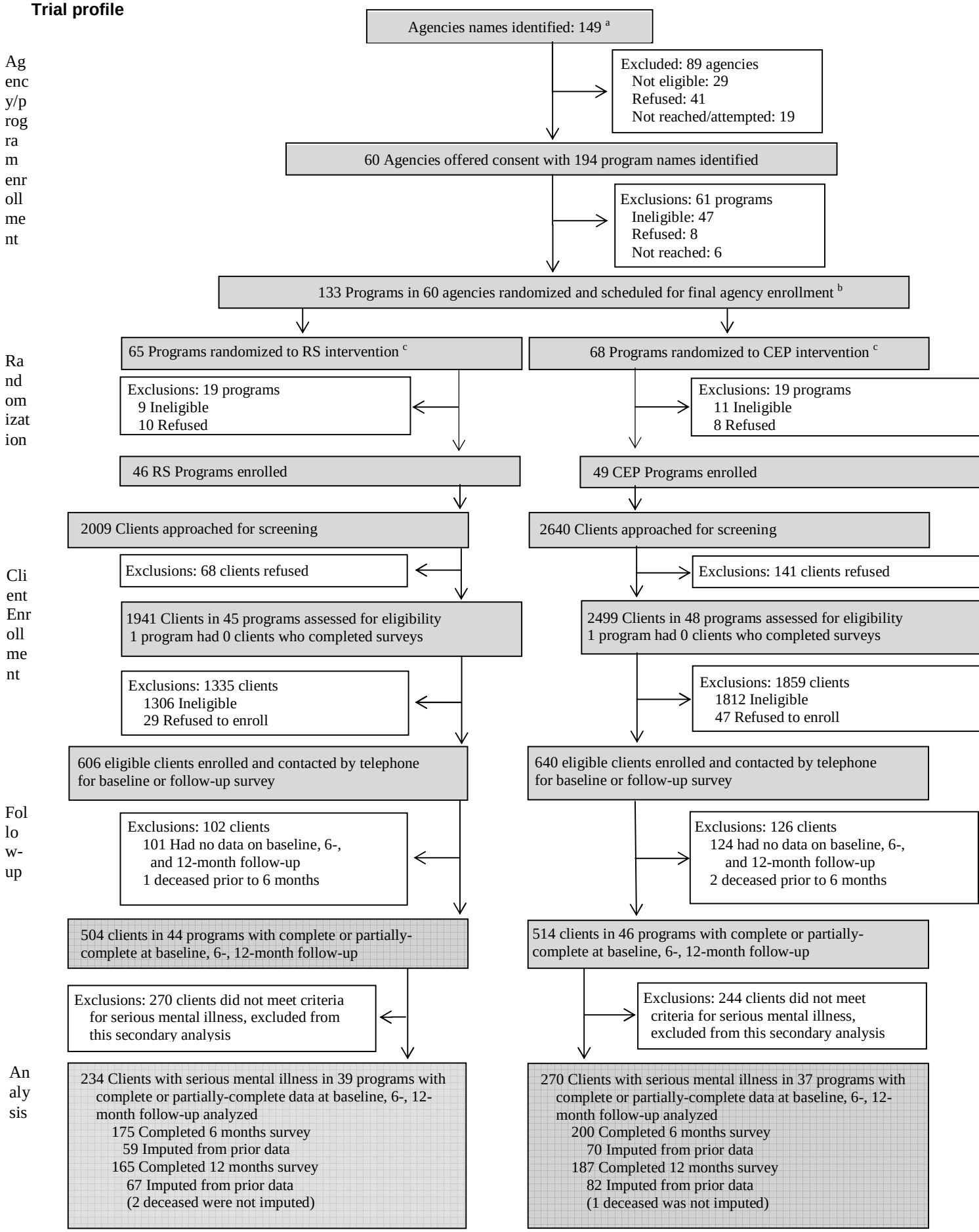
Trial profile



Footnotes:
[a]Agency eligibility criteria: agencies had to provide services for adults or parents of child clients and be financially stable, i.e., not expecting to close during the study time period. Agencies were entities with administrative responsibilities
[b]Program eligibility criteria: programs had to serve at least 15 clients per week, have one or more staff, not focused on psychotic disorders or home services, and be willing to identify a staff liaison
[c]Within sectors, programs were matched on client size and smaller programs (faith-based, hair salons) were joined based on established relationships. Programs/clusters were randomized within communities, but a few unique programs were randomized across communities. We used a random number generator and CPIC Council members who provided seed numbers to initiate randomization. Randomization was overseen by a statistician not involved in recruitment.

Supplementary Appendix for

Comparative Effectiveness of Community Coalitions and Program Technical Support for Depression Quality Improvement on Adults with Serious Mental Illness in Under-Resourced Communities

Table S1. CPIC parent study screening, enrollment, and data completion status by service sector[a]

	Overall		Primary care		Mental health		Substance abuse		Homeless		Social community	
	N	%	N	%	N	%	N	%	N	%	N	%
Total approached for screening	4649		1478		463		827		673		1208	
Refused screening	209		79		5		28		17		80	
Screened	4440		1399		458		799		656		1128	
Screened but not eligible for study												
Modified PHQ-8<10	2965	66.8	905	64.7	221	48.3	520	65.1	400	61.0	919	81.5
Modified PHQ-8≥10 but no contact information provided	153	3.4	89	6.4	5	1.1	5	0.6	43	6.6	11	1.0
Eligible for study												
Eligible but refused	76	1.7	32	2.3	10	2.2	4	0.5	8	1.2	22	2.0
Eligible and enrolled	1246	28.1	373	26.7	222	48.5	270	33.8	205	31.3	176	15.6
Excluded from the CPIC parent study sample												
No data on baseline, 6-mo, and 12-mo follow-up or deceased prior to 6 month	228	18.3	83	22.3	27	12.2	40	14.8	43	21.0	35	19.9
Parent study sample: completed 1 or more surveys at baseline, 6-mo, or 12-mo follow-up	1018	81.7	290	77.7	195	87.8	230	85.2	162	79.0	141	80.1
SMI status of CPIC parent study sample[b]												
Without serious mental illness	514	50.5	173	59.8	88	45.1	86	37.2	70	43.3	96	68.4
With serious mental illness	504	49.5	117	40.2	107	54.9	144	62.8	92	56.7	45	31.6
Subgroup with serious mental illness[b]												
Completed 6-mo survey	375	74.5	91	78.4	84	78.9	97	66.9	69	74.9	35	77.6
Imputed from prior data	129	25.5	25	21.6	23	21.1	48	33.1	23	25.1	10	22.4
Completed 12-mo survey	352	70.2	80	70.1	75	70.8	90	62.5	72	78.3	35	77.8
Imputed from prior data[c]	149	29.8	34	29.9	31	28.2	54	37.5	20	21.7	10	22.2

[a]Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis

[b]Total participants in each row below may not sum to numbers in the "Overall" column due to imputation procedures for missing data

[c]2 deceased in Primary Care and 1 in Mental Health were not imputed

TABLE S2. Intervention effects on primary and community-prioritized outcomes at 12 months among participants with serious mental illness[a]

	Unadjusted Estimates[b]						Adjusted Analysis[c]		
	RS			CEP			CEP vs RS		
	Total N	N	%	Total N	N	%	OR	95% CI	p
Primary outcomes									
Poor mental health quality of life (MCS-12≤ 40)[d]	159	88	55	177	92	52	.84	.55-1.28	.407
PHQ-9 ≥10[e]	160	122	76	176	124	71	.88	.53-1.46	.614
Community-prioritized (secondary)									
Mental wellness[f]	162	59	36	178	74	42	1.17	.62-2.18	.608
Homelessness or ≥ 2 risk factors for homelessness[g]	160	64	40	177	66	37	.95	.59-1.53	.819
Any behavioral health hospitalizations, past 6 months	162	8	5	178	11	6	.87	.37-2.06	.751

[a] Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis

[b] Raw data without weighting or imputation

[c] Adjusted analyses used multiply imputed data, weighted for eligible sample for enrollment; logistic regression models adjusted for baseline status of the dependent variable, age, race/ethnicity, 12-month depressive disorder, and community and accounted for the design effect of the cluster randomization

[d] MCS-12 = mental component summary score of the Short Form-12. MCS-12 ≤ 40 = one standard deviation below the population mean

[e] Nine-item PHQ. Possible scores range from 0 to 27, with higher scores indicating greater depression severity

[f] At least good bit of time on any of three items: feeling peaceful or calm, being a happy person, having energy

[g] Homeless or living in a shelter, or at least two risk factors of four (at least two nights homeless, food insecurity, eviction, financial crisis)

TABLE S3. Intervention effects on services utilization at 12 months among participants with serious mental illness[a]

	Unadjusted Estimates[b]						Adjusted Analysis[c]		
	RS			CEP			CEP vs RS		
	Total N	M	SD	Total N	M	SD	IRR	95% CI	p
Healthcare sector visits for depression[d e]	160	11.1	25.1	177	13.2	24.9	1.06	.65-1.72	.821
Outpatient primary care services for depression	161	1.0	2.8	177	1.1	2.8	1.19	.57-2.48	.629
Mental health outpatient visits	161	7.1	17.7	177	7.0	13.1	.92	.61-1.39	.678
Mental health outpatient visits received advice for medication	159	3.6	8.6	177	4.4	9.8	1.06	.64-1.75	.817
Mental health outpatient visits received counseling	160	4.7	9.8	177	5.3	11.6	.97	.59-1.62	.920
Community sector visit for depression [f]	161	3.0	1.9	177	5.3	23.8	1.54	.69-3.44	.284
Religious services for depression	161	2.0	1.6	177	1.2	7.1	.71	.26-1.92	.489

[a] Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis.

[b] Raw data without weighting or imputation

[c] Adjusted analyses used multiply imputed data, weighted for eligible sample for enrollment; Poisson regression models (presented as incidence rate ratios, IRR), adjusted for baseline status of the dependent variable, age, race/ethnicity, 12-month depressive disorder, and community and accounted for the design effect of the cluster randomization

[d] Total healthcare sector visits for depression defined as outpatient primary care services for depression; emergency or urgent care visits for alcohol, drug, and mental health problems; mental health specialty outpatient visits; outpatient substance abuse services for depression

[e] For all service settings, depression-related visits were defined as services for which clients reported talking about depression or medications for depression; counseling for depression, stress, or emotional problems; or being referred to specialty mental health services

[f] Community sector visits for depression defined as homeless and social/community sector services for depression

Longitudinal analysis

Although the study design called for the CEP intervention to be active only during the first 6 months post-baseline, as a sensitivity analysis, we conducted a longitudinal analysis using all waves of data (baseline, 6 months, 12 months) without response weights, adjusting for the same set of baseline covariates as in the primary analysis. We carried out analyses both on data sets where imputation procedures encompassed the entire duration of the study and on data sets where only baseline values were imputed, thereby relying on the implicit missing-at-random assumption widely invoked in analyses using mixed-effects models for unbalanced repeated measures(1). For these longitudinal analyses, the PHQ-8 instead of PHQ-9 was used as a primary outcome (depression severity cut-points for both scales are the same, ≥ 10; PHQ-8 does not include suicide risk item), as PHQ-8 data was available at all time points(2). The PHQ-9 was administered in the 6- and 12-month follow-up surveys but not at baseline.

In analyzing a binary dependent variable (e.g. MCS12$\leq$40), we fitted a 3-level mixed-effect logistic regression models using the GLIMMIX procedure, incorporating terms for intervention condition, time point, and condition-by-time-point interactions and considering alternative covariance structures. From the fitted model, we evaluated a contrast involving a linear combination of coefficients to test intervention effects at each endpoint (baseline, 6 months, 12 months) and tested differences between intervention groups in change from baseline to 6 months, and 12 months. For count variables (e.g. number of healthcare sector visits for depression), the GLIMMIX procedure with the Poisson distribution failed to converge. As a result, we only present results from mixed-effect logistic regression models for binary outcomes based on raw data. The results are presented in Tables S4.

We also utilized a generalized estimating equation (GEE) framework with a logistic link for binary outcomes and a Poisson link for count data across multiply imputed datasets. Specifically, we used the SAS GENMOD procedure assuming exchangeable correlation at the program level. The results are presented in Tables S5-6**.**

References

1. Collins LM, Schafer JL, Kam C-M: A comparison of inclusive and restrictive strategies in modern missing data procedures. Psychological Methods 6: 330–351, 2001.

2. Kroenke K, Strine TW, Spitzer RL, et al.: The PHQ-8 as a measure of current depression in the general population. Journal of affective disorders 114: 163–173, 2009.

TABLE S4. Intervention effects on primary and community-prioritized outcomes from mixed-effect logistic regression models[a b]

	CEP vs. RS at specific time			CEP vs. RS in change from baseline		
Primary outcomes	OR	95% CI	p	OR	95% CI	p
Poor mental health quality of life (MCS-12 ≤ 40)[c]						
Baseline	.96	.64-1.44	.852			
6-month follow-up	.58	.38-.89	.013	.61	.35-1.04	.069
12-month follow-up	.92	.60-1.40	.687	.95	.54-1.69	.867
PHQ-8 ≥10[d]						
Baseline	1.29	.46-3.64	.63			
6-month follow-up	.54	.31-.94	.029	.42	.14-1.21	.108
12-month follow-up	.68	.41-1.14	.143	.53	.17-1.71	.287
Community-prioritized (secondary)						
Mental wellness[e]						
Baseline	1.00	.64-1.56	.993			
6-month follow-up	1.89	1.17-3.05	.01	1.89	1.05-3.39	.033
12-month follow-up	1.44	.91-2.27	.121	1.44	.78-2.65	.242
Homelessness or ≥2 risk factors for homelessness[f]						
Baseline	.52	.32-.86	.01			
6-month follow-up	.42	.25-.71	.001	.81	.46-1.42	.458
12-month follow-up	.69	.41-1.15	.157	1.32	.72-2.40	.369
Any behavioral health hospitalizations, past 6 months						
Baseline	1.39	.84-2.32	.199			
6-month follow-up	.56	.28-1.11	.094	.40	.18-.86	.02
12-month follow-up	.86	.38-1.95	.717	.62	.24-1.55	.303

[a]Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis

[b]Adjusted analyses used data sets where only baseline values were imputed; 3-level mixed-effect logistic regression models adjusted for age, race/ethnicity, education, 12-month depressive disorder, and community.

[c] MCS-12 = mental component summary score of the Short Form-12. MCS-12 ≤ 40 = one standard deviation below the population mean

[d] Eight-item PHQ. Possible scores range from 0 to 24, with higher scores indicating greater depression severity

[e]At least good bit of time on any of three items: feeling peaceful or calm, being a happy person, having energy

[f] Homeless or living in a shelter, or at least two risk factors of four (at least two nights homeless, food insecurity, eviction, financial crisis)

TABLE S5. Intervention effects on primary and community-prioritized outcomes from logistic regression models with generalized estimating equations[a b]

	CEP vs. RS at specific time			CEP vs. RS in change from baseline		
Primary outcomes	OR	95% CI	p	OR	95% CI	p
Poor mental health quality of life (MCS-12 ≤ 40)[c]						
Baseline	.95	.65-1.39	.798			
6-month follow-up	.61	.41-.92	.019	.64	.37-1.10	.107
12-month follow-up	.82	.56-1.20	.302	.86	.51-1.46	.571
PHQ-8 ≥10[d]	.					
Baseline	1.10	.48-2.53	.812			
6-month follow-up	.66	.37-1.18	.156	.60	.25-1.47	.264
12-month follow-up	.77	.50-1.17	.217	.69	.27-1.75	.437
Community-prioritized (secondary)						
Mental wellness[e]	.					
Baseline	1.06	.73-1.54	.744			
6-month follow-up	1.69	1.05-2.73	.032	1.59	.99-2.56	.054
12-month follow-up	1.27	.79-2.04	.308	1.20	.63-2.27	.568
Homelessness or ≥2 risk factors for homelessness[f]						
Baseline	.56	.35-.89	.015			
6-month follow-up	.51	.35-.75	<.001	.91	.56-1.47	.702
12-month follow-up	.70	.43-1.13	.141	1.26	.66-2.39	.477
Any behavioral health hospitalizations, past 6 months						
Baseline	1.38	.90-2.10	.137			
6-month follow-up	.56	.32-1.00	.05	.41	.22-.77	.005
12-month follow-up	.78	.38-1.63	.505	.57	.25-1.28	.17

[a]Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis

[b]Adjusted analyses used multiply imputed data; logistic regression models with generalized estimating equations (GEE) adjusted for age, race/ethnicity, education, 12-month depressive disorder, and community.

[c] MCS-12 = mental component summary score of the Short Form-12. MCS-12 ≤ 40 = one standard deviation below the population mean

[d] Eight-item PHQ. Possible scores range from 0 to 24, with higher scores indicating greater depression severity

[e]At least good bit of time on any of three items: feeling peaceful or calm, being a happy person, having energy

[f] Homeless or living in a shelter, or at least two risk factors of four (at least two nights homeless, food insecurity, eviction, financial crisis)

TABLE S6. Intervention effects on service utilization from Poisson regression models with generalized estimating equations[a] [b]

		CEP vs. RS at specific Time		CEP vs. RS in change from baseline		
Healthcare sector visits for depression[c] [d]	IRR	95% CI	p	IRR	95% CI	p
Baseline	.96	.70-1.31	.79			
6-month follow-up	.90	.59-1.38	.624	.94	.61-1.45	.773
12-month follow-up	.94	.61-1.46	.798	.99	.58-1.67	.957
Outpatient primary care services for depression						
Baseline	1.18	.77-1.80	.44			
6-month follow-up	1.17	.74-1.87	.496	.99	.56-1.77	.986
12-month follow-up	1.00	.52-1.91	.994	.85	.36-1.97	.688
Mental health outpatient visits						
Baseline	.92	.62-1.37	.683			
6-month follow-up	.65	.41-1.05	.078	.71	.46-1.09	.114
12-month follow-up	.81	.47-1.40	.445	.88	.50-1.54	.646
Mental health outpatient visits received advice for medication						
Baseline	1.15	.81-1.63	.432			
6-month follow-up	.52	.32-.83	.006	.45	.27-.74	.002
12-month follow-up	.83	.51-1.35	.451	.72	.44-1.19	.2
Mental health outpatient visits received counseling past 6 months						
Baseline	1.13	.72-1.77	.588			
6-month follow-up	.56	.35-.90	.016	.50	.29-.85	.011
12-month follow-up	.88	.51-1.53	.646	.78	.45-1.35	.365
Community sector visit for depression[e]						
Baseline	1.06	.59-1.92	.836			
6-month follow-up	1.19	.60-2.35	.612	1.12	.51-2.45	.777
12-month follow-up	1.68	.81-3.51	.165	1.58	.59-4.24	.361
Religious services for depression						
Baseline	.90	.48-1.68	.731			
6-month follow-up	1.29	.61-2.73	.502	1.44	.63-3.31	.387
12-month follow-up	.92	.37-2.27	.849	1.02	.34-3.04	.966

[a]Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis

[b]Adjusted analyses used multiply imputed data; Poisson regression models with generalized estimating equations (GEE) adjusted for age, race/ethnicity, education, 12-month depressive disorder, and community; IRR = incidence rate ratio.

[c] Total healthcare sector visits for depression defined as outpatient primary care services for depression; emergency or urgent care visits for alcohol, drug, and mental health problems; mental health specialty outpatient visits; outpatient substance abuse services for depression

[d] For all service settings, depression-related visits were defined as services for which clients reported talking about depression or medications for depression; counseling for depression, stress, or emotional problems; or being referred to specialty mental health services

[e] Community sector visits for depression defined as homeless and social/community sector services for depression

TABLE S7. Intervention effects on primary and community-prioritized outcomes at 6 months from Intervention-by-serious mental illness interaction model

	Participants without SMI			Participants with SMI					
	CEP vs RS			CEP vs RS			Interaction effects		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Primary outcomes									
Poor mental health quality of life (MCS-12≤ 40)[a]	.81	.55-1.19	.279	.63	.41-.96	.032	.78	.44-1.38	.383
PHQ-9 ≥10[b]	.92	.49-1.76	.793	.59	.30-1.18	.121	.64	.25-1.61	.305
Community-prioritized (secondary)									
Mental wellness[c]	1.61	1.03-2.53	.039	1.97	1.10-3.52	.026	1.22	.62-2.41	.557
Homelessness or ≥ 2 risk factors for homelessness[d]	.76	.35-1.67	.447	.49	.29-.82	.009	.64	.24-1.70	.322
Any behavioral health hospitalizations, past 6 months	.58	.11-3.04	.477	.45	.23-.90	.024	.78	.12-5.14	.775

Intervention-by-Sector interaction models used multiply imputed data, weighted for eligible sample for enrollment; logistic regressions adjusted for baseline status of the dependent variable, age, race/ethnicity, 12-month depressive disorder, and community and accounted for the design effect of the cluster randomization. Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis.

[a] MCS-12 = mental component summary score of the Short Form-12. MCS-12 ≤ 40 = one standard deviation below the population mean.

[b] Nine-item PHQ. Possible scores range from 0 to 27, with higher scores indicating greater depression severity

[c] At least good bit of time on any of three items: feeling peaceful or calm, being a happy person, having energy

[d] Homeless or living in a shelter, or at least two risk factors of four (at least two nights homeless, food insecurity, eviction, financial crisis)

TABLE S8. Intervention effects on services utilization at 6 months from Intervention-by-serious mental illness interaction model

	Participants without SMI			Participants with SMI					
	CEP vs RS			CEP vs RS			Interaction effects		
	IRR	95% CI	p	IRR	95% CI	p	IRR	95% CI	p
Healthcare sector visits for depression[a b]	1.05	.34-3.30	.914	.87	.57-1.32	.497	.83	.31-2.21	.666
Outpatient primary care services for depression	1.32	.74-2.33	.330	1.13	.73-1.74	.581	.86	.42-1.76	.664
Mental health outpatient visits	.83	.27-2.53	.685	.70	.44-1.10	.118	.85	.33-2.18	.701
Mental health outpatient visits, received advice for medication	.52	.15-1.79	.241	.43	.28-.66	<.001	.83	.27-2.58	.717
Mental health outpatient visits received counseling	.87	.33-2.26	.732	.55	.35-.87	.012	.64	.29-1.42	.249
Community sector visit for depression[c]	1.99	.81-4.88	.131	1.36	.67-2.78	.393	.68	.21-2.20	.519
Religious services for depression	2.66	.93-7.61	.067	2.84	1.22-6.60	.016	1.07	.29-3.94	.918

Intervention-by-Sector interaction models used multiply imputed data, weighted for eligible sample for enrollment; Poisson regressions adjusted for baseline status of the dependent variable, age, race/ethnicity, education, 12-month depressive disorder, and community and accounted for the design effect of the cluster randomization. Serious mental illness, defined as the presence of 1 or more of the following: severe major depressive disorder (PHQ-8 score ≥ 20), lifetime history of bipolar disorder or psychosis.

[a] Total healthcare sector visits for depression defined as outpatient primary care services for depression; emergency or urgent care visits for alcohol, drug, and mental health problems; mental health specialty outpatient visits; outpatient substance abuse services for depression

[b] For all service settings, depression-related visits were defined as services for which clients reported talking about depression or medications for depression; counseling for depression, stress, or emotional problems; or being referred to specialty mental health services

[c] Community sector visits for depression defined as homeless and social/community sector services for depression