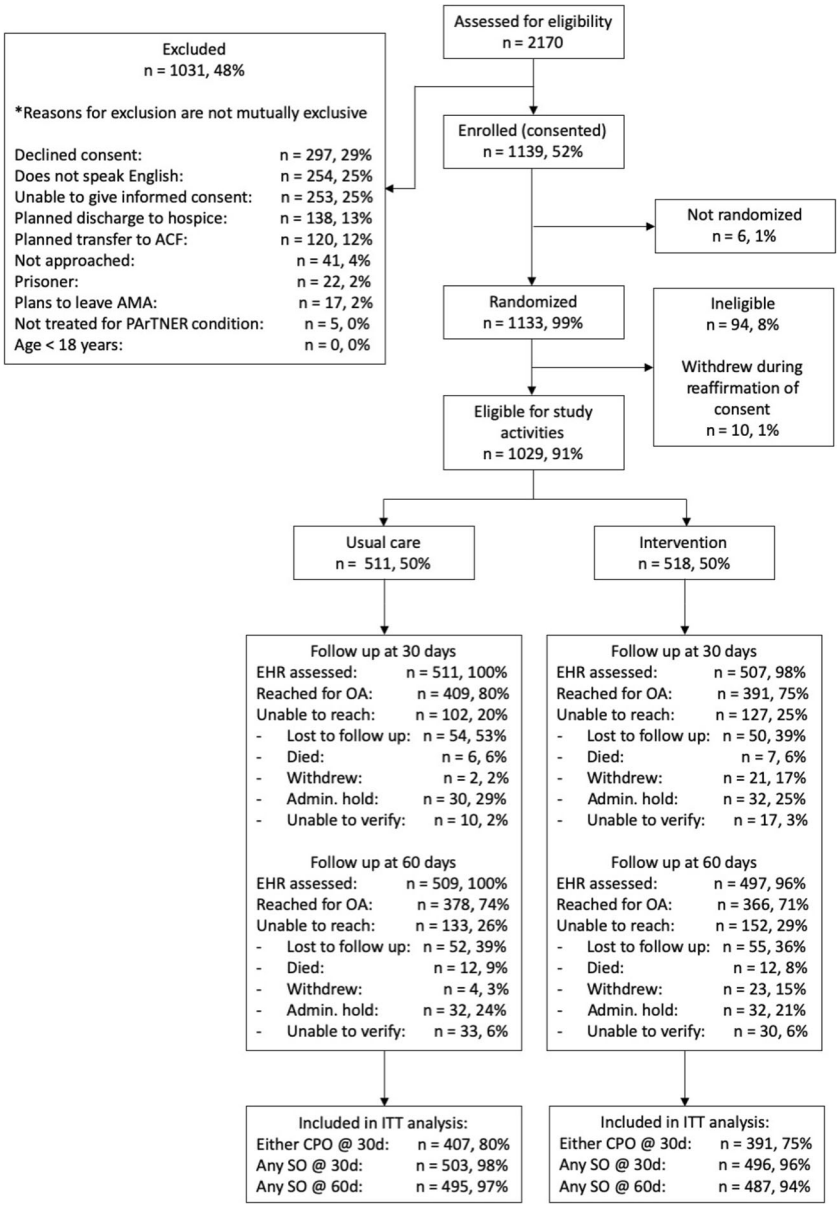

Figure 2 CONSORT diagram for the PArTNER study, *n*=1029 randomized. Figure 2 outlines the Consolidated Standards for Reporting of Trials (CONSORT) Flow Diagram for the PArTNER study. Of the 2170 patients assessed for eligibility, 1031 were excluded for not meeting full eligibility criteria, declining to give consent, or inability to approach the participant. Participants who were not randomized, deemed ineligible after randomization, or declined to re-affirm consent (see Supplemental Appendix) were removed from the final study cohort. Electronic health records (EHR) were reviewed to assess follow-up outcomes in addition to participant self-report (reached for outcomes assessment [OA]). We could not assess EHRs in some participants in the Navigator intervention group due to withdrawal from the study. Participants were considered unable to reach if they were known to have died or withdrew consent before the end of their outcomes assessment window (on or before 44 days post-discharge for the 30-day OA; on or before 81 days post-discharge for the 60-day OA), were unable to be reached during an administrative hold period while awaiting Institutional Review Board approval, source document(s) for participant data were not available, or were unable to be reached for reasons that did not fall into these categories. Participants who provided enough data to compute either of our co-primary outcomes (either CPO at 30d) or sufficient data to compute any of our secondary outcomes at 30 days or 60 days (any SO @ 30d and any SO @ 60D, respectively) were included in the final intention-to-treat analysis. Abbreviations: ACF = acute care facility; AMA = against medical advice; EHR = electronic health record; OA = outcomes assessment; ITT = intention to treat; CPO = co-primary outcomes; SO = secondary outcome.

re-affirm consent in some participants (Supplemental Appendix).

The study cohort had a mean age of 50 years, approximately half were women, and over 80% were non-Hispanic Black (Table 1). The most common enrollment condition was sickle cell disease (29%), followed by heart failure (28%), pneumonia (22%), COPD (11%), and MI (10%). Levels of emotional, social, and physical health at baseline were similar in both groups.

In the Navigator group, 84% reported barriers to health or healthcare. The most common barriers were employment/income insecurity (63%), poor social supports (42%),

Table 1 Baseline (on Enrollment During Hospitalization) Characteristics and Emotional, Social, and Physical Health of Study Population

Characteristic	Overall (*n*=1029)	Usual care (*n*=511)	Intervention (*n*=518)
Demographics			
Age at admission (mean ± SD)	49.9 ± 16.8	49.9 ± 17.0	49.8 ± 16.5
Gender: female	567 (55%)	290 (57%)	277 (53%)
Race: non-Hispanic Black	842 (82%)	422 (83%)	420 (81%)
Socioeconomic resources			
Highest level of education: high school or less	558[a] (54%)	287 (56%)	271[a] (52%)
Has health insurance: yes	989 (96%)	494 (97%)	495 (96%)
Clinical factors			
Enrollment condition			
Sickle cell disease	298 (29%)	148 (29%)	150 (29%)
Heart failure	285 (28%)	140 (27%)	145 (28%)
Pneumonia	231 (22%)	112 (22%)	119 (23%)
COPD	115 (11%)	62 (12%)	53 (10%)
Myocardial infarction	100 (10%)	49 (10%)	51 (10%)
Hospitalization in past 12 months: at least 1	863[f] (84%)	427[d] (84%)	436[b] (84%)
ED visits in past 12 months: at least 1	865[e] (85%)	429[c] (85%)	436[b] (84%)
Source of healthcare			
Usual location for healthcare			
Doctor's office	637[c] (62%)	335[c] (66%)	302 (58%)
Emergency department	273[c] (27%)	124[c] (24%)	149 (29%)
Community health clinic	92[c] (9%)	36[c] (7%)	56 (11%)
Other	23[c] (2%)	12[c] (2%)	11 (2%)
Has a primary care provider: yes	858 (83%)	432 (85%)	426 (82%)
PROMIS scores at enrollment (mean ± SD)			
Anxiety	51.7 ± 10.9	51.5 ± 10.8	51.9 ± 11.1
Informational support	52.2[a] ± 12.5	52.6 ± 12.1	51.9[a] ± 12.8
Emotional support	53.3[a] ± 10.2	53.5[a] ± 9.9	53.2 ± 10.5
Instrumental support	49.9[b] ± 10.5	49.6[a] ± 10.3	50.2[a] ± 10.7
Physical health (global)	37.0[a] ± 7.7	37.2 ± 7.5	36.8[a] ± 7.9
Mental health (global)	45.6 ± 8.1	45.7 ± 7.8	45.5 ± 8.3

The total study population included 1029 individuals. Values above reflect frequency (%) unless otherwise specified. Review of electronic health records and confirmation by treating clinician was used to define diagnosis on hospital admission (enrollment condition). Other information was based on participant-report and an interviewer-administered questionnaire that included PROMIS measures of emotional, social, and physical health. Values of PROMIS measures reflect mean T-scores (±SD) to permit comparisons with the US general population (mean T-score 50, standard deviation of 10)
Abbreviations: SD standard deviation; COPD chronic obstructive pulmonary disease; ED emergency department; PROMIS Patient-Reported Outcomes Measurement Information System
Superscripts denote the number of participants with missing data for that characteristic or measure: [a] = 1 participant; [b] = 2 participants; [c] = 4 participants; [d] = 5 participants; [e] = 6 participants; [f] = 7 participants

transportation needs (40%), housing insecurity (37%), utility insecurity (31%), food insecurity (22%), and interpersonal violence (3%).

Implementation of the Navigator Intervention

The CHWs completed 94% of barrier assessments, 88% of discharge visits, and 82% of home visits. One or more peer-coaching calls were completed in 60% of participants (only 39% completed at least 3 calls). Only 151 (29%) Navigator group participants received the intervention per protocol.

Outcomes

Co-primary Outcomes, Intention-to-Treat. The 30-day co-primary outcomes were collected in 409/511 (80%) Usual care and 391/518 (75%) Navigator group participants. Data to calculate the 30-day changes in anxiety and informational support were available in 391 (75%) of the Navigator group participants. However, a small number of participants in the Usual care group were unable to complete baseline measurements of anxiety or informational support. Therefore, data to calculate the 30-day change in anxiety were available in 406 (79%) Usual care group participants, and data to calculate the 30-day change in informational support were available in 405 (79%) Usual care group participants. Participants with missing data for the co-primary outcomes were 3 years younger than participants without missing data (Supplemental Appendix); otherwise, the two groups were similar. There was a significant within-group reduction in 30-day anxiety in the Navigator group, but not in the Usual care group (Table 2). There were also significant within-group improvements in 30-day informational support in both the Usual care and Navigator groups. In multivariable analyses, we found no significant between-group differences in the 30-day change in either anxiety (adjusted difference: −1.6, 97.5% CI −3.3 to 0.1) or informational support (−0.01, 97.5% CI −2.0 to 1.9).

Co-primary Outcomes, Heterogeneity of Treatment Effects (Figure S4, Figure S5 in Supplemental Appendix). Exploratory analyses suggested greater improvements in 30-day anxiety among Navigator group participants with COPD

Table 2 Thirty- and 60-Day Change in PROMIS Measures of Emotional, Social, and Physical Health

PROMIS scores	Usual care*n*=511 (unadjusted)		Intervention*n*=518 (unadjusted)		Between-group difference (adjusted)	
Primary 30-day changes	**Mean change (97.5% CI)**	***p*-value**	**Mean change (97.5% CI)**	***p*-value**	**Mean difference (97.5% CI)**	***p*-value**
Anxiety	−0.2[b] (−1.4, 0.9)	0.63	−1.7[f] (−2.9, −0.5)	<0.01	−1.6 (−3.3, 0.1)	0.03
Informational support	2.3[c] (1.0, 3.6)	<0.01	2.5[f] (1.1, 3.9)	<0.01	−0.01 (−2.0, 1.9)	0.99
Secondary 30-day changes	**Mean change (95% CI)**	***p*-value**	**Mean change (95% CI)**	***p*-value**	**Mean difference (95% CI)**	***p*-value**
Emotional support	−0.1[e] (−1.1, 0.8)	0.80	−0.1[g] (−1.1, 0.8)	0.79	−0.12 (−1.5, 1.2)	0.86
Instrumental support	1.0[d] (0.1, 2.0)	0.03	0.6[f] (−0.4, 1.5)	0.23	−0.43 (−1.7, 0.93)	0.53
Physical health (global)	4.6[a] (3.8, 5.4)	<0.01	4.4[h] (3.5, 5.2)	<0.01	−0.18 (−1.4, 1.0)	0.76
Mental health (global)	0.8[d] (−0.0, 1.5)	0.06	0.6[h] (−0.2, 1.5)	0.14	−0.06 (−1.2, 1.1)	0.93
Secondary 60-day changes	**Mean change (95% CI)**	***p*-value**	**Mean change (95% CI)**	***p*-value**	**Mean difference (95% CI)**	***p*-value**
Anxiety	0.3[i] (−0.8, 1.4)	0.57	−1.1[n] (−2.3, 0.1)	0.07	−1.4 (−3.1, 0.22)	0.09
Informational support	1.7[k] (0.5, 2.9)	0.01	2.0[o] (0.7, 3.3)	<0.01	0.13 (−1.7, 1.9)	0.88
Emotional support	0.1[l] (−0.9, 1.1)	0.86	−0.1[o] (−1.1, 0.9)	0.79	−0.40 (−1.8, 1.0)	0.59
Instrumental support	0.8[j] (−0.2, 1.8)	0.12	1.0[o] (−0.0, 2.1)	0.05	0.21 (−1.3, 1.7)	0.78
Physical health (global)	3.4[l] (2.5, 4.3)	<0.01	3.6[n] (2.7, 4.5)	<0.01	0.09 (−1.2, 1.4)	0.89
Mental health (global)	−1.3[l] (−2.2, −0.4)	<0.01	−1.0[m] (−1.9, −0.2)	0.02	0.23 (−1.0, 1.5)	0.72

The total study population included 1029 individuals who were asked to complete an interviewer-administered questionnaire that included PROMIS measures of emotional, social, and physical health on enrollment and at follow-up visits at 30 and 60 days (see METHODS). Mean changes for the Usual care and Intervention groups reflect mean (unadjusted) within-person change in T-scores on day 30 or day 60 compared to day 0. A T-score difference of 2 to 5 units is generally considered the minimum clinically important difference; see METHODS. A positive value (>0) for the "30-day changes" and "60-day changes" indicates higher scores on day 30 compared to day 0 and higher scores on day 60 compared to day 0, respectively. Thus, a positive value indicates more of the construct assessed (i.e., higher anxiety, higher informational support, higher emotional support, higher instrumental support, higher physical health, or higher mental health). With the exception of anxiety, a positive difference indicates improvement. For anxiety, a negative difference (<0) indicates improvement. The between-group differences represent adjusted comparisons between groups (Intervention group minus Usual care) using multivariable linear regression. The p-values above are testing the hypothesis that the within-group change or between-group difference is significantly different than 0. The analyses pre-specified a 2-sided alpha =0.025 for comparisons at 30 days between groups (primary time point for analyses of the two co-primary outcomes: anxiety and informational support), and a 2-sided alpha = 0.05 for all other comparisons. There were no significant between-group differences in PROMIS measures of emotional, social, and physical health

Abbreviations: PROMIS Patient-Reported Outcomes Measurement Information System; CI confidence interval

Superscripts denote the number of participants with missing data for that measure:

[a]= 103 participants; [b] = 105 participants; [c] = 106 participants; [d] = 108 participants; [e] = 110 participants; [f] = 127 participants; [g] = 128 participants; [h] = 129 participants; [i] = 136 participants; [j] = 137 participants; [k] = 138 participants; [l] = 139 participants; [m] = 154 participants; [n] = 155 participants; [o] = 157 participants

(adjusted difference −4.9, 95% CI −9.3 to −0.6), a primary care provider (−2.0, 95% CI −3.6 to −0.4), a previous hospitalization in the past 12 months (−1.9, 95% CI −3.5 to −0.3), and higher baseline anxiety (−2.0, 95% CI −4.0 to −0.1). Exploratory analyses also suggested greater improvements in 30-day informational support among Navigator group participants without health insurance (+11.9, 95% CI 2.3 to 21.4).

Per-Protocol and Dose-Response Analyses. Per-protocol and dose-response analyses did not demonstrate an effect of the intervention on the primary and secondary outcomes (Table S3, Table S4 in Supplemental Appendix).

Secondary Outcomes, Intention-to-Treat. Both the Usual care and Navigator groups experienced significant within-group improvements in physical health at 30 days and in informational support, physical health, and mental health at 60 days (Table 2). There was also a significant within-group improvement in instrumental support in the Usual care group at 30 days. However, none of the between-group differences in the PROMIS-related secondary outcomes were significant in multivariable analyses at 30 or 60 days. There were also no significant between-group differences in healthcare utilization and deaths at 14 days, 30 days, and 60 days (Table 3).

Barriers and Facilitators of Implementing Navigator Intervention

We interviewed 19 PArTNER staff members, 2 clinicians who cared for study participants, and 10 participants spanning all enrollment conditions to identify barriers and facilitators of delivering the Navigator intervention. Several overarching themes emerged (Table S7, Table S8 in Supplemental Appendix). Study participants identified several patient-level barriers, including difficulties aligning the patient and navigator schedules, a reduced capacity to manage the demands of their illness and the intervention, and the need for greater personalization between their needs and the information/support they were provided. Study staff highlighted challenges with coordination between various study staff members, alignment between study processes and real-world patient contexts, and integration between the study and hospital operations as barriers to delivering the intervention. Facilitators included having well-structured procedures while also allowing for some flexibility to adapt to patient and situational context, the additional support to enhance self-care, and the perception that study staff members were helpful to participants and hospital staff.

Table 3 Fourteen-, 30-, and 60-Day Healthcare Utilization Outcomes

Healthcare utilization outcome	Usual care *n*=511	Intervention *n*=508	Adjusted OR (95% CI)	*p*-value
Outpatient visit within 1–14 days (self-reported)	137[k] (34%)	112[l] (29%)	0.79 (0.58, 1.1)	0.15
Outpatient visit within 1–14 days (EHR-reported)	236 (46%)	232[c] (46%)	1.0 (0.78, 1.3)	0.97
Death within 0–30 days	4[b] (0.8%)	7[g] (1.4%)	1.8 (0.51, 6.2)	0.37
Death within 0–60 days	9[f] (1.8%)	9[j] (1.8%)	0.95 (0.36, 2.5)	0.91
Death or hospitalization within 0–30 days	100[a] (20%)	112[h] (23%)	1.2 (0.91, 1.7)	0.18
Death or hospitalization within 0–60 days	147[e] (30%)	159[i] (33%)	1.2 (0.91, 1.6)	0.18
Death, hospitalization, or ED visit within 0–30 days	156[a] (31%)	154[h] (31%)	1.0 (0.79, 1.4)	0.79
Death, hospitalization, or ED visit within 0–60 days	210[d] (43%)	216[i] (44%)	1.1 (0.86, 1.5)	0.40

Values for the Usual care and Intervention groups reflect frequency (%). The association p-values represent adjusted odds ratios using multivariable logistic regression. There were no significant associations between the Navigator intervention and healthcare utilization outcomes
Abbreviations: OR odds ratio; EHR electronic health records; ED emergency department
Superscripts denote the number of participants with missing data for that measure:
[a]= 8 participants; [b] = 9 participants; [c] = 11 participants; [d] = 17 participants; [e] = 18 participants; [f] = 19 participants; [g] = 22 participants; [h] = 23 participants; [i] = 31 participants; [j] = 32 participants; [k] = 106 participants; [l] = 130 participants

DISCUSSION

The site of the PArTNER study, a single minority-serving hospital, exposed the remarkable social needs of the population it served—almost two-thirds suffered unemployment/income insecurity, and about two out of five reported housing insecurity, poor social supports, and inadequate transportation. Understanding this environment led to evaluating the effectiveness of a CHW- and peer coach-led Navigator intervention on improving patient experience and outcomes following hospital discharge. Yet, this pragmatic randomized controlled trial (RCT) in 1029 patients hospitalized with heart failure, pneumonia, MI, COPD, or sickle cell disease showed no improvement in participant anxiety or informational support at 30 days with the Navigator intervention. While these conservative Bonferroni adjusted analyses were not significant, the *p*-value for 30-day change in anxiety (adjusted difference: −1.6) was 0.03. Recent recommendations[23] emphasize estimated treatment effects, and the 97.5% CI −3.3 to 0.1 mostly demonstrated a relative reduction in anxiety in the Navigator group. Nonetheless, the intervention yielded no improvements in post-hospital patient experience, outcomes, or healthcare utilization over 60 days. These results are consistent with the RCT evaluating the Camden Coalition's "hot-spotting" approach to improving patient outcomes in healthcare superutilizers with complex social needs.[24] Notably, the mixed-methods approach documented that implementing the Navigator intervention in routine healthcare practice proved to be more challenging than expected.

Exploratory analyses offer some insight into specific subpopulations that might benefit from the Navigator intervention. Exploratory analyses suggested the potential for improving post-hospital anxiety among participants with COPD, a primary care provider, a previous hospitalization in the past 12 months, and higher baseline anxiety. Exploratory analyses also suggested greater improvements in 30-day informational support among Navigator group participants without health insurance. While these findings should be considered hypothesis-generating and interpreted with caution since we did not apply an adjustment for multiple comparisons, they suggest MSHs may benefit from providing navigational services to more targeted groups of patients. Nonetheless, as our study did not significantly improve the primary or secondary outcomes, we cannot advocate for the use of a CHW and phone-based peer-coaching model of a navigator intervention to improve hospital-to-home transitions without some modifications.

Given the size of the PArTNER study, its unique focus on patient experience, and consistent pattern of no difference across multiple measures of emotional, social, and physical health and healthcare utilization, the findings should be acknowledged to contribute to a mixed pattern of results from other RCTs examining the role of navigation services by CHWs, telephone coaching, and other patient navigation services.[6,12,13,24–32] In a study by Balaban and colleagues[12], navigation services delivered by CHWs to high-risk safety-net patients did not improve outpatient follow-up or 30-day readmissions among all participants. However, improved outpatient follow-up and reduced readmissions were observed among those older than 60 years, while participants younger than 60 years demonstrated increased readmissions. Participants older than 60 years were also significantly more likely to complete various components of the intervention in this study, which may explain the differential response. Improved outpatient follow-up has also been observed among medically complex elderly patients[25] and patients of low socioeconomic status[13] who received navigation services administered by social workers via telephone[25] or CHWs via telephone and home visits.[13] However, the interventions in these studies were not successful at reducing 30-day readmissions.[13,25] Several other RCTs involving navigation or transitional care services delivered by CHWs, nurses, or multidisciplinary teams also demonstrate mixed results, including improved readmission rates[26–28] or no difference in readmission

rates.[6,24,29,30] The PArTNER study adds to the growing body of evidence that the effectiveness of navigation services in one population or setting may not transfer to another. The study population, the comparator, implementation fidelity, and prespecified primary outcomes can all affect the applicability of findings in one context to another.

Health system interventions are often multicomponent, and when care or outcomes are not improved, it is unclear if barriers to implementation (fidelity) or lack of efficacy contributed to a lack of effect. While we had relatively high fidelity in implementing the CHW-based intervention, the peer-coaching intervention was less reliably completed (40% did not complete any coaching calls). Our debriefing with study staff and participants determined that a greater alignment between study processes and those of the real-world acute care setting, enhancement of the participants' ability to engage with study staff and community resources, and improved contextualization of the support provided could have further strengthened the effectiveness of the Navigator intervention. We also found substantial evidence of socioeconomic barriers to health and healthcare in our study population (reported by 84%). It is possible the Navigator intervention was insufficient in addressing some barriers in a meaningful way (e.g., employment/income insecurity), or the barriers acted as competing responsibilities for patients who may have prioritized providing for their basic needs over healthcare. These findings could inform the design of future studies,[33] which may benefit from addressing core social issues more broadly, collecting data about participant interest in and engagement with referral to social services, real-time audit-and-feedback mechanisms to promote intervention fidelity, and piloting the bundle of interventions in the actual study context, even if elements of the intervention have been previously used successfully.[12,13]

Our study has several limitations. Our study took place at a single MSH which could limit external validity. Another potential limitation is the missing data for our co-primary outcomes in approximately 20% of participants. Participants with missing data were about 3 years younger compared with those without missing data but did not differ in other baseline characteristics. Although we cannot exclude the potential for selection bias, sensitivity analyses using multiple imputations under missing at random and missing not at random assumptions (Supplemental Appendix) were reassuring and yielded qualitatively and quantitatively similar results as the complete-case analyses. Also, the smaller than planned sample size and difficulty in implementing some aspects of the Navigator intervention may have reduced our ability to detect differences between groups. For example, the peer-coaching calls that were part of the Navigator intervention were less consistently completed than other components (barrier assessments, education during discharge visits, home visits by a CHW), leading to intervention heterogeneity across study participants. Future studies should consider the feasibility of individual components of multicomponent interventions during the design and planning phases to identify opportunities to improve acceptability and adoption before implementing the clinical trial. Lastly, we measured our co-primary outcomes at 30 days after discharge, a time frame consistent with many hospital quality metrics.[4] Our study design precluded the assessment of short-term effects that coincided with the most intensive period of the intervention (peri-discharge period) and long-term impacts of navigation services. Benefits that could have lasting effects beyond the study time frame, like coordinating care or connecting patients with social services, are challenging to measure given the nature of a patient navigator's role in patient management.

In conclusion, a Navigator intervention using CHWs and peer coaches to support patients during hospital-to-home transitions did not improve anxiety or informational support at 30 days among adults hospitalized at a single MSH with heart failure, pneumonia, MI, COPD, or sickle cell disease. Although the intervention was tailored to meet the needs of patients served at a MSH, challenges remain for designing and implementing evidence-based interventions that are adaptable to different patient, provider, and health system contexts. We recommend increased attention during the planning period to ensure that the transitional care interventions are fit-for-purpose and the use of adaptive study designs for such interventions.[34]

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Declarations:

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