

A Call for Inclusivity: The Feasibility of Engaging Patients with Serious Mental Illness and Cancer in a Randomized Trial





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Background

- Patients with serious mental illness (SMI) experience <u>barriers to cancer care</u>, 1,2 including being:
 - Less likely to receive preventative cancer screening.
 - More likely to present with later-stage disease.
 - Less likely to receive guideline-concordant care.
- Early psychiatry involvement can protect against cancer care disruptions. 1
- Patients with SMI are <u>systematically excluded</u> from clinical trials.
- Patients with SMI experience barriers to technology use.3

Specific Aims

- Assess the <u>feasibility</u> of a randomized collaborative-care trial for adults with SMI and cancer during the pandemic, by examining:
 - Consent rates
 - Trial completion
 - Predominant modality of study assessments

Methods

- Conducted single-site, 24-week randomized trial that examined the impact of BRIDGE (person-centered collaborative care including proactive psychiatry consultation and case management) on cancer care and psychiatric illness severity for adults with SMI and a recent cancer.
- Identified patients using a population-based registry and community-based referrals.
- Clinicians consented patients verbally.
- Researchers offered multiple modalities (in-person, phone, email) to complete study assessments.
- Patients reported depression (Patient Health Questionnaire, (PHQ-9)) and anxiety (Generalized Anxiety Disorder (GAD-7)) symptoms at 6, 12 and 24 weeks.
- Clinicians assessed psychiatric illness severity (Brief Psychiatric Rating Scale (BPRS)) at 12 and 24 weeks.
- Researchers defined feasibility as enrolling 120 patients in 36 months and consenting 60% of approached patients to the study.
- Tracked enrollment, consent and trial completion rates pre- and post-COVID-19.

Results

Table 1: Enrollment and Consent Rates in the BRIDGE trial

Goal	Result	Ove
Enroll 120 patients in 36 months	120 patients enrolled in 31 months	201
approached patients consent to enroll in study	85% of approached patients consented	

Eligible 151 Approached 146 Consented 124 (84.9%) Enrolled 120
Consented 124 (84.9%)
Enrolled 120
Withdrew 5
Deceased 10

(May 2019 -		Post-COVID-19 (April 2020 - Dec 2021)		
Eligible	58	Eligible	93	
Approached	58	Approached	88	
Consented	54 (93.1%)	Consented	70 (79.6%)	
Enrolled	53	Enrolled	67	

Table 2: Trial Completion Rates in the BRIDGE trial

		Post-COVID-19 (April 2020		
		- Dec 2021)		
PHQ-9 and GAD-7		PHQ-9 and GAD-7		
6-week	97.92% (n=47)	6-week	95.83% (n=69)	
12-week	95.12% (n=39)	12-week	87.34% (n=69)	
24-week	93.10% (n=27)	24-week	78.02% (n=71)	
Clinician administered		Clinician administered		
assessment (BPRS)		assessment (BPRS)		
12-week	97.56% (n=40)	12-week	84.81% (n=67)	
24-week	89.66% (n=26)	24-week	75.82% (n=69)	

Table 3: Predominant Modality of the BPRS throughout the BRIDGE trial

		Post-COVID-19 (April 2020 - Dec 2021)		
12-week	in-person, 67.50% (n=27)	12-week	by phone, 68.66% (n=46)	
24-week	in-person, 53.85% (n=14)	24-week	by phone, 81.16% (n=56)	

Conclusions

- Patients with SMI and cancer <u>can enroll in and complete</u> a randomized trial of person-centered collaborative care.
- Exclusion criteria related to preexisting mental illness need to be reconsidered.
- Flexible, hybrid, and targeted approaches can promote trial inclusion for marginalized populations.

Citations

1. Irwin KE, Park ER, Fields LE, et al. Bridge: Person-Centered Collaborative Care for Patients with Serious Mental Illness and Cancer. *Oncologist*. 2019;24(7):901-910. doi:10.1634/theoncologist.2018-0488

2. Irwin KE, Callaway CA, Corveleyn AE, et al. Study protocol for a randomized trial of bridge: Person-centered collaborative care for serious mental illness and cancer. *Contemp Clin Trials*. 2022;123:106975. doi:10.1016/j.cct.2022.106975 3. Young, A. S., Cohen, A. N., Niv, N., Nowlin-Finch, N., Oberman, R. S., Olmos-Ochoa, T. T., Goldberg, R. W., & Whelan, F. (2020). Mobile Phone and Smartphone Use by People With Serious Mental Illness. Psychiatric services (Washington, D.C.), 71(3), 280–283. https://doi.org/10.1176/appi.ps.201900203







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