Plan for Generating Empirical Support of Psychodrama Effects
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This is a proposal for a multi-site investigation of the effects of Psychodrama. The following is a general overview of the main aspects of methods to be employed.

Research Design/Approach

This project combines aspects of various models: naturalistc, meta-analytic, action, large sample, survey, case anecdotal, evaluation, outcome and feminist models are incorporated.

The Research Question

Is Psychodrama, as an intervention modality, demonstrably, empirically effective?

Participants

Participants are to be service providers and recipients.

Providers will be psychodramatists and other therapists and facilitators worldwide willing to collect data on at least one Psychodrama or equivalent experience.

Service recipients are clients, patients, students or others willing to reflect on the experiences offered by the providers and allow their data to be included in the study.

Instruments

Six instruments will be used:
4 universal outcome scales:
positive growth/impact,
symptom reduction,
relationship common factor, and
threat negative impact**,**
plus an intervention fidelity checklist on elements of the psychodrama, and a demographic questionnaire.

The 4 universal scales. See Appendix 1. Each universal scale is a single dimension item and applicable to the many situations in which providers practice. Each is designed to measure the overall participant's experience in a given dimension. Each is a simple self report measure, asking for a simple mark on a visual continuum marked with gradations. Reliability, content, face and construct validity, readability and language equivalence for all language versions will be addressed.

Scale 1: Sense of Well-being. Measures degree of positive sense of self, including such experiences as feeling capable, resilient, confident, empowered, adapatable, spontaneous, creative, prepared, knowledgeable, energized, and

similarly. A positive change score on this scale (pre and post intervention) will be a positive outcome.

Scale 2: Anxiety. Measures degree of general anxiety or negative sense of self, including feeling uncertain, unprepared, guilty, ashamed, defensive, and similarly. A negative change score on the Anxiety scale pre and post intervention will be a Symptom Reduction.

Scale 3: Connectedness. Measures degree of being related/relating to others such as therapists, facilitators, group members, significant others and feeling accepted, connected, supported, belonging, understood, and similarly. A positive change score on the Connectedness scale will be an increase in Relationship Strength.

Scale 4: Negative Impact/Threat. Measures the degree of perceived harm the intervention has done, including such experiences as feeling wounded, distressed, threatened, overwhelmed, caught off guard, coerced, and similarly. An increase on this scale pre and post intervention will be a negative impact or threat.

Intervention Fidelity Checklist. See Appendix 2. A brief basic checklist identifies the presence or absence of defining elements of Psychodrama Intervention. The checklist is intended to provide a structure comparable to treatment manuals for Empirically Supported Interventions [ESI] and or Evidence Based Practice [EBP].

Demographic Questionnaire. See Appendix 3. Designed to obtain general background characteristics for description and categorization of participants.

Research and Statistical Hypotheses

H1. Psychodramatic intervention will significantly impact positive change. The mean change score on the Sense of Well-being scale will be significantly positive. The effect size for change scores on Well-being will be psitive and practically significant.

$H_1 : \mu_{W\text{-}b} > 0$

H2. Psychodramatic intervention will significantly impact Symptom Reduction. The mean change score on the Anxiety Scale will be negative and practically significant. The effect size and change scores for Anxiety will be negative and practically significant.

$H_2 : \mu_A < 0$

H3. Psychodramatic intervention will significantly impact connectedness. The mean change score on the Connectedness Scale will be significantly

positive. The effect size for change scores on Connectedness will be positive and practically significant.

$H_3 : \mu_C > 0$

H4. Psychodramatic intervention will not have a significant negative impact. The mean post-test score of Negative Impact Threat will not be significant. The effect size for post intervention scores on the Negative Impact (NI) scale will be negligible and practically insignificant.

$H_4 : \mu_{NI} > 0$

Procedures

Psychodramatists and other providers will be contacted via email, postings to newsletters, and snowball-sampling to elicit participation in the study. The purpose, procedures, and requirements of the study will be explained. Participants will be asked to use the four scales pre and post for at least one session they conduct, to complete the Intervention Fidelity Checklist and the Demographic Questionnaire.

(See announcement and informed consent for providers, Appendix 4. They will be instructed in soliciting the permission of their service recipients' data using the script provided and the informed consent for recipients, Appendix 4.)

Sessions will be conducted as they typically would be. Before a session, the study will be discussed, informed consents executed, and pre-tests administered. After a session, recipient participants will be offered the opportunity to submit their post ratings on the four scales. Submission of the data will constitute recipient participant informed consent. These participants will also be offered the opportunity to be assigned an ID# and complete a Demographic Questionnaire, if they would be interested and willing to be involved further (e.g., other studies—longitudinal follow-up, evaluation of more specific interventions.)

Data from both level participants will be sent to a central data collection repository for entry, collation, and analysis.

Integration of the use of the four scales pre- and post- all sessions as part of the intervention process will be one aim of the study. Among other things, the intent is to create and maintain conscious and continual focus on intervention impact to become part of the psychodrama culture, provide a consistent orientation (warm-up) to sessions.

Analyses

Analyses are in three stages: Outcome Scales Psychometric Properties, Preliminary Data Analysis, and Primary Study Analyses.

Outcome scales psychometric properties. The scale data will be analyzed for language-version equivalence, readability, content/face/construct validity, and reliability.

Language-version equivalence. After translation/back-translation protocol for accurately rendering instruments in another language have been implemented, the various language versions of the outcome scales will be analyzed for differential item functioning using Item Response Theory (IRT) analysis. The three parameter logistic model (3PL) will be used to fit the data, to take into account the adjustment for possible social desirability influence. Different language versions will be linked/equated to ensure comparable metrics and converted to T-score scales to facilitate interpretation of results.

Readability. A readability analysis will be done to ensure scales can be adequately understood by participants. Readability level will be calculated and reported for each version and overall.

Content/face/construct validity. Scales will be submitted to three member expert panels for each language version to assess the validity of the scales for measuring the purported constructs. Inter-rater agreement will be calculated and reported for each version and overall.

Reliability. Appling the IRT 3PL Model, each scale's reliability will be calculated and reported for each version and overall.

Preliminary Data Analysis. Summary statistics will be produced for each scale. Data will be analyzed for skewness, kurtosis, univariate and multivariate out-liers, sphericity and so forth, to ensure that the data meet the assumptions for the primary analyses. Required adjustments will be implemented (e.g., data transformations, elimination of outliers). Missing data, if any, will be addressed by using the IRT approach.

Primary Study Analyses. Three levels of primary analyses will be applied to the data to address the hypotheses stated previously—multivariate analysis, univariate analysis by scale, and meta-analysis by scale and overall.

Multivariate analysis. A Hotelling's-T will calculated for the vector of scale mean change scores.

Univariate analysis. Univariate-t's will calculated for the each scale mean change score.

Meta-analyses. The effect sizes will be calculated for each scale language version. These data will be subjected to meta-analytic techniques combining across scales and language versions.

Appendix 1: Outcome Scales

Please mark your self-ratings by a vertical line at the point that indicates you response. For example, if the scale were how much you enjoy hiking, and you want to indicate a little more than 8 (say 8.4) you would mark response:

0……1……2……3……4……5……6……7……8…|…9……10

Scale 1: Sense of Well-being

Indicate your positive sense of self, including such experiences as feeling: capable, resilient, confident, empowered, adaptable, spontaneous, creative, prepared, knowledgeable, energized, and so forth.

My sense of well-being is:

0……1……2……3……4……5……6……7……8……9……10

Scale 2: Anxiety

Indicate your negative sense of self, including such experiences as feeling: uncertain, unprepared, guilty, defensive, ashamed, and so forth.

My degree of anxiety is:

0……1……2……3……4……5……6……7……8……9……10

Scale 3: Negative Impact/Threat

Indicate how much harm the intervention will do/has done you, including such experiences as feeling: wounded, distressed, threatened, and so forth.

My sense of being harmed is:

0……1……2……3……4……5……6……7……8……9……10

Scale 4: Connectedness

Indicate your degree of being related/relating to others (therapist[s]/facilitator[s], group members, etc.), including such experiences as feeling: accepted, connected, supported, belonging, understood, and so forth.

My sense of being connected is:

0……1……2……3……4……5……6……7……8……9……10

Appendix 2: Intervention Fidelity Checklist

Check if the following elements/aspects of psychodramatic intervention were present.

Components

☐ Warm-up
Theme/Issue Selection
☐ Scene Setting
☐ Catharsis of Abreaction
☐ Surplus Reality
☐ Catharsis of Integration
☐ Sharing

Roles

☐ Protagonist
☐ Auxiliary Ego
☐ Double
☐ Audience

Techniques

☐ Role-reversal
☐ Mirror
☐ Concretization

Session Data

Date: _____ Title: _____

Type of Session ☐ Group ☐ Individual ☐ Couple ☐ Family
☐ Therapy ☐ Training ☐ Growth ☐ Supervision Other (please specify)_____

☐ Classical Psychodrama ☐ Situational Psychodrama ☐ Sociodrama ☐ Other (please specify)_____

Length of Session: _____ Number of Participants: _ Participants' Age Range:_____

Facilitator (Provider) Data

Name or ID# of Facilitator: _____ Years of Professional Experience:_____
Certification: ☐ TEP ☐ CP ☐ Other (please specify)_____Years of Psychodrama Experience:_____
Number of Psychodrama Training Hours:_____ Highest Degree Earned: _____
_____

Appendix 3: Demographic Questionnaire

A standard demographic questionnaire will be included to ascertain such information as participant's age, gender, sex, race, ethnic background, primary language, and so forth. Only those participants willing to complete the questionnaire for the initial evaluation will do so, and no names or ID #'s will be included. For those willing to participate in a longitudinal follow-up, and/or other studies, space will included to allow for providing a name and contact information, or an ID# if one has been previously assigned. Once an ID# has been assigned, the identifying information (name and contact data) will be removed from the data and filed separately, to ensure confidentiality.

Appendix 4: Informed Consents

Standard Informed Consents will be included for service recipients. A total of four Informed Consent Statements will be produced. The primary one will indicate that consent to participate will be inferred by the submission of the pre and post rating scales at the conclusion of the facilitated experience. Two Additional Informed Consent statements will be linked to the submission of the Demographic Questionnaire with or without the providing contact information (or ID#) and for longitudinal follow-up and/or participation in other facilitated experiences.

An Informed Consent will also be produced for the service providers. It will indicate what is required/requested of them as a study participant (e.g., informing their participants, completing the Intervention Fidelity Check-list, and collecting the materials submitted, conveying the materials for entry and analysis).

Informed Consent to Participate in Study of Psychodrama Effects

INTRODUCTION

You are invited to join a research study to look at the effectiveness of psychodrama. Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. The decision to join, or not to join, is up to you.

In this research study, we are investigating/testing/comparing/evaluating the results of psychodrama therapy.

WHAT IS INVOLVED IN THE STUDY?

If you decide to participate you will be asked to fill out 4 scales, one demographic questionnaire, and a checklist before and after a session of psychodrama. We think this will take you 5-10minutes at the start of the session and less than that at the conclusion.

The investigators may stop the study or take you out of the study at any time they judge it is in your best interest. They may also remove you from the study for various other reasons. They can do this without your consent.

You can stop participating at any time. If you stop you will not lose any benefits.

RISKS

This study involves no known risks.

There may be risks that we cannot predict.

BENEFITS TO TAKING PART IN THE STUDY
It is reasonable to expect the following benefits from this research: that your answers will help us understand what results come from psychodrama. However, we can't guarantee that you will personally experience benefits from participating in this study. Others may benefit in the future from the information we find in this study.

CONFIDENTIALITY

We will take the following steps to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage:
_____

Data will be coded and kept in confidential files so that your answers will not be traceable to you. Numeric data will be aggregated and analyzed at a central location from a number of different locations, but identifiers will have been removed before that occurs. The study is concerned with how psychodrama is or is not effective and is not directed at any particular individual's reactions to it. Every effort will be made to keep your identity confidential. The only place where a file will exist that contains your name in this study will be in the office where you sign up to participate.

INCENTIVES none

YOUR RIGHTS AS A RESEARCH PARTICIPANT
Participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with your provider.

CONTACTS FOR QUESTIONS OR PROBLEMS
Call _____ at _____ or email_____ at _____if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

Contact _____if you have any questions or

concerns about your rights as a research participant.

Consent of Subject (or Legally Authorized Representative) Signature of Subject or Representative Date

_____

[The template for this consent form was taken from the Office for Protection of Research Subjects website of the Department of Health and Human Services on Oct. 21, 2014.] Your state or institution may have different requirements.
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