ClinicalTrials.gov Protocol Document

Official Title: IC-Growth: Enhancing Post-Traumatic Growth in Cancer Survivors Through Group-Based Psychosocial Intervention

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Study Protocol

Study Design

IC-Growth is a multi-phase, non-pharmacological, randomized controlled trial (RCT) aimed at enhancing post-traumatic growth (PTG) among cancer survivors. The study includes an intervention group and a control group, with participants randomly assigned to either condition. The trial targets three cancer populations: breast, colorectal, and head & neck cancer. The intervention is a structured, manualized group program informed by Acceptance and Commitment Therapy (ACT) principles.

The study is conducted in three phases:
1. Preparation Phase: A literature review and expert consultation will inform the development of a novel PTG intervention manual. The manual will be co-developed with academic experts and patient organizations and revised based on feedback.
2. Implementation Phase: Participants will be randomly assigned to either the intervention or control group. The intervention will be delivered in small, cancer-specific groups (8–10 participants) over 6–8 weekly sessions lasting 90 minutes each. Control group participants will receive standard oncology follow-up without psychosocial intervention. Due to the nature of the study, it will be open-label (no blinding). Baseline and post-intervention data will be collected.
3. Synthesis Phase: Based on study results and stakeholder feedback, recommendations for integrating psychosocial support into oncology care in Greece will be developed. A policy brief will address potential implementation barriers and outline practical solutions.

Participants

Participants will be recruited from two oncology hospitals in Thessaloniki, Greece: Theageneio Cancer Hospital and AHEPA University General Hospital. Eligible participants must:
- Be adults (≥18 years old)
- Have completed scheduled chemotherapy and hospitalization
- Have a diagnosis of breast, colorectal, or head & neck cancer within the past five years

Exclusion criteria include:
- Current psychiatric treatment
- Untreated mental health conditions
- Cognitive impairments
- Inability to consent or communicate in Greek
- Cancer recurrence
- Diagnosis of a different cancer in the past 5 years
- Life expectancy <12 months

Randomization will be performed via specialized software developed by the Centre for Research and Technology Hellas (CERTH), ensuring strict allocation concealment.

Intervention

The intervention will focus on promoting PTG using structured sessions grounded in ACT. Topics include psychological flexibility, mindfulness, narrative reconstruction, meaning-making, and value-based goal setting. Sessions will be led by a trained facilitator and a co-facilitator as needed. Participant feedback will be gathered post-intervention.

Statistical Analysis Plan

Software

All analyses will be conducted using SPSS version 23.

Preliminary Data Handling

- Outliers and data normality will be examined.
- Reliability of all instruments will be assessed using Cronbach's alpha.
- Demographic and clinical data will be reported using descriptive statistics.

Primary Analysis

The primary outcome—Post-Traumatic Growth (PTG)—will be analyzed using:
- Paired t-tests within groups (pre- vs. post-intervention)
- Independent t-tests or ANCOVA to compare intervention and control groups, adjusting for baseline PTG scores.

Secondary Outcomes

Secondary outcomes will be analyzed similarly:
- Quality of Life and Spiritual Well-being (FACIT-Sp, FACT subscales)
- Anxiety and Depression (HADS)
- Trauma-Related Distress (IES-R)
- Illness Perceptions (BIPQ)
- Salivary Cortisol (biomarker analysis)

Group comparisons will use independent t-tests or ANOVA for continuous variables, chi-square tests for categorical variables, and non-parametric tests as appropriate.

Multivariate and Predictive Analysis

- Multiple regression analyses will explore baseline predictors of PTG and intervention response.
- Factor analysis will examine the structure of PTG domains within the Greek population.
- Exploratory network analysis may identify interactions among psychological and biological variables.

Sample Size Estimation

Power calculations (via G*Power 3) determined a minimum of 70–80 participants per group, totaling 140–160 participants, to detect moderate effect sizes with adequate power

($\beta = 0.80$) and $\alpha = 0.05$. Power analysis was informed by Robson & McCartan (2016) to reduce the risk of Type I and II errors.