IMPACT OF RELAXATION TRAINING ACCORDING TO YOGA IN DAILY LIFE® SYSTEM ON MENTAL HEALTH IN WOMEN AFTER BREAST CANCER SURGERY: PILOT STUDY USING EXPERIMENTAL DESIGN

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BREAST CANCER DISCOURSES

- **1. BIOMEDICAL DISCOURSE**
- 2. BREAST CANCER ACTIVISTS' DISCOURSE
- **3. FEMINISTS' DISCOURSE**

METHODOLOGICAL PROBLEMS IN RESEARCH ON COMPLEMENTARY INTERVENTIONS FOR BREAST CANCER PATIENTS

Variations in sample characteristics

- After-only studies with non-randomised control grup
- **Quasi/Non-experimental designs**
- Threats to internal/external validity
- **Structured interventions**

Non-sensitive, unreliable and non-valid outcome measures

AIMS, OBJECTIVES AND HYPOTHESES

- 1. To examine the effects on psychological well being in BC patients
- 2. To test the short-term effects of relaxation training on stress, self-esteem, mental health and anxiety
- 3. To determine the feasibility of conducting a clinical trial of relaxation training in a clinical care setting
- 4. To examine the potential role of this specific relaxation on mental health and quality of life

HYPOTHESIS

- Ha1 The experimental group mean scores of psychological distress at 1 week and 4 weeks post-attendance, and at 4 weeks post-attendance will be lower than the controls.
- Ha2 The experimental group mean scores of state and trait anxiety level at post test and at 1 week and 4 weeks post-attendance will be lower than the controls.
- Ha3 The experimental mean scores of self-esteem at 1 week and 4 weeks post-attendance will be higher (indicating higher self-esteem) than the controls.
- Ha0 Any differences in the data between both experimental and control group will be just due to chance.

METHODS

Research design; pilot study using standard randomised clinical trial methodology

Sample; 40 women from accesible population at the Institute for Oncology of Ljubljana

INCLUSION CRITERIA

- 1. Initial diagnosis: breast cancer
- 2. Stage I & II breast cancer
- 3. Postoperative hospitalisation: 1 week
- 4. 40 years of age or older
- 5. Surgical options: breast conserving surgery (BCS) or radical modified mastectomy (MRM)
- 6. Patients who were willing to accept the randomisation to any group
- 7. Multimodal therapy (surgery, radiotherapy, chemotherapy)

EXCLUSION CRITERIA

- **1.** Known and documented psychiatric disorders
- 2. Active substance abuse (a history of dependence on alcohol or drugs, taking psychotropic drugs)
- 3. Stage III & IV breast cancer
- 4. Patients with seriously impaired hearing
- 5. Patients with seriously reduced cognitive capacity
- 6. Patients that have received psychotherapy

STRATIFIED RANDOMISATION PROCEDURES

CONTROL GROUP (n=16): standard physiotherapy

EXPERIMENTAL GROUP (n=16): standard physiotherapy + relaxation training

OUTCOME MEASURES

- 1. At baseline (after the surgery)
- 2. At 1 week (at discharge)
- 3. At 4 weeks (prior the commencement of chemotherapy/radiation)

Outcome measures were obtained by blinded investigators using standardised questionnaires.

RESEARCH INSTRUMENTS

1. PSYCHOLOGICAL DISTRESS General Health Questionnaire-12 Rotterdam Symptom Checklist Perceived Stress Scale

2. ANXIETY

Self-evaluation questionnaire The STAI State-Anxiety Scale The STAI Trait-Anxiety Scale

3. SELF ESTEEM Rosenberg Self-Esteem Scale

RESULTS

- 1. AGE (t-test, p=0.893)
- **2. MARITAL STATUS (**χ², p=0.713)
- 3. EMPLOYMENT STATUS (χ^2 , p=0.317)
- **4. EDUCATION (**χ², p=1.000)

Baseline outcome measures' values regarding marital status



Baseline outcome measures' values regarding employment status



(χ², p=0.05)

Baseline outcome measures' values regarding employment status



(KW test, p=0.021)

Baseline outcome measures' values regarding type of surgery



(t-test, p=0.022)

Baseline outcome measures' values regarding type of surgery



(t-test, p=0.022)

Psychological dystress GHQ-12

Repeated measures analysis of variance

ANOVA (F=113.8887, p<0.0005)

Psychological dystress GHQ-12



* statistically significant (p<0.05)

** statistically significant (p<0.0005)

Psychological dystress RSCL

Repeated measures analysis of variance

ANOVA (F=288.389, p<0.0005)

Psychological dystress RSCL



Psychological dystress PSS

Repeated measures analysis of variance

ANOVA (F=80.801, p<0.0005)

Psychological dystress PSS



**** statistically significant (p<0.0005)**

Repeated measures analysis of variance

ANOVA (F=137.361, p<0.0005)



**** statistically significant (p<0.0005)**

Repeated measures analysis of variance

ANOVA (F=77.055, p<0.0005)



* statistically significant (p<0.05)

** statistically significant (p<0.0005)

Self-esteem RSE

Repeated measures analysis of variance

ANOVA (F=131.150, p<0.0005)

Self-esteem RSE

* statistically significant (p<0.05)

****** statistically significant (p<0.0005)

POSSIBLE MECHANISMS FOR EFFECTIVENESS OF RELAXATION

- **1.** A patient expectation
- 2. An attentional diversion
- 3. An induction of a state of deep relaxation
- 4. An inspiring hope
- 5. A sense of control

LIMITATIONS OF THE STUDY

Statistical significance vs. clinical significance Short-term effectiveness vs. long-term Small sample-size Psychological evaluation vs. immunological markers