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Expressive writing to combat distress associated with the COVID-19 pandemic in people with inflammatory bowel disease (WriteForIBD): A trial protocol

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ABSTRACT

Objective: A large proportion of patients with inflammatory bowel disease (IBD) receive immunosuppressive medication, may be at higher risk of complications if they contract SARS-CoV-2 virus, and therefore report high levels of COVID-19-related distress. This trial will evaluate a brief, evidence-based, online, group-based expressive writing intervention to reduce COVID-19-related distress in people living with IBD at the time of pandemic.

Methods: A parallel double-blind randomised controlled trial will be conducted. Overall, up to 154 adult participants with IBD and mild-moderate distress will be recruited via patient organisations. Participants will be allocated to the expressive writing intervention or an active control group. All participants will complete questionnaires including measures of distress, quality of life, resilience, self-efficacy, social support and disease activity before and after the intervention (1 week) and at 3 months post-intervention. The expressive writing group will participate in the evidenced-based 4-day writing program adapted from Pennebaker and Beall, 1986. The active control group will write about untherapeutic topics provided by researchers. Statistical analysis will be carried out on an intention-to-treat basis and will involve linear mixed effects models.

Conclusions: If successful, this simple intervention may bring personal and societal benefits, particularly because it is low cost, can be easily implemented online, ensuring social distancing, and be made widely available, during future disasters and to help with trauma-related distress in IBD.

Trial registration: The trial has been prospectively registered in the Australian New Zealand Trial Registry - ACTRN12620000448943p.

1. Introduction

The COVID-19 pandemic presents significant risks to the mental health of people living with chronic health problems. This project evaluates an expressive writing intervention to help people living with inflammatory bowel disease (IBD) cope with distress related to SARS-CoV-2 virus and COVID-19 (i.e., a disease resulting from the virus) at the time of the COVID-19 pandemic.

1.1. IBD, COVID-19 pandemic and distress

IBD is an inflammatory condition affecting 3 million people in the United States [1] and 85,000 Australians, with symptoms including diarrhoea, faecal urgency, rectal bleeding, abdominal pain, and fatigue. IBD is chronic and increasingly considered a disease of brain-gut interaction, with emerging evidence of the bi-directional brain-gut and gut-brain links [2], translating into a significant mental illness comorbidity (i.e. >60% of patients report clinically significant anxiety during disease flares [3]). A large proportion of patients with IBD receive

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immunosuppressive medication and may be at higher risk of complications if they contract SARS-CoV-2 virus. A recent survey showed that 64% of 3815 respondents reported that immunosuppressive drugs increased risk of infection and 30% believed that IBD itself increases the risk of developing COVID-19 [4]. In addition, the recent COVID-19 related product shortages, specifically those relating to medication, protective equipment and toilet paper, but also challenges in accessing care, have presented a novel and additional stressor for this population. Further, isolation enforced by the governments in some countries or self-imposed to protect oneself from the virus is yet another stressor and a possible contributor to future risks of social anxiety. These factors have resulted in significant distress expressed by the members of the IBD community [5]. For example, a COVID-19 focused survey ($n = 124$) showed that close to 50% of patients with IBD reported moderate to severe symptoms of anxiety and 20% of depression [6]. To date, studies have not documented positive aspects of COVID-19 pandemic for those with IBD but these could potentially include lower distress due to not being faced with anxiety-provoking situations such as lack of knowing where the toilet is, lack of stress associated with travel, work or socialising. Nonetheless, these potential benefits are likely to be overshadowed by the overwhelming fear of catching the virus or infecting others [4].

Psychotherapy trials for those living with IBD who report distress are scarce [7], with most existing trials testing interventions with unselected IBD samples (i.e. anyone with IBD) and focused on disease activity. No psychological interventions focused on coping with the stress of the COVID-19 pandemic have been conducted in an IBD population to date. Such interventions can facilitate individual's processing of challenging situations more effectively and facilitate emotional regulation resulting in improved physical and psychological functioning.

1.2. Expressive writing

Disclosing one's thoughts and feelings (experimental disclosure) concerning difficult events through expressive writing has been shown to lead to broad health improvements. A major comprehensive meta-analysis on experimental disclosure ($n = 146$ RCTs) demonstrated significant improvements in psychological outcomes, including distress, anxiety, depression, anger, positive functioning and ability to make sense of a traumatic event [8]. In terms of physiological and health outcomes, significant improvements were seen in immune functions, specific disease outcomes and illness behaviours. Work-related outcomes and social relationships were also significantly improved (with small to medium effect sizes ranging from -0.291 to 0.592). A more recent meta-analysis on expressive writing in cancer ($n = 13$ RCTs) showed significant (though small) improvements in cancer symptoms and quality of life [9]. However, while expressive writing interventions are effective for a variety of outcomes and have high satisfaction, some participants do not perceive them as helpful or engaging and their efficacy is dependent on individual differences, e.g., optimists observe greater benefits [8,10].

Several theories propose how expressive writing may improve a broad spectrum of outcomes. Inhibition theory links its effects to Freudian concept of catharsis where expression of inhibited thoughts and feelings may release stress and consequently improve other biopsychosocial outcomes. However, experimental research has shown that people equally benefit from writing about imaginary emotions and thus it is doubtful that writing helps through releasing unresolved internal conflicts [11]. Cognitive-processing theory posits that writing helps via allowing people to gain insight into what they have experienced, to make sense of a traumatic event and integrate a difficult experience into their self-concept [12]. Self-regulation theory proposes that writing creates opportunities to observe oneself expressing and controlling emotions, boosting one's self-efficacy in regulating emotions [13]. The social integration model proposes that writing interventions work because they change the way people interact with their social world

[14]. The exposure model compares writing about a traumatic event to flooding therapy useful in treating PTSD via confronting and relieving trauma and eventually extinction of unpleasant thoughts and feelings [15]. Each of the models has been critiqued in the recent meta-analysis but the greatest support is available for the exposure model [8].

1.3. Expressive writing in gastroenterology cohorts

Pennebaker's expressive writing intervention has been one of the first and most influential expressive writing interventions to date [16], comprising four short writing sessions, with its various derivatives tested widely [8]. In the context of gastroenterology, it has been piloted in one non-randomised trial, which included patients with irritable bowel syndrome (IBS, $n = 103$) [17]. Significant improvements at 1 and 3 months were observed in IBS severity. To date, no randomised control trials of expressive writing have been conducted on inflammatory gut conditions, such as Crohn's disease and ulcerative colitis (subtypes of IBD).

Expressive writing offers promise for IBD patients since it may improve immune functions and reduce distress [8]. Following the recommendations from the meta-analyses on expressive writing and the relevant study on IBS [8,17,18], we propose to adapt Pennebaker's evidence-based intervention by adding an element of gratitude writing. Although good-quality systematic reviews are lacking on the effect of gratitude writing, some early trials ($n = 293$) reported its significant benefits [19] on mental health as compared to no intervention controls or expressive writing controls. Gratitude, and a related concept of resilience (i.e. human ability to bounce back from adversity), can protect victims of disasters against post-traumatic stress, with resilience acting to prevent an adverse response to trauma and gratitude promoting positive outcomes post-trauma [20]. In the IBD context, resilience has been associated with lower disease activity and fewer surgeries as well as improved quality of life [21].

Further, since the literature supports the exposure model as the most likely explanation of how writing interventions work [8], the benefits to those with IBD may be because of the high co-morbidity of IBD with post-traumatic stress disorder [22] and because those with history of trauma (IBD diagnosis is often considered a traumatic experience) respond particularly well to writing interventions [8]. Further, of all the examined outcomes, writing interventions are particularly effective for distress, immune parameters, and specific disease outcomes, with higher effect sizes reported in those with pre-existing physical health problems [8]. In addition, stress is a significant moderator of the effect of writing interventions, with those reporting high stress receiving greatest benefits. Those with IBD report very high perceived stress which has been associated with poor disease activity [23,24].

Finally, convincing meta-analytic evidence [8,18] demonstrates that expressive writing may be:

1. particularly useful to participants with poorer health (higher reported health effect sizes than in other populations)
2. more effective when undertaken at participants' home (higher psychological health effect sizes than studies in which participants wrote in a controlled setting)
3. more effective if sessions last at least 15 min (larger effect sizes than studies with sessions that lasted less than 15 min)
4. more effective when the intervention includes three or more sessions (marginally larger effect sizes than studies with fewer than three sessions)
5. more effective when participants write about recent challenging events (larger effect sizes compared to older events)
6. more effective when participants are asked to write about specific questions or examples (larger effect sizes than studies that did not give directed questions or examples)

7. more effective when participants are not asked to hand in their writing to the investigators (marginally higher psychological health effect sizes than studies in which participants turned in their writing)
8. equally effective if handwritten or typed.
9. more effective when facilitated rather than unfacilitated.

Therefore, we designed our brief facilitator-assisted online intervention, specifically following the above evidence-based strategies and propose to investigate:

1.3.1. Primary outcome

Whether the expressive writing intervention improves patient distress compared with an active control group at post-intervention and 3 months since baseline.

1.3.2. Secondary outcomes

Whether the expressive writing intervention improves patient anxiety, depression, stress, disease activity, quality of life, resilience, self-efficacy and sense of isolation at post-intervention and 3 months since baseline.

1.3.3. Hypothesis

We hypothesise that our expressive writing intervention will have a significant and positive impact on the symptoms of distress as compared to an active control condition.

2. Method

2.1. Ethical approval and trial registration

This protocol has been approved by the Deakin University Human Research Ethics Committee in May 2020 (Ref. 2020-122). The trial was prospectively registered in the Australian New Zealand Trial Registry on 06 April 2020 (ID: ACTRN12620000448943p). The trial is likely to start recruiting in June 2020 and complete recruitment by July 2021.

2.2. Design

See Fig. 1 for a study design overview. A parallel randomised double-blind controlled trial, involving intention to treat analyses will be

conducted. Participants will be randomly allocated to one of two groups: expressive writing intervention or active control, with a ratio of 1:1. Simple randomisation, with no blocks, using a randomisation table created by computer software (i.e. computerised sequence generation) will be used. Allocation will involve contacting the holder of the allocation schedule (the study statistician) who is based at central administration site with no access to participants. No stratification is envisaged. Participants, as well as research staff assessing outcomes and analysing the data will be blinded to group allocation, with masking and an active control condition used for participants. Participants in both treatment arms will remain on their current IBD medication. All participants will complete questionnaires before and after the intervention (1 week) and at 3 months since baseline.

2.3. Participants

2.3.1. Inclusion criteria

- Diagnosis of IBD: Crohn’s disease, ulcerative colitis or indeterminate colitis established using standard criteria (we will ask participants for the details of their gastroenterologist, and these will be verified by our team);
- Distress: at least mild distress on K10 (scores 20–29);
- Age: 18 years and older; receiving care in Australia, New Zealand or Singapore, able to read and write in English, with access to internet to participate in online intervention, able to download Zoom and available to participate for approximately 30 min for 4 consecutive days.

2.3.2. Exclusion criteria

- No distress based on K10 (scores under 20) as the intervention targets distress.
- Severe distress based on K10 (scores 30–50 very high distress) as it is anticipated that these participants would require a more intensive therapeutic approach before benefiting from the current intervention. These participants will be contacted individually by the research team to indicate they are not eligible to participate due to screening highly for severe distress. We will then recommend that

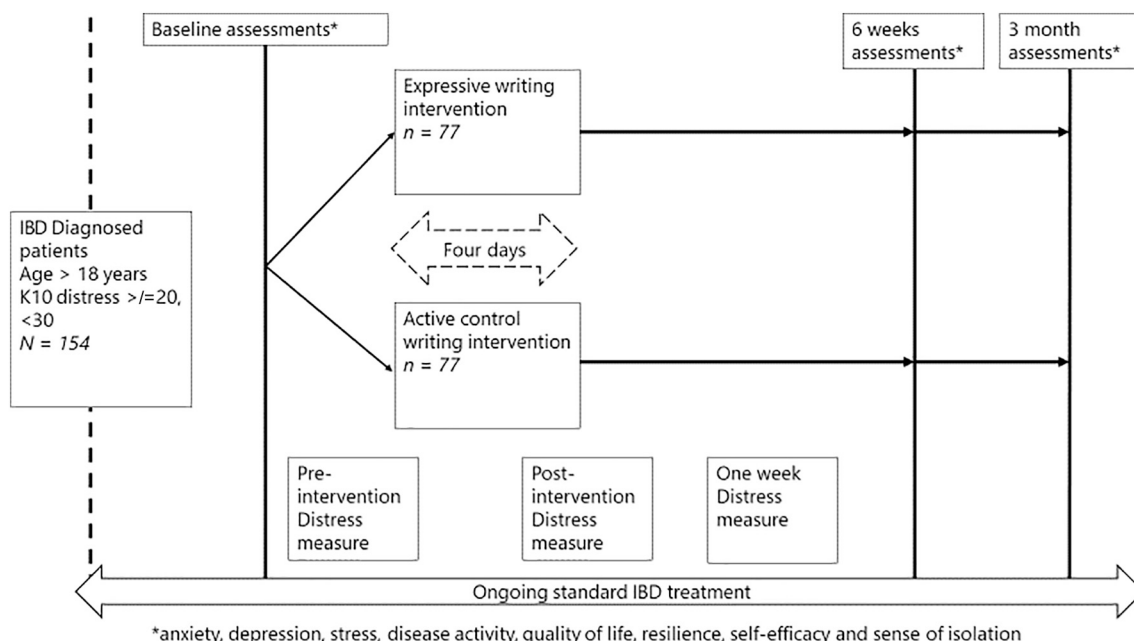


Fig. 1. Study design overview.

they seek additional support from their GP or other appropriate providers.

2.3.3. *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.

2.4. *Recruitment*

We will recruit via IBD-related social media, largely via Facebook, Twitter and Instagram sites of Crohn’s & Colitis Australia, Crohn’s & Colitis New Zealand and Crohn’s & Colitis Society of Singapore. We will be recruiting through the COVID-19 Pandemic period.

2.5. *Intervention and control condition*

Expressive writing intervention – This group will participate in the adapted evidenced-based [25] 4-day writing program. Participants will meet with the facilitator using Zoom four times in one week for approx. 30 min (25 min of writing time). Privacy of sessions will be ensured by using Zoom passwords and the waiting rooms which allow the facilitator to monitor who joins the session. Daily e-mail reminders about the on-line sessions will be sent during the 4 days of writing. The instruction each day will be adapted from Pennebaker [25] (Table 1). Participants

Table 1
Session structure.

	Expressive writing	Active control
Step 1	Greetings, record participant codename, check that participants can hear the instructions, reminder that video use is not compulsory, and writing does not need to be shared with the investigators	Greetings, record participant codename, check that participants can hear the instructions, reminder that video use is not compulsory, and writing does not need to be shared with the investigators
Step 2	Complete VAS distress measure (1 min)	Complete VAS distress measure (1 min)
Step 3 (sessions 2–4)	Write reflections on the last session (5 min)	Write reflections on the last session (5 min)
Step 4	Write about thoughts and feelings (15 min) <i>Please write about your thoughts and feelings about your IBD and the recent situation with COVID-19. Try to select something that you had a strong reaction to – perhaps this was a thought that was challenging or unpleasant. Feel free to really let go and explore your very deepest emotions and thoughts. You might tie your topic to your relationships with others, including parents, lovers, friends or relatives, to your past, your present, your future, or to who you have been, who you would like to be, or who you are now. All of your writing will be completely confidential. Please don't worry about spelling, sentence structure, or grammar. Feel free to type or write by hand.</i>	Write about thoughts and feelings (20 min) day 1 – describe the furniture in your room day 2 – describe the place of your work day 3 – describe your suburb day 4 – describe your best friend
Step 5	Write about things you are grateful for (5 min)	N/A
Step 6	Complete VAS distress measure (1 min)	Complete VAS distress measure (1 min)

will not need to share their writing with the study investigators to ensure free expression.

Active control – This group will write about trivial untherapeutic topics provided by researchers (Table 1) for 4 consecutive days. Participants will meet with the facilitator using Zoom (audio required, video use is optional) four times in one week for approx. 30 min (25 min of writing time). Daily e-mail reminders will be sent during the 4 days of writing. On request, the active control group will be offered self-directed version of the intervention after the final follow-up.

The intervention will be facilitated by Psychology research students. Facilitators will provide the intervention interchangeably to different groups (i.e., each facilitator will deliver intervention in both groups). See Table 1 for detail of intervention structure.

2.6. *Measures*

Table 2 details the measures used in this study, including their scoring and assessment time.

2.7. *Procedure*

Participants will be recruited online via social media. They will be asked to email the researchers if they are interested in participating. They will then be asked to read and consider the study’s Plain Language Statement and, if still interested, to sign a consent form and return to the investigators via email. Participants will then be asked to complete K10 to ensure their distress is within the mild-moderate range. Those eligible will then be asked to complete all the remaining baseline measures. Participants will be given codenames to facilitate data collection at multiple times. Participants will then be randomised to one of the two groups, informed about the starting date and sent the Zoom link with any necessary instructions. During each session, participants will be reminded they are not required to use video. They only need to be able to hear the facilitator. The facilitator will then provide the link to the distress VAS measure and after its completion writing will start. At the end of the session, the facilitator will provide the participants with another link to the distress VAS measure (both via Qualtrics). Sessions will continue for 4 consecutive days and attendance will be recorded each day. After the final day of the intervention the participants will be asked to complete the post-intervention measures. They will then be contacted after 3 months to complete the follow-up measures. Participants who complete the study including the 3-month follow-up will be entered into a prize draw for one of ten AU \$50 online gift vouchers. At the trial completion, participants will be debriefed about their group allocation.

2.8. *Power calculation*

Two large, comprehensive meta-analyses on the beneficial effect of therapeutic writing for psychological distress in chronic disease suggest small improvements to psychological wellbeing compared to control and indicate that the effect is magnified in the presence of facilitators [8,18]. As such, we power the study for a small but meaningful between-groups effect at post-intervention of standardised mean difference = 0.3. Using an alpha level of 0.05 and 80%, a minimum sample size of n = 128 is required. We assume a drop-out of 20%, so will recruit 154 persons (77 per group).

2.9. *Statistical analysis*

We will use Qualtrics to collect the data at 3 time points and before/ after each writing session. The data will then be transferred into SPSS for analysis. The data will be anonymized by adding code names. The files containing personal or identifiable data will be encrypted or password protected. Analyses will be carried out on intention-to-treat basis, and significance tests will be two-sided at the 5% level. No adjustment for

Table 2
Outcome measures.

		No. of items	Scoring	Assessment time
Demographics	Age, sex, level of education, marital status, employment, language spoken at home, postcode, private insurance	8	N/A	Baseline
Health-related questions	IBD subtype (CD, UC, IC)	1	N/A	Baseline
	When was your IBD diagnosed?	1	N/A	Baseline
	Do you currently have any of the following (click all that apply): Stoma (bag) Fistula Perianal disease Unsure	1	N/A	Baseline
	Do you suffer from other chronic illnesses? If yes, please list.	1	N/A	Baseline
	What treatment do you currently take for IBD?	1	N/A	Baseline
	Do you regularly use opioid medication such as oxycontin, codeine, tramadol, fentanyl or similar painkillers? If yes, please list.	1	N/A	Baseline
	Do you take antidepressants or anti-anxiety medication?	1	N/A	Baseline
	Smoking habits	1	N/A	Baseline
	Alcohol	1	N/A	Baseline
	BMI (weight and height)	2	N/A	Baseline
COVID-19 questions	Were you in paid employment prior to the COVID-19 pandemic?	8	N/A	Baseline
	Has your employment been negatively affected by COVID-19 (e.g. you were made redundant, received a pay cut or your hours were reduced)?			
	Has anyone in your household tested positive for COVID-19?			
	How has COVID-19 affected your life?			
	What strategies are helping you to stay calm in the current situation?			
	Have you been impacted by any			

Table 2 (continued)

		No. of items	Scoring	Assessment time
	shortages related to COVID-19? No, toilet paper shortages, food shortages, medicine shortages, other – list			
	To what extent do you experience the following when thinking about your ability to deal with COVID-19? Worry, fear, confidence hope, (not at all 1 – a great deal 4)			
IBD activity	What's your greatest fear regarding COVID-19 pandemic? IBD Control Scale [1]	14	A validated patient reported outcome measure (PROM), with two subscales: IBD-Control-8 (0–16, with 0 meaning worst control, with a cut-off of for remission ≥ 13 points) and IBD-Control-VAS (0–100, with 0 meaning worst control, with a cut-off for remission of ≥ 85).	Baseline & post-intervention, follow-up
	Manitoba index [2]	1	A single item IBD activity measure, using a 6-point scale ranging from 'Constantly active, giving me symptoms everyday' to 'I was well in the past 3 months, what I consider a remission or absence of symptoms'.	Baseline & post-intervention, follow-up
Measure of mental health	Kessler Psychological Distress Scale (K10) [3]	10	A simple measure of psychological distress, using a 5-point Likert scale. The maximum score is 50 indicating severe distress, the minimum score is 10	Baseline & post-intervention, follow-up

(continued on next page)

Table 2 (continued)

	No. of items	Scoring	Assessment time
DASS-21 (depression, anxiety, somatization symptoms) [4]	21	indicating no distress. A brief measure of symptoms of depression, anxiety and stress. Standard cut-offs apply: Depression symptoms >10 Anxiety symptoms >7 Stress symptoms >14	Baseline & post-intervention, follow-up
Distress VAS scale: On a scale from 0 to 10, how distressed do you feel right now?	1	An 11-point scale ranging from no distress to extremely severe distress.	Before and after each session, so 8 times during the intervention
Multidimensional Scale of Perceived Social Support [5]	12	Three subscales of social support are measured: friends, family and significant other. Each scale ranges from 1 (very strongly disagree) to 7 (very strongly agree). A total average score is calculated, ranging from 0 to 7, with higher total scores indicating higher social support levels.	Baseline & post-intervention, follow-up
AQOL8D [6]	35	The 35-item scale examines eight dimensions of physical and psychosocial QoL (eg. pain, senses, relationships, self-worth, coping), including 4–6 response levels for each item. Scores for each dimension and a total score, ranging from 0 to 100, with the higher score indicating better QoL.	Baseline & post-intervention, follow-up
Brief Resilience Scale [7]	6	A brief measure of resilience, with a 5-point scale, ranging from strongly	Baseline & post-intervention, follow-up

Table 2 (continued)

	No. of items	Scoring	Assessment time
General Self-efficacy Scale [8]	10	disagree to strongly agree. A brief 10-item, 4-point measure of self-efficacy, ranging from not at all to exactly true.	Baseline & post-intervention, follow-up
Satisfaction	4	VAS 0–10 satisfaction rating: On a scale from 0 to 10 how satisfied are you with the writing intervention you participated in? Open-ended questions: what was the best aspect of this intervention? What was the worst aspect of this intervention? How did the writing experience affect your mental health?	Post-intervention

References

1. Bodger K, Ormerod C, Shackcloth D, Harrison M. Development and validation of a rapid, generic measure of disease control from the patient’s perspective: the IBD-Control questionnaire. *Gut*. 2014;63:1092-102.
2. Clara I, Lix LM, Walker JR, Graff LA, Miller N, Rogala L, et al. The Manitoba IBD Index: evidence for a new and simple indicator of IBD activity. *The American journal of gastroenterology*. 2009;104(7):1754-63.
3. Andrews G, Slade T. Interpreting score on the Kessler Psychological Distress Scale (K10). *Australia and New Zealand Journal of Public Health*. 2001;25(6):494-7.
4. Osman A, Wong JL, Bagge CL, Freedenthal S, Gutierrez PM, Lozano G. The Depression Anxiety Stress Scales-21 (DASS-21): further examination of dimensions, scale reliability, and correlates. *J Clin Psychol*. 2012;68(12):1322-38.
5. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The Multidimensional Scale of Perceived Social Support. *Journal of Personality Assessment*. 1988;52:30-41.
6. Richardson J, Iezzi A. Psychometric validity and the AQoL-8D multi attribute utility instrument. Centre for Health Economics, Monash University; 2011.
7. Smith BW, Dalen J, Wiggins K, Tooley E, Christopher P, Bernard J. The brief resilience scale: assessing the ability to bounce back. *International journal of behavioral medicine*. 2008;15(3):194-200.
8. Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston M, editors. *Measures in health psychology: A user’s portfolio Causal and control beliefs*. Windsor, UK: NFER-NELSON; 1995. p. 35-7.

multiple testing will be made to *p*-values, however, effect sizes for each outcome measure will be presented. The study hypothesis will be tested with a series of linear mixed effects models, which are known to compensate for missing data. 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 being the formal test of the hypothesis. A per protocol analysis will also be undertaken, with adjustment for adherence to intervention. The latter will be defined as ≥80% of sessions completed. Other adjustments (e.g., age, sex, disease activity, IBD treatment type) will be made, if required.

3. Discussion

IBD is increasingly considered a disease of brain-gut interaction, with emerging evidence of the bi-directional brain-gut and gut-brain links

[2], which translates into a high prevalence of anxiety and depression [3]. Conversely, anxiety and depression co-existing with IBD have a significant impact on disease outcomes, such as IBD flares [26], disease presentation [27], hospital readmissions and surgery [28]. Even during remission, 28% and 20% of patients report symptoms of anxiety and depression, respectively, while these rates rise to 66% and 35% during IBD relapses [3]. Therefore, a large proportion of this population could benefit from psychological screening and treatment. Yet, while the international IBD guidelines [29] and the Australian IBD Standards [30] recommend regular screening for symptoms of mental illness and incorporating mental healthcare in IBD management, very few (12.2%) patients actually receive the psychological help they need [31,32].

A recent meta-analysis has showed that psychotherapy, and particularly cognitive-behavioral therapy (CBT), improves quality of life and symptoms of depression in patients with IBD [7], but also disease-related outcomes such as pain in other common gastrointestinal conditions [33]. Other psychotherapies, for example those targeting trauma, are increasingly being tested in gastroenterology in hope to identify alternatives for those people not engaging or responding to CBT. One example is emotional awareness and expression therapy which has been shown to reduce bowel symptoms and improve quality of life in patients with irritable bowel syndrome in a recent RCT [34]. The proposed intervention will further contribute to the enquiry into the role of expressive interventions in gastroenterology populations.

Minimal contact therapies have not received much attention in gastroenterology, although the preliminary evidence is promising in terms of reducing healthcare seeking behaviour [35]. In IBD specifically, little research on low intensity or online psychotherapy is available [7]. Given poor access to psychological care reported by people with IBD [36], minimal contact online and low cost therapies such as the proposed intervention have a potential to fill the current gap in services. Further, the recent meta-analysis highlighted a dearth of interventions focused on people “in need” of psychological therapy (e.g. those with comorbid distress), as most available trials have focused on the unselected patients with IBD (anyone with the diagnosis).

To date, there have been no studies focused on expressive writing in people with IBD, very few online psychotherapies designed for people with IBD specifically or targeting distress particularly at the time of adversity, for example major disasters such as the COVID-19 pandemic. Offering solutions to address high levels of distress currently experienced by the members of the IBD community is paramount to improving patients' emotional wellbeing. It can potentially also prevent stress-related flares, which can have serious implications for patients but also cost healthcare systems, already weakened by the COVID-19 pandemic. In addition, more research is needed on moderators of psychological intervention effects in IBD. While a large number of moderators have been examined in previous writing interventions [8], understanding IBD-specific moderators such as IBD activity and complications (e.g., fistulas), but also broader factors which have not been extensively studied in previous writing interventions for chronically ill cohorts such as disease duration, social support, self-efficacy, and resilience may help explain current limited long-term effects of psychotherapy in IBD [7] and inform future trials of tailored interventions for the subgroups likely to benefit. Other researchers have started pinpointing moderators relevant to gastrointestinal cohorts [37].

If effective, this simple intervention can be a useful tool for patients and multidisciplinary health professionals supporting the IBD community. More broadly, the intervention can bring personal and societal benefits, particularly because it is low cost, can be easily implemented online, ensuring social distancing, and be made widely available throughout Australia and internationally, during future disasters and to help with trauma-related distress in IBD.

4. Limitations

While expressive writing has proven efficacy in reducing distress and

improving broad biopsychosocial outcomes in a variety of contexts, many interventions conducted to date have produced small-moderate effect sizes [8]. Effect sizes for psychological interventions are generally low (e.g., 0.2 for psychotherapy [38]) and the present intervention may produce even lower effects [8]. However, since the present intervention is low effort/cost in comparison to psychotherapy which takes weeks and is facilitated by a therapist who might not be easily available, we believe producing even a small effect is important and might be a good solution for people with no easy access to psychologists. Further, this study is about distress caused by the COVID-19 pandemic (largely due to fear of the possibility to contract the virus) and our advertising and the Plain Language Statement clearly refer to this source of distress. However, distress may have a variety of sources and not all might respond to writing or psychological interventions equally. The present study's results may therefore only apply to specific disaster-related distress scenarios.

Competing interest statement

The authors have no competing interests to report.

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References

- [1] Centre for Disease Control and Prevention, Inflammatory Bowel Disease Prevalence (IBD) in the United States: Centre for Disease Control and Prevention, Available from, <https://www.cdc.gov/ibd/data-statistics.htm>, 2019.
- [2] D.J. Gracie, E.A. Guthrie, P.J. Hamlin, A.C. Ford, Bi-directionality of brain-gut interactions in patients with inflammatory bowel disease, *Gastroenterology* 154 (6) (2018) 1635–46.e3.
- [3] A. Mikocka-Walus, S.R. Knowles, L. Keefer, L. Graff, Controversies revisited: a systematic review of the comorbidity of depression and anxiety with inflammatory bowel diseases, *Inflamm. Bowel Dis.* 22 (3) (2016) 752–762.
- [4] F. D'Amico, J.F. Rahier, S. Leone, L. Peyrin-Biroulet, S. Danese, Views of patients with inflammatory bowel disease on the COVID-19 pandemic: a global survey, *Lancet Gastroenterol. Hepatol.* 5 (7) (2020) 631–632.
- [5] Crohn's & Colitis Australia, CORONAVIRUS (COVID-19) RESPONSE, Available from, <https://www.crohnsandcolitis.com.au/news/coronavirus-covid-19-health-alert/>, 2020.
- [6] I.A. Trindade, N.B. Ferreira, COVID-19 Pandemic's effects on disease and psychological outcomes of people with inflammatory bowel disease in Portugal: a preliminary research, *Inflamm. Bowel Dis.* (2020), <https://doi.org/10.1093/ibd/izaa261>.
- [7] D.J. Gracie, A.J. Irvine, R. Sood, A. Mikocka-Walus, P.J. Hamlin, A.C. Ford, 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.* 2 (3) (2017) 189–199.
- [8] J. Frattaroli, Experimental disclosure and its moderators: a meta-analysis, *Psychol. Bull.* 132 (6) (2006) 823–865.
- [9] P.J. Oh, S.H. Kim, The effects of expressive writing interventions for patients with cancer: a meta-analysis, *Oncol. Nurs. Forum* 43 (4) (2016) 468–479.
- [10] L.D. Cameron, G. Nicholls, Expression of stressful experiences through writing: effects of a self-regulation manipulation for pessimists and optimists, *Health Psychol.* 17 (1) (1998) 84–92.
- [11] M.A. Greenberg, C.B. Wortman, A.A. Stone, Emotional expression and physical health: revising traumatic memories or fostering self-regulation? *J. Pers. Soc. Psychol.* 71 (3) (1996) 588–602.
- [12] J.W. Pennebaker, Putting stress into words: health, linguistic, and therapeutic implications, *Behav. Res. Ther.* 31 (6) (1993) 539–548.
- [13] S.J. Lepore, M.A. Greenberg, M. Bruno, J.M. Smyth, Expressive writing and health: Self-regulation of emotion-related experience, physiology, and behavior, in: S.J.L. J.M. Smyth (Ed.), *The Writing Cure: How Expressive Writing Promotes Health and Emotional Well Being*, American Psychological Association, Washington, DC, 2002, pp. 99–117.
- [14] J.W. Pennebaker, A. Graybeal, Patterns of natural language use: disclosure, personality, and social integration, *Curr. Dir. Psychol. Sci.* 10 (2001) 90–93.

- [15] R.R. Bootzin, Examining the theory and clinical utility of writing about emotional experiences, *Psychol. Sci.* 8 (1997) 167–169.
- [16] J.W. Pennebaker, S.K. Beall, Confronting a traumatic event: toward an understanding of inhibition and disease, *J. Abnorm. Psychol.* 95 (3) (1986) 274–281.
- [17] A. Halpert, D. Rybin, G. Doros, Expressive writing is a promising therapeutic modality for the management of IBS: a pilot study, *Am. J. Gastroenterol.* 105 (11) (2010) 2440–2448.
- [18] O.P. Nyssen, S.J. Taylor, G. Wong, E. Steed, L. Bourke, J. Lord, et al., Does therapeutic writing help people with long-term conditions? Systematic review, realist synthesis and economic considerations, *Health Technol. Assess. (Winchester, England)* (27) (2016) 20 (vii–xxxvii, 1–367).
- [19] Y.J. Wong, J. Owen, N.T. Gabana, J.W. Brown, S. McInnis, P. Toth, et al., Does gratitude writing improve the mental health of psychotherapy clients? Evidence from a randomized controlled trial, *Psychother. Res.* (2016) 1–11.
- [20] J. Vieselmeier, J. Holguin, A. Mezulis, The role of resilience and gratitude in posttraumatic stress and growth following a campus shooting, *Psychol. Trauma* 9 (1) (2017) 62–69.
- [21] P. Sehgal, R.C. Ungaro, C. Foltz, B. Iacoviello, M.C. Dubinsky, L. Keefer, High levels of psychological resilience associated with less disease activity, better quality of life, and fewer surgeries in inflammatory bowel disease, *Inflamm. Bowel Dis.* (2020), <https://doi.org/10.1093/ibd/izaa196>.
- [22] T.H. Taft, A. Bedell, M.R. Craven, L. Guadagnoli, S. Quinton, S.B. Hanauer, Initial assessment of post-traumatic stress in a US cohort of inflammatory bowel disease patients, *Inflamm. Bowel Dis.* 25 (9) (2019) 1577–1585.
- [23] R.J. Cámara, R. Ziegler, S. Bégre, A.M. Schoepfer, R. von Känel, The role of psychological stress in inflammatory bowel disease: quality assessment of methods of 18 prospective studies and suggestions for future research, *Digestion.* 80 (2) (2009) 129–139.
- [24] C.N. Bernstein, S. Singh, L.A. Graff, J.R. Walker, N. Miller, M. Cheang, A prospective population-based study of triggers of symptomatic flares in IBD, *Am. J. Gastroenterol.* 105 (9) (2010) 1994–2002.
- [25] J.W. Pennebaker, Writing about emotional experiences as a therapeutic process, *Psychol. Sci.* 8 (3) (1997) 162–166.
- [26] A. Mikocka-Walus, V. Pittet, J.B. Rossel, R. von Känel, Symptoms of depression and anxiety are independently associated with clinical recurrence of inflammatory bowel disease, *Clin. Gastroenterol. Hepatol.* 14 (6) (2016) (829–35.e1).
- [27] B. Kochar, E.L. Barnes, M.D. Long, K.C. Cushing, J. Galanko, C.F. Martin, et al., Depression is associated with more aggressive inflammatory bowel disease, *Am. J. Gastroenterol.* 113 (1) (2018) 80–85.
- [28] A.N. Ananthakrishnan, V.S. Gainer, R.G. Perez, T. Cai, S.C. Cheng, G. Savova, et al., Psychiatric co-morbidity is associated with increased risk of surgery in Crohn's disease, *Aliment. Pharmacol. Ther.* 37 (4) (2013) 445–454.
- [29] W. Hauser, G. Moser, P. Klose, A. Mikocka-Walus, Psychosocial issues in evidence-based guidelines on inflammatory bowel diseases: a review, *World J. Gastroenterol.* 20 (13) (2014) 3663–3671.
- [30] CCA, Australian IBD Standards: Standards of Healthcare for People with Inflammatory Bowel Disease in Australia, Crohn's & Colitis Australia, Camberwell, VIC, Australia, 2016.
- [31] F. Bennebroek Evertsz, N.A. Thijssens, P.C. Stokkers, M.A. Grootenhuys, C. L. Bockting, P.T. Nieuwkerk, et al., Do inflammatory bowel disease patients with anxiety and depressive symptoms receive the care they need? *J. Crohns. Colitis.* 6 (1) (2012) 68–76.
- [32] S. Knowles, J.M. Andrews, A. Porter, Predictors of impaired mental health and support seeking in adults with inflammatory bowel disease: an online survey, *Gastroenterol. Nurs.* 41 (1) (2018) 38–46.
- [33] C.J. Black, E.R. Thakur, L.A. Houghton, E.M.M. Quigley, P. Moayyedi, A.C. Ford, Efficacy of psychological therapies for irritable bowel syndrome: systematic review and network meta-analysis, *Gut.* 69 (8) (2020) 1441–1451.
- [34] E.R. Thakur, H.J. Holmes, N.A. Lockhart, J.N. Carty, M.S. Ziadni, H.K. Doherty, et al., Emotional awareness and expression training improves irritable bowel syndrome: A randomized controlled trial, *Neurogastroenterol. Motil.* 29 (12) (2017).
- [35] A. Ahl, A. Mikocka-Walus, A. Gordon, J.M. Andrews, Are self-administered or minimal therapist contact psychotherapies an effective treatment for irritable bowel syndrome (IBS): a systematic review, *J. Psychosom. Res.* 75 (2) (2013) 113–120.
- [36] A. Mikocka-Walus, W. Massuger, S.R. Knowles, G.T. Moore, S. Buckton, W. Connell, et al., Psychological distress is highly prevalent in inflammatory bowel disease: a survey of psychological needs and attitudes, *JGH Open* 4 (2) (2020) 166–171.
- [37] H.J. Holmes, E.R. Thakur, J.N. Carty, M.S. Ziadni, H.K. Doherty, N.A. Lockhart, et al., Ambivalence over emotional expression and perceived social constraints as moderators of relaxation training and emotional awareness and expression training for irritable bowel syndrome, *Gen. Hosp. Psychiatry* 53 (2018) 38–43.
- [38] P. Cuijpers, A. van Straten, E. Bohlmeijer, S.D. Hollon, G. Andersson, The effects of psychotherapy for adult depression are overestimated: a meta-analysis of study quality and effect size, *Psychol. Med.* 40 (2) (2010) 211–223.