A RANDOMISED CONTROLLED TRIAL OF CONQUER FEAR DELIVERED IN A GROUP FORMAT

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4. Radboud University Medical Centre and University of Sydney
AIMS

Translate the CF manual into Danish

1. Adapt CF into a group format (CF-G),
2. Evaluate the efficacy of CF-G on FCR and secondary outcomes, including emotion regulation, distress, health-related QoL, survivors’ unmet needs, intervention satisfaction, sleep and diurnal cortisol.
3. Explore metacognitions, working alliance, and adherence as mediators, and demographic and clinical variables as moderators.
Pilot 1
- Translation of CF manual.
- Pilot test of Danish version on six participants.

Pilot 2
- Adaptation to group format.
- Pilot test of CF-G in one group of eight participants.

RCT
- 64 women.
- Randomized to CF-G or CC.
  - 4 groups receive CF-G.
  - 4 groups receive one group session of psychoeducation and relaxation training.
PARTICIPANTS

Therapists: Two psychologists, attended one-day training workshop by Belinda.

Patients: 64 women treated for breast cancer, recruited from the Oncology Department at Aarhus University Hospital

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Past diagnosis of stage 1-3 breast cancer</td>
<td>• Self-reported current major depression</td>
</tr>
<tr>
<td>• Treated with curative intent</td>
<td>• Currently receiving psychological treatment from a therapist not involved in the study</td>
</tr>
<tr>
<td>• Completed hospital-based adjuvant treatments 3 months to 5 years prior to study entry</td>
<td>• Self-reported active psychotic illness or other severe psychiatric condition</td>
</tr>
<tr>
<td>• Disease free</td>
<td></td>
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<tr>
<td>• Have scores in the clinical range (≥22) on the Short Form of the Fear of Cancer Recurrence Inventory (FCRI-SF)</td>
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<tr>
<td>• Able to read and write Danish</td>
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<tr>
<td>• ≥18 years</td>
<td></td>
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<tr>
<td>• Able to give informed consent</td>
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</tbody>
</table>
PROCEDURE

Recruitment: Online screening
Information about study
Assessment appointment
Baseline questionnaires (T0)
Experience sampling
Collection of saliva
Baseline questionnaire (T1)
Randomisation
Intervention
Questionnaires – post (T2)
Experience sampling
Collection of saliva
Questionnaires FU 3 mo. (T3)
Questionnaires FU 6 mo. (T4)

Excluded:
FCRI <22
Do not wish to participate

Excluded:
Depression or other psychiatric disorder
Other psychological treatment

AARHUS UNIVERSITET
PSYKOLOGISK INSTITUT
10 JANTUAR 2018
NINA MØLLER TAUBER
PHD-STUDERENDE
## OUTCOME MEASURES

<table>
<thead>
<tr>
<th>Variable type</th>
<th>Variable</th>
<th>Measure</th>
<th>Pre</th>
<th>Before session #</th>
<th>Post</th>
<th>3 mo. FU</th>
<th>6 mo. FU</th>
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<tbody>
<tr>
<td>Primary</td>
<td>Fear of Cancer Recurrence (FCR)</td>
<td>Fear of Cancer Recurrence Inventory (FCRI) – 42 items</td>
<td>+</td>
<td>1,2,3,4,5,6</td>
<td>+</td>
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<td>+</td>
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<tr>
<td>Secondary</td>
<td>Cancer-specific distress</td>
<td>Impact of Event Scale – Revised (IES-R) – 22 items</td>
<td>+</td>
<td>-</td>
<td>+</td>
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<td>+</td>
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<tr>
<td></td>
<td>General distress</td>
<td>Depression, Anxiety, Stress Scale, short form (DASS21) – 21 items</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Quality-of-Life</td>
<td>EORTC QLQ – 30 items</td>
<td>-</td>
<td>-</td>
<td>+</td>
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<tr>
<td></td>
<td>Unmet Needs</td>
<td>Survivors Unmet Need Survey (SUNS-8) – 8 items</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td></td>
<td>Intervention satisfaction</td>
<td>Single item, measures overall satisfaction with intervention</td>
<td>-</td>
<td>-</td>
<td>+</td>
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<tr>
<td></td>
<td>Emotion regulation repertoire and flexibility</td>
<td>Variance decided by experience sampling method – 29 items</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td></td>
<td>Fear of Cancer Recurrence</td>
<td>Concerns About Recurrence Questionnaire (CAR-Q) – 5 items</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td></td>
<td>Sleep</td>
<td>Insomnia Severity Index (ISI) – 7 items</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td></td>
<td>Salivary cortisol</td>
<td>Diurnal slope, the area under the curve, and cortisol awakening response (CAR)</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
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</table>
## MODERATORS AND MEDIATORS

<table>
<thead>
<tr>
<th>Variable type</th>
<th>Variable</th>
<th>Measure</th>
<th>Pre</th>
<th>Before session #</th>
<th>Post</th>
<th>3 mo. FU</th>
<th>6 mo. FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderator</td>
<td>Background</td>
<td>Demographic (14-item questionnaire) and clinical data (patient record)</td>
<td>+</td>
<td>-</td>
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<tr>
<td></td>
<td>Treatment expectancy*</td>
<td>Credibility/Expectancy questionnaire (CEQ) – 6 items</td>
<td>+</td>
<td>-</td>
<td></td>
<td></td>
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<tr>
<td>Mediator</td>
<td>Emotion Regulation</td>
<td>Brooding (RRS) Rumination and Reflection Scale – 5 items</td>
<td>+</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td></td>
<td>Emotion Regulation</td>
<td>Penn State Worry Questionnaire (PSWQ) – 16 items</td>
<td>+</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Emotion Regulation</td>
<td>Difficulties in Emotion Regulation (DERS) – 36 items</td>
<td>+</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Metacognitions</td>
<td>Metacognitions Questionnaire-30 (MCQ-30) – 30 items</td>
<td>+</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>+</td>
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<tr>
<td></td>
<td>Working Alliance</td>
<td>Working Alliance Inventory Revised Short Form (WAI-RS) – 12 items</td>
<td>-</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>+</td>
<td>-</td>
<td>-</td>
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<tr>
<td></td>
<td>Patient Adherence</td>
<td>Diary of home exercise adherence</td>
<td>-</td>
<td>1, 2, 3, 4, 5, 6</td>
<td>+</td>
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<td>+</td>
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</tbody>
</table>
EXPERIENCE SAMPLING

• A method used to capture the individual’s subjective experiences as they occur.
• It involves asking participants to provide self-reports of their thoughts, emotions and actions in their everyday lives.
• Individuals are prompted at random moments with a pager/smartphone
• When prompted, the individual respond to questions about their current psychological experiences.
EXPERIENCE SAMPLING

- Used to measure emotion regulation (ER) flexibility.
- Prompted at random moments 4 times a day between 10 a.m. and 10 p.m. for one week pre and post intervention.
- Participants will rate their current emotions and ER strategies.
- Approx. 2 minutes each time.
- A Pearson correlation will be calculated for all possible pairs of ER strategies.
- A larger average correlation indicates less ER flexibility.

**Emotion regulation (ER):** Up- or downregulation of positive or negative emotions.

**ER flexibility:** The ability to regulate emotion in a context sensitive manner, relying on a broad repertoire of ER strategies.

**Dysfunctional ER:** Overreliant on certain ER strategies (e.g., worry), using them in a context insensitive manner.
EXPERIENCE SAMPLING

On a scale of 1 (not at all) to 5 (a great deal). Do you feel:

<table>
<thead>
<tr>
<th>Emotion</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amusement</td>
<td></td>
<td></td>
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<tr>
<td>Fear</td>
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<tr>
<td>Curiosity</td>
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<tr>
<td>Sadness</td>
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<tr>
<td>Nervousness</td>
<td></td>
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<tr>
<td>Anger</td>
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</tbody>
</table>

Consider how you handle your emotions at this moment

<table>
<thead>
<tr>
<th>Handling</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am overwhelmed by worry</td>
<td></td>
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<tr>
<td>I re-experience in my thoughts how I acted in a specific situation</td>
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<tr>
<td>I observe my emotions without being caught up in them</td>
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<td></td>
<td></td>
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<tr>
<td>I am afraid of my emotions</td>
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CONQUER FEAR AND EMOTION REGULATION

• Conquer Fear may increase ER flexibility by:
  ➢ Broadening the individual’s repertoire of ER strategies (mindfulness and acceptance-based strategies).
  ➢ Reducing overreliance on worry.
  ➢ Increasing context sensitivity (through detached mindfulness and attentional skills)

• First study to employ an experience sampling method to evaluate ER flexibility as an outcome in an RCT of a psychological intervention.
Diurnal cortisol as a biomarker of the effect of Conquer Fear?

- Abnormalities of circadian variation in cortisol is associated with increase risk of
  - depression in cancer survivor
  - cancer-relate fatigue
  - disturbed sleep.
- Dysregulated HPA function mediates the effects of psychosocial stress and sleep disruption in cancer patients and survivors.
- Dysregulated HPA function is a predictor of breast cancer survival
- Improved psychosocial outcomes following psychological interventions are correlated with changes in cortisol.
SALIVA SAMPLING

- Home-collection of saliva samples four times a day for two days pre and post intervention.
- Samples are collected at:
  - Personal waking time
  - 30 minutes following awakening
  - Between 4 p.m. and 6 p.m.
  - At bedtime
INTERRUPTION

- Eight participants.
- Two therapists.
- The therapy consists of 6 sessions:
  - Session 1 individually delivered (1.5h).
  - Session 2 to 6 delivered in group (2h).
CONTROL CONDITION

• One group session (3 hours):
  ➢ Psychoeducation
  ➢ Relaxation training
  ➢ Peer discussion

• CC participants reporting high levels of FCR (FCRI-SF score ≥22) at 6 months follow-up will be offered CF-G.
ADAPTATION TO GROUP FORMAT

• Combination of therapist presentations, exercises, discussions in pairs, and group discussions.
• 6 sessions instead of 5 (1 individual and 5 group sessions)
• “Past issues” discussed in session 1 instead of session 2.
• Work on values and goal setting is discussed in session 2 instead of session 1.
• Brief introduction to model and aim with treatment in session 1 – elaborated in session 2.
• In case of relapse: individual session is arranged in order to clarify whether the patient wishes to continue in the group or discontinue treatment.
GENERAL STRUCTURE FOR CF-G

Since the last time
- Patients share by turn reflections from the past week
- Homework is reviewed.

Therapist presents the agenda
- Therapists present the structure and content of the day.

Work with content
- Alternating therapist presentations, exercises, discussions in pairs, and discussions in the group

Wrap up
- Discussion of homework.
- Summary of the session and question time.
• Jan – Apr 2018: Individual therapy - six patients.

• Apr – May 2018: Initiation of screening
• May – Jul 2018: Treatment of one group (N = 8)

• Aug 2018: Initiation of screening
• Sep 2018 – Nov 2019: Intervention
• Nov 2019 – May 2020: Follow-up
• Jun 2020 - Oct 2020: Intervention for CC participants with FCRI-SF ≥22
• Feb 2021: Termination of project
GROUP THERAPY – PROS AND CONS?

Pros
• Contact with peers – not alone – belongingness – support each other.
• Develop insight into own issues by listening to others.
• More affordable.

Cons
• The attention of the therapist is spread - not as focused treatment.
• Less opportunity to explore each person’s issues (e.g., values and meta-cognitions).
• Less speaking time.
• Group therapy is not appropriate for some individuals.