Evaluating the Single-Session Consultation Service at the Krasner Psychological Center and Putnam

Hypotheses, Aims, and Analytic Plan
February 13, 2020

Study Aims and Hypotheses

The goals of the study will be as follows:

1. To examine the perceived acceptability, usefulness, and client satisfaction following participation in the Single-Session Consultation (SSC) service at the Krasner Psychological Center (KPC) and Mind Body Clinical Research Center (MBCRC) among waitlisted adolescent and adult clients
2. To examine therapists' perceived acceptability, feasibility, and effectiveness of the single session consultation at three time points: pre-training, post-training, and post-SCC administration
3. To assess the demand for and feasibility of providing the SSC service at the Krasner Psychological Center and Mind Body Clinical Research 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 proximal clinical outcomes (e,g, hope, agency) are improved immediately following completion of the SSC, both in adolescent and adult clients.
5. To assess whether levels of psychological symptoms are improved two weeks following completion of the SSC, both in adolescent and adult clients.
6. To assess rates of (a) remaining on the clinic waitlist for therapy and (b) length of subsequent treatment at the Mind Body Clinical Research Center and Krasner Psychological Center among individuals participating in the SSC, relative to clients who sought out services in the six months prior to the SSC being offered to clients (January - June 2019).

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

1. Clients' proximal clinical outcomes (e,g, hope, measured by the Beck Hopelessness Scale – 4 item version, and Agency, measured by the State Hope Scale; both primary study outcomes), which are hypothesized to serve as mechanisms for intervention effects, will improve from immediately pre-SSC completion to immediately post-SSC.
2. Adolescent and adult clients will perceive the SSC at the Mind Body Clinical Research Center and Krasner Psychological Center as acceptable and useful in addressing their clinical needs, indexed by mean ratings of at least 3.5 out of 5 across the five items on the "Consultation Feedback Form".
3. The SSC will show feasibility as a model for service provision at the Mind Body Clinical Research Center and Krasner Psychological Center (i.e., a majority [>50%] of clients who are offered the SSC service will elect to receive it, and most [>75%] of clients who schedule an SSC appointment will attend)
4. Clients' overall psychological symptom levels will reduce two weeks after the SSC, relative to symptoms immediately prior to the SSC

5. No prediction is made about therapists' perceived acceptability, feasibility, and effectiveness of single session interventions at baseline or their subsequent assessment, given the novelty of research in this domain.
6. Clients who receive the SSC will be less likely to remain on the clinic wait list—and, among those who elect to remain on the clinic wait list, total therapy duration will be briefer— relative to clients who sought service at the Mind Body Clinical Research Center and Krasner Psychological Center prior to the SSC service being offered.

   Note that data will be available for testing hypotheses 1-5 substantially sooner than for testing hypothesis 6, as the duration of clients' potential future psychotherapy at the Krasner Psychological Center and Mind Body Clinical Research Center is impossible to determine. Whereas data for the first four hypotheses will be available two weeks subsequent to recruitment completion, data for the fifth hypothesis may be unavailable for up to a year subsequent to recruitment completion. Accordingly, the authors may report results from hypotheses 1-5 in a manuscript or conference presentation prior to completion of data collection for hypothesis 6, noting that data relevant to hypothesis 6 will be reported at a to-be-determined future date. Data relevant to hypothesis 6 (which requires extraction of aggregate client information associated with previous Mind Body Clinical Research Center and Krasner Psychological Center clients) will not be collected, and thus will remain unknown to investigators, until all relevant data are available for analysis (i.e., until all clients who completed the SSC and chose to receive full-length psychotherapy have terminated their course of treatment at the clinic).

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, agency), which will aid in the planning of a larger-scale efficacy trial. A client sample size of 40 from two outpatient sites will allow us to be relatively precise in our conclusions regarding feasibility outcomes, as well as change in hope and agency scores from pre-to-post-intervention, based on guidelines for pilot study planning proposed by Joulius (2005) and Whitehead et al (2016).

We will also recruit therapists to take part in this study. Specifically, all therapists attending the initial training will be offered the opportunity to voluntarily and anonymously complete a questionnaire on their perceptions of the single-session consultation program. Since we have no way of knowing how many therapists will choose to participate in this study, the sample size for therapist participants is unknown. Therapist data will be exploratory, serving as pilot data for potential future studies.

Note: the trial initially recruited three outpatient centers (Krasner Psychological Center, Mind Body Clinical Research Center, and Child Adolescent Outpatient Services). Due to logistical and administrative issues encountered at the Child Adolescent Outpatient Services during study set up, this site was excluded. Based on the ongoing recruitment rates at the two remaining sites, the sample size of 40 is feasible to recruit.

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 State Hope Scale, respectively, 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, agency, 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 3.5 out of 5 or higher across participants in this study would indicate participants found the SSC more than somewhat helpful in addressing their concerns.

To address Hypothesis 3, we will first divide the number of people who accepted the Mind Body Clinical Research Center and Krasner Psychological Center's invitation to take part in the 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 SSC service. We will then divide the number of people who attended their scheduled SSC session by the total number of people who scheduled an 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' brief symptom inventory score significantly reduced from pre-SSC to follow-up. A pre to follow-up difference with a p value of $< .05$ will indicate a significant change.

To address our fifth research question (for which no hypotheses are proposed), we will aggregate descriptive statistics from the "Therapist Beliefs about SSC" scales and will compare the scales between (1) pre-training and post-training and (2) post-training and post-SSC administration. Positive perceptions of the SSC at any given time-point will be defined by a mean rating of at least 3.5 out of 5 across all items; less-than-positive perceptions will be defined by a mean rating of less than 3.5 out of 5 across all Likert scale-rated items. We will report all qualitative data collected via this measure—specifically, we will report therapists' written responses to open-ended questions about their perceptions of the SSC. Because the scope and amount of this qualitative data are likely to be limited, and given the exploratory nature of the present study, we do not intend to conduct any formal qualitative data analyses in this study.

To address Hypothesis 6, we will conduct two 2-tailed independent-samples t tests. First, we will assess whether the percentage of individuals removing themselves from the clinic's waitlist after completing the SSC differs from the percentage of individual who had removed themselves from the waitlist in the six months prior to the SSC's being offered at the clinic. A difference with a p value of $< .05$, with a higher value for the SSC group, would suggest that individuals who receive the SSC may be more likely to voluntarily remove themselves from the clinic waitlist than individuals who had not received the SSC in the past. Second, we will calculate the mean number of psychotherapy sessions completed at the Mind Body Research Clinical Center and Krasner Psychological Center among individuals who receive the SSC and elect to remain on the clinic's waitlist. We will then test whether this mean number of sessions differs from the mean

number of sessions completed by clients who began psychotherapy in the six months prior to the SSC's being offered at the clinic. A difference with a p value of < .05, with a lower value for the SSC group, would suggest that individuals who receive the SSC may be more likely to have a shorter course of psychotherapy than those who do not receive the SSC prior to full-length treatment. Note that for both of our Hypothesis 6 analyses, we will restrict our sample of previously-seen clients to those in the same age-range as in the study sample, in order to optimize comparability between groups.

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 October 2019 and extend through approximately May 2020. Results are projected to be available for hypotheses 1-5 by September 2020, and for Hypothesis 6, by May 2021.

References

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