Evaluating the Telehealth-Single-Session Consultation Service at the Krasner Psychological Center

Jenna Sung, Michael Mullarkey, Matteo Bugatti, Elden Flores, Dina Vivian, Jessica Schleider

Hypotheses, Aims, and Analytic Plan
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Study Aims and Hypotheses

The goals of the study will be as follows:

1. To assess whether levels of proximal clinically-relevant outcomes (e,g, hope; readiness for change) is improved immediately following completion of the SSC, both in adolescent and adult clients.
2. To examine the perceived acceptability, usefulness, and client satisfaction following participation in the telehealth-Single-Session Consultation (SSC) service at the Krasner Psychological Center (KPC) among waitlisted adolescent and adult clients (ages 13 and older).
3. To assess the demand for and feasibility of providing the telehealth-SSC service at the Krasner Psychological Center (i.e., documenting the proportion of clients who choose to participate in the service when it is offered; documenting the number of sessions successfully completed, rescheduled, and/or cancelled).
4. To assess whether levels of psychological symptoms (e.g. anxiety, depression) significantly improve from pre-SSC to two weeks following completion of the telehealth-SSC.
5. To assess for the quality of therapeutic alliance established between the client and clinician during the telehealth-SSC

Hypotheses associated with each of these aims will be as follows:

1. Clients' proximal clinically-relevant outcomes (e,g, hope, measured by the Beck Hopelessness Scale – 4 item version, and readiness for change, assessed by the three-item "Readiness for Change Ruler"), which are hypothesized to serve as mechanisms for intervention effects, will improve from immediately pre to immediately post telehealth-SSC.
2. Adolescent and adult clients will perceive the telehealth-SSC at the KPC as acceptable and useful in addressing their clinical needs, indexed by mean ratings of at least 3.0 out of 5 across the five items on the "Consultation Feedback Form".
3. The telehealth-SSC will show feasibility as a model for service provision at the KPC (i.e., a majority [>50%] of clients who are offered the telehealth-SSC service will elect to receive it, and most [>75%] of clients who schedule a telehealth-SSC appointment will attend)

4. Clients' overall levels of depression (measured by PHQ-9) and anxiety (measured by GAD-7) will reduce two weeks after the telehealth-SSC, relative to symptoms immediately prior to the telehealth-SSC
5. Adolescent and adult clients will report a satisfactory level of therapeutic alliance, defined as a mean rating of 4 on the 12-item scale

Sample Size Justification

We are primarily interested in obtaining precise estimates of feasibility and acceptability outcomes; client satisfaction ratings; and changes in possible change mechanisms (hope, readiness for change) and mental health outcomes (levels of anxiety, depression), which will aid in the planning of a larger-scale efficacy trial. A minimum client sample size of 30 will allow us to be relatively precise in our conclusions regarding feasibility outcomes, as well as change in hope, anxiety, and depression scores from pre-to-post-intervention, based on guidelines for pilot study planning proposed by Joulius (2005) and Whitehead et al (2016).

Analytic Plan

To address Hypothesis 1, we will conduct two 2-tailed paired samples t-tests to assess whether participants scores on the Beck Hopelessness Scale – 4 item version and the readiness change ruler significantly reduced from pre-SSC to post-SSC. A pre-post difference with a p-value of $< .05$ will indicate a significant change in hope from pre-SSC to post-SSC.

To address Hypothesis 2, we will examine mean scores on the "Consultation Feedback Form," which contains 5 items rated on a 1-5 Likert scale by participants (e.g., "Did you find the consultation helpful in addressing your concern(s)?"; "How motivated do you feel to use your action plan?") A mean score of 3.0 out of 5 or higher across participants in this study would indicate participants found the telehealth-SSC more than somewhat helpful in addressing their concerns.

To address Hypothesis 3, we will first divide the number of people who accepted the KPC's invitation to take part in the telehealth-SSC service (whether or not they subsequently attend their scheduled session) by the number of people who declined the invitation to take part in the telehealth-SSC service. We will then divide the number of people who attended their scheduled telehealth-SSC session by the total number of people who scheduled an telehealth-SSC session, regardless of future attendance. If the first number exceeds .5 (50%), and the second number exceeds .75 (75%), we will conclude the SSC's feasibility as a service delivery model.

To address Hypothesis 4, we will again use a 2-tailed paired samples t-test to assess whether participants' GAD-7 and PHQ-9 score significantly reduced from pre-SSC to 2-week follow-up. A pre to follow-up difference with a p-value of $< .05$ will indicate a significant change.

To address Hypothesis 5, we will examine the mean scores on the Working Alliance Inventory (WAI), which contains 12 items rated on a 1-7 Likert scale by participants. A mean score of 4 (out of 7) or higher would represent a basic agreement between the SSC clinician and the client

on the tasks and goals of therapy as well as the existence of a quality therapeutic alliance. Thus, a mean score of 4 across participants in this study would indicate that the working alliance established in the telehealth-SSC is satisfactory.

We will use maximum likelihood estimation to address any item- and subject-level missing data that may emerge.

The false discovery rate (FDR) will be applied to identify potential false-positive results. Q-values will be computed for p-values from t tests using an online calculator applying Benjamini and Hochberg's (1995) approach (https://www.sdmproject.com/utilities/?show=FDR). Results will be considered significant if FDR corrected $q < 0.05$ (incurring maximum 5% false-positive rate amongst all tests meeting significance at $p < 0.05$). Both p and q values will be reported.

Study Timeline

Recruitment is projected to begin in approximately February 2021 and extend through approximately July 2021, but precise dates of study duration are difficult to predict with certainty, as they will depend on patient flow and waitlist length at the clinic where the trial is being conducted. Results are projected to be available for hypotheses 1-4 by September 2021.

References

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