STUDY TITLE: Attitudes towards receiving mental health care using telehealth during the COVID-19 pandemic

PRINCIPAL INVESTIGATOR:

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Indicate Vulnerable Population(s) to be Enrolled	☐ Children (you must **complete Appendix A** in addition to this protocol document if you plan to enroll children) ☐ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☐
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☐
Research has U.S. Federal government funding via direct award or a sub-award (e.g., NIH, NSF, other federal agencies or departments)	☐

1.0 Purpose and rationale of the study:

During the COVID-19 pandemic, starting around mid-March 2020, most healthcare providers began offering telehealth appointments to minimize the risk of spreading COVID-19 infection. While mental health care is considered essential care, most healthcare organizations including academic hospitals began offering telehealth primarily, with limited presence of staff onsite for any long acting injectable medication administrations or if care cannot be administered through telehealth. This care has been offered through various forms including phone calls and video calls through various platforms not limited to Zoom, doxy.me, Doximity, and WhatsApp.

During this time private insurance companies and public aid Medicare and Medicaid all have offered reimbursement for care at a similar rate as in-person visits. This had not

been the case previously, and telehealth for mental health care had been primarily limited to rural areas. However, it is uncertain how long insurance companies will continue to pay for these telehealth services at a similar rate. The COVID-19 pandemic situation remains uncertain with potential for a second wave with reduction in limits of social distancing.

Psychiatric and mental health care is different from other forms of medical care in that it is a more emotionally intimate and personal setting. However, with changes in technology, it may be possible to provide continued mental health care through telehealth appointments to prevent the risk of spread of COVID-19 infection and maintain social distancing.

Based on our literature review, we have found a few articles showing promising outcomes for using telehealth appointments specifically for mental health care during the COVID-19 pandemic. An article published in April 2020 by [1] Kannarkat, J.T indicates outpatient attendance has increased dramatically through use of telehealth during the COVID-19 pandemic.

An article by [2] Uscher-Pines, Lori published in *Psychiatric Services* stresses the importance of telehealth visits and mentions while there are limitations, many psychiatrists had a positive perception of telehealth. The limitations of telehealth were directly mostly at phone calls rather than video calls, but more patients had access to a phone compared to video. Lindsay et al. (2020)[3] conducted a study investigating the benefits of video appointments for rural patients during the pandemic and found that patients felt that conversational rhythm and rapport with their provider was maintained well through video.

An article published by Perrin et al. (2020)[4] in the *Journal of Clinical Psychology* suggests that telehealth is well-suited to become a permanent part of mental health care practice if there are appropriate policies in place. While this article focuses on psychology rather than psychiatry, many of the implications and benefits of telehealth can carry over to psychiatry.

We did not find any controlled, randomized experimental studies comparing mental health care delivered via telehealth appointments to in-person appointments during the pandemic, nor did we find any quantitative survey studies asking patients about their experiences and perceptions of telehealth appointments during the pandemic. While Perrin et al. (2020) and Lindsay et al. (2020) touch on some patient feedback in their findings, Perrin et al. report anecdotal feedback from patients and Lindsay et al. conducted qualitative interviews to solicit feedback from patients.

Our search on clinicaltrials.gov did not yield any current studies focused on attitudes of mental health care patients towards receiving care through telehealth. We found only one study in the US, which is a survey focused towards getting perceptions of telehealth use among clinical psychologists but does not include patients' perceptions. (ClinicalTrials.gov Identifier: NCT04360850)

Our hypothesis is that most patients may like receiving mental health care through telehealth and would potentially be interested in continuing a combination of telehealth and in-person appointments in the future. Understanding patient perceptions and collecting their feedback now is critically important as the spread of COVID-19 infection

is unknown, and telehealth appointments may continue throughout the course of the pandemic. If we can learn more now about patients' perceived benefits and challenges using telehealth services, we can prioritize improvements to better their experience and potentially, patient adoption of and comfort with remote appointments. This study's results would also inform policy makers and insurance companies about the potential utility of delivering mental health care through telehealth, even beyond the duration of the COVID-19 pandemic.

We will collect data from patients who had in-person mental health care appointments at Northwestern *prior to* telehealth implementation due to the COVID-19 pandemic, and who had at least one mental health care appointment at Northwestern between mid-March 2020 and September30th 2020. Our analysis will focus on patients' perceptions of availability of care, usage, ease of use, comfort of use, quality of interaction, interface interaction, overall quality, and satisfaction with mental health care appointments via telehealth. We will also ask them if they would prefer to continue receiving telehealth care after the COVID-19 situation resolves and how it compares to receiving in-person care, as well as reasons why they might choose a telehealth appointment if offered in the future. They will be also asked to answer some self-report questions about their mental health and demographic.

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Inclusion Criteria

1. Adults age 18 and over who received mental health care at Northwestern prior to telehealth implementation from March 15th 2019 to March 14th 2020 and had at least one mental health care appointment at Northwestern between March 15th 2020 and September 30th 2020.

Exclusion Criteria

1. Adults unable to access study questionnaires via computer or mobile device

3.0 Sample Size:

We will recruit participants through Northwestern's outpatient behavioral health clinics. We plan to have about 600 participants with completed surveys.

4.0 Recruitment and Screening Methods:

Participants will be pre-screened through Northwestern Medicine Enterprise Datawarehouse (NM EDW) report. The EDW report would only contain participant's name, email, and if they received care through telehealth or not between March 15, 2020 and September 30th 2020. No mental health information would be extracted in the EDW report. There will be no reviewing of participants' medical charts during both prescreening and post screening phases for the purposes of this study. Participants in the EDW report would be sent an email link to a REDCap online survey to complete the study questionnaire. The REDCap survey will be created using the Northwestern REDCap platform and Northwestern email. Participants will be emailed up to five (5)

times to remind them to complete the survey, in addition to the original invitation email. The reminders will be sent no more than six (6) days apart, with the exception of the final email reminder sent on the day the survey closes.

5.0 Research Locations:

Participants will receive a link to a REDCap online survey on their email to complete the study questionnaires. The REDCap surveys will be created using the Northwestern REDCap platform and Northwestern email and will be accessible on any internet enabled electronic device. The research regulatory, and other files will be maintained on NU research storage servers, secure Microsoft team's sharepoint channel and NU REDCap software.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

This is a single site research study.

7.0 Procedures Involved:

We plan to use Questionnaire/survey to be sent to participants. Participants will receive a link to a REDCap online survey to complete the study questionnaires. The REDCap survey will be created using the Northwestern REDCap platform and the sender will show up as a Northwestern email address. Participants will be emailed up to five (5) times to remind them to complete the survey, in addition to the original invitation email. The reminders will be sent no more than six (6) days apart, with the exception of the final email reminder sent on the day the survey closes.
Our analysis will focus on patients' perceptions of availability of care, usage, ease of use, comfort of use, quality of interaction, interface interaction, overall quality, and satisfaction with mental health care appointments via telehealth. We will also ask them if they would prefer to continue receiving telehealth care after the COVID-19 situation resolves and how it compares to receiving in-person care, as well as reasons why they might choose a telehealth appointment if offered in the future. They will be also asked to answer some self-report questions about their mental health and demographics.
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Once enrollment begins, we plan to complete all data collection in a period of six months. Participants will have access to complete the survey before the survey is shutdown.

8.0 Consent Process:

This study collects anonymous self-reported responses and participant's medical chart will not be reviewed for purposes of this study and would hence qualify for a waiver of HIPAA authorization. We will utilize an online consent and potential participants will read the consent form on their own online using REDCap and answer "I Agree" if they choose to consent or "I Disagree" if they do not consent. They will also be informed that they can skip any answers they do not want to answer, and they can close the window at any time to exit the survey. They will also be given the option to download a blank PDF copy of the consent form. Once participants agree to consent, they will be routed to the study questionnaires/surveys. Respondents who do not consent will receive a termination message stating that they are choosing to end the survey.

9.0 Waiver of Participant Signature on Consent Form:

This study collects anonymous self-reported responses and participant's medical chart will not be reviewed for purposes of this study and would hence qualify for a waiver of HIPAA authorization. We will utilize an online consent without HIPAA section and participants will not sign the form instead click "I Agree" if they choose to consent or "I Disagree" if they do not want to consent.

10.0 Waivers and Alterations of Consent Information:

This study collects anonymous self-reported responses and participant's medical chart will not be reviewed for purposes of this study and would hence qualify for a waiver of HIPAA authorization. We will utilize an online consent without HIPAA section and participants will not sign the form instead click "I Agree" if they choose to consent or "I Disagree" if they do not want to consent.

11.0 Financial Compensation

Participants who complete the entire survey honestly will be provided a $5 Starbucks gift card for their time.

12.0 Potential Benefits of this Research:

There is no direct benefit to participants participating in this study. However, if the results of this study lead to policy changes towards reimbursement of mental health care through telehealth, participants who prefer receiving mental health care through telehealth may benefit in having this additional choice.

13.0 Potential Risks to Participants:

A potential risk of participating in this study includes accidental disclosure of information. However, we are not collecting any health information from medical charts neither during prescreening nor during the study.

14.0 Provisions to Protect Participant Privacy and Data Confidentiality:

Participant Privacy:
All responses will be collected anonymously and will not be linked to their medical record. No identifying information is being collected except their name and contact information during prescreening. Also, participant's individual responses will not be viewed by their mental health care provider including the director of the study Dr. Jeffrey T. Rado MD, MPH. Only research team will have access to the data, and it will be stored on secure password-protected Northwestern servers. De-identified data may be shared with the larger community or with collaborators.

The participant's identifiers will be removed prior to data analysis. Contact information and responses will be retained in REDCap until it is determined we have the required study sample for analysis. After we have the required data, all contact information and identifiers would be removed from all platforms and NM EDW portal access report for this study would be removed.

Confidentiality of data
All responses will be collected anonymously. Only research team will have access to this data, and it will be stored on secure password-protected Northwestern servers.
After all data is analyzed the patient name and email identifiers will be removed.

15.0 Data Monitoring Plan to Ensure the Safety of Participants:

The assessments collected do not affect participant mental health or physical health. There will be no specific data monitoring plan for this study. Data storage will be stored per NU policy

16.0 Long-term Data and Specimen Storage and Sharing:

Data will be stored per NU policy.

17.0 Qualifications of Research Team to Conduct the Research:

Staff and qualifications

Person	Research Role	Research Experience
Jeffrey Rado, MD	Principal investigator	15+ years in clinical trials acting as principal and sub investigator.
Marko Mihailovic, MA, LCPC, CCRC	Project Manager/Backup coordinator	10+ years of research experience as a rater and budget contact. Experience in management, coordination, and rating in clinical trials. 6+ years in psychology and 7+ years in biological research.
Ankit Jain, MS	Study Coordinator	3+year experience in clinical trials, 6 years' experience in IT
Rebecca Prettyman, MA	Research Assistant	7 years psychology research experience and 1+years' experience in clinical trials

Prior to the study start date, research personnel will undergo the protocol training as well as training on assessments, evaluations, study specific procedures, and data-reporting tools utilized in this trial.

References

1. Kannarkat, J.T., Smith, N.N. & McLeod-Bryant, S.A. Mobilization of Telepsychiatry in Response to COVID-19—Moving Toward 21st Century Access to Care. Adm Policy Ment Health 47, 489–491 (2020). https://doi.org/10.1007/s10488-020-01044-z
2. Lori Uscher-Pines, Jessica Sousa, Pushpa Raja, Ateev Mehrotra, Michael L. Barnett, Haiden A. Huskamp Suddenly Becoming a "Virtual Doctor" Experiences of Psychiatrists Transitioning to Telemedicine During the COVID-19 Pandemic, Psychiatric Services (2020). doi: 10.1176/appi.ps.202000250 , RAND.org (May 19, 2020)
3. Lindsay et al. (2020). The Importance of Video Visits in the Time of COVID-19. *The Journal of Rural Health.* Accepted, unedited article available from https://doi.org/10.1111/jrh.12480
4. Perrin, PB, Rybarczyk, BD, Pierce, BS, Jones, HA, Shaffer, C, Islam, L. Rapid telepsychology deployment during the COVID-19 pandemic: A special issue commentary and lessons from primary care psychology training. J Clin Psychol. 2020; 76: 1173– 1185. https://doi.org/10.1002/jclp.22969