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Acceptance and Commitment Therapy for Adults Living With Inflammatory Bowel Disease and Distress: A Randomized Controlled Trial

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INTRODUCTION: **The bidirectional relationship between disease activity and mental health in inflammatory bowel disease (IBD) has prompted investigations into the efficacy of psychotherapeutic interventions such as acceptance and commitment therapy (ACT) on biopsychosocial outcomes. We aimed to examine the efficacy of an ACT program (intervention) in comparison with a cognitive behavioral therapy–informed psychoeducation program (active control) for individuals with IBD and coexistent psychological distress. Both programs were delivered online through a hybrid format (i.e., therapist-led and participant-led sessions).**

METHODS: **A total of 120 adults with IBD were randomized to either the intervention (N = 61) or active control groups (N = 59). Efficacy was determined using linear mixed models for group differences, in rate of changes in study outcomes, between baseline, postintervention, and 3-month follow-up.**

RESULTS: **The primary outcome health-related quality of life significantly improved in the intervention group when compared with the active control group, with a significantly different rate of change observed from baseline to postintervention ($t[190] = 2.15$, $P = 0.033$) in favor of the intervention group with a medium effect size ($\beta = 0.41$, mean difference = 0.07, 95% confidence interval 0.01–0.12, $P = 0.014$). Similarly, the secondary outcome Crohn's disease activity significantly reduced in the intervention group when compared with the active control group, with a significantly different rate of change observed from baseline to 3-month follow-up ($t[90] = -2.40$, $P = 0.018$) in favor of the intervention group with a large effect size ($\beta = -0.77$, mean difference = −9.43, 95% confidence interval −13.72 to −5.13, $P < 0.001$) ($P = 0.014$). Furthermore, when observing the rate of change in outcomes over time for the groups separately, anxiety symptoms and pain significantly improved in the intervention group only, and conversely, ulcerative colitis activity and stress symptoms significantly improved in the active control group only. All other outcomes (N = 14) significantly improved over time in both groups including IBD activity, gastrointestinal unhelpful thinking patterns, visceral anxiety, fatigue interference, fatigue severity, fatigue frequency, psychological inflexibility, self-efficacy, resilience, current health status, depression symptoms, IBD control, and pain catastrophizing; however, these changes were not significantly different between the groups.**

DISCUSSION: **Both programs were of benefit to people with IBD and distress. However, ACT offers a significant added benefit for health-related quality of life and self-reported Crohn's disease activity and may be a useful adjuvant therapy in integrated IBD care.**

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INTRODUCTION

Inflammatory bowel disease (IBD) is an umbrella term for several chronic relapsing-remitting inflammatory conditions of the gastrointestinal tract, including 2 main types—ulcerative colitis and Crohn's disease (1). Typical symptoms include diarrhea, abdominal pain, fecal urgency, nausea, fatigue, and weight loss (2). IBD has a rising global prevalence of 6.8 million people and accounts for a significant financial burden (3). In Australia alone, direct and indirect costs are $2.7 billion and $380 million, respectively (4). Importantly, those living with IBD experience a significantly impacted health-related quality of life (HRQoL) (5,6). The etiology of IBD remains unclear; however, key factors are believed to include a dysfunctional interaction between the immune system and intestinal microbiota, with genetic susceptibility and environmental factors also implicated (2,7).

More recently research has attributed mental health as contributing to the pathogenesis of IBD, classifying it as a mind-body disease with mounting evidence for a bidirectional brain-gut relationship (8–11). Those living with IBD experience 2–3 times higher rates of mental health comorbidities in comparison with healthy populations (12–14). Numerous studies have provided evidence for this bidirectionality, e.g., several large longitudinal studies have found a significant 2-way relationship between psychological distress and clinical disease recurrence (15–17).

The significance of these results has led to changes in international IBD management guidelines to include mental health screening and treatment (18). Conversely, research has found that IBD quality of care does not meet standards of international guidelines (19). In Australia, e.g., only 4% of IBD clinical services have psychological interventions incorporated into routine treatment protocols (20). Further to this, current psychological interventions for IBD, such as cognitive behavioral therapy (CBT) and hypnotherapy, have offered limited evidence for changes to mental health or disease activity, mostly finding short-term improvements in HRQoL (21). This presents a major gap in integrated IBD care.

Third-wave psychotherapies such as acceptance and commitment therapy (ACT) and mindfulness-based interventions have more recently been investigated in IBD. Third-wave psychotherapies have evolved from CBT; however, they implement key differences in interpreting, managing, and responding to experiences (22). By definition, people living with a chronic disease face enduring and realistic challenges (e.g., greater morbidity and mortality rates than the general population) which traditional cognitive restructuring techniques, such as changing or eliminating difficult inner states, may not always resolve (22,23). Third-wave therapies instead promote acceptance and nonjudgment of difficult thoughts and emotions in response to the challenges of living with a chronic disease (22,23).

Recent meta-analytic evidence (K = 8, N = 575) found mindfulness-based interventions to be an effective psychotherapy for IBD, not only improving psychological outcomes such as stress, and HRQoL but also significantly reducing disease activity through lowered C-reactive protein levels (24). Only 1 trial to date, however, has examined the efficacy of ACT in the context of IBD, finding promising results including decreased stress and improved HRQoL (25). ACT has, however, been used successfully with a broad range of other chronic health conditions showing significant improvements to several important biopsychosocial outcomes such as HRQoL, disease activity, pain, fatigue, anxiety, depression, stress, resilience, and self-efficacy (26–31). Importantly, given the bidirectional brain-gut relationship in IBD, biopsychosocial outcomes can impact one another, e.g., research has found that individuals with IBD and comorbid anxiety and depression report lower HRQoL than those without emotional comorbidities (32).

The unique aim of ACT is to not control or suppress unwanted thoughts or emotions (known as experiential avoidance) but instead to foster a willingness to consciously experience the present moment, which includes both positive and negative thoughts and emotions (known as psychological flexibility) (22,23,33–35). Ultimately, ACT aims to promote a commitment to engaging in value-driven life activities even in the presence of negative inner experiences (22,23,33–35). The rationale is that improved psychological well-being may have flow-on effects on IBD course and vice versa. Given the potential for the positive effect of ACT for IBD, further high-quality trials are warranted and contribute to the gold standard of integrated IBD healthcare.

In the context of psychotherapy trials for IBD, researchers have also highlighted several limitations. Importantly, the continued recruitment of unselected participants without psychological distress provides limited outcomes for psychotherapeutic interventions to target (24,36,37). Another limitation is rare use of active control groups which strengthen the study methodology and reduce bias (23). Furthermore, current psychological interventions are largely based on existing treatment modules developed for nonchronic disease populations and are, therefore, not informed by consumer needs (24,38). Given that research has shown that individuals living with IBD experience unique disease-related beliefs or worries, it is suggested that interventions be codesigned together with consumers to meet their specific needs (39). Finally, there are specific barriers that those living with IBD face when attempting to engage in face-to-face psychological interventions, such as travel from rural/remote areas, appointment wait times, and high treatment costs (40,41). The online delivery of such interventions may assist in overcoming these barriers, providing a cost-effective, widely accessible, noninvasive treatment, reducing pressure on the healthcare system (40,41).

Therefore, the current study aims to evaluate the efficacy of an online delivered codesigned ACT program (intervention) in comparison with a CBT-informed psychoeducation program (active control) for several biopsychosocial outcomes in individuals living with IBD and coexistent psychological distress.

Aim 1: Is the improvement in biopsychosocial outcomes greater for the intervention group in comparison with the active control group?

Aim 2: Is there a change in biopsychosocial outcomes for either the intervention group or active control group from baseline to postintervention and 3-month follow-up?

METHODS

Design

A randomized single-blind controlled trial was conducted to assess the efficacy of ACT on several biopsychosocial outcomes for individuals living with IBD. The trial was registered prospectively in the Australian New Zealand Clinical Trials Registry (ACTRN12621001316897). Participants were randomly allocated to either the intervention group (ACTforIBD program) or the active control group (CBT-informed psychoeducation program). Both have been found to have excellent feasibility and acceptability (42). To ensure participants were blinded to group allocation, the program materials of both groups were masked, and the delivery of active control aimed to mimic the time and attention received by the intervention group. Study investigators were also blinded to group allocation. However, this was not practicable for the psychologists delivering the intervention. All participants remained on their treatment as usual.

Randomization was performed using Qualtrics computer-generated sequence with a 1:1 ratio. Randomization was stratified by IBD activity using the Manitoba IBD Index which equally divided participants with "low" disease activity (score of 1–3) and "high" disease activity (score of 4–6) between both study groups (43). All participants were asked to complete Qualtrics online questionnaires at baseline, postintervention, and 3-month follow-up. Participants who completed all study questionnaires were compensated for their time with a $30 online gift voucher.

Participants, recruitment, and sample size

Participants were recruited online between 2021 and 2023 through promotion on social media and IBD support organizations (i.e., Crohn's & Colitis Australia and Crohn's & Colitis New Zealand). Eligible participants were adults (aged 18+ years) with a formal diagnosis of IBD, residing in Australia or New Zealand, and proficient in English. Participants were included if they provided document evidence of their IBD diagnosis which was confirmed by the study team and scored mild to moderate (16–29) on the Kessler Psychological Distress Scale (K10) (44). Participants with too low distress were excluded as the aim of the study was to only include participants experiencing some distress. Participants with too severe distress were also excluded, and as for safety reasons, they may benefit from more intensive ongoing therapy.

For the power calculation, as the efficacy of ACT within the context of IBD is largely underexplored, we relied on meta-analytic evidence of ACT's efficacy for outcomes in other chronic disease populations. This available evidence suggests effect sizes ranging from 0.4 to 0.9 at postintervention and follow-up across a wide range of outcomes, including quality of life, psychological distress, and depression (27,45,46). Assuming $\alpha = 0.05$ (2-tailed test), a final sample size of 120 participants (60 per group) would achieve 80% power to detect a standardized mean difference >0.50 at postintervention for our outcome measures. This power calculation was conservative as the main analysis considered the repeated measures structure of the data.

Intervention and active control

The intervention (ACTforIBD program) was based on the core principles of ACT and was codesigned with people living with IBD and comorbid psychological distress in a previous study (47). The active control (CBT-informed psychoeducation program) was based on the Center for Clinical Interventions CBT-based materials and was also adapted to people living with IBD (48). Both programs consisted of 8, 1-hour, weekly sessions and were delivered in the same hybrid format, with only their content differing. Four of the sessions were led by a registered (or provisionally registered) psychologist and were conducted through Zoom. The provisional psychologists had undertaken training in CBT and ACT theory and application, with their knowledge and skills assessed through an objective structured clinical examination. The provisional psychologists met regularly for group supervision with a senior clinical psychologist with extensive training and expertise in CBT and ACT. Intervention content and processes were reviewed in supervision to ensure consistency in delivery by the provisional psychologists. The other 4 sessions were self-led by participants using online modules (including video and self-assessment activities) and were conducted through a dedicated study website using secure login. Please see Table 1 for a breakdown of the ACTforIBD and CBT-informed psychoeducation programs.

Screening measure

Psychological distress. The Kessler Psychological Distress Scale (K10) measures psychological distress (44). It consists of 10 items (e.g., "About how often did you feel so sad that nothing could cheer you up?") rated on a 5-point response scale (1 = none of the time to 5 = all of the time). Scores range from 10 to 50 indicating no distress to severe distress, and only participants with mild to moderate distress (scores of 16–29) were eligible to participate in the study ($\alpha = 0.70$).

Table 1. Weekly topics of the intervention and active control programs

	Intervention group (ACTforIBD)	Active control group (CBT-informed psychoeducation)
Therapist-led		
Module 1	Introduction to ACT	Stress management
Module 2	Avoidance	Progressive muscle relaxation
Module 3	Discovering values	Problem-solving
Participant-led		
Module 4	Mindfulness	Coping strategies
Module 5	Defusion	How to think more assertively
Module 6	Acceptance	How to behave more assertively
Module 7	Moving toward values	Sleeping for better well-being
Therapist-led		
Module 8	Staying committed	Toward a healthy self-esteem

ACT, acceptance and commitment therapy; CBT, cognitive behavioral therapy; IBD, inflammatory bowel disease.

Primary outcome

HRQoL The EQ-5D-5L measures HRQoL through 5 domains including mobility, personal care, usual activities, pain/discomfort, and anxiety/depression (49). It consists of 5 items (e.g., "personal care") rated on a 5-point response scale (e.g., 1 = I have no problems washing or dressing myself to 5 = I am unable to wash or dress myself). A total HRQoL score is computed by weighting item scores relative to normative Australian data to create index scores, with a higher score indicating better total HRQoL. There is an additional 1-item measure of current health status (i.e., "Please mark on the scale how good or bad your health is today") rated on a 0–100 response scale (0 = the worst health you can imagine to 100 = the best health you can imagine) with a higher score indicating better current health status.

Secondary outcomes

Depression, anxiety, and stress symptoms. The Depression Anxiety Stress Scale-21 provides 3 subscales measuring symptoms of depression, anxiety, and stress (50). It consists of 21 items, with 7 items per subscale (e.g., "I found it hard to wind down") rated on a 4-point response scale (0 = did not apply to me at all to 3 = applied to me very much or most of the time). Higher scores indicate higher symptoms of depression ($\alpha = 0.81$), anxiety ($\alpha = 0.61$), and stress ($\alpha = 0.73$).

Psychological inflexibility/experiential avoidance. The Acceptance and Action Questionnaire-II measures psychological flexibility and experiential avoidance (51). It consists of 7 items (e.g., "Worries get in the way of my success") rated on a 7-point response scale (1 = never true to 7 = always true). Higher scores indicate worse psychological inflexibility/experiential avoidance ($\alpha = 0.84$).

Resilience. The Brief Resilience Scale measures resilience (52). It consists of 6 items (e.g., "I tend to bounce back quickly after hard times") rated on a 5-point response scale (1 = strongly disagree to 5 = strongly agree). Higher scores indicate greater resilience ($\alpha = 0.85$).

Self-efficacy. The General Self-Efficacy Scale measures self-efficacy (53). It consists of 10 items (e.g., "Thanks to my resourcefulness I know how to handle unforeseen situations") measured on a 4-point response scale (1 = not at all true to 4 = exactly true). Higher scores indicate greater self-efficacy ($\alpha = 0.80$).

Gastrointestinal unhelpful thinking patterns. The Gastrointestinal Unhelpful Thinking Scale provides an overall measure of gastrointestinal-focused unhelpful thinking, as well as 2 subscales measuring pain catastrophizing and visceral anxiety (54). It consists of 15 items, with 9 items for the pain catastrophizing subscale and 6 items for the visceral anxiety subscale (e.g., "All I can think about is how I just want the pain to stop") rated on a 6-point response scale (0 = strongly disagree to 5 = strongly agree). Higher scores indicate greater gastrointestinal-focused unhelpful thinking ($\alpha = 0.98$), pain catastrophizing ($\alpha = 0.97$), and visceral anxiety ($\alpha = 0.95$).

Ulcerative colitis activity. The Patient-Reported Outcome 2-item is an adapted measure of ulcerative colitis activity (55). It consists of 2 items, item 1 (i.e., "Over the past week, how many bowel movements have you had on average per day?") and item 2 (i.e., Did you experience rectal bleeding over the past week?") rated on a 4-point response scale (0 = none to 3 = mostly blood). Higher scores indicate higher ulcerative colitis activity.

Crohn's disease activity. The Patient-Reported Outcome 3-item is an adapted measure of Crohn's disease activity (56). It consists of 3 items, item 1 (i.e., "Over the past week, how many of your bowel movements have been loose/watery stools on average per day?"), item 2 (i.e., "How was your abdominal pain or cramping over the past week?") rated on a 4-point response scale (0 = none to 3 = severe), and item 3 (i.e., "How was your general well-being over the past week?") rated on a 5-point response scale (0 = generally well to 4 = terrible). Higher scores indicate higher Crohn's disease activity.

IBD activity. The Manitoba IBD Index is a single-item measure of IBD disease activity (i.e., "In the past 3 months my disease has been?") rated on a 6-point response scale (1 = constantly active giving me symptoms every day to 6 = I was well in the past 3-months) (43). Higher scores indicate higher IBD disease activity.

IBD control. The IBD control questionnaire measures perceived IBD control and provides 2 subscales, the IBD control 8 and the IBD control Visual Analog Scale (VAS) (57). The IBD control 8 subscale consists of 8 items (e.g., "Do you believe that your IBD has been well controlled in the past 2 weeks?") with the first 2 items measured on a 3-point response scale (0 = no to 2 = yes) and the last 6 items measured on a different 3-point response scale (0 = yes to 2 = no). Higher scores indicate higher perceived IBD control ($\alpha = 0.86$). The IBD control VAS subscale is a single item (i.e., "How would you rate the overall control of your IBD in the past 2 weeks") measured on a 0–100 response scale (0 = worst possible control to 100 = best possible control). Higher scores indicate higher perceived IBD control.

Fatigue. The Fatigue Symptom Inventory measures the perceived severity, frequency, pattern, and interference of fatigue; however, we did not include fatigue pattern in our analysis (58). *Fatigue severity* consists of 4 items (e.g., "Rate your level of fatigue on the day you felt the most fatigued during the past week") rated on an 11-point response scale (0 = not at all fatigued to 10 = as fatigued as I could be). *Fatigue interference* consists of 7 items (e.g., "Rate how much in the past week fatigue interfered with your enjoyment of life") rated on an 11-point response scale (0 = no interference to 10 = extreme interference) ($\alpha = 0.94$). *Fatigue frequency* consists of 2 items, with item 1 (i.e., "Indicate how many days of the past week you felt fatigued for any part of the day") rated on an 8-point response scale (0 days to 7 days) and item 2 (i.e., "Rate how much of the day on average you felt fatigued over the past week") rated on an 11-point response scale (0 = none of the day to 10 = the entire day).

Pain. The Pain Numerical Rating Scale is a single-item measure of pain level (i.e., "We would like to learn about your pain levels in the past 7 days, this could be pain because of your IBD but also any other pain you have experienced") measured on a 0–10 response scale (0 = no pain to 10 = most severe pain) (59). Higher scores indicate greater pain levels.

Descriptive demographic and health-related information

Demographic and health-related information was collected at baseline through Qualtrics. Demographic information included age, gender, relationship status, main language spoken, education status, and employment status. Health information included IBD subtype, length of diagnosis, other chronic disease status, opioid medication use, antidepressant medication use, smoking status, alcohol use, body mass index, and whether they were currently seeing a mental health professional.

Statistical analyses

The analysis followed the intention-to-treat paradigm using jamovi software version 2.3 (60). To examine the efficacy of ACT on the primary and secondary outcomes, we performed linear

mixed models over the 3 data collection timepoints (i.e., baseline [T1], postintervention [T2], and 3-month follow-up [T3]) to compare the rate of change in outcomes over time between the intervention and active control groups. In line with multilevel modeling convention, we reported group × time interaction effects to determine group differences in rate of change, in outcomes over time (T1 and T2, and T1 and T3), with effect sizes reported as both unstandardized and standardized coefficients. We further reported simple effects of time to determine rate in change in outcomes over time (T1 and T2, and T1 and T3), for the intervention and active control groups, with effect sizes reported as mean differences and β weights. Missing data were not imputed, as the analyses used full information maximum likelihood for parameter estimates.

Most outcomes residuals met the assumptions of normality—homogeneity of variance and homoscedasticity. The exceptions were moderate to severe skew and/or kurtosis for total HRQoL corrected with cube transformation, current health status and IBD control (VAS subscale) corrected with square transformation, depression symptoms and anxiety symptoms correct with square root transformation, and ulcerative colitis activity corrected with log10 transformation.

Descriptive statistics were also provided for all baseline demographic and health-related data, including mean values and SDs for continuous data, and number and percentage for categorical data. We performed a 1-way ANOVA test to check for baseline group differences in descriptive demographic/health-related data, as well as primary and secondary outcomes, and no significant group differences were found ($P > 0.05$).

Ethical considerations

This study received ethics approval in Australia from Deakin University Research Ethics Committee (DUREC Ref. 2021-263) and in New Zealand from the Central Health and Disability Ethics Committee (CHDEC Ref. 2021-EXP-11384). Written informed consent was obtained from all participants. The study also adhered to the Consolidated Standards of Reporting Trials statement (61).

RESULTS

Participant recruitment, follow-up, and retention

Of the 461 participants who expressed interest in the study, 120 were found eligible to participate and were randomized into the intervention (N = 61) or active control groups (N = 59). The overall participant retention rate for those who completed the program across both groups was 88% (N = 105). The intervention program was completed by 50 (82%) participants, and of these, 46 (92%) completed the postintervention survey, and 43 (86%) completed the 3-month follow-up survey. The active control program was completed by 55 (93%) participants, and of these, 54 (98%) completed the postintervention survey, and 50 (91%) completed the 3-month follow-up survey. Please see Figure 1 for the Consolidated Standards of Reporting Trials diagram of the flow of participants throughout the study.

Main findings

Please see Table 2 for the study sample's baseline descriptive demographic and health-related information. For all study outcomes, please see Table 3 for mean values and SDs and Table 4 for linear mixed model results.

Significant group × time interaction effects. The primary outcome HRQoL significantly improved in the intervention group when compared with the active control group, with a significantly different rate of change observed from baseline to postintervention. The rate of change was greater for the intervention group with a moderate effect size (Table 4 and Figure 2). The

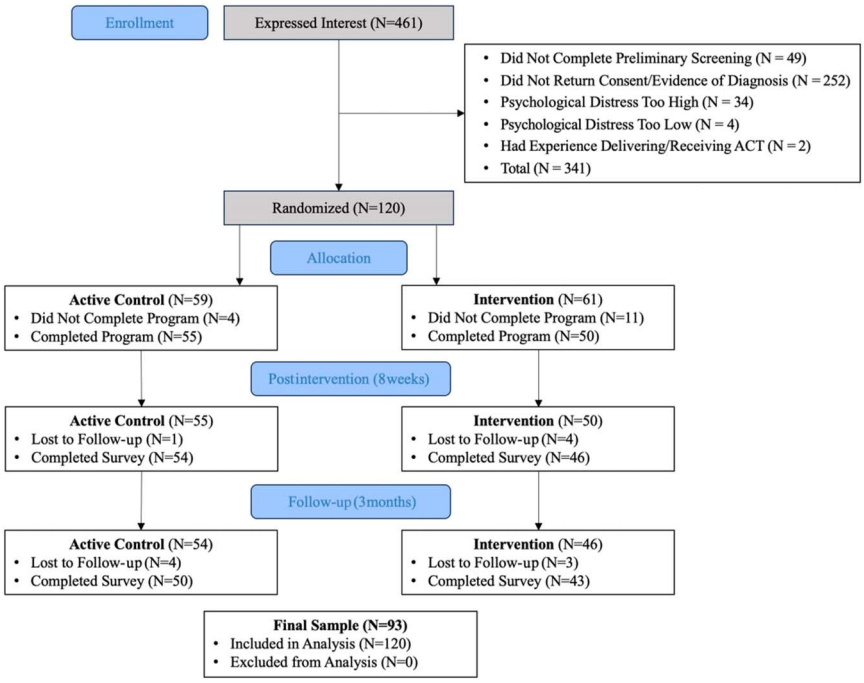

Figure 1. Consolidated Standards of Reporting Trials diagram of participant flow throughout the study.

Table 2. Study sample baseline descriptive demographic and health-related information

	Intervention (N = 61)	Active control (N = 59)
Age, yr, mean ± SD	34.3 ± 11.3	33.7 ± 10.5
Sex, n (%)		
Male	10 (16.4)	12 (20.3)
Female	51 (83.6)	47 (79.7)
IBD subtype, n (%)		
Crohn's disease	34 (55.7)	29 (49.2)
Ulcerative colitis	25 (41)	30 (50.8)
Indeterminate colitis	2 (3.3)	0 (0)
Length of diagnosis, yr, mean ± SD	10.6 ± 9.06	10.6 ± 9.18
Other chronic disease status, n (%)		
Yes	19 (31.1)	22 (40)
No	42 (68.9)	43 (60)
K10, mean ± SD	22.2 ± 4.11	23.4 ± 3.81
Currently seeing a mental health professional, n (%)		
Yes	14 (23)	10 (16.9)
No	47 (77)	49 (83.1)
BMI, mean ± SD	26.5 ± 5.85	26.1 ± 6.44
Opioid medication use, n (%)		
Yes	6 (9.8)	9 (15.3)
No	55 (90.2)	50 (84.7)
Antidepressant medication use, n (%)		
Yes	18 (29.5)	18 (30.5)
No	43 (70.5)	41 (69.5)
Smoking status, n (%)		
Never smoked	44 (72.1)	44 (74.6)
Former smoker	15 (24.6)	14 (23.7)
Occasional smoker	2 (3.3)	1 (1.7)
Current smoker	0 (0)	0 (0)
Alcohol use, n (%)		
More than 2 standard drinks per day	0 (0)	0 (0)
Fewer than 2 standard drinks per day	2 (3.3)	4 (6.8)
I drink several times a week	10 (16.4)	5 (8.5)
I occasionally drink	35 (57.4)	37 (62.7)
I never drink	14 (23)	13 (22)
Education status, n (%)		
Less than year 12	3 (4.9)	4 (6.8)
Year 12 or equivalent	6 (9.8)	8 (13.6)
Vocational education (TAFE)	8 (13.1)	13 (22)
Bachelor's degree	30 (49.2)	23 (39)
Master's degree	6 (9.8)	7 (11.9)
PhD or doctorate	0 (0)	0 (0)
Other	8 (13.1)	4 (6.8)
Employment status, n (%)		
Employed full-time	33 (54.1)	32 (54.2)
Employed part-time	13 (21.3)	13 (22)
Unemployed and not currently looking for work	1 (1.6)	1 (1.7)
Student	4 (6.6)	5 (8.5)
Retired	3 (4.9)	1 (1.7)
Homemaker	0 (0)	1 (1.7)
Self-employed	2 (3.3)	2 (3.4)
Unable to work	2 (3.3)	1 (1.7)
Other	3 (4.9)	3 (5.1)
Relationship status, n (%)		
Single (never married)	27 (44.3)	16 (27.1)
Married/de facto	29 (47.5)	39 (66.1)
Divorced	2 (3.3)	4 (6.8)
Separated	2 (3.3)	0 (0)
Other	1 (1.6)	0 (0)
Main language spoken, n (%)		
English	57 (95)	58 (98.3)
Other	3 (5)	1 (1.7)

BMI, body mass index; IBD, inflammatory bowel disease; TAFE, technical and further education.

secondary outcome Crohn's disease activity significantly decreased in the intervention group when compared with the active control group, with a significantly different rate of change observed from baseline to 3-month follow-up. The rate of change was greater for the intervention group with a large effect size (Table 4 and Figure 2). All other outcomes had nonsignificant group × time interactions (effects plots for all study outcomes in Supplemental Material).

Significant simple effect of time for the ACTforIBD program (intervention). From baseline to postintervention, and maintained at 3-month follow-up, there were significant improvements in pain catastrophizing, IBD control (8 subscale), IBD control (VAS subscale), gastrointestinal unhelpful thinking patterns, IBD activity, visceral anxiety, fatigue interference, self-efficacy, and current health status. From baseline to 3-month follow-up, there were significant improvements in pain, anxiety symptoms, resilience, depression symptoms, fatigue severity, psychological inflexibility/experiential avoidance, and fatigue frequency.

Significant simple effect of time for the CBT-informed psychoeducation program (active control). From baseline to postintervention, and maintained at 3-month follow-up, there were significant improvements in ulcerative colitis activity, pain catastrophizing, IBD control (8 subscale), gastrointestinal unhelpful thinking patterns, IBD activity, visceral anxiety, fatigue interference, self-efficacy, and resilience. From baseline to

Table 3. Mean values and SDs for all study outcomes

Outcome	Group	Time	Mean	SD	Outcome	Group	Time	Mean	SD
Resilience	Intervention	1	2.97	0.76	IBD control (8 subscale)	Intervention	1	9.59	2.58
	Active control	1	2.89	0.67		Active control	1	9.82	2.69
	Intervention	2	3.09	0.67		Intervention	2	8.18	3.16
	Active control	2	3.13	0.72		Active control	2	7.58	2.61
	Intervention	3	3.32	0.77		Intervention	3	6.52	2.81
	Active control	3	3.19	0.66		Active control	3	6.83	2.41
Self-efficacy	Intervention	1	28.57	3.66	IBD control (VAS subscale)	Intervention	1	64.12	24.76
	Active control	1	29.00	3.63		Active control	1	69.79	19.82
	Intervention	2	30.18	3.34		Intervention	2	72.33	20.18
	Active control	2	30.09	3.80		Active control	2	74.70	17.83
	Intervention	3	30.48	3.63		Intervention	3	75.67	18.38
	Active control	3	30.59	3.37		Active control	3	79.52	18.96
Gastrointestinal unhelpful thinking patterns	Intervention	1	2.73	1.03	Depression symptoms	Intervention	1	4.75	3.67
	Active control	1	2.67	0.93		Active control	1	5.78	3.07
	Intervention	2	2.23	1.10		Intervention	2	4.69	4.58
	Active control	2	2.13	1.02		Active control	2	4.67	3.47
	Intervention	3	2.10	1.13		Intervention	3	3.98	3.96
	Active control	3	2.30	1.06		Active control	3	4.88	3.44
Pain catastrophizing	Intervention	1	2.50	1.15	Anxiety symptoms	Intervention	1	3.84	2.82
	Active control	1	2.50	1.07		Active control	1	3.35	2.47
	Intervention	2	2.09	1.25		Intervention	2	3.20	2.94
	Active control	2	1.88	1.13		Active control	2	3.57	3.12
	Intervention	3	1.83	1.26		Intervention	3	2.91	2.70
	Active control	3	2.14	1.17		Active control	3	2.86	3.06
Visceral anxiety	Intervention	1	2.95	1.05	Stress symptoms	Intervention	1	7.79	3.50
	Active control	1	2.84	1.03		Active control	1	7.64	3.36
	Intervention	2	2.39	1.09		Intervention	2	7.73	3.96
	Active control	2	2.41	1.16		Active control	2	6.56	3.68
	Intervention	3	2.38	1.10		Intervention	3	6.86	3.86
	Active control	3	2.46	1.14		Active control	3	5.82	3.54
IBD activity	Intervention	1	2.67	1.29	Psychological inflexibility/ experiential avoidance	Intervention	1	26.72	7.69
	Active control	1	2.86	1.33		Active control	1	26.37	7.98
	Intervention	2	3.39	1.48		Intervention	2	24.72	7.30
	Active control	2	3.28	1.50		Active control	2	25.48	7.39
	Intervention	3	3.74	1.51		Intervention	3	23.23	6.66
	Active control	3	3.54	1.39		Active control	3	24.22	7.26
Fatigue severity	Intervention	1	19.92	6.36	Total HRQoL	Intervention	1	0.87	0.10
	Active control	1	20.42	5.82		Active control	1	0.87	0.13
	Intervention	2	18.72	8.00		Intervention	2	0.90	0.09
	Active control	2	18.85	6.50		Active control	2	0.87	0.16
	Intervention	3	16.40	8.02		Intervention	3	0.91	0.07
	Active control	3	17.42	7.42		Active control	3	0.90	0.09
Fatigue interference	Intervention	1	29.20	15.00	Current health status	Intervention	1	61.00	18.50
	Active control	1	32.19	12.30		Active control	1	64.30	16.00
	Intervention	2	24.22	15.23		Intervention	2	67.40	21.60
	Active control	2	25.74	14.26		Active control	2	67.00	19.70
	Intervention	3	20.23	14.92		Intervention	3	67.90	21.10
	Active control	3	24.32	13.76		Active control	3	71.60	16.70

Table 3. (*continued*)

Outcome	Group	Time	Mean	SD	Outcome	Group	Time	Mean	SD
Fatigue frequency	Intervention	1	10.00	3.77	Ulcerative colitis activity	Intervention	1	3.48	2.52
	Active control	1	10.90	3.53		Active control	1	3.52	1.96
	Intervention	2	9.89	3.97		Intervention	2	4.05	6.95
	Active control	2	10.13	4.03		Active control	2	2.93	1.94
	Intervention	3	8.86	4.33		Intervention	3	2.78	1.59
	Active control	3	9.68	3.96		Active control	3	2.88	2.13
Pain	Intervention	1	3.85	2.33	Crohn's disease activity	Intervention	1	21.10	9.58
	Active control	1	4.03	2.48		Active control	1	18.80	9.88
	Intervention	2	3.54	2.75		Intervention	2	17.10	9.93
	Active control	2	3.69	2.63		Active control	2	14.70	8.97
	Intervention	3	2.88	2.51		Intervention	3	10.80	5.82
	Active control	3	3.30	2.56		Active control	3	16.90	11.02

HRQoL, health-related quality of life; IBD, inflammatory bowel disease; VAS, Visual Analog Scale.

postintervention, there were significant improvements in depression symptoms. From baseline to 3-month follow-up, there were significant improvements in stress symptoms, IBD control (VAS subscale), current health status, fatigue severity, psychological inflexibility/experiential avoidance, and fatigue frequency.

DISCUSSION

To the best of our knowledge, this was the first randomized controlled trial to examine the efficacy of a codesigned online hybrid ACT program in comparison with a CBT-informed psychoeducation program for individuals living with IBD.

The ACTforIBD program (and not the CBT-informed psychoeducation program) improved Crohn's disease activity, total HRQoL, anxiety symptoms, and pain. Importantly, improvement in Crohn's disease activity is a novel result, as changes to disease activity as a result of psychological intervention trials for IBD are uncommon, reaffirming the importance of the brain-gut connection in IBD (21). The improvement in total HRQoL is in line with previous research on psychotherapy trials for IBD (62). Improvements to anxiety symptoms and pain were based on relatively small simple mean differences (not interaction effects) and should, therefore, be interpreted with caution yet are still novel results because changes to anxiety symptoms and pain are uncommon in psychotherapy trials for IBD.

Conversely, the CBT-informed psychoeducation program (and not the ACTforIBD program) improved ulcerative colitis activity and stress symptoms. Both results, however, are also based on relatively small simple mean differences (not interaction effects) so should be interpreted with caution. Improvement in ulcerative colitis activity is a novel result for a psychological intervention trial for IBD but is well documented in antidepressant trials (63). Improvement to stress is a novel outcome because changes to mental health are uncommon in psychotherapy trials for IBD (62). The CBT-informed psychoeducation program contained activities that dealt with stress directly, such as education on stress management and relaxation breathing techniques, which may account for this result.

All other outcomes significantly improved in both the ACTforIBD program and the CBT-informed psychoeducation program including IBD activity, gastrointestinal unhelpful thinking patterns, visceral anxiety, fatigue interference, fatigue severity, fatigue frequency, psychological inflexibility, self-efficacy, resilience, current health status, depression symptoms, pain catastrophizing, and IBD control. These are promising results and show that regardless of program type, psychotherapy interventions for IBD may be useful in improving important biopsychosocial outcomes, particularly if their content is tailored to IBD and is delivered to the right subpopulation (i.e., those with mild to moderate psychological distress). These results may also be due to the benefits participants experience in engaging in a therapeutic relationship with an IBD therapist regardless of the program type, including unconditional positive regard, understanding, presence, and warmth. This may also speak to the success of the blinding of participants, potentially indicating that the expectation, of participants in the CBT-informed psychoeducation program, that they were receiving an ACT intervention, positively influenced this group's results.

The current trial has several strengths that contribute to overcoming limitations frequently reported in psychotherapy trials for IBD (24). Importantly, previous trials have recruited participants without psychological distress providing limited

Table 4. Linear mixed model results for all study outcomes

				Fixed effects (group × time interaction)					Simple effects (time)						
Outcome	**Result**	**Time**	**Group**	***t* statistic**	**MD (95% CI)**	**β weight**	***df***	***P* value**	**Result**	**Time**	**Group**	**MD (95% CI)**	**β weight**	***df***	***P* value**
ACTforIBD program (intervention) significant outcomes															
Total HRQoL	Interaction effects	T1 × T2	Intervention × active control	2.15	0.08 (0.01 to 0.15)	0.41	190	0.033[a]	Simple effects	T1 × T2	Intervention	0.07 (0.01 to 0.12)	0.34	195	**0.014**[b]
											Active control	−0.01 (−0.06 to 0.04)	−0.06	184	0.630
		T1 × T3	Intervention × active control	1.43	0.06 (−0.02 to 0.13)	0.28	191	0.16		T1 × T3	Intervention	0.07 (0.02 to 0.13)	0.36	196	**0.011**[b]
											Active control	0.02 (−0.03 to 0.07)	0.09	186	0.517
Crohn's disease activity	Interaction effects	T1 × T2	Intervention × active control	0.04	0.12 (−5.99 to 6.23)	0.01	90	0.97	Simple effects	T1 × T2	Intervention	−3.70 (−7.96 to 0.55)	−0.38	94	0.087
											Active control	−3.83 (−8.32 to 0.68)	−0.39	85	0.095
		T1 × T3	Intervention × active control	−2.40	−7.48 (−13,59 to −1.38)	−0.77	90	0.018[a]		T1 × T3	Intervention	−9.43 (−13.72 to −5.13)	−0.96	93	**<0.001**[b]
											Active control	−1.94 (−6.40 to 2.52)	−0.20	87	0.389
Anxiety symptoms	Interaction effects	T1 × T2	Intervention × active control	−1.50	−0.28 (−0.64 to 0.09)	−0.31	205	0.14	Simple effects	T1 × T2	Intervention	−0.23 (−0.49 to 0.04)	−0.25	210	0.095
											Active control	0.05 (−0.20 to 0.30)	0.06	199	0.682
		T1 × T3	Intervention × active control	−0.64	−0.12 (−0.50 to 0.25)	−0.14	207	0.52		T1 × T3	Intervention	−0.32 (−0.59 to −0.05)	−0.36	212	**0.019**[b]
											Active control	−0.20 (−0.46 to 0.06)	−0.23	202	0.128
Pain	Interaction effects	T1 × T2	Intervention × active control	−0.003	−0.001 (−0.96 to 0.95)	−4.93	201	1.00	Simple effects	T1 × T2	Intervention	−0.23 (−0.93 to 0.48)	−0.09	206	*0.528*
											Active control	−0.22 (−0.88 to 0.43)	−0.09	194	*0.503*
		T1 × T3	Intervention × active control	−0.65	−0.32 (−1.30 to 0.66)	−0.13	202	0.52		T1 × T3	Intervention	−0.87 (−1.59 to −0.15)	−0.34	208	**0.018**[b]
											Active control	−0.55 (−1.22 to 0.13)	−0.21	196	*0.112*
CBT-informed psychoeducation program (active control) significant outcomes															
Ulcerative colitis activity	Interaction effects	T1 × T2	Intervention × active control	0.36	0.02 (−0.11 to 0.16)	0.09	90	0.72	Simple effects	T1 × T2	Intervention	−0.07 (−0.18 to 0.03)	−0.25	91	0.169
											Active control	−0.10 (−0.19 to −0.01)	−0.34	88	**0.034**[b]
		T1 × T3	Intervention × active control	0.46	0.03 (−0.11 to 0.17)	0.12	91	0.64		T1 × T3	Intervention	−0.09 (−0.20 to 0.02)	−0.31	92	0.109
											Active control	−0.12 (−0.21 to −0.03)	−0.42	89	**0.012**[b]
Stress symptoms	Interaction effects	T1 × T2	Intervention × active control	1.25	1.01 (−0.57 to 2.58)	0.27	207	0.21	Simple effects	T1 × T2	Intervention	−0.02 (−1.17 to 1.14)	−0.004	213	0.978
											Active control	−1.02 (−2.11 to 0.07)	−0.28	200	0.066
		T1 × T3	Intervention × active control	1.03	0.85 (−0.77 to 2.45)	0.23	209	0.31		T1 × T3	Intervention	−0.80 (−1.97 to 0.37)	−0.22	214	0.180
											Active control	−1.64 (−2.76 to −0.53)	−0.45	203	**0.004**[b]
Both ACTforIBD program and CBT-informed psychoeducation program have significant outcomes															
Pain catastrophizing	Interaction effects	T1 × T2	Intervention × active control	1.07	0.20 (−0.17 to 0.56)	0.17	196	0.29	Simple effects	T1 × T2	Intervention	−0.38 (−0.64 to −0.11)	−0.32	199	**0.006**[b]
											Active control	−0.58 (−0.83 to −0.32)	−0.48	192	**<0.001**[b]
		T1 × T3	Intervention × active control	−1.74	−0.33 (−0.70 to 0.04)	−0.28	197	0.08		T1 × T3	Intervention	−0.63 (−0.90 to −0.35)	−0.53	200	**<0.001**[b]
											Active control	−0.30 (−0.55 to −0.04)	−0.25	193	**0.025**[b]
IBD control (8 subscale)	Interaction effects	T1 × T2	Intervention × active control	1.15	−0.37 (−2.10 to 1.36)	−0.09	188	0.68	Simple effects	T1 × T2	Intervention	2.91 (1.66 to 4.15)	0.66y	193	**<0.001**[b]
											Active control	3.28 (2.05 to 4.50)	0.75	183	**<0.001**[b]
		T1 × T3	Intervention × active control	−0.26	0.68 (−1.11 to 2.46)	0.16	193	0.46		T1 × T3	Intervention	4.37 (3.10 to 5.65)	1.00	195	**<0.001**[b]
											Active control	3.70 (2.43 to 4.97)	0.85	191	**<0.001**[b]
Gastrointestinal unhelpful thinking patterns	Interaction effects	T1 × T2	Intervention × active control	0.15	0.03 (−0.31 to 0.36)	0.02	195	0.88	Simple effects	T1 × T2	Intervention	−0.45 (−0.69 to −0.21)	−0.42	197	**<0.001**[b]
											Active control	−0.48 (−0.71 to −0.24)	−0.45	192	**<0.001**[b]
		T1 × T3	Intervention × active control	−1.66	−0.29 (−0.62 to 0.05)	−0.27	195	0.10		T1 × T3	Intervention	−0.58 (−0.83 to −0.34)	−0.55	198	**<0.001**[b]
											Active control	−0.29 (−0.53 to −0.06)	−0.28	192	**0.014**[b]
IBD activity	Interaction effects	T1 × T2	Intervention × active control	1.48	0.39 (−0.13 to 0.90)	0.27	202	0.14	Simple effects	T1 × T2	Intervention	0.75 (0.37 to 1.12)	0.52	206	**<0.001**[b]
											Active control	0.36 (0.005 to 0.71)	0.25	196	**0.047**[b]
		T1 × T3	Intervention × active control	1.85	0.50 (−0.03 to 1.03)	0.34	203	0.07		T1 × T3	Intervention	1.07 (0.68 to 1.46)	0.74	208	**<0.001**[b]
											Active control	0.57 (0.21 to 0.94)	0.39	198	**0.002**[b]
Visceral anxiety	Interaction effects	T1 × T2	Intervention × active control	−0.80	−0.14 (−0.50 to 0.21)	−0.13	198	0.42	Simple effects	T1 × T2	Intervention	−0.51 (−0.77 to −0.26)	−0.46	202	**<0.001**[b]
											Active control	−0.37 (−0.61 to −0.13)	−0.33	195	**0.003**[b]
		T1 × T3	Intervention × active control	−1.34	−0.25 (−0.61 to 0.12)	−0.22	199	0.18		T1 × T3	Intervention	−0.54 (−0.80 to −0.27)	−0.48	202	**<0.001**[b]
											Active control	−0.29 (−0.54 to −0.04)	−0.26	196	**0.023**[b]

Table 4. (*continued*)

				Fixed effects (group × time interaction)					Simple effects (time)						
Outcome	**Result**	**Time**	**Group**	***t* statistic**	**MD (95% CI)**	**β weight**	***df***	***P* value**	**Result**	**Time**	**Group**	**MD (95% CI)**	**β weight**	***df***	***P* value**
Fatigue interference	Interaction effects	T1 × T2	Intervention × active control	0.41	1.10 (−4.24 to 6.45)	0.08	201	0.69	Simple effects	T1 × T2	Intervention	−5.17 (−9.07 to −1.27)	−0.35	206	**0.010**[b]
											Active control	−6.27 (−9.98 to −2.57)	−0.43	196	**<0.001**[b]
		T1 × T3	Intervention × active control	−0.47	−1.30 (−6.79 to 4.18)	−0.09	203	0.64		T1 × T3	Intervention	−8.44 (−12.44 to −4.44)	−0.58	208	**<0.001**[b]
											Active control	−7.14 (−10.94 to −3.34)	−0.49	198	**<0.001**[b]
Self-efficacy	Interaction effects	T1 × T2	Intervention × active control	0.25	0.17 (−1.19 to 1.53)	0.05	190	0.81	Simple effects	T1 × T2	Intervention	1.24 (0.24 to 2.24)	0.34	195	**0.016**[b]
											Active control	1.07 (0.14 to 2.00)	0.29	183	**0.025**[b]
		T1 × T3	Intervention × active control	0.15	0.11 (−1.29 to 1.50)	0.03	191	0.88		T1 × T3	Intervention	1.61 (0.59 to 2.63)	0.44	196	**0.002**[b]
											Active control	1.51 (0.55 to 2.46)	0.41	185	**0.002**[b]
Resilience	Interaction effects	T1 × T2	Intervention × active control	−0.66	−0.08 (−0.30 to 0.15)	−0.11	197	0.51	Simple effects	T1 × T2	Intervention	0.15 (−0.01 to 0.32)	0.21	201	0.071
											Active control	0.23 (0.07 to 0.39)	0.32	193	**0.004**[b]
		T1 × T3	Intervention × active control	0.54	0.06 (−0.17 to 0.30)	0.09	198	0.59		T1 × T3	Intervention	0.34 (0.17 to 0.51)	0.47	202	**<0.001**[b]
											Active control	0.27 (0.11 to 0.43)	0.38	194	**<0.001**[b]
IBD control (VAS subscale)	Interaction effects	T1 × T2	Intervention × active control	0.64	364.6 (−745 to 1,474)	0.14	200	0.52	Simple effects	T1 × T2	Intervention	917 (105 to 1,729)	0.35	207	**0.027**[b]
											Active control	553 (−214 to 1,319)	0.21	192	*0.156*
		T1 × T3	Intervention × active control	0.06	32.9 (−1,101 to 1,167)	0.01	202	0.96		T1 × T3	Intervention	1,310 (479 to 2,141)	0.50	209	**0.002**[b]
											Active control	1,277 (496 to 2,059)	0.49	194	**0.001**[b]
Current health status	Interaction effects	T1 × T2	Intervention × active control	0.86	443.72 (−566 to 1,454)	0.19	200	0.39	Simple effects	T1 × T2	Intervention	924 (189 to 1,660)	0.40	206	**0.014**[b]
											Active control	480 (−221 to 1,181)	0.21	194	0.178
		T1 × T3	Intervention × active control	0.004	1.94 (−1,023 to 1,027)	8.46	202	1.00		T1 × T3	Intervention	999 (251 to 1,746)	0.44	208	**0.009**[b]
											Active control	997 (286 to 1,707)	0.43	195	**0.006**[b]
Depression symptom	Interaction effects	T1 × T2	Intervention × active control	1.57	0.26 (−0.07 to 0.59)	0.28	201	0.12	Simple effects	T1 × T2	Intervention	−0.05 (−0.29 to 0.19)	−0.06	205	0.676
											Active control	−0.32 (−0.54 to −0.09)	−0.34	196	**0.007**[b]
		T1 × T3	Intervention × active control	−0.41	−0.07 (−0.41 to 0.27)	−0.08	202	0.68		T1 × T3	Intervention	−0.28 (−0.53 to −0.04)	−0.31	206	**0.024**[b]
											Active control	−0.21 (−0.45 to 0.02)	−0.23	198	0.072
Fatigue severity	Interaction effects	T1 × T2	Intervention × active control	0.20	0.26 (−2.23 to 2.74)	0.04	204	0.84	Simple effects	T1 × T2	Intervention	−1.19 (−3.02 to 0.64)	−0.17	209	*0.201*
											Active control	−1.45 (−3.15 to 0.25)	−0.21	197	*0.095*
		T1 × T3	Intervention × active control	−0.48	−0.62 (−3.17 to 1.93)	−0.09	205	0.63		T1 × T3	Intervention	−3.22 (−5.09 to −1.34)	−0.46	211	**<0.001**[b]
											Active control	−2.60 (−4.34 to −0.85)	−0.37	199	**0.004**[b]
Psychological inflexibility/ experiential avoidance	Interaction effects	T1 × T2	Intervention × active control	−0.46	−0.59 (−3.07 to 1.90)	0.04	198	0.65	Simple effects	T1 × T2	Intervention	−1.53 (−3.36 to 0.29)	−0.17	203	0.100
											Active control	−0.95 (−2.65 to 0.76)	−0.21	193	0.274
		T1 × T3	Intervention × active control	−0.64	−0.83 (−3.38 to 1.72)	−0.09	200	0.52		T1 × T3	Intervention	−2.68 (−4.55 to −0.80)	−0.46	204	**0.005**[b]
											Active control	−1.84 (−3.60 to −0.09)	−0.37	195	**0.039**[b]
Fatigue frequency	Interaction effects	T1 × T2	Intervention × active control	0.79	0.50 (−0.74 to 1.75)	0.13	201	0.43	Simple effects	T1 × T2	Intervention	−0.11 (−1.03 to −0.80)	−0.03	205	*0.808*
											Active control	−0.62 (−1.47 to 0.23)	−0.16	196	*0.155*
		T1 × T3	Intervention × active control	−0.09	−0.06 (−1.33 to 1.22)	−0.01	202	0.93		T1 × T3	Intervention	−0.97 (−1.91 to −0.04)	−0.25	205	**0.042**[b]
											Active control	−0.92 (−1.79 to −0.04)	−0.23	197	**0.040**[b]

ACT, acceptance and commitment therapy; CBT, cognitive behavioral therapy; CI, confidence interval; HRQoL, health-related quality of life; IBD, inflammatory bowel disease; MD, mean difference; VAS, Visual Analog Scale.
[a]Significant interaction group × time effects.
[b]Significant simple effects of time for the groups separately are bolded.

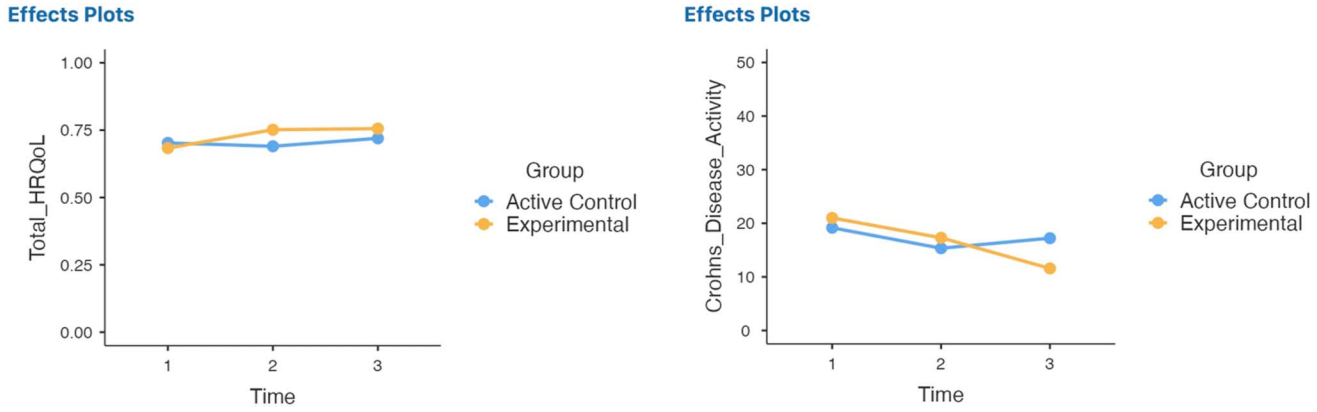

Figure 2. Effects plots for the outcomes of total HRQoL and Crohn's disease activity. HRQoL, health-related quality of life.

outcomes for interventions to target, whereas the current trial recruited participants experiencing mild to moderate psychological distress, overcoming this potential floor effect. The current trial also used an active control group where participants were blinded to group allocation, not only reducing bias, but also providing a higher threshold for the effectiveness of ACT vs another intervention instead of a waitlist control. This answers the question of whether people *believing* that they are receiving ACT is as effective as receiving ACT itself. The current trial also used an ACT intervention, which was codesigned with individuals living with IBD and comorbid psychological distress, therefore, providing a consumer-driven intervention, which was more likely to have met consumer needs, particularly given that research has shown that those living with IBD face unique disease-related challenges. Both programs also overcame typical face-to-face barriers by providing an online delivered alternative, which also likely contributed to the high participant retention rate.

The current trial has several important limitations for consideration in future research. As recruitment occurred during the COVID-19 pandemic with extensive lockdowns and limited access to medical facilities, it was not feasible to obtain objective evidence of IBD disease activity, and instead, self-report measures were used. Future studies could include objective measures of disease activity (such as C-reactive protein or fecal calprotectin levels). Furthermore, other self-reported IBD treatments such as corticosteroid use, biologic/IMM use, and surgeries were not collected throughout the study, is it also suggested that future studies collect this information to contribute to the understanding of changes in IBD disease activity from multiple treatment perspectives. The sample was also predominantly female, educated with a bachelor's degree, and worked full-time, thereby limiting the generalizability of findings to the wider IBD population. Furthermore, it is likely that the participants were highly motivated to participate in the study, as they were self-selected through seeing the study advertisements through IBD support organizations and social media, further limiting the generalizability of findings. Future research would benefit from using a more diverse sample and investigate how to tailor therapy to underrepresented populations such as those residing in low socioeconomic areas, those with low rates of education, those residing in rural/regional areas, and those from different cultural backgrounds. The hybrid structure of the intervention relies on the availability of ACT-trained therapists, and future research may, therefore, benefit by investigating the efficacy of a fully participant-led ACT intervention to increase program availability and cost-effectiveness. The study also used the K10, a nonspecific measure of distress, to assess the eligibility of participants for inclusion in the trial. Future studies may benefit from using a more defined measure, which separates symptoms of anxiety and depression. Finally, the inclusion of a waitlist control alongside an active control is suggested to provide a measure of the efficacy of ACT against no treatment or treatment as usual.

Both the ACTforIBD program and CBT-informed psychoeducation program are of benefit to individuals living with IBD and psychological distress. ACT is a promising intervention that holds up well to CBT-information psychoeducation when both are delivered online in a hybrid format (i.e., therapist-led and part participant-led). However, ACT offers significant added benefit for improving HRQoL and self-reported Crohn's disease activity. Given the beneficial effect of ACT for IBD, ACT may be a useful adjuvant therapy in integrated IBD care, with further high-quality trials warranted.

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CONFLICTS OF INTEREST

Guarantor of the article:

Specific author contributions:

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Potential competing interests: The authors report no conflicts of interest in relation to the current study; however, outside this work, S.K. has served as an educational speaker for Janssen, Ferring, and Takeda. P.G. has served as a consultant or advisory board member for Anatara, Atmo Biosciences, Topas, and Comvita. He has received research grants for investigator-driven studies from Atmo Biosciences and Mindset Health and speaker honoraria from Dr Falk Pharma and Mindset Health. He holds shares in Atmo Biosciences. L.

Raven served on the Roche International Patient Advisory Council and the Takeda IBD Patient Expert Council. R.G. has served on advisory boards for AbbVie New Zealand and Australia, Zespri New Zealand, and Jannsen New Zealand and has received research funding from AbbVie and Atmo Biosciences. A.M.-W. has served as an educational speaker for Janssen and Ferring.

Registration: The trial was registered prospectively in the Australian New Zealand Clinical Trials Registry (ACTRN12621001316897: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=382493&isReview=true).

Study Highlights

WHAT IS KNOWN

- ✓ There is a bidirectional relationship between disease activity and mental health in inflammatory bowel disease (IBD).
- ✓ Psychotherapeutic interventions such as acceptance and commitment therapy (ACT) have increasingly been investigated for improving IBD biopsychosocial outcomes.

WHAT IS NEW HERE

- ✓ Both ACT and cognitive behavioral therapy–informed psychoeducation show promising results for improving several IBD-related biopsychosocial outcomes.
- ✓ ACT is significantly better than cognitive behavioral therapy–informed psychoeducation at reducing health-related quality of life and Crohn's disease activity.
- ✓ ACT may be a useful adjuvant therapy in integrated IBD care.

REFERENCES

1. Chang JT. Pathophysiology of inflammatory bowel diseases. N Engl J Med 2020;383(27):2652–64.
2. Nakase H, Uchino M, Shinzaki S, et al. Evidence-based clinical practice guidelines for inflammatory bowel disease 2020. J Gastroenterol 2021;56(6):489–526.
3. GBD 2017 Inflammatory Bowel Disease Collaborators. The global, regional, and national burden of inflammatory bowel disease in 195 countries and territories, 1990–2017: A systematic analysis for the Global Burden of Disease Study 2017. Lancet Gastroenterol Hepatol 2020;5(1):17–30.
4. Crohn's and Colitis Australia. Final Report of the First Audit of the Organisation and Provision of IBD Services in Australia 2016. Victoria, Australia: Crohn's and Colitis Australia; 2016.
5. Knowles SR, Graff LA, Wilding H, et al. Quality of life in inflammatory bowel disease: A systematic review and meta-analyses: Part I. Inflamm Bowel Dis 2018;24(4):742–51.
6. Knowles SR, Keefer L, Wilding H, et al. Quality of life in inflammatory bowel disease: A systematic review and meta-analyses: Part II. Inflamm Bowel Dis 2018;24(5):966–76.
7. Fiocchi C. Inflammatory bowel disease: Complexity and variability need integration. Front Med 2018;5:75.
8. Bonaz BL, Bernstein CN. Brain-gut interactions in inflammatory bowel disease. Gastroenterology 2013;144(1):36–49.
9. Black J, Sweeney L, Yuan Y, et al. Systematic review: The role of psychological stress in inflammatory bowel disease. Aliment Pharmacol Ther 2022;56(8):1235–49.
10. Gracie DJ, Irvine AJ, Sood R, et al. Effect of psychological therapy on disease activity, psychological comorbidity, and quality of life in inflammatory bowel disease: A systematic review and metaanalysis. Lancet Gastroenterol Hepatol 2017;2(3):189–99.
11. Gracie DJ, Guthrie EA, Hamlin PJ, et al. Bi-directionality of brain-gut interactions in patients with inflammatory bowel disease. Gastroenterology 2018;154(6):1635–46.e3.
12. Bisgaard TH, Allin KH, Keefer L, et al. Depression and anxiety in inflammatory bowel disease: Epidemiology, mechanisms and treatment. Nat Rev Gastroenterol Hepatol 2022;19(11):717–26.
13. Barberio B, Zamani M, Black CJ, et al. Prevalence of symptoms of anxiety and depression in patients with inflammatory bowel disease: A systematic review and meta-analysis. Lancet Gastroenterol Hepatol 2021;6(5):359–70.
14. Mikocka-Walus A, Knowles SR, Keefer L, et al. Controversies revisited: A systematic review of the comorbidity of depression and anxiety with inflammatory bowel diseases. Inflamm Bowel Dis 2016;22(3):752–62.
15. Mikocka-Walus A, Pittet V, Rossel J-B, et al. Symptoms of depression and anxiety are independently associated with clinical recurrence of inflammatory bowel disease. Clin Gastroenterol Hepatol 2016;14(6):829–35.e1.
16. Fairbrass KM, Gracie DJ, Ford AC. Relative contribution of disease activity and psychological health to prognosis of inflammatory bowel disease during 6.5 years of longitudinal follow-up. Gastroenterology 2022;163(1):190–203.e5.
17. Sexton KA, Walker JR, Graff LA, et al. Evidence of bidirectional associations between perceived stress and symptom activity: A prospective longitudinal investigation in inflammatory bowel disease. Inflamm Bowel Dis 2017;23(3):473–83.
18. Fiorino G, Allocca M, Chaparro M, et al. "Quality of care" standards in inflammatory bowel disease: A systematic review. J Crohns Colitis 2019;13(1):127–37.
19. Mikocka-Walus A, Massuger W, Knowles SR, et al. Quality of care in inflammatory bowel disease: Actual health service experiences fall short of the standards. Intern Med J 2020;50(10):1216–25.
20. Crohn's and Colitis Australia. Australian IBD standards: Standards of healthcare for people with inflammatory bowel disease in Australia. 2016. (https://crohnsandcolitis.org.au/advocacy/australian-ibd-standards/). Accessed June 20, 2022.
21. Torres J, Ellul P, Langhorst J, et al. European Crohn's and Colitis Organisation topical review on complementary medicine and psychotherapy in inflammatory bowel disease. J Crohns Colitis 2019;13(6):673–85e.
22. Hayes SC, Levin ME, Plumb-Vilardaga J, et al. Acceptance and commitment therapy and contextual behavioral science: Examining the progress of a distinctive model of behavioral and cognitive therapy. Behav Ther 2013;44(2):180–98.
23. Hayes SC, Luoma JB, Bond FW, et al. Acceptance and commitment therapy: Model, processes and outcomes. Behav Res Ther 2006;44(1):1–25.
24. Naude C, Skvarc D, Knowles S, et al. The effectiveness of mindfulness-based interventions in inflammatory bowel disease: A systematic review & meta-analysis. J Psychosom Res 2023;169:111232.
25. Wynne B, McHugh L, Gao W, et al. Acceptance and commitment therapy reduces psychological stress in patients with inflammatory bowel diseases. Gastroenterology 2019;156(4):935–45.e1.
26. Fang P, Tan L, Cui J, et al. Effectiveness of acceptance and commitment therapy for people with advanced cancer: A systematic review and meta-analysis of randomized controlled trials. J Adv Nurs 2023;79(2):519–38.
27. Konstantinou P, Ioannou M, Melanthiou D, et al. The impact of acceptance and commitment therapy (ACT) on quality of life and symptom improvement among chronic health conditions: A systematic review and meta-analysis. J Context Behav Sci 2023;29:240–53.
28. Hughes LS, Clark J, Colclough JA, et al. Acceptance and commitment therapy (ACT) for chronic pain: A systematic review and meta-analyses. Clin J Pain 2017;33(6):552–68.
29. Maunick B, Skvarc D, Olive L, et al. Effects of acceptance and commitment therapy on fatigue for patients with cancer and other chronic health conditions: A systematic review and meta-analysis. J Psychosom Res 2023;171:111366.
30. Ernst MM, Mellon MW. Acceptance and commitment therapy (ACT) to foster resilience in pediatric chronic illness. In: DeMichelis C, Ferrari M (eds). Child and Adolescent Resilience Within Medical Contexts. Springer: Cham, 2016.
31. Hayes SC. ACT Randomized Controlled Trials (1986 to Present). Association for Contextual Behavioral Science, 2021. (https://contextualscience.org/act_randomized_controlled_trials_1986_to_present). Accessed January 15, 2023.
32. Prendergast KL, Gowey MA, Barnes MJ, et al. Treating anxiety and depression in inflammatory bowel disease: A systematic review. Psychol Health 2022;37(1):105–30.

33. Hayes SC, Villatte M, Levin M, et al. Open, aware, and active: Contextual approaches as an emerging trend in the behavioral and cognitive therapies. Annu Rev Clin Psychol 2011;7:141–68.
34. Hayes SC, Strosahl KD, Wilson KG. Acceptance and Commitment Therapy: The Process and Practice of Mindful Change. 2nd edn. Guilford Press: New York, 2012.
35. Hayes SC, Strosahl KD, Wilson KG. Acceptance and Commitment Therapy. Guilford Press: New York, 1999.
36. Timmer A, Preiss JC, Motschall E, et al. Psychological interventions for treatment of inflammatory bowel disease. Cochrane Database Syst Rev 2011(2):CD006913.
37. McCombie AM, Mulder RT, Gearry RB. Psychotherapy for inflammatory bowel disease: A review and update. J Crohns Colitis 2013;7(12):935–49.
38. Hadlandsmyth K, White KS, Nesin AE, et al. Proposing an acceptance and commitment therapy intervention to promote improved diabetes management in adolescents: A treatment conceptualization. Int J Behav Consult Ther 2013;7(4):12–5.
39. Keeton RL, Mikocka-Walus A, Andrews JM. Concerns and worries in people living with inflammatory bowel disease (IBD): A mixed methods study. J Psychosom Res 2015;78(6):573–8.
40. Ankersen DV, Noack S, Munkholm P, et al. E-Health and remote management of patients with inflammatory bowel disease: Lessons from Denmark in a time of need. Intern Med J 2021;51(8):1207–11.
41. Nguyen NH, Martinez I, Atreja A, et al. Digital health technologies for remote monitoring and management of inflammatory bowel disease: A systematic review. Am J Gastroenterol 2022;117(1):78–97.
42. Romano D, Chesterman S, Fuller-Tyszkiewicz M, et al. Feasibility, acceptability, and preliminary efficacy of acceptance commitment therapy for adults living with inflammatory bowel disease and distress. Inflamm Bowel Dis 2023;30(6):911–21.
43. Clara I, Lix LM, Walker JR, et al. The Manitoba IBD Index: Evidence for a new and simple indicator of IBD activity. Am J Gastroenterol 2009; 104(7):1754–63.
44. Andrews G, Slade T. Interpreting scores on the Kessler Psychological Distress Scale (K10). Aust N Z J Public Health 2001;25(6):494–7.
45. Lai L, Liu Y, McCracken LM, et al. The efficacy of acceptance and commitment therapy for chronic pain: A three-level meta-analysis and a trial sequential analysis of randomized controlled trials. Behav Res Ther 2023;165:104308.
46. Ma T-W, Yuen AS-K, Yang Z. The efficacy of acceptance and commitment therapy for chronic pain: A systematic review and meta-analysis. Clin J Pain 2023;39(3):147–57.
47. Dober M, Mikocka-Walus A, Evans S, et al. Perspectives on an Acceptance and Commitment Therapy (ACT) based program for patients with inflammatory bowel disease and comorbid anxiety and/or depressive symptoms. Psychother Res 2021;31(5):668–81.
48. Centre for Clinical Interventions. Looking After Yourself. 2022. Accessed March 16, 2024 (https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself).
49. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011;20(10):1727–36.
50. Lovibond PF, Lovibond SH. The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behav Res Ther 1995;33(3): 335–43.
51. Bond FW, Hayes SC, Baer RA, et al. Preliminary psychometric properties of the Acceptance and Action Questionnaire-II: A revised measure of psychological inflexibility and experiential avoidance. Behav Ther 2011; 42(4):676–88.
52. Smith BW, Dalen J, Wiggins K, et al. The brief resilience scale: Assessing the ability to bounce back. Int J Behav Med 2008;15(3):194–200.
53. Schwarzer R, Jerusalem M. Generalized self-efficacy scale. In: Weinman J, Wright S, Johnston M, eds. Measures in Health Psychology: A User's Portfolio Causal and Control Beliefs. Windsor: NFERNELSON; 1995: 35–7.
54. Knowles SR, Apputhurai P, Burgell RE, et al. Development and validation of the gastrointestinal unhelpful thinking scale (GUTs): A brief self-report measure for clinical and research settings. Gastrointest Nurs 2021;45(1): E1–12.
55. Jairath V, Khanna R, Zou GY, et al. Development of interim patient-reported outcome measures for the assessment of ulcerative colitis disease activity in clinical trials. Aliment Pharmacol Ther 2015;42(10):1200–10.
56. Khanna R, Zou G, D'Haens G, et al. A retrospective analysis: The development of patient reported outcome measures for the assessment of Crohn's disease activity. Aliment Pharmacol Ther 2015;41(1):77–86.
57. Bodger K, Ormerod C, Shackcloth D, et al. Development and validation of a rapid, generic measure of disease control from the patient's perspective: The IBD-Control questionnaire. Gut 2014;63(7):1092–102.
58. Hann DM, Jacobsen PB, Azzarello LM, et al. Measurement of fatigue in cancer patients: Development and validation of the Fatigue Symptom Inventory. Qual Life Res 1998;7(4):301–10.
59. Daut RL, Cleeland CS, Flanery RC. Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. Pain 1983; 17(2):197–210.
60. The jamovi project. jamovi: Version 2.3 [computer software]. 2023. Accessed May 23, 2024 (https://www.jamovi.org).
61. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332.
62. Gracie DJ, Irvine AJ, Sood R, et al. Effect of psychological therapy on disease activity, psychological comorbidity, and quality of life in inflammatory bowel disease: A systematic review and meta-analysis. Lancet Gastroenterol Hepatol 2017;2(3):189–99.
63. Mikocka-Walus AA, Turnbull DA, Moulding NT, et al. Antidepressants and inflammatory bowel disease: A systematic review. Clin Pract Epidemiol Ment Health 2006;2:24.