Study Protocol and Statistical Analysis Plan
Official Title:
Effects of Ericksonian Hypnotherapy Versus Cognitive Behavioral Therapy on Prolonged Grief Among University Students in Istanbul: A Randomized Controlled Trial

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Principal Investigator:
Metin Çınaroğlu, PhD
Assistant Professor, Psychology Department
Istanbul Nişantaşı University

Affiliation:
Istanbul Nişantaşı University, Istanbul, Turkey

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Contact Information:
Metin Çınaroğlu, PhD
Email: metincinaroglu@gmail.com
Phone: +90 532 473 2070

1. Title and Objective

Title:
"Effects of Ericksonian Hypnotherapy Versus Cognitive Behavioral Therapy on Prolonged Grief Among University Students: A Randomized Clinical Trial"

Objective:
The objective of this study is to compare the efficacy of Ericksonian Hypnotherapy (EH) and Cognitive Behavioral Therapy (CBT) in reducing prolonged grief symptoms among university students in Istanbul. Prolonged grief is characterized by an intense longing and emotional distress related to a loss that extends beyond typical bereavement, impacting mental health and daily functioning. By evaluating the effectiveness of EH, a flexible therapeutic approach using indirect suggestion and metaphoric techniques, against the structured approach of CBT, the study aims to identify a potentially effective and culturally adaptable intervention for young adults coping with prolonged grief.

This study will address the following primary research question:

- Does Ericksonian Hypnotherapy provide a more effective reduction in prolonged grief symptoms than Cognitive Behavioral Therapy among university students?

Secondary research questions include:

- How do these interventions affect depressive symptoms associated with prolonged grief?
- Can EH offer a culturally sensitive therapeutic alternative in diverse university settings?

2. Study Design

Type:
This is a randomized controlled trial (RCT) employing an expertise-based parallel group design to evaluate the effects of Ericksonian Hypnotherapy (EH) and Cognitive Behavioral Therapy (CBT) on prolonged grief symptoms among university students. Participants are randomly assigned to one of three groups: (1) Ericksonian Hypnotherapy, (2) Cognitive Behavioral Therapy, or (3) a Waitlist Control group.

Groups:

1. **Ericksonian Hypnotherapy (EH) Group**: Receives 8 weekly sessions of EH, delivered by a certified therapist specializing in Ericksonian methods.
2. **Cognitive Behavioral Therapy (CBT) Group**: Receives 8 weekly sessions of CBT, focusing on structured techniques to address grief-related thoughts and behaviors.
3. **Waitlist Control Group**: Does not receive any therapeutic intervention during the study period. After study completion, participants are provided information on available grief support services.

Sample Size:
A total of 39 participants are recruited and distributed equally across the three groups (13 per group). The sample size was determined based on preliminary data indicating a moderate effect size, with an allocation ratio of 1:1:1 to ensure balanced group representation.

Randomization and Allocation Concealment:
Participants are randomly assigned to one of the three groups using a computer-generated randomization sequence to ensure unbiased group allocation. Allocation concealment is maintained by using sealed envelopes for group assignments, opened only by the treatment providers at the start of each intervention.

Blinding:
While therapists and participants cannot be blinded to the intervention due to the nature of the therapies, outcome assessors are blinded to group assignments to reduce detection bias during assessments.

Duration:
The total study duration for each participant is 8 weeks, with interventions taking place once a week. Follow-up assessments are conducted after the fourth session (midpoint) and immediately after the eighth session (post-intervention).

3. Participants

Inclusion Criteria:
Participants must meet the following criteria to be eligible for the study:

- University students aged 18–29 years.

- Ability to communicate and comprehend English proficiently.
- A self-reported experience of significant loss within the past year and symptoms consistent with prolonged grief (as indicated by the Prolonged Grief Scale).
- Willingness and ability to attend weekly therapy sessions for 8 weeks and complete all required assessments.

Exclusion Criteria:
To ensure a focused study population, participants will be excluded if they meet any of the following criteria:

- Currently undergoing psychopharmacological treatment or psychotherapy for any psychological condition.
- Diagnosed with any major psychological disorder other than prolonged grief as assessed by the SCL-90 Symptom Checklist.
- Inability to commit to the full duration of the study, including weekly sessions and follow-up assessments.
- History of severe psychiatric disorders or significant medical conditions that could interfere with participation in a therapeutic setting.

Recruitment Process:
Participants are recruited through university networks, social media, and campus advertisements targeting students who have experienced a significant loss. Interested students complete an initial online screening questionnaire, including the SCL-90 and a sociodemographic form, to determine preliminary eligibility. Eligible students are then contacted for a brief interview to confirm their eligibility based on the full inclusion and exclusion criteria.

Screening and Baseline Assessment:
Following confirmation of eligibility, participants complete a baseline assessment, including the Prolonged Grief Scale (PGS) and the Beck Depression Inventory (BDI), administered in a confidential and controlled setting. This baseline assessment provides initial data on grief and depressive symptoms to be compared throughout the study.

4. Interventions

Intervention Groups:
Both intervention groups participate in weekly therapy sessions lasting approximately 60 minutes each over the course of 8 weeks. The two interventions—Ericksonian Hypnotherapy (EH) and Cognitive Behavioral Therapy (CBT)—are administered by therapists specialized in their respective methods, ensuring that each approach is implemented with expertise and consistency.

1. **Ericksonian Hypnotherapy (EH) Group**:
   This group undergoes a tailored EH intervention focusing on the use of indirect suggestion, metaphors, and personal storytelling. Key components of EH include:
   - **Initial Sessions (1-2)**: Establishing therapeutic rapport and identifying personal strengths and inner resources related to the participant's grief experience.

- **Mid-Sessions (3-5)**: Use of guided imagery and metaphoric language to facilitate connection with the loss in a way that promotes healing and acceptance.
- **Later Sessions (6-8)**: Reframing the loss through narrative techniques that encourage integration of the loss into one's life story, fostering resilience and a sense of meaning beyond the grief. The EH sessions aim to engage the unconscious mind, using the participants' personal associations and stories to aid in processing grief in a supportive, non-directive manner.

2. **Cognitive Behavioral Therapy (CBT) Group**:
   The CBT intervention is structured and manualized, addressing maladaptive thoughts and behaviors associated with prolonged grief. The key components of the CBT sessions include:
   - **Initial Sessions (1-2)**: Psychoeducation on the CBT model and grief, focusing on the relationship between thoughts, emotions, and behaviors in response to loss.
   - **Mid-Sessions (3-5)**: Identifying and challenging grief-related maladaptive thoughts, practicing gradual exposure to situations or reminders of the deceased, and developing coping skills to manage emotional responses.
   - **Later Sessions (6-8)**: Emphasis on rebuilding life goals, re-engaging in meaningful activities, and reinforcing coping strategies to foster a renewed sense of purpose and engagement with life. The structured nature of CBT provides participants with concrete tools and cognitive restructuring techniques to process grief and mitigate its impact on daily functioning.

Control Group (Waitlist):
Participants in the control group are placed on a waitlist and do not receive any form of intervention during the study period. Upon study completion, they are offered information on grief counseling resources to ensure they have access to supportive options.

Consistency in Intervention Delivery:
To maintain intervention fidelity, both EH and CBT sessions are conducted using standardized session outlines. Both interventions span eight sessions, as previous studies indicate this duration effectively allows for meaningful therapeutic impact without undue burden on university students. Each therapist follows a session-by-session manual to ensure consistency in approach while allowing for individualized adaptation based on the participant's unique grief experience.

5. Outcome Measures

Primary Outcome Measure

- **Prolonged Grief Scale (PGS)**: The primary outcome measure is the Prolonged Grief Scale (PGS), a validated tool for assessing the intensity and severity of prolonged grief symptoms. The scale consists of 13 items measuring symptoms such as persistent yearning for the deceased, emotional pain related to the loss, and difficulty accepting the reality of the death. Each item is rated on a Likert scale, providing a quantifiable grief score for each participant. This scale is administered at baseline, midpoint (after the fourth session), and post-intervention (after the eighth session) to track changes in grief severity over time. Higher scores indicate more intense grief symptoms.

Secondary Outcome Measure

- **Beck Depression Inventory (BDI)**: The secondary outcome measure is the Beck Depression Inventory (BDI), a 21-item self-report questionnaire widely used to assess the severity of depressive symptoms. The BDI measures various aspects of depression, including sadness, pessimism, loss of interest, and fatigue. Each item is scored on a scale from 0 to 3, with higher scores indicating greater depressive symptomatology. Like the PGS, the BDI is administered at baseline, midpoint, and post-intervention to evaluate any changes in depressive symptoms alongside grief processing.

Screening Measure

- **Symptom Checklist-90 (SCL-90)**: The SCL-90 is used solely as a screening tool before participants are enrolled in the study. This 90-item checklist assesses a broad range of psychological symptoms and provides a Global Severity Index (GSI) to identify individuals with significant psychological distress. Only participants meeting the inclusion criteria, including low levels of distress on the SCL-90, are enrolled to minimize confounding factors.

Data Collection Schedule

1. **Baseline Assessment**: PGS, BDI, and SCL-90 are administered to eligible participants prior to randomization.
2. **Midpoint Assessment**: PGS and BDI are re-administered after the fourth session to evaluate initial therapeutic progress.
3. **Post-Intervention Assessment**: Final assessment of PGS and BDI scores takes place after the eighth session, allowing for comparison of pre- and post-intervention symptom levels.

Data Handling and Confidentiality
All data collected from participants are anonymized and stored securely in a password-protected database accessible only to the research team. Participants' confidentiality is strictly maintained throughout the study, with data identified solely by randomized participant codes.

6. Data Collection and Analysis

Data Collection Process

- **Baseline Assessment**: After eligibility is confirmed, participants complete the baseline assessment, including the Prolonged Grief Scale (PGS), Beck Depression Inventory (BDI), and Symptom Checklist-90 (SCL-90). These baseline scores establish the initial levels of grief, depression, and overall psychological distress.
- **Midpoint Assessment**: After the fourth session, participants in both the Ericksonian Hypnotherapy (EH) and Cognitive Behavioral Therapy (CBT) groups complete the PGS and BDI. This interim assessment evaluates changes in grief and depressive symptoms, allowing for preliminary comparisons of therapeutic progress.
- **Post-Intervention Assessment**: Upon completion of the eighth and final session, participants complete the PGS and BDI once more. This final assessment enables an analysis of the overall effect of each intervention on grief and depressive symptoms.

Data Entry and Confidentiality
Data are anonymized, coded, and entered into a secure electronic database. All identifying

information is removed to maintain participant confidentiality. Only authorized members of the research team have access to the data.

Statistical Analysis

- **Descriptive Statistics**: Descriptive statistics will summarize the demographic characteristics of participants and provide baseline data on grief and depressive symptoms for each group. Mean, standard deviation, and percentage values will be reported for categorical and continuous variables.
- **Primary Analysis**: Repeated measures ANOVA will be conducted to examine the effects of each intervention (EH and CBT) across the three time points (baseline, midpoint, post-intervention) on the primary outcome measure (PGS) and secondary outcome measure (BDI). This analysis allows for the comparison of changes in grief and depressive symptoms within and between groups over time.
- **Post-Hoc Comparisons**: Following significant ANOVA results, post-hoc pairwise comparisons will be conducted to determine specific differences between time points and intervention groups. This analysis will help identify any statistically significant improvements in grief and depressive symptoms from baseline to midpoint and from midpoint to post-intervention.
- **Effect Size Calculation**: Cohen's d will be calculated to quantify the effect size of EH and CBT interventions on grief and depressive symptoms, providing insights into the practical significance of each therapeutic approach.

Handling Missing Data
For any missing data due to participant non-completion of assessments, multiple imputation methods will be applied to reduce bias. The study will follow an intent-to-treat approach, analyzing all participants as randomized to their initial groups to maintain the study's validity and statistical power.

7. Ethical Considerations

Ethics Approval and Compliance
This study has received ethical approval from the Institutional Review Board of Istanbul Nişantaşı University (Approval No: 2023/2). All study procedures comply with ethical guidelines for research involving human participants, as outlined in the Declaration of Helsinki. The study is registered on ClinicalTrials.gov (Registration No: NCT06398886), ensuring transparency and adherence to clinical trial regulations.

Informed Consent
Informed consent is obtained from all participants prior to their enrollment in the study. The consent form details the study's purpose, procedures, potential risks, and benefits. Participants are informed of their voluntary participation status, confidentiality safeguards, and their right to withdraw from the study at any time without consequences.

Confidentiality and Data Protection
Participant confidentiality is rigorously protected. All data collected are anonymized and stored securely, with access restricted to authorized research team members only. Unique identification codes are assigned to participants to maintain privacy, and all identifying information is removed from the dataset.

Risk Management
This study involves minimal risk, primarily associated with emotional discomfort that may arise during discussions of grief. Therapists conducting the sessions are trained professionals, capable of identifying signs of distress and providing immediate support or referrals if necessary. Participants are also informed of this possibility during the consent process and encouraged to communicate any concerns during the sessions.

Post-Study Support for Control Group
Participants assigned to the waitlist control group do not receive therapeutic intervention during the study period. Upon study completion, these participants are provided with information on local grief counseling resources to ensure they have access to support if desired.

Data Availability Statement
All anonymized data supporting the findings of this study will be made publicly available upon request. Data will be accessible in line with open science principles while maintaining participant confidentiality.