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Acceptance commitment therapy (ACT) for psychological distress associated with inflammatory bowel disease (IBD): protocol for a feasibility trial of the ACTforIBD programme

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ABSTRACT

Introduction Inflammatory bowel disease (IBD) involves an abnormal immune response to healthy gut bacteria. When a person develops IBD, their susceptibility to anxiety and/or depression increases. The ACTforIBD programme, specifically designed for people with IBD and comorbid psychological distress, draws on acceptance and commitment therapy (ACT), which promotes acceptance of situations that cannot be solved such as persistent physical symptoms. There are no ACT trials for IBD using an active control group or a telemedicine approach, which is important to improve accessibility, particularly in the context of the ongoing COVID-19 pandemic. The ACTforIBD programme is administered online with a 4-hour therapist involvement per participant only; if successful it can be widely implemented to improve the well-being of many individuals with IBD.

Methods and analysis Our team have codesigned with consumers the ACTforIBD programme, an 8-week intervention of 1-hour sessions, with the first three sessions and the last session delivered one-to-one by a psychologist, and the other sessions self-directed online. This study aims to evaluate the feasibility and preliminary efficacy of ACTforIBD to reduce psychological distress in patients with IBD. Using a randomised controlled trial, 25 participants will be randomised to ACTforIBD, and 25 patients to an active control condition.

Ethics and dissemination This protocol has been approved by Deakin University Research Ethics Committee in September 2021 (Ref. 2021-263) and the New Zealand Central Health and Disability Ethics Committee in December 2021 (Ref. 2021 EXP 11384). The results of this research will be published in peer-reviewed journals and shared with various stakeholders, including community members, policy-makers and researchers, through local and international conferences.

Trial registration number ACTRN12621001316897.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This feasibility randomised controlled trial of acceptance and commitment therapy (ACT) in people with inflammatory bowel disease (IBD) will use an active control group (a psychoeducation-focused programme adapted to IBD).
⇒ ACTforIBD is an 8-week blended-delivery intervention, with the first three sessions and the last session delivered one-to-one by a psychologist, and the other sessions self-directed online.
⇒ Participants will be randomised to ACTforIBD and an active control condition in equal numbers (1:1), but the study is not powered to examine efficacy as its focus is on feasibility of ACTforIBD.
⇒ This internet-delivered study may be slow to recruit and associated with high attrition rates due to COVID-19-related internet fatigue.

INTRODUCTION

Inflammatory bowel disease (IBD) is an umbrella term for several relapsing-remitting inflammatory conditions of the gastrointestinal tract involving an abnormal immune response to healthy gut bacteria in those with a genetic predisposition.[1] The most common forms of IBD are Crohn's disease and ulcerative colitis. Key IBD-related symptoms include chronic pain, bloody diarrhoea with frequent bowel movements, weight loss, anaemia and fatigue, causing significant impairments in daily functioning. The disease affects as many as 3 million people in the USA,[2] with the prevalence expected to reach 1% in the Western world by 2030.[3]

Bidirectional gut-brain links are considered part of the pathophysiology of IBD; when a person develops IBD, their susceptibility to anxiety and/or depression increases.[4] Up

to 66% of individuals report symptoms during an active disease phase.[5] Our meta-analyses found that people with IBD experience a consistently poor quality of life (QoL) both during disease flare-ups and remission.[6 7] Further, IBD is negatively affected by mental disorders, resulting in more frequent flare-ups,[8] a more aggressive presentation,[9] increased rates of hospital readmissions and increased risk of surgery.[10] In addition, a registry-based observational study has shown that the top 5% of patients with highest medical charges had high prevalence of depression, anxiety and chronic pain, suggesting that these comorbidities need to be managed adequately to reduce the financial burden of IBD.[11]

Our meta-analysis[12] demonstrates the efficacy of psychotherapy in improving QoL and depression in IBD. However, the findings also highlight the urgent need for trials of psychotherapy interventions targeting the groups at risk of suboptimal outcomes (eg, people with psychological distress), to improve both mental and physical health management in IBD. This is because most studies conducted to date have focused on people without psychological comorbidities and this could have contributed to low efficacy of psychotherapy in IBD on psychological outcomes such as anxiety or coping.

The ACTforIBD programme, specifically designed for people with IBD and comorbid psychological distress, is an 8-week intervention that draws on acceptance and commitment therapy (ACT). ACT promotes acceptance of situations that cannot be solved such as persistent physical symptoms, and is taught as an alternative to experiential avoidance. The application of acceptance processes, along with commitment and value-directed behaviour change processes, is aimed at increasing psychological flexibility (eg, being fully present in the present moment, without trying to avoid/fight unwanted thoughts/feelings).[13] The psychological flexibility afforded by ACT is associated with reduced psychological distress in debilitating chronic diseases.[14 15] ACT is derived from cognitive–behavioural therapy (CBT). Both these therapies support adaptive emotion regulation but while CBT focuses on antecedent emotion regulation, ACT targets maladaptive regulation strategies such as suppression.[16] CBT has been found to be effective in reducing symptoms of depression and improving QoL in IBD.[12] ACT demonstrates similar efficacy to CBT for improving psychological distress in the general population[17 18] and those with pain-related chronic illness.[18]

To date, only one previous trial examined ACT in the treatment of IBD,[19] demonstrating its preliminary efficacy in improving levels of depression and QOL. Another trial is currently in progress.[20] Both these trials use an inactive control group (ie, treatment as usual). There are no ACT trials utilising an active control group or combining therapist-led sessions with self-directed online sessions (a telemedicine approach). These modalities are an important advancement to improve accessibility, particularly in the context of the ongoing COVID-19 pandemic. To address this gap, our team have codesigned with consumers the ACTforIBD program.[21]

This study aims to evaluate the feasibility and efficacy potential of ACTforIBD to reduce psychological distress in patients with IBD and inform the subsequent design of a definitive large-scale efficacy trial. Using a randomised controlled trial (RCT), our primary objectives are:

- The feasibility of recruitment to a full trial, reasons for withdrawal and session attendance in the ACTforIBD group versus an active control group at 8 weeks since baseline (primary outcomes).
- Consumer satisfaction with ACTforIBD at 8 weeks since baseline and 3 months postintervention (secondary outcomes).

Noting both uncertainties in effect estimates that may arise from small pilot studies[22] and absence of suitable prior studies to guide sample size guidelines for a definitive RCT for this population, our secondary objectives are to:

- Obtain estimates (rate of completion, mean differences at post-treatment timepoints and associated 95% CIs and SD on outcome measures) that may both enable evaluation of efficacy potential of ACTforIBD in improving patient psychological distress, disease activity, QoL, fatigue, pain, resilience and self-efficacy at 8 weeks since baseline and 3 months postintervention (secondary outcomes) and facilitate sample size calculations for a large-scale RCT.
- Derive preliminary indication of cost-effectiveness based on healthcare utilisation (secondary outcomes).

METHODS AND ANALYSIS

Ethical approval

This protocol has been approved by Deakin University Research Ethics Committee in September 2021 (Ref. 2021—263) and the New Zealand Central Health and Disability Ethics Committee in December 2021 (Ref. 2021 EXP 11384). The trial will adhere to the Consolidated Standards of Reporting Trials (CONSORT) statement.

Design

A parallel, mixed-methods, randomised, controlled feasibility trial will be conducted. Since psychological interventions for IBD tested to date have not been codesigned with consumers and offer only limited efficacy,[12] we will incorporate a comprehensive qualitative evaluation alongside the quantitative data collection. Participants will be randomly allocated with a 1:1 ratio to one of two groups: the ACTforIBD programme or active control. Randomisation will be stratified by IBD activity measured on the Manitoba Index.[23] Those with no to low activity (occasionally active, giving me symptoms 1–2 days/month; rarely active, giving me symptoms on a few days in the past 3 months; and I was well in the past 3 months, what I consider a remission or absence of symptoms) will be grouped into one category and those with moderate to high activity into another (Constantly active, giving me symptoms every day; Often active, giving me symptoms most days; and Sometimes active, giving me symptoms on some days). Computer-generated random sequences will

be embedded in the Qualtrics platform ensuring allocation concealment. Participants and all the investigators including statisticians will be blinded to group allocation. However, the trial managers enrolling participants and psychologists delivering therapy will not be blinded, for practical reasons. Participants in both treatment arms will remain on their treatment as usual. All participants will complete questionnaires before and after the intervention (8 weeks since baseline and 3 months postintervention) and a subsample will also participate in qualitative interviews at 8 weeks since baseline and 3 months postintervention. The trial will follow the intention-to-treat paradigm.

Participants

Inclusion criteria

1. Diagnosis of IBD: Crohn's disease, ulcerative colitis or indeterminate colitis established by a health professional using standard criteria (participants will need to provide a letter from their general practitioner or gastroenterologist or provide other proof of diagnosis such as endoscopy reports).
2. Psychological distress: scores 16–29 (mild to moderate distress) on Kessler Psychological Distress Scale (K10).[24]
3. Age: 18 years and older.
4. People with IBD residing in Australia or New Zealand, able to read and write in English, with access to the internet to ensure participation in the online intervention.

Exclusion criteria

1. No psychological distress (scores <16 on K10) or severe distress (scores 30–50 on K10).

Participants with active IBD can participate in the study and a flare will not prevent them from continuing the intervention should they wish to remain in the study.

Recruitment

We will recruit via consumer organisations and IBD-related social media, for example, Facebook, Twitter, Instagram of Crohn's & Colitis Australia (a social media following of 30 000 across all platforms). Crohn's and Colitis New Zealand will assist with recruitment in a similar way. We will ask participants for confirmation of diagnosis. It is anticipated that recruitment will take 1 year, with 4–5 participants recruited per month.

Sample size

Feasibility studies do not require power calculations as they are not focused on efficacy. However, the selected sample size needs to be adequate to estimate clinical parameters with a degree of precision[25] and, where possible, should factor in a plausible target effect size for a subsequent, definitive RCT.[26] In the absence of prior findings to accurately inform a likely effect size, we used a recommended, reasonably conservative standardised mean difference of 0.30.[27] Based on this value, and Whitehead *et al*'s[26] calculations for the optimal pilot study sample size, we aim to recruit 50 participants (25 per group).

Box 1 The ACTforIBD programme modules

- ⇒ Module 1: Commitment to therapy and assessment (therapist led).
- ⇒ Module 2: Creative hopelessness (therapist led).
- ⇒ Module 3: Personal values (therapist led).
- ⇒ Module 4: Mindfulness (self-directed).
- ⇒ Module 5: Fusion and defusion (self-directed).
- ⇒ Module 6: Acceptance (self-directed).
- ⇒ Module 7: Values and goals (self-directed)
- ⇒ Module 8: Commitment and overcoming barriers moving forward (therapist led).

ACT, acceptance and commitment therap; IBD, Inflammatory bowel disease.

Intervention and control condition

The ACTforIBD programme

People with IBD experience unique worries related to QoL (eg, toilet use frequency, travelling, embarrassment), unpredictability (of flares in symptoms), the symptoms themselves and treatment concerns (eg, medication side effects).[28] Our intervention is consistent with the core principles of ACT (eg, mindfulness, value-based decision making, defusion[29] and tailored to people with IBD to relate to some of these key concerns).[28] The intervention includes eight fully-scripted modules (each session is broken down into activities which need to be delivered), each addressing a different ACT process, with each session building on the previous process (see box 1). It has a blended design: the first three sessions and the last session are therapist-led and delivered one-to-one (via a Zoom/Skype appointment scheduled by the trial managers with the same therapist working with a given participant throughout the programme), and the between sessions are self-led (using a video/podcast available on our website without restrictions plus self-assessment activities). The protocol for the intervention was codesigned with consumers.[21] The sessions occur weekly for 8 weeks and take 1 hour (duration established as effective.[30] The therapist-led individual sessions will be delivered by provisionally registered psychologists under the supervision of a fully registered clinical psychologist, with extensive training and experience in the provision of ACT. Quality assurance will include regular therapist supervision and session content audits conducted by Dr van Niekerk (senior psychologist). While we will not be formally recording and comparing the delivery of sessions by various therapists, fidelity of the intervention is monitored through training of the therapists (all therapists will be provided with a manual explaining IBD, its treatment, psychological comorbidities, etc), use of detailed scripts for each session (ie, instructions for therapists of what needs to be discussed with the participant with any relevant worksheets provided to both the participant and therapist) and group supervision where adherence to scripts is discussed.

Box 2 The active control group programme

⇒ Module 1: Stress management (therapist led).
⇒ Module 2: Progressive muscle relaxation (therapist led).
⇒ Module 3: Problem solving (therapist led).
⇒ Module 4: Coping strategies (self-directed).
⇒ Module 5: How to think more assertively (self-directed).
⇒ Module 6: How to behave more assertively (self-directed).
⇒ Module 7: Sleeping for better well-being (self-directed).
⇒ Module 8: Towards a healthy self-esteem (therapist led).

The goals of treatment with this programme broadly include: assisting clients to define valued directions and take committed action in the direction of their identified values; increasing understanding and insight into the client's personal experiences by promoting presence and increasing cognitive defusion; improved coping with physical symptoms through the process of acceptance and cognitive defusion; and increasing psychological flexibility around psychological distress associated with IBD. The specific goals of treatment with each person will vary depending on their symptoms, life experiences and importantly, what they want to gain from therapy.

The active control group will be asked to use a psychoeducation-focused programme adapted to IBD based on the Centre for Clinical Interventions materials (https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself) (see box 2).

The duration of the control condition will mirror the experimental group with 8 weeks of 1-hour involvement with the website recommended. Participant demands across both groups will be the same including allocated time for homework activities. This group will also be facilitated in a similar fashion to the ACT group, that is, the first three sessions and the last session are therapist-led one-to-one (via a Zoom/Skype appointment). The therapists will be advised to focus on the content of the sessions rather than therapeutic processes. Experience with this and potential challenges will be monitored via supervision.

Withdrawal criteria

Participants are free to withdraw at any time. We will ask about their reasons for withdrawal for statistical and reporting purposes but answering this question will not be compulsory. No aspect of participant IBD care will be affected by their decision to withdraw from the study. We will monitor dropout/attrition closely to be able to establish satisfaction with the intervention.

Measures

Quantitative measures

Measures of feasibility for progression to a full RCT

- Feasibility of recruitment assessed based on data from study database (n=50 recruited during a 1-year period of recruitment).
- Feasibility of retention in the study based on data from study database (at least 80% of recruited participants retained at 8 weeks follow-up).

Consumer satisfaction for progression to a full RCT: see table 1 for detail re measures of satisfaction. In addition, reasons for withdrawal and session attendance (at least 50% of sessions attended) will be examined.

Measures for evaluating efficacy potential: patient psychological distress, disease activity, QoL, fatigue, pain, resilience and self-efficacy. See table 1 for detail of the scales including their scoring and assessment time.

Preliminary cost-effectiveness: see online supplemental appendix 1 for detail of treatment utilisation scale.

Qualitative interviews

A rich sample capturing key demographics (representatives of different genders, age groups, urban/rural location, IBD types, group allocation) of 20 participants will be invited to participate in a longitudinal qualitative study consisting of 2 semistructured interviews conducted via phone or zoom/Teams (~30–45 min) immediately postintervention (8 weeks)[31 32] and at 3 months postintervention. The longitudinal design of this qualitative study follows qualitative principles of change across time,[33] and will help us monitor the use of ACT strategies over time, to inform ongoing support. The proposed sample size is consistent with recommended guidelines for thematic analysis.[31] The aim of the interviews is to understand: (1) perceived barriers and enablers to undertaking the programme, including elements of the programme that are of continued use and (2) meaningful change experienced by participants. To understand meaningful change, we will use most significant change (MSC) principles, an interviewing technique developed for the purpose of evaluating complex interventions.[32] Interview questions begin with inquiry about the individual's circumstances, or 'story' about what led them to consider being involved in the study, and narrow in focus to ask participants what the MSCs were for them during the intervention, and postintervention. Interviews aim to understand what significant changes were experienced, why these changes were significant for the individual, and what meaning the individual attributed to these changes. The changes reported by participants in interviews will triangulate quantitative outcomes.

Procedure

Participants will largely be recruited online via social media. They will be asked to email the researchers or complete an online expression of interest form if they are interested in participating. Participants will then be asked to read and consider the study's plain language statement which tells them that they will be allocated randomly to one of the two study groups and, if still interested, to sign a consent form and return to the investigators along with evidence of their IBD diagnosis via email. After consenting, participants will be asked to complete the K10, and the trial managers will

Table 1 Quantitative measures

		No of items	Assessment time
Demographics	Age, sex, level of education, marital status, employment, language spoken at home, postcode, private insurance	8	Baseline
Health-related questions	IBD subtype (CD, UC, IC)	1	Baseline
	When was your IBD diagnosed?	1	Baseline
	Do you currently have any of the following (click all that apply): Stoma (bag); Fistula; Perianal disease; Unsure	1	Baseline
	Do you suffer from other chronic illnesses (eg, diabetes, arthritis, depression)? If so, please list.	1	Baseline
	Please list all your prescribed, over the counter and complementary therapies	1	Baseline
	What treatment do you currently take for IBD?	1	Baseline
	Do you regularly use opioid medication such as oxycontin, codeine, tramadol, fentanyl or similar painkillers? If yes, please list.	1	Baseline
	Do you take antidepressants or antianxiety medication?	1	Baseline
	Are you currently seeing a mental health professional?	1	Baseline
	Smoking habits	1	Baseline
	Alcohol	1	Baseline
	BMI (weight and height)	2	Baseline
IBD activity	IBD Control Scale[55]	14	Baseline and postintervention, follow-up
	Manitoba index[23]	1	Baseline and postintervention, follow-up
	PRO3 for Crohn's disease[56]	3	Baseline and postintervention, follow-up
	1-item re usual bowel function	1	Baseline and postintervention, follow-up
	PRO2 for ulcerative colitis[57]	2	Baseline and postintervention, follow-up
Pain	A Numeric Rating Pain Scale (on a scale 0–10, with 0 meaning no pain and 10 meaning the worst possible pain, how much pain are you having now?)	1	Baseline and postintervention, follow-up
	Gastrointestinal Unhelpful Thinking Scale[58]	15	Baseline and postintervention, follow-up
Fatigue	Fatigue Symptom Inventory[59]	14	Baseline and postintervention, follow-up
Measure of mental health	Kessler Psychological Distress Scale[24]	10	Baseline to confirm eligibility
	DASS-21 (depression, anxiety, somatiSation symptoms)[60]	21	Baseline and postintervention, follow-up
	EQ5D5L[61]	6	Baseline and postintervention, follow-up
	Brief Resilience Scale[62]	6	Baseline and postintervention, follow-up
	General Self-efficacy Scale[63]	10	Baseline and postintervention, follow-up
	Acceptance and Action Scale[64]	7	Baseline and postintervention, follow-up
Satisfaction	A 0–10 satisfaction rating scale: On a scale from 0 to 10 how satisfied are you with the intervention you participated in? Open-ended questions: For example: What did you find most helpful about the programme? What would you say to a friend interested in taking part? The Credibility/Expectancy Questionnaire[65]	10	Postintervention
Safety	Did the intervention produce any undesired effects? If yes, please specify	1	
Treatment utilisation	A series of questions on outpatient and emergency department visits; hospitalisations; diagnostic and investigation use, etc	8–9	Baseline and postintervention, follow-up

BMI, body mass index; IBD, inflammatory bowel disease.

confirm their eligibility. Those eligible will complete the baseline quantitative measures via a Qualtrics link. Participants will then be randomised to one of the two groups by the randomisation software built into Qualtrics, informed about the starting date and sent the Zoom link with any necessary instructions. Participants will meet weekly with the psychologist for the first 3 weeks, will then switch to self-directed learning in weeks 4–7, and have their final session with the psychologist again. After the final day of the intervention, participants will be asked to complete the quantitative post-intervention measures via Qualtrics. They will then be

contacted after 3 months postintervention to complete the follow-up measures via Qualtrics. An $A30 gift card will be offered to participants who complete all three surveys (baseline, 8 weeks and 3 months postintervention). Participants invited to take part in the longitudinal qualitative aspect of the study will also receive an $A30 gift card when they complete both interviews.

The researchers will use a range of evidence-based cohort retention strategies to minimise attrition, including having a facilitator and a short intervention duration, sending reminders and minimising time spent completing surveys.[34] At the trial completion, participants will be debriefed about their group allocation. All participants who express interest in receiving a summary data leaflet will be provided with one via email. In addition, the researchers will post this document on the consumer organisations' websites and associated social media platforms.

Data analysis

Quantitative analysis

Analyses will be carried out on an intention-to-treat basis. As feasibility trials cannot establish efficacy, the analysis will be largely descriptive (including measures of uncertainty, such as 95% CIs). However, we will attempt to run a group comparison on the main outcome measures with linear mixed effects models, which enable retention of participants with missing waves of data, under the assumption that data are missing at random. In these models, the dependent variable is the outcome measure, with predictors being Time, Group and the Interaction between Time and Group. The coefficient for interaction and its 95% CI will provide a range of estimates for change attributable to the target intervention. Following Bell *et al*,[22] estimates of the point estimate and upper CI values (at 80%) for SD in the outcome measures, as well as estimates of drop-out and the time × group intervention effect will be used to calculate a range of possible sample sizes required for a definitive RCT. Consistent with CONSORT guidelines[35] for pilot and feasibility studies, these sample size calculations will be offered tentatively and with caveats concerning potential instability in estimates from small sampled pilots.

A trial-based cost–utility analysis will evaluate the incremental resource use and cost of ACTforIBD programme compared with control group at 8 weeks and 3 months follow-up. Mean costs will be estimated using: costs of the ACTforIBD programme; outpatient and emergency department visits; hospitalisations; medication use; diagnostic and investigation use; general practitioner visits; and quality-adjusted life-years .

Qualitative analysis

Longitudinal qualitative data collected during semi-structured interviews with participants will be transcribed and analysed thematically, following the main procedural steps of reflexive thematic analysis,[36–38] which include: (1) becoming familiar with the data; (2) generating initial codes; (3) constructing initial themes; (4) reviewing potential themes; (5) defining and naming themes and (6) producing the report. All steps will be completed by the first author, with the wider qualitative research team discussing the content of codes and candidate themes, to agree on final themes. We will examine the data inductively, allowing participants' reflections to speak for themselves. In reporting results, we will adhere to Consolidated Criteria for Reporting Qualitative research.[39]

ETHICS AND DISSEMINATION

Participants will be provided with the Plain Language Statement detailing the participant commitment, potential risks and benefits of the study, and the investigators' contact details. After perusing the plain language statement and before participants are randomised to the groups, they will sign an informed consent form. Participation in the trial is voluntary and the participants can withdraw at any time without providing a reason. Those with severe psychological distress (scores 30–50 on K10) will not be eligible for the study as it is anticipated that these participants would require a more intensive therapeutic approach before benefiting from the current intervention. Similarly, participants whose mental health worsens during the study will be referred back to their treating doctors and provided with publicly available mental health helplines. Only deidentified data will be published. Our article will include a discussion section that details deviations from protocol, and trial limitations related to imprecision in estimates, sources of bias and generalisability threats (as per Consolidated Standards of Reporting Trials - CONSORT). Findings will be disseminated via peer-reviewed publications, conference presentations and briefs on the consumer organisations' websites.

Patient and public involvement

People with IBD were engaged to help develop the ACTforIBD program.[21] We will also incorporate a comprehensive qualitative evaluation alongside the quantitative data collection to help further inform the programme development to test in future large-scale RCTs.

DISCUSSION

IBD is increasingly considered a disease of brain–gut interaction, with emerging evidence of the bidirectional brain–gut and gut–brain links.[4] These links frequently translate into a high prevalence of anxiety and depression in people with IBD.[5] For example, as many as 28% and 20% of people report symptoms of anxiety and depression, respectively, during remission, while these rates rise to 66% and 35% during IBD relapses.[5] Consistent with brain–gut links, these episodes of anxiety and depression then have a significant impact on IBD disease outcomes, including IBD flares,[40] and hospital readmissions and surgery.[10] Consequently,

international IBD guidelines[41] and the Australian IBD Standards[42] recommend not only regular screening for mental illness in people with IBD, but also incorporation of mental healthcare in IBD management. Unfortunately, very few patients actually receive psychological treatment. In our recent Australia-wide study, we have shown that psychological support for people with IBD is very poor, with close to 70% of those with severe psychological distress not seeing a mental health practitioner.[43 44] This study has the potential to reach many more people with IBD as it is delivered online. However, ACTforIBD relies on therapist support rather than being exclusively self-directed and that means that, while it might reduce the time spent by the therapist with a patient and thus create time for psychologist to see more clients, the programme will likely be administered by hospitals/IBD centres rather than being publicly available.

Psychological treatment to improve adaptation to IBD typically involves CBT, and there is some support for its efficacy on QOL and symptoms of depression.[12] However, the findings of this meta-analysis also highlight the need for trials of psychotherapy interventions specifically targeting the groups at risk of suboptimal outcomes (eg, people with psychological distress), to improve both mental and physical health management in IBD. The proposed intervention will further contribute to understanding the utility of interventions that specially target those with IBD and psychological distress. Other limitations of existing research on psychological interventions include a focus on traditional models of CBT, developed primarily for non-chronic disease populations and without consultation with patients with IBD. This has often resulted in interventions that (1) are not informed by consumer preferences, which is associated with poor treatment retention and low efficacy[45 46]; and (2) omit important targets for psychological treatment relevant to this population, including psychological strategies to address negative disease-specific beliefs and disease-related thoughts and feelings, such as fear or shame.[47] It is likely that the core processes of ACT, which include acceptance and cognitive defusion (which can be described as changing the relationship with one's thoughts), are highly suited to chronic, incurable health conditions such as IBD. In addition, existing CBT interventions for IBD offer only short-term benefits for mental health and QoL in IBD,[12] with a dearth of studies focused on psychological distress as the outcome, and little telemedicine used.

Minimal contact therapies have not received adequate attention in gastroenterology, although the preliminary evidence is promising in terms of reducing healthcare seeking behaviour.[48] In IBD specifically, little research on low intensity or online psychotherapy is available.[12] Online interventions importantly increase equity and access to therapy for people living in rural and remote communities, as well as convenience for all by removing barriers such as time, transportation cost and inconvenience, and motivation to be physically present. As stated above, this intervention can be potentially implemented via existing hospital psychology clinics and made available throughout Australia contributing to integrated biopsychosocial healthcare in IBD. Given poor access to psychological care reported by people with IBD,[44] minimal contact online and low-cost therapies, such as the proposed intervention, have the potential to fill a current gap in services. ACT is considered one of the most promising psychological interventions in serious chronic illness.[49] Due to the efficacy of ACT in other chronic disease populations,[50 51] it is likely that our intervention may be feasible and improve outcomes in IBD, including psychological distress, disease activity, QoL, fatigue and pain. ACT delivered by a mental health practitioner is a safe, non-invasive, non-drug intervention worth investigating in the context of IBD.

LIMITATIONS

Many psychological interventions conducted to date have produced small-to-moderate effect sizes (though clinically meaningful), such as 0.2 for psychotherapy.[52] It is possible that ACTforIBD will produce a similarly small effect. However, since the present intervention is accessible to those in rural and remote communities via the hospitals utilising telemedicine appointments and reduces the reliance on therapists in comparison to psychotherapy facilitated by a face-to-face therapist each week, we believe even a small effect is meaningful for the future availability of psychotherapy in hospitals supporting people with IBD in Australia. It is also possible that given the current COVID-19 pandemic, there may be internet fatigue and coupled with ACT being a potentially lesser-known psychotherapy, recruitment might be slow and attrition high. However, we will employ strategies to enhance retention, including a short follow-up, brief surveys and small incentives throughout the study. We decided not to screen participants using a full-length psychological interview. This was dictated by the practicality of this once the intervention is implemented into practice but also by the fact that K10, we will rely on while screening, is a highly sensitive measure which outperforms other commonly used scales and correlates highly with diagnostic measures such as the *Mini* International Neuropsychiatric Interview (MINI).[53 54]

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Contributors SE contributed to the trial design, drafted the protocol paper, approved its final version and is the guarantor of the submission. LO, MD, SRK, MF-T, EO, PG, LR, RG, AM-W, LvN, SC and DR contributed to the trial design, commented

on drafts of the protocol paper, and approved the final version. AM-W designed the trial, contributed to drafts of the protocol paper and approved the final version.

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Competing interests We do not have any conflicts of interest in relation to the present study, however, outside this work, SK has served as an educational speaker for Janssen, Ferring and Takeda. PG has served as a speaker, a consultant and an advisory board member for Allergan, Janssen, MSD, Pfizer, Anatara, Atmo Biosciences, Immunic Therapeutics, Novozymes and Takeda and Bristol-Meyers Squibb, and has received research funding from from MSD and Atmo Biosciences; and RG owns stocks and shares in Atmo Biosciences. LR served on the Roche International Patient Advisory Council and the Takeda IBD Patient Expert Council. RG 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. AM-W has served as an educational speaker for Janssen and Ferring.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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