Virtual engagement in an ongoing clinical trial for individuals with serious mental illness during the COVID-19 pandemic

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Background

- Individuals with serious mental illness –Schizophrenia, Bipolar, Major Depressive Disorder- experience increased cancer mortality due to inequities in cancer care.[1,2]
- Individuals with serious mental illness (SMI) are underrepresented in research and are excluded from half of clinical trials.[2]
- Technology access is variable among this population, particularly with computer and smartphone usage necessary for remote research and care.
- The COVID-19 pandemic threatens to widen health disparities and increase barriers to research for individuals with SMI.

Objectives

- To characterize trial procedures during COVID-19 for an ongoing Randomized Controlled Trial (Bridge).
- To identify strategies to promote research participation and engagement and implications for future research design.

Methods

- We developed procedures to promote virtual engagement for Bridge, a 24-week trial for patients with SMI and cancer, and their caregivers.[3]
- Bridge is a person-centered, team-based care model including proactive psychiatry consultation, case management, and collaboration with oncology.
  - Patients are proactively identified using a registry embedded in the electronic health record and consented verbally.
  - All patients complete patient-reported measures and clinician assessments of psychiatric illness severity.
  - Intervention patients (Bridge) have an initial clinical evaluation of treatment goals and barriers to cancer care.
- We employed virtual engagement strategies to in the post COVID-19 period:
  - **Assessed** technology access and preference for all participants
  - **Utilized** multiple modalities for outreach (Zoom, Facetime, text, email, partnership with caregivers)
  - **Tracked** access, consent rates, and assessment modalities pre-and post COVID

Results

- We tracked access to technology and consent, and assessment modalities pre-and-post COVID-19.

Pre-COVID (May 2019- March 2020)

Identified/ month	Total Eligible	Consented
64 (average)	58 (total)	**53/58 (91%)**

Consent Modality	N (%)
In- Person	**40 (75.5%)**
Telephone	13 (24.5%)
Patient Assessment Modality	**N (%)**
In-person	**41 (77.4%)**
Telephone	12 (22.6%)
Initial Assessment Modality (Bridge Patients)	**N (%)**
In-person	**22/25 (88%)**
Telephone	3/25 (12%)

Post-COVID onset (April-Oct 2020)

Identified/ month	Total Eligible	Consented
45 (average)	20 (total)	**15/20 (75%)**

Consent Modality	N (%)
Telephone	**15 (100%)**
Patient Assessment Modality	**N (%)**
In-Person	2 (13.3%)
Email	4 (26.7%)
Telephone	**9 (60%)**
Initial Assessment Modality (Bridge Patients)	**N=6**
In-person	2
Virtual (Telehealth/phone)	**4**

- Prior to COVID, the registry identified 64 individuals with SMI and a new cancer appointment/month. Post COVID onset, 45 individuals were identified/ month.
- Following shift to remote procedures, all consents and most assessments were completed over the telephone or by videoconferencing.
- 8% of study participants lacked access to a personal phone (mobile or landline).

Technology Access	
Personal Phone	92% had access to a phone
Email	47% had access to email

Conclusions and Next Steps

- Fewer new oncology consultations during the pandemic corresponded to slower study accrual and lower consent rate.
- It was feasible to enroll a marginalized population with flexible, multi-modal, patient-centered outreach during COVID-19.
- Targeted models of virtual engagement merit further investigation to promote virtual research access for marginalized populations.

References

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Study funded by the National Cancer Institute (NCI) K08 Career Development Award 232922 (Irwin, PI)