RESEARCH ARTICLE

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The Effectiveness of Acceptance and Commitment Therapy on Fear of Cancer Recurrence in Patients with Gastrointestinal Cancer with a Stoma: A Randomized Controlled Trial

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Abstract

Background: Patients with gastrointestinal cancer (GIC) experience multiple psychological and physical complications during cancer treatment. A major psychological concern is the fear of cancer recurrence (FCR), which can negatively affect mental health and quality of life. Therefore, implementing effective interventions to manage FCR is essential. **Objectives:** This study aimed to evaluate the effectiveness of an Acceptance and Commitment-Based Therapy Program (ACBTP) in reducing FCR among patients with GIC with a stoma. **Methods:** In this single-blinded randomized clinical trial, 40 patients with GIC and a stoma were randomly assigned to intervention (n = 20) and control (n = 20) groups. The intervention group received eight ACBTP sessions, while the control group received routine care. Data were collected using the FCR-7 questionnaire before and one month after the intervention. **Results:** There were no statistically significant baseline differences between the two groups regarding gender, age, education, marital status, or stoma duration. Post-intervention, the intervention group had a significantly lower mean FCR score than the control group ($p < 0.001$). **Conclusion:** The ACBTP was effective in improving psychological adaptation and significantly reducing FCR in patients with GIC and a stoma. This approach could be considered as part of supportive care in cancer management.

Keywords: Acceptance and Commitment Therapy- Fear of Cancer Recurrence- Gastrointestinal Cancer- Stoma

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Introduction

Cancer remains one of the leading global health challenges, accounting for over 60% of deaths in developing countries and ranking as the third leading cause of mortality in Iran [1, 2]. Among different types of malignancies, gastrointestinal cancers (GICs)—including esophageal, gastric, and colorectal cancers—are highly prevalent, responsible for approximately 18.7% of new cancer cases and 22.6% of cancer-related deaths worldwide in 2020[3].

Surgical interventions, particularly ostomy procedures, are frequently performed in colorectal cancer management to improve survival and quality of life[4–6]. However, ostomy patients often face long-term physical and psychological complications, such as altered body image, loss of bowel control, unpleasant odors, sexual dysfunction, and increased hospital readmissions[7–14]. These challenges frequently lead to social withdrawal, emotional distress, and impaired daily functioning[15–19].

In addition to these complications, fear of cancer recurrence (FCR) is highly prevalent among cancer survivors, with more than 70% reporting clinically significant levels of FCR[20]. Despite its profound negative impact on mental health, treatment adherence, and quality of life, intervention studies specifically targeting FCR in ostomy patients remain scarce.

Psychological interventions can play a crucial role in enhancing treatment adherence and coping mechanisms. Acceptance and Commitment-Based Therapy (ACT), introduced by Hayes in 1986, focuses on developing psychological flexibility the ability to select adaptive behaviors aligned with personal values rather than avoiding distressing thoughts and feelings[22]. This therapeutic approach has shown promise in improving mental well-being among cancer patients[21–24].

Given the paucity of targeted interventions for managing FCR in patients with GIC and a stoma, this study aimed to evaluate the effectiveness of an Acceptance and Commitment-Based Therapy Program (ACBTP) in reducing FCR within this vulnerable population.

Materials and Methods

Study Design

This single-blinded randomized clinical trial was

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conducted from June 2024 to June 2025 at a teaching hospital in Zahedan, Iran.

Participants and Setting

Eligible participants were patients aged 14–70 years, diagnosed with gastrointestinal cancer (GIC) and having either a temporary or permanent stoma. Additional inclusion criteria included:

• At least one month since ostomy surgery

• Not having attended prior stoma care training courses

Exclusion criteria were disease exacerbation requiring hospitalization or withdrawal of consent at any stage.

Sample Size Calculation

The sample size was determined based on findings by Hasannezhad Reskati et al. (2019), considering:

• Type I error = 0.05

• Power = 80%

• Expected difference between groups = 10

• Standard deviation = 12

This calculation indicated 10 participants per group, but to account for potential attrition and ensure adequate power for statistical testing, we recruited 20 participants in each group (total = 40).

Measurement Tools

Data were collected using:

1. Demographic Checklist: Age, gender, education, marital status, and stoma duration.

2. Fear of Cancer Recurrence Questionnaire (FCR-7):

• The FCR-7 is a 42-item self-report instrument designed to assess FCR over the past month.

• The name "FCR-7" reflects its seven dimensions: triggers, intensity, agitation, dysfunction, insight, confidence, and coping.

• Items are scored on a 0–4 Likert scale, with one reverse-scored item ("I believe that I am cured and my disease will not return").

• Scores are summed to yield a total FCR score; higher scores indicate greater fear.

• The Persian version's content validity was confirmed by 10 faculty experts, and Cronbach's alpha values for dimensions ranged from 0.83 to 0.91, demonstrating high reliability.

Randomization and Intervention

Participants were randomly assigned to either:

• Intervention group (n = 20): Received eight sessions of Acceptance and Commitment-Based Therapy Program (ACBTP)

• Control group (n = 20): Received routine care only

Randomization was performed using block randomization via the website www.sealedenvelope.com.

Each ACBTP session lasted 45–60 minutes, held three times per week for three consecutive weeks, conducted by the first author in the hospital's cancer ward classroom.

The session outline is provided in Table 1.

Participants in both groups completed baseline assessments before the intervention and follow-up assessments one month after completion.

Follow-Up

To enhance adherence, participants in the intervention group received weekly phone follow-ups, addressing potential difficulties, satisfaction, and willingness to continue. After study completion, control group participants were given the educational material for ethical compliance.

Data Analysis

Statistical analyses were performed using SPSS v16.

• Normality: Kolmogorov–Smirnov test

• Baseline comparisons: Independent t-test (quantitative) and Chi-square test (categorical variables)

• Effectiveness: Paired t-test (within-group), Independent t-test (between-group)

• Significance level: $P < 0.05$

Ethical Considerations

The study was approved by the Ethics Committee

Table 1. Outline of the Sessions of an Acceptance and Commitment-based Therapy Training Program

Session	Practice
First	Introducing himself,
	Explaining the purpose of the intervention, the importance of their collaboration, the signs, causes, and symptoms of gastrointestinal cancer, types of treatment, and the importance of patient care
	Participants get to know each other and the therapist, explain the concepts of thinking, feeling and behavior, basic principles, importance of assignments and exercises
Second	Explaining avoidance experiences and practicing frustration and patients' underlying beliefs about change
Third	Training on the principle of acceptance and its strategies, suppression exercises and awareness training
Fourth	Review of previous material,
	explaining contact with the present time and conscious attention, and strategies for fault and context assumption with examples
Fifth and sixth	Explaining strategies for clarifying, measuring values, and taking committed action along the path of values by providing exercises and examples, and reviewing past sessions.
Seventh and eighth	Reviewing the content of previous sessions,
	Group discussion on the problems members had with previous exercises,
	Paying attention to patterns of committed action and providing suggestions for continuing the exercises in daily life

of Zahedan University of Medical Sciences (Approval Code: IR.ZAUMS.REC.1403.084) and registered in the Iranian Clinical Trials Registry (IRCT Code: IRCT20231120060120N3) (Figure 1).

Written informed consent was obtained from all participants, and the study adhered to the Declaration of Helsinki.

Results

The study included 40 patients with gastrointestinal cancer and a stoma, evenly divided into intervention (n = 20) and control (n = 20) groups.

Baseline Characteristics

The mean age of participants was 41.3 ± 14.0 years in the intervention group and 42.0 ± 12.3 years in the control group. There were no significant differences between groups regarding gender, age, education, marital status, or stoma duration before the intervention (P > 0.05, Table 2).

Effect of Intervention on FCR

Within the intervention group, the mean FCR score significantly decreased from 147.70 ± 4.92 at baseline to 55.30 ± 6.91 post-intervention (P < 0.001, paired t-test).

In the control group, no significant change was observed (baseline: 147.10 ± 3.17 vs. post-intervention: 147.25 ± 3.99, P = 0.65).

Between groups, the post-intervention FCR score was significantly lower in the intervention group compared to the control group (P < 0.001, independent t-test) (Table 3).

Discussion

The present randomized controlled trial demonstrated that Acceptance and Commitment-Based Therapy (ACBTP) significantly reduced fear of cancer recurrence (FCR) among patients with gastrointestinal cancer (GIC) and a stoma. One month after the intervention, participants in the therapy group showed a substantial decline in FCR scores compared to the control group, indicating the effectiveness of ACT-based psychological interventions in addressing cancer-related fears.

These findings align with previous research. For example, Mardani et al. [25] identified themes of living with insecurity and fear of cancer return among prostate cancer survivors, highlighting that fear of recurrence is common across cancer types. Similarly, Goebel et al. [26]reported that 42% of patients with primary brain tumors experienced high levels of fear of progression, which correlated with anxiety, depression, and reduced quality of life. Our results are consistent with these studies, reinforcing the need for targeted psychological interventions.

Moreover, Zarei et al. [27] demonstrated that perceived social support mediates the relationship between FCR and quality of life in patients undergoing active cancer treatment. The psychological flexibility cultivated by ACT may enhance patients' ability to cope with uncertainty and engage in supportive social interactions, indirectly

Table 2. Characteristics of Participants (n = 40)

Variable	Group	Intervention	Control	P
		Mean ± SD or n (%)	Mean ± SD or n (%)	
Age (years)		00/14 ± 30/41	30/12 ± 00/42	0/72[a]
Duration of stoma placement (months)		76/2 ± 45/4	35/4 ± 90/5	0/75[a]
Gender	Men	14 (51/9)	13(48/1)	0/73[b]
	Female	6 (46/2)	7 (53/8)	
Marital status	Single	7 (58/3)	5 (41/7)	0/49 [b]
	Married	13 (46/4)	15 (53/6)	
Education level	Elementary and middle school	12 (60/0)	8 (40/0)	0/44 [b]
	high school	5 (41/7)	7 (58/3)	
	Bachelor's degree	3 (37/5)	5 (62/5)	
Occupation	Unemployed	8(50/0)	8(50/0)	0/88 [b]
	Employee	1(33/3)	2(66/7)	
	freelance job	9 (50/0)	9 (50/0)	
	Other	2 (66/7)	1(33/3)	

[a], Data presented as independent t-test; [b], Chi-square test, the significance level is p<0.05

Table 3. Comparison of the Fear of Cancer Recurrence before and after the Intervention

Variable	Group	Before intervention	After intervention	P[b]
		Mean ± SD	Mean ± SD	
fear of cancer recurrence	intervention	147/70±4/92	55/30±6/91	P<0.001
	Control	147/10 ± 3/17	147/25± 3/99	P<0.001
	P[a]	0/65	0/00	

[a], Data presented as independent t-test; [b], paired t-test

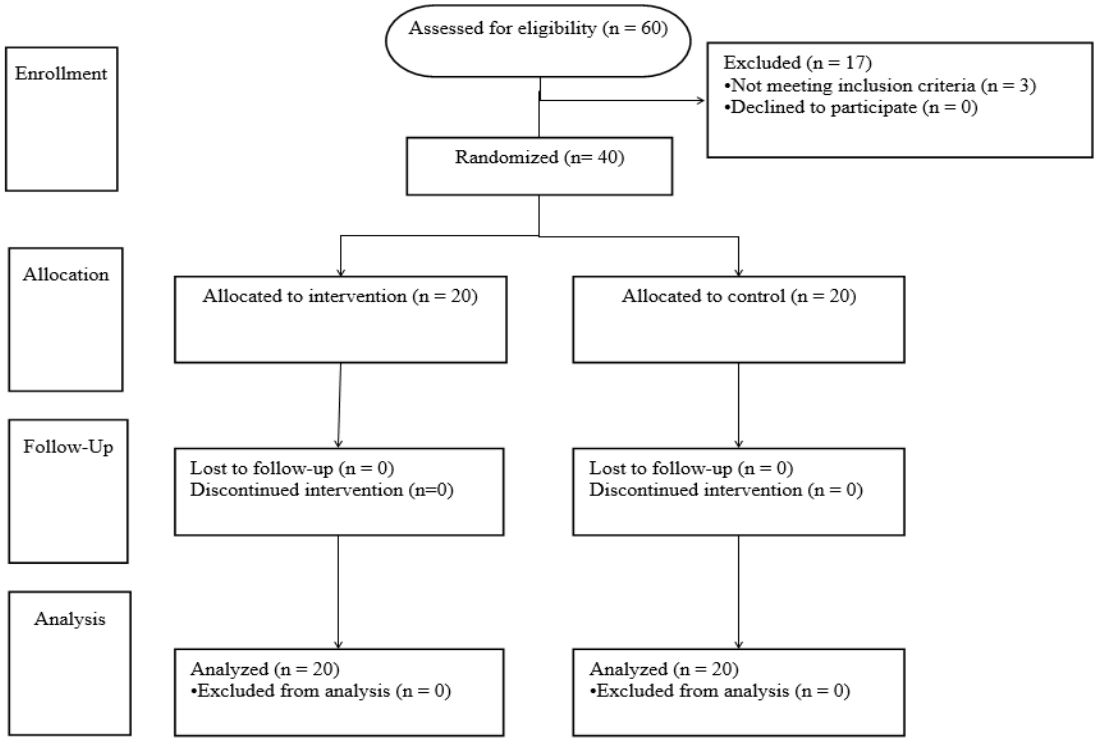

Figure 1. Presents the CONSORT Flow Diagram of Participant Recruitment, Allocation and Analysis

improving overall well-being.

This study adds to the limited body of literature on interventions specifically addressing FCR in ostomy patients, a subgroup that often faces additional psychosocial challenges due to body image disturbances, social stigma, and physical complications related to stoma management. By tailoring ACT principles to these unique needs, the intervention provided participants with strategies to accept distressing emotions, reduce avoidance behaviors, and commit to value-driven actions, leading to reduced fear of recurrence.

Limitations

Several limitations should be acknowledged:

• Short follow-up duration: Outcomes were assessed only one month after intervention; longer follow-up is needed to evaluate sustained effects.

• Sample size and generalizability: Although adequately powered, the study was conducted in a single center, which may limit generalization to broader populations.

• Self-reported outcomes: Reliance on questionnaires may introduce response bias.

• Lack of active control group: Future studies could compare ACBTP with other psychological interventions.

Implications

Despite these limitations, this study provides strong preliminary evidence that ACBTP can effectively reduce FCR in GIC patients with stomas. Integration of ACT-based therapy into routine cancer care could improve psychological outcomes, promote treatment adherence, and enhance quality of life for this vulnerable population. Future multicenter trials with longer follow-up periods are warranted to confirm these findings and refine intervention protocols.

Author Contribution Statement

Hanie Dahmardeh (HD): Conceptualization, methodology, investigation, data collection. Mehdi Rezvaniamin (MR): Supervision, validation, project administration. Alireza Salar (AS): Data analysis, writing-review and editing. All authors contributed significantly to the manuscript preparation, approved the final version, and agreed to be accountable for all aspects of the work.

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Data Availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Trial Registration

This study is registered at IRCT (Iranian Clinical Trials Registry) with registration code IRCT20231120060120N3 (available at: https://irct.behdasht.gov.ir).

Conflict of Interest

The authors declare no conflict of interest related to this study.

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