ACT for Cancer Survivors with Clinically Significant Fear of Recurrence: Results of a 3-Arm Randomized Pilot

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BACKGROUND

- Fear of cancer recurrence (FCR) is one of the most prevalent, persistent, and disruptive sources of distress for adult cancer survivors, with 44-56% of survivors reporting clinically-significant FCR after successful treatment with curative intent.
- FCR is common regardless of the type or stage of cancer, extends for a decade or longer in many disease-free survivors, and can negatively affect medical follow-up behavior, mood, relationships, work, and quality of life.
- FCR is the most frequently identified unmet supportive care need reported by breast cancer survivors (BCS).
- Few empirically supported treatments for FCR exist. Butow and colleagues (2017) conducted one of the largest (N=222) and most rigorous randomized FCR trials to date:
  - FCR was primary outcome of the trial
  - Used clinically significant FCR as an eligibility criterion
  - Found significant reductions in FCR favoring their multi-component intervention over attention control; however, the intervention combined components of several intervention approaches, including acceptance of uncertainty and values clarification from Acceptance and Commitment Therapy (ACT) and strategies for "controlling worry" and "modifying unhelpful beliefs about worry" (Butow et al., 2017, p. 4067), which are inconsistent with ACT
  - The study reported 32% attrition and the intervention was delivered individually, which is resource-intensive and may limit uptake in practice
- Primary objective of the current 3-arm randomized pilot was to assess feasibility, acceptability, and preliminary efficacy of an ACT-based group intervention in reducing FCR and cancer-related avoidant coping and improving global health compared to a survivorship education (SE) group and enhanced usual care (EUC)

INTERVENTIONS

- 91 breast cancer survivors (BCS) were randomly assigned to one of the following intervention groups:
- **Acceptance and Commitment Therapy (ACT)**
  - 6 weekly 2-hour group sessions
  - Focused on strategies for coping adaptively with FCR, including acceptance, cognitive defusion, contact with the present moment, self-as-context, values, and committed action
- **Survivorship Education (SE)**
  - 6 weekly 2-hour group sessions
  - Focused on heightening survivors' awareness of behaviors [e.g., exercise, nutrition, surveillance] that may help reduce risk of recurrence
- **Enhanced Usual Care (EUC)**
  - Self-administered intervention with reading materials on coping with FCR and other common survivorship challenges
  - Brief coaching at data collection events

METHODS

- Eligible participants met the following criteria:
  - Breast cancer diagnosis
  - Early stage (I-III)
  - Completed curative treatment (no recurrence)
  - Clinically significant FCR (score ≥ 13 on Fear of Cancer Recurrence Inventory-Short Form)

- **Outcomes:**
  - **Feasibility** was assessed with:
    - ✓*Enrollment rate* of eligible participants
    - ✓*Attendance* across 6 weekly sessions (ACT & SE arms)
    - ✓*Retention* through end of trial (all arms)
  - **Acceptability** was assessed post-intervention:
    - ✓ *Intervention satisfaction*, measured on a 1 to 5 Likert scale (1=extremely dissatisfied, 5=extremely satisfied).
    - ✓ *Helpfulness* in managing FCR, measured on a 0 to 10 Likert scale (0=not at all helpful, 10=completely helpful)
  - **Preliminary Efficacy** was assessed with:
    - ✓ Fear of Cancer Recurrence Inventory (FCRI) total score (primary outcome) and 7 subscales
    - ✓ Cancer-related avoidant coping (AAQ-Cancer)
    - ✓ Global health (PROMIS Global Health Scale)
- **Analysis**: Intent-to-treat ANCOVA for pair-wise Cohen's d effect sizes of change scores between the 3 arms on efficacy outcomes immediately post-intervention (T2) and 6-months later (T3) controlling for baseline (T1) scores. Tukey was used to adjust for multiple comparisons. All P-values were compared to an alpha of 0.05.

PARTICIPANT DEMOGRAPHICS

Table 1

	ACT (N=33)	SE (N=32)	EUC (N=26)	*p* value
Age, mean (SD)	59.8 (11.1)	57.5 (10.5)	58.7 (10.5)	0.79
Race, N (%)				
White	28 (30.8)	27 (29.7)	21 (23.1)	0.83
Black/African American	3 (3.3)	3 (3.3)	4 (4.4)	
Other	2 (2.2)	2 (2.2)	1 (1.1)	
Hispanic/Latino, N (%)	0 (0.0)	0 (0.0)	2 (2.3)	0.08
Partner Status, N (%)				
Partnered	23 (25.3)	23 (25.3)	19 (20.9)	0.82
Not Partnered	10 (11.0)	9 (9.9)	7 (7.7)	
Highest Level of Education, N (%)				
High School Graduate or Less	13 (14.3)	10 (11.0)	9 (9.9)	0.61
College Graduate	13 (14.3)	13 (14.3)	7 (7.7)	
Post-Baccalaureate	7 (7.7)	9 (9.9)	10 (11.0)	
Employed Full time, N (%)	16 (17.6)	13 (14.3)	14 (15.4)	0.60
Household Income, N (%)				
<$15,000	1 (1.1)	3 (3.4)	1 (1.1)	0.70
$15,000 - $24,999	3 (3.4)	1 (1.1)	0 (0.0)	
$25,000 - $49,999	5 (5.7)	3 (3.4)	5 (5.7)	
$50,000 - $74,999	7 (8.0)	7 (8.0)	5 (5.7)	
$75,000 - $99,999	6 (6.8)	6 (6.8)	8 (9.1)	
>$100,000	10 (11.4)	11 (12.5)	6 (6.8)	
Months Post Cancer Dx, mean (SD)	48.3 (28.2)	77.5 (76.6)	67.0 (51.1)	0.61
Stage at Diagnosis, N (%)				
I	17 (21.2)	12 (14.3)	8 (9.5)	0.62
II	10 (11.9)	13 (15.5)	12 (14.3)	
III	5 (6.0)	4 (4.8)	3 (3.6)	

PRELIMINARY EFFICACY

Table 2

Estimated Slopes (Change) from Baseline to Post-treatment (S1), Baseline to 6-Month Follow-Up (S3), and Effect Sizes (Cohen's d)

	ACT LSM [95% CI]	SE LSM [95% CI]	EUC LSM [95% CI]	ACT vs. SE d	ACT vs. EUC d	SE vs. EUC d
FCRI Total Score						
S1	-0.29 [-0.43, -0.14]***	-0.02 [-0.17, 0.13]	-0.10 [-0.27, 0.07]	0.69*	0.46	-0.20
S3	-0.44 [-0.53, -0.35]***	-0.10 [-0.19, -0.00]*	-0.26 [-0.36, -0.15]***	0.73***	0.42*	-0.38
FCRI Triggers						
S1	-0.43 [-0.66, -0.19]***	-0.04 [-0.29, 0.20]	-0.06 [-0.34, 0.22]	0.61	0.60	-0.03
S3	-0.63 [-0.76, -0.50]***	-0.24 [-0.37, -0.11]***	-0.42 [-0.57, -0.28]***	0.64***	0.33	-0.31
FCRI Severity						
S1	-0.45 [-0.62, -0.28]***	-0.11 [-0.29, 0.07]	-0.19 [-0.39, 0.01]	0.68*	0.58	-0.19
S3	-0.70 [-0.82, -0.58]***	-0.19 [-0.32, -0.07]**	-0.39 [-0.53, -0.25]***	0.80***	0.61**	-0.36
FCRI Psychological Distress						
S1	-0.54 [-0.80, -0.27]***	-0.11 [-0.38, 0.17]	0.05 [-0.26, 0.36]	0.67	0.81*	0.22
S3	-0.66 [-0.81, -0.50]***	-0.20 [-0.36, -0.05]*	-0.26 [-0.44, -0.09]**	0.67***	0.52**	-0.08
FCRI Functioning Impairments						
S1	-0.31 [-0.50, -0.12]**	0.13 [-0.07, 0.33]	-0.17 [-0.39, 0.06]	0.97**	0.23	-0.56
S3	-0.38 [-0.51, -0.26]***	0.03 [-0.10, 0.16]	-0.16 [-0.31, -0.01]*	0.69***	0.35	-0.30
FCRI Insight						
S1	-0.30 [-0.52, -0.07]*	-0.04 [-0.28, 0.20]	-0.29 [-0.56, -0.02]*	0.41	0.01	-0.50
S3	-0.39 [-0.54, -0.25]***	0.01 [-0.14, 0.16]	-0.19 [-0.36, -0.02]*	0.54***	0.31	-0.32
FCRI Reassurance						
S1	-0.03 [-0.32, 0.25]	0.03 [-0.27, 0.32]	0.06 [-0.27, 0.39]	0.08	0.13	0.05
S3	-0.18 [-0.38, 0.01]	0.03 [-0.17, 0.23]	-0.05 [-0.28, 0.17]	0.23	0.15	-0.11
FCRI Coping Strategies						
S1	0.04 [-0.21, 0.29]	-0.01 [-0.27, 0.25]	-0.05 [-0.34, 0.25]	-0.08	-0.14	-0.06
S3	-0.05 [-0.20, 0.09]	0.05 [-0.11, 0.20]	-0.11 [-0.28, 0.06]	0.14	-0.08	-0.25
AAQ-Cancer						
S1	-0.45 [-0.67, -0.23]***	-0.05 [-0.28, 0.18]	-0.03 [-0.29, 0.23]	-0.66*	-0.68*	0.04
S3	-0.69 [-0.82, -0.56]***	-0.05 [-0.18, 0.09]	-0.22 [-0.37, -0.07]**	-0.97***	-0.80***	-0.32
PROMIS Global – Physical						
S1	1.31 [0.68, 1.94]***	0.00 [-0.68, 0.68]	-0.34 [-1.13, 0.45]	0.72*	0.95**	0.23
S3	1.32 [0.93, 1.71]***	0.07 [-0.34, 0.48]	-0.51 [-0.99, -0.03]*	0.62***	0.82***	0.32
PROMIS Global – Mental						
S1	1.36 [0.52, 2.19]**	-0.26 [-1.18, 0.67]	0.18 [-0.80, 1.15]	0.68*	0.55	-0.24
S3	1.28 [0.83, 1.72]***	0.11 [-0.36, 0.58]	0.03 [-0.49, 0.54]	0.52**	0.58**	0.04

Note. LSM = least squares mean; ACT = acceptance and commitment therapy; SE = survivorship education; EUC = enhanced usual care; CI = confidence interval; FCRI = fear of cancer recurrence inventory
* p <.05 , ** p < .01 , *** p <.001

RESULTS

- Participant demographics are shown in Table 1
- **Feasibility**
  - Enrollment: 61.7% of eligible BCS enrolled in trial
  - Attendance: 5.0 sessions in ACT group and 5.2 sessions in SE group; no significant difference between groups (*p*=0.47)
  - Retention: 94.5% through T3; no significant differences between groups (*p*-values range from 0.61-0.94)
- **Acceptability**
  - Intervention satisfaction: ACT and SE participants reported moderately high mean satisfaction scores (3.64 and 3.92, respectively), with no significant between-group difference (p=0.12). EUC participants reported significantly less satisfaction (2.75) than ACT and SE participants (p<0.0001)
  - Helpfulness: Mean helpfulness scores were 6.52 in ACT, 7.50 in SE, and 3.76 in EUC. SE participants rated their intervention as marginally more helpful than ACT participants (p=0.069); ACT and SE participants rated their respective interventions as being significantly more helpful than EUC (both p<0.0001)
- **Preliminary Efficacy**: Outcomes are reported in Table 2

CONCLUSIONS

- Trial was feasible and BCS were engaged, as evidenced by high attendance and retention rates.
- Intervention satisfaction and helpfulness were moderately high in ACT and SE arms.
- Findings suggest BCS are interested in behavioral interventions to address FCR; however, an active & engaging intervention may be more satisfying and helpful than reading materials & brief coaching.
- ACT was superior to SE & EUC in reducing FCR, cancer-related avoidant coping, and improving mental & physical global health at 6-mos post-intervention, generally with moderate-to-large effects.
- Limitations include: small sample size and limited generalizability due to demographic characteristics of sample.
- ACT is a promising intervention for BCS with FCR - warrants fully powered efficacy trial with more diverse sample for generalizability

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