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Original Article

A Randomized Controlled Trial of Mindfulness in Recovery from Colorectal Cancer

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ABSTRACT **Objective:** This study examined whether a 4-week group-based mindfulness intervention would be superior in reducing psychological distress in colorectal cancer (CRC) patients compared to a psychoeducation and cognitive behavioural skills learning support active control group. **Methods:** Patients with CRC were randomized via Computerised Permuted Block Randomisation to mindfulness or active control groups (2-h weekly sessions over 4 weeks). Outcomes were measured pre-intervention, and 8 weeks and 6 months post-baseline. The primary outcome was psychological distress measured by the Hospital Anxiety and Depression Scale. Secondary outcomes were generic quality of life (QoL), disease specific QoL, mindfulness, and intervention credibility and acceptability. **Results:** Sixty-eight participants were randomized to mindfulness (n=35) or active control group (n=33). Uptake of potentially eligible patients consenting was low (28.0%) and the dropout rate was 33.8%. Depression scores were reduced in both groups at week 8 (P=0.020). Control participants had greater improvement in generic mental QoL scores at week 8 than mindfulness (P=0.023). In disease specific QoL, there was reduction in impotence symptom in the mindfulness group (P=0.022) and reduction in faecal incontinence in the control group (P=0.019). The embarrassment symptom had a significantly lower increase in the mindfulness group at week 8 compared to the control group (P=0.009). Both groups rated the treatments as credible and acceptable. **Conclusions:** Mindfulness was not superior to the active control group in terms of alleviating psychological distress but both treatments were associated with some improvements in depression. There was low uptake of both interventions. (Trial registration number: ACTRN12616001033437)

KEYWORDS anxiety, colorectal cancer, depression, distress, mindfulness, psychoeducation, psychology, psychological distress, randomized controlled trial, quality of life

Colorectal cancer (CRC) is the third most common cancer worldwide.[1] Most studies on CRC have focused on survival, treatment options (e.g. laparoscopic versus open surgery, and chemotherapy or radiotherapy protocols) and the frequency and management of complications of treatment. However, understanding of survivorship now means that studies need to go beyond such measures of success and consider issues such as quality of life (QoL) and mental wellbeing of those affected by CRC.

Initial research has demonstrated that CRC is associated with impaired QoL[2] as well as increased psychosocial distress (usually measured as anxiety and depression)[3] in most patients. Psychosocial distress and QoL in CRC patients have been shown to improve through psychological interventions.[4] With increased understanding of the importance of psychosocial outcomes in patients who are treated for CRC, it is useful to explore various psychological interventions to address these.

One psychological intervention that has shown promise in patients with physical illness is mindfulness.[5]

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Originating and clearly elaborated in Buddhism with principles that are very much universal, it aims to relieve suffering and nurture compassion, and could play an important part in health care.[6] Mindfulness is focusing one's whole attention on what is happening at the present moment with a non-judgmental and acceptance stance.[7] Mindfulness entails self-regulation of attention and orientation to experience.[8] It may modulate subjective experiences of pain and disability and therefore help people to cope better[9] by allowing the person to experience their condition in a less anxiety-provoking way. Several psychosocial interventions utilise the practice of mindfulness, with the most studied being mindfulness-based stress reduction (MBSR). MBSR was designed specifically to assist people in pain management and stress secondary to long-term chronic conditions.[10] Another mindfulness intervention is mindfulness-based cognitive therapy (MBCT) which was developed originally to reduce the risk of depression relapse.[11,12] MBCT has been found to be effective in reducing psychological distress in patients with cancer[13] and also has been adapted for supporting those with cancer in an 8-week program.[14] In general, mindfulness interventions have been shown to reduce depression and anxiety in physically or mentally ill people,[15,16] including those with cancer.[17]

The primary aim of this study was to see if a 4-week group-based mindfulness intervention would reduce psychological distress in CRC patients to a greater extent than the active control: group-based patient psychoeducation and cognitive behavioural skills learning support.

METHODS

Trial Design

This was a randomized controlled trial comparing group-based mindfulness based intervention with group-based psychoeducation and cognitive behavioural skills learning and support (no mindfulness components) for those with CRC. Questionnaires for the main outcome measures were completed at baseline (i.e. preintervention), 8 weeks post baseline, and 6 months post baseline. Post intervention questionnaires were given 8 weeks post baseline (i.e. 4 weeks post treatment) to give time for the intervention to take effect.

Participants

Participants were recruited from the publicly funded Canterbury District Health Board and from referrals from the private sector colorectal specialists and clinics. The surgeons and oncologists screened initial participants. Suitable participants were given information about the study by their surgeon or oncologist prior to surgery but were referred to Andrew McCombie or Michelle Falloon who explained the study and obtained informed content post-surgery. Apart from the referral, the surgeon or oncologist were not involved in recruitment. Participants were approached between May 3, 2017 and December 17, 2018. The last follow-up date was 18 August, 2019.

Ethics

The study received ethical approval from the New Zealand Health and Disability Ethics Committee (16/NTA/106), and is registered at https://www.anzctr.org.au (ACTRN12616001033437; Universal Trial Number: U1111-1179-0598).

Inclusion

All patients who received a diagnosis of CRC (localised or metastatic) within the last year, were aged 18 years and over, lived within a 1-h drive to the group location, and were willing and able to consent were approached regarding participation.

Exclusion

Non-ambulatory patients, non-English speakers and those with significant cognitive impairment or life expectancy of less than 6 months were excluded.

Interventions

Group-Based Mindfulness

The treatment group received a mindfulness intervention which comprised 4 2-h group sessions over 4 weeks. The intervention included a combination of key elements of MBSR and MBCT which were found to be effective and accepted in earlier pilot runs for patients with cancer. Specifically experiential mindfulness practices included: mindfulness of breathing, body scans, mindfulness of thoughts, mindful walking and the cognitive aspects included elements such as pleasant and unpleasant calendars, thoughts and feelings, mood and thoughts, activity and mood. The practices are intended to support participants to become more aware of their thoughts, feelings, and bodily sensations and in relating with less judgemental attitude to their experiences, and learning to step out of reactivity into skilful responding. Delivery was adapted to take into account any

limitations posed by participants' medical conditions.

These sessions were facilitated by a senior mindfulness teacher with more than 25 years of mindfulness experience, meeting Mindfulness-based Teaching Assessment Criteria. There was also a co-facilitator who was a PhD-level psychologist trained in Mindfulness-Based Stress Reduction with a background in psycho-oncology (3 years of experience).

Group-Based Patient Psychoeducation and Cognitive-Behavioral Skills Learning Support

The control intervention contained four 2-h group sessions over 4 weeks. The sessions were facilitated by a social worker with post-graduate cognitive behaviour therapy qualifications, with parts of each session being led by invited speakers including a cancer nurse, a oncologist, a dietitian and a representative from a cancer support group. Psychoeducation topics covered included lifestyle advice including diet and physical activity; the biology of cancer, post-operative care, and psychological and interpersonal impacts including on intimate relationships/sexual functioning. The remainder of each session involved teaching coping strategies based on cognitive behavioural principles and providing the opportunity for socialising and social support with a tea break mid-session.

Assessments

All assessments were self-report in a hard copy format. Demographic information included age and sex. Cancer stage was also recorded. Self-report questionnaires assessed psychological distress (anxiety and depression), mindfulness, QoL (general and cancer specific) and treatment credibility and acceptability.

Treatment Integrity

For each group session of each treatment arm, a checklist of respective content and strategies to be delivered in each session by facilitators was rated by one of the research team who was not a group facilitator regarding whether or not key elements within each session were delivered (Appendix 1).

Outcomes

Primary

The primary outcome was psychological distress measured by the Hospital Anxiety and Depression Scale (HADS), a scale widely used in medical patients to measure anxiety and depression.[18] It has 7 questions about anxiety and 7 questions about depression which are scored from 0 to 3. Subscale scores range from 0 to 21 with higher scores indicating more severe symptoms. Clinical significance is commonly indicated by scores over a cut-off of 8/21.[19] For the purposes of this study, the anxiety and depression subscales were also combined into one encapsulating psychological distress. The HADS has been validated in oncology patients.[19]

Secondary

Generic QoL was measured using the Short Form-12 version 2 (SF-12 v2) every 4 weeks. Twelve questions assess 8 domains across 2 subscales: physical and mental health components.[20] A scoring algorithm calculates summary scores using weighted domain means. Higher scores represent greater QoL. The SF-12 has well-established psychometric properties across a range of samples[21] including those with cancer.[22]

Disease specific QoL was measured using European Organisation for Research and Treatment of Cancer Questionnaire Module for Colorectal Cancer (QLQ-CR29).[23] The QLQ-CR29 has 29 questions about the past week, with 5 functional and 18 symptom scales.[23] Patients rate their symptoms during the past week(s). Scores are transformed to provide a score from 0 to 100. Higher scores indicate better functioning on the functional scales but a higher level of symptoms on the symptom scales. Initial studies were promising regarding psychometric properties of this scale with CRC patients,[23] although a recent review was less positive regarding this.[24]

Mindfulness skills were measured using the Five Facet Mindfulness Questionnaire (FFMQ) which contains 39 items and 5 factors: observing, describing, acting with awareness, nonjudging of inner experience, and non-reactivity to inner experience.[25] Participants rate on a 1–5 point Likert scale how true items are for them. High scores indicate higher levels of mindfulness. The FFMQ has good psychometric properties, which reported to be negatively correlated with emotional disorders,[26] and it has been found to be sensitive to change in mindfulness-based therapies,[16] although the discriminative validity has been questioned.[27] Completers are asked "what is generally true for you"

without a specific timeframe given.

Treatment credibility questions were adapted from the Credibility and Expectancy Questionnaire.[28] Previous research indicates good psychometric properties for this measure.[29]

After session 1, participants rated on a 1–7 point scale (from 1=not at all to 7=very much) for evaluating how logical, how useful, how likely to be successful for them, and whether they would recommend the group to others. Higher scores indicate positive beliefs about the therapy to which they had been randomised.

Posttreatment, participants rated on a 1–7 point scale (from 1=not at all to 7=very much), how valuable they found the content of the group sessions, the relationship with the group therapists, to what extent there has been an improvement in their symptoms, their general functioning since they began group therapy and the extent to which the group therapy contributed to any improvement. Higher scores indicate positive ratings of the therapy.

Sample Size

A review of reviews and meta-analyses reported an average effect size of change for depressive symptoms of d=0.37 and anxiety of d=0.49.[30] However, a meta-analysis of mindfulness for reducing depression and anxiety in cancer patients reported an overall average effect size of d=0.20.[17] For the purpose of this study, it was assumed d=0.30. Assuming 80% power, a 2-tailed *P*-value of 0.05, and d=0.30, 176 patients needed to be recruited into each arm.

Recruitment was ceased short of the power calculation of 176 in each group as it became apparent that the number of people willing to complete a 4-session group intervention was lower than anticipated, as evidenced by the 28% response rate.

Randomization

Computerised permuted block randomisation, stratified by stage 1 and 2 *versus* 3 and 4, was undertaken by the biostatistician prior to the commencement of the trial. Sequentially numbered sealed envelopes were stored in a locked cabinet and allocated by an independent research staff member after the baseline interview and questionnaire was complete. No blinding was possible for facilitators or for participants.

Statistical Analysis

Data was managed securely at the main study centre in Christchurch. Statistical procedures were carried out using Statistical Packages for Social Sciences (version 26).[31] Means, standard deviations, frequencies and percentages were calculated. Repeated measures were done on a per protocol basis (i.e. completers were defined as attending 3 or more of the 4 sessions) with time and group by time interactions calculated. Analyses were conducted separately for baseline *vs*. 8 weeks and baseline *vs*. 6 months. Acceptability was compared between groups via *t*-tests and chi square analyses. All comparisons were made assuming an alpha level of 0.05 (2 tailed). Intention-to-treat analyses were performed on the primary outcome, namely psychological distress at 8 weeks post baseline, using the baseline assessment where the 8 week assessment was not completed. A one way ANOVA was performed to compare baseline anxiety, depression and distress (dependent) to cancer stage (discrete independent variable).

RESULTS

Participant Flow

The participant flow is shown in Figure 1. Two-hundred and seventy-six CRC patients were assessed for eligibility and 33 were ineligible. Sixty-eight people were randomized out of 243 who were eligible (28.0% response rate). There were no differences in gender between the consenters and the decliners (χ^2=0, *P*=–0.995). Randomized participants (mean age 67.32) were slightly younger than decliners (mean age 70.69, *t*=1.94, *P*=0.053). The randomized group sizes were 4 to 9 (median 8) participants in mindfulness and 3 to 9 (median 8) participants in the active control group. Of the 35 randomized to mindfulness, 23 completed 3 or more sessions (65.7% completers), while 22 out of 33 (66.7%) of those randomized to the active control group completed 3 or more sessions. Of the 23 mindfulness completers, 19 completed the primary outcome measure (i.e. HADS distress) at week 8 (82.6%), while 20 did so at month 6 (87.0%). Nineteen of 21 of the active control intervention completers completed the HADS at week 8 (90.5%), while 16 of 21 did so at 6 months (76.2%).

Baseline Data

Baseline demographics and questionnaire data are shown in Table 1. QLQ-CR29 baseline data are shown in Table 2. There were no associations between cancer stage and anxiety (*P*=0.54),

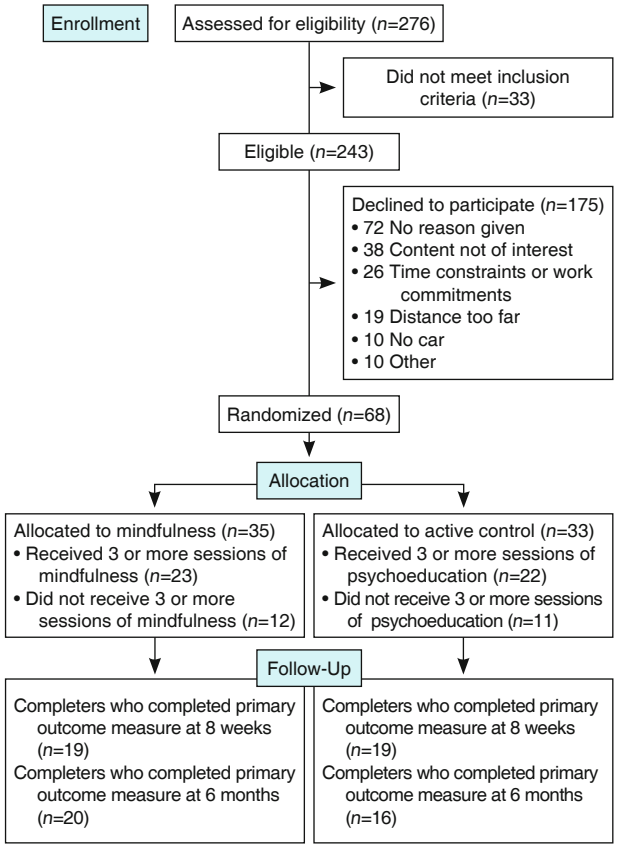

Figure 1. Flow Diagram of the Trial in Colorectal Cancer Patients

depression (*P*=0.27), or distress (*P*=0.41).

Outcomes

Primary

The mean HADS scores for both depression and anxiety subscales at pre-treatment in both arms were below the commonly used cut off of 8 (Table 1), above which clinical symptoms are likely to be present.

In terms of the primary outcome (Table 3), there were no differences in change scores between groups for HADS distress, HADS anxiety, or HADS depression. HADS depression did demonstrate significant time effects such that these outcomes reduced in both groups at 8 weeks (*P*=0.020). Intention-to-treat analysis of HADS distress at week 8 revealed no significant time (*P*=0.222) or group by time interaction effects (*P*=0.192), although there was a trend towards more reduction in distress in the psychoeducation group (effect size=0.32).

Secondary

All repeated measures analyses with *P*-values for group by time effects for secondary outcomes

Table 1. Baseline Demographics and Questionnaire Answers

Variable	Statistic	Active control (*n*=33)	Mindfulness (*n*=35)
Age	M (SD)	67.30 (13.05)	67.34 (11.03)
Gender (Male)	*n* (%)	20 (60.6%)	16 (45.7%)
Cancer stage			
0	*n* (%)	2 (6.1%)	2 (5.7%)
1	*n* (%)	12 (36.4%)	11 (31.4%)
2	*n* (%)	7 (21.2%)	8 (22.9%)
3	*n* (%)	10 (30.3%)	10 (28.6%)
4	*n* (%)	2 (6.1%)	4 (11.4%)
HADS			
Distress	M (SD)	8.78 (6.30)	6.93 (4.25)[a]
Anxiety	M (SD)	5.55 (4.00)	4.24 (2.83)
Depression	M (SD)	3.23 (3.04)	2.82 (2.38)[a]
SF-12			
Physical	M (SD)	46.13 (7.92)[b]	44.13 (8.05)
Mental	M (SD)	51.07 (9.45)[b]	53.90 (6.62)
FFMQ			
Overall	M (SD)	3.45 (0.50)	3.52 (0.54)
Observe	M (SD)	2.94 (0.87)	3.10 (0.79)
Describe	M (SD)	3.47 (0.68)	3.56 (0.75)
Awareness	M (SD)	3.87 (0.66)	3.90 (0.84)
Non judgement	M (SD)	3.82 (0.84)	4.05 (0.80)
Non reactivity	M (SD)	2.96 (0.87)	2.92 (0.98)

Notes: HADS: Hospital Anxiety and Depression Scale; SF-12: Short Form 12; FFMQ: Five Facet Mindfulness Questionnaire; *n*: number; M: mean; SD: standard deviation. [a]1 person out of 35 did not answer enough to calculate or impute; [b]1 person out of 33 did not answer enough to calculate or impute

of intervention completers are shown in Table 3. Greater gains in the SF-12 mental subscale at week 8 were shown in the active control group compared to mindfulness group (*P*=0.023). There were also significant time effects indicating improvement for SF-12 mental at week 8 (*P*=0.022) as well as SF-12 physical at week 8 (*P*=0.004) and 6 months (*P*=0.025). In terms of QoL subscales on QLQ-CR29, there was a time effect indicating an improvement for the taste symptom at week 8 (*P*=0.010). The mindfulness group had an increase in the faecal incontinence symptom at week 8 compared to a decrease for active control (*P*=0.019) as the case for the embarrassment symptom (*P*=0.009). Impotence decreased in the mindfulness group but increased in the active control group at week 8 (*P*=0.022). At month 6, the blood and mucus symptom decreased in the mindfulness group but increased in the active control group (*P*=0.027).

Table 2. European Organisation for Research and Treatment of Cancer Questionnaire Module for Colorectal Cancer Subscales at Baseline

Variable	Active control		Mindfulness	
	n	Mean (Standard Deviation)	*n*	Mean (Standard Deviation)
QLQ CR29 Functional				
Body image	33	79.46 (24.55)	34	84.64 (19.15)
Anxiety	33	62.63 (27.33)	35	75.24 (21.91)
Weight	33	67.68 (30.60)	35	77.14 (23.94)
Sexual interest (men)	18	48.15 (30.73)	14	76.19 (24.21)
Sexual interest (women)	8	83.33 (17.82)	17	74.51 (27.71)
QLQ CR29 Symptom				
Urinary frequency	33	37.88 (27.41)	35	42.86 (16.31)
Blood and mucus in stool	32	3.65 (9.21)	35	2.38 (5.92)
Stool frequency	27	23.46 (26.25)	32	25.52 (23.18)
Urinary incontinence	33	13.13 (18.52)	35	7.62 (16.34)
Dysuria	33	4.04 (11.05)	35	3.81 (10.76)
Abdominal pain	33	13.13 (18.52)	35	20.95 (25.67)
Buttock pain	33	11.11 (15.96)	35	9.52 (19.08)
Bloating	32	27.08 (28.63)	35	18.10 (24.71)
Dry mouth	33	26.26 (24.66)	35	29.52 (28.89)
Hair loss	33	6.06 (13.06)	34	8.82 (22.19)
Taste	33	12.12 (24.75)	34	10.78 (19.63)
Flatulence	27	32.10 (29.93)	32	33.33 (29.33)
Faecal incontinence	27	19.75 (26.57)	31	11.83 (20.27)
Sore skin	27	17.28 (23.33)	32	19.79 (23.74)
Embarrassment	26	26.92 (32.69)	32	14.58 (20.63)
Stoma care	9	7.41 (14.70)	11	3.03 (10.05)
Impotence	17	41.18 (44.92)	12	55.56 (43.42)
Dyspareunia	6	5.56 (13.61)	14	11.90 (16.57)

Notes: QLQ-CR29: European Organization for Research and Treatment of Cancer Questionnaire for Colorectal Cancer Patients

There was a time effect for sexual interest in women such that both groups decreased at month 6 (P=0.014).

In terms of mindfulness outcomes, observe (P=0.022) and non-reactivity (P=0.029) had significant time effects at month 6 such that both groups had a significant increase in these subscales.

On the total score for the pre-treatment credibility measure, rated by participants after session 1, both therapies were rated as credible and were not significantly different (Table 4). Amongst all people who completed the acceptability questionnaire, there was no difference between the groups in terms of acceptability (Table 4). Most patients in both groups reported the 4 weekly sessions and the length of those session to be "Just Right".

The therapy adherence measure rated at each session by a member of the research team who was not a group facilitator. Group facilitators were highly adherent to the intervention plan, with all scheduled items delivered as intended. In the active control group though, in one group series, content was switched between groups two and three due to illness in one of the guest speakers.

DISCUSSION

Mindfulness was not superior to psychoeducation and cognitive behavioural skills learning support in reducing levels of distress in patients with CRC using group treatment. Both treatments were associated with improvements in depression but the active control intervention was superior to mindfulness in improving the secondary outcome of mental QoL as measured by the SF-12 at week 8. Both therapies were rated as credible and acceptable by participants.

Clinical Implications

Although mindfulness interventions have shown promise in a range of health conditions including cancer, this present study is important because mindfulness has not been tested in the context of CRC. As noted earlier, CRC is a very common cancer with much psychological and physical morbidity associated with the disease and its treatment.[3,15,16,30]

A review of all systematic reviews and meta-analyses of randomized controlled trials (RCTs) of mindfulness-based interventions for a variety of conditions reported that mindfulness-based interventions significantly improved depressive symptoms, anxiety, stress, QoL, and physical functioning compared to wait list control or treatment as usual.[30] There were 16 independent RCTs including 1,668 participants with cancer, and significant improvements were consistently reported in the domains of depressive symptoms, anxiety, stress, and QoL. However, while 5 colon cancer patients were included in a study of 109 cancer patients[32] and 6 rectal cancer patients were included in a study of 111 women with cancer,[33] mindfulness has not been specifically studied in CRC patients previous to this study.

The failure to find a difference between the two arms, referred to as "the dodo bird verdict"[34]

Table 3. Analyses of Change in All Outcomes 8 Weeks and 6 Months Post-Baseline

Variable	At 8 weeks								At 6 months							
	Active control			Mindfulness			Effect size[c]	*P*	Active control			Mindfulness			Effect size	*P*
	n[a]	Mean	SD[b]	*n*	Mean	SD			*n*	Mean	SD	*n*	Mean	SD		
Total distress	19	–1.53	3.45	19	–0.11	3.90	–0.39	0.24	16	–1.85	5.01	20	0.25	3.18	–0.51	0.13
Anxiety	19	–0.74	2.18	19	0.53	2.61	–0.52	0.11	16	–1.38	3.42	20	–0.30	1.78	–0.41	0.23
Depression	19	–0.79	1.62	19	–0.63	1.95	–0.09	0.79	16	–0.48	2.36	20	0.55	2.65	–0.41	0.23
Short Form 12																
Physical	18	2.48	7.03	18	4.42	6.53	0.29	0.40	16	4.68	7.97	19	2.21	9.18	–0.29	0.41
Mental	18	5.08	7.18	19	0.03	5.72	–0.78	0.02*	16	–0.90	9.71	19	0.08	5.83	0.13	0.71
QLQ CR29' Functional																
Body image	19	1.17	11.65	19	1.17	13.81	0.00	1.00	15	1.48	11.78	20	–2.78	13.90	–0.33	0.35
Anxiety	19	7.02	21.02	19	–3.51	24.58	–0.46	0.17	16	2.08	19.12	20	–5.00	22.36	–0.34	0.32
Weight	19	–1.75	23.50	19	1.75	17.48	0.17	0.61	16	–6.25	18.13	20	–3.33	14.91	0.18	0.60
Sexual interest (men)	9	–7.41	27.78	7	–19.05	32.53	–0.39	0.45	9	–14.81	29.40	7	–9.52	31.71	0.17	0.74
Sexual interest (women)	5	–6.67	14.91	7	–4.76	12.60	0.14	0.82	3	–22.22	19.25	10	–6.67	14.05	1.03	0.15
QLQ CR29d Symptom																
Urinary frequency	19	1.75	13.49	19	–0.88	21.85	0.15	0.66	16	–7.29	16.07	20	–2.50	22.47	–0.24	0.48
Blood and mucus in stool	18	0.00	0.00	19	–1.75	9.45	0.27	0.44[e]	16	2.08	2.08	19	–2.63	6.24	0.79	0.03*
Stool frequency	16	–7.29	12.12	16	1.04	23.94	–0.44	0.22	16	–3.13	17.45	17	0.00	32.27	–0.12	0.73
Urinary incontinence	19	–1.75	13.49	19	3.51	26.98	–0.25	0.45	16	–4.17	16.67	20	0.00	15.29	–0.26	0.44
Dysuria	19	0.00	0.00	19	1.75	7.65	–0.32	0.32	16	–4.17	11.39	20	0.00	0.00	–0.55	0.11
Abdominal Pain	19	1.75	17.48	19	–8.77	24.45	0.50	0.14	16	0.00	21.08	20	–5.00	19.57	0.25	0.47
Buttock pain	19	–3.51	15.29	19	–1.75	13.49	–0.12	0.71	16	2.08	19.12	20	–1.67	13.13	0.23	0.49
Bloating	18	–11.11	25.57	19	–1.75	20.71	–0.40	0.23	15	4.44	30.52	20	1.67	22.88	0.11	0.76
Dry mouth	19	–1.75	20.71	19	–5.26	16.72	0.19	0.57	16	0.00	21.08	19	–5.26	25.49	0.22	0.52
Hair loss	19	0.00	11.11	18	1.85	7.86	–0.19	0.56	15	0.00	12.60	19	0.00	24.85	0.00	1.00
Taste	19	–7.02	17.84	18	–7.41	14.26	0.02	0.94	16	–6.25	27.81	19	1.75	13.49	–0.38	0.27
Flatulence	16	0.00	32.20	17	3.92	20.01	–0.15	0.68	16	0.00	32.20	17	1.96	21.96	–0.07	0.84
Faecal incontinence	16	–6.25	18.13	17	7.84	14.57	–0.86	0.02*	16	–2.08	14.75	17	1.96	14.29	–0.28	0.43
Sore skin	16	–4.17	16.67	17	0.00	16.67	–0.25	0.48	15	–4.44	21.33	17	5.88	21.20	–0.49	0.18
Embarrassment	15	–11.11	20.57	16	6.25	13.44	–1.01	0.01*	16	–6.25	21.84	17	3.92	11.07	–0.59	0.10
Stoma care	4	0.00	0.00	7	–4.76	12.60	0.46	0.48	3	0.00	0.00	5	–6.67	14.91	0.55	0.48
Impotence	8	12.50	30.54	6	–27.78	25.09	1.42	0.02*	8	8.33	23.57	6	–27.78	38.97	1.17	0.05
Dyspareunia	3	11.11	19.24	4	8.33	16.67	0.16	0.85	2	16.67	23.57	7	4.76	12.60	0.81	0.35
Five Facet Mindfulness Questionnaire																
Overall	19	–0.04	0.47	18	0.04	0.25	0.22	0.51	15	0.06	0.50	20	0.00	0.30	–0.15	0.65
Observe	19	0.07	0.60	18	0.30	0.68	0.58	0.09	15	0.28	0.54	20	0.15	0.52	–0.25	0.47
Describe	19	–0.26	0.63	18	–0.09	0.50	0.31	0.36	15	–0.07	0.56	20	–0.14	0.61	–0.11	0.74
Awareness	19	0.12	0.52	18	–0.09	0.46	–0.43	0.20	15	–0.04	0.62	20	–0.23	0.56	–0.32	0.36
Non judgement	19	0.31	0.63	18	–0.06	0.49	–0.66	0.05	15	0.10	0.60	20	–0.13	0.74	–0.33	0.34
Non reactivity	19	–0.04	0.60	18	0.17	0.75	0.30	0.37	15	0.39	0.82	20	0.34	1.02	–0.05	0.89

Notes: [a]*n*=sample size; [b]SD=standard deviation; [c]Negative effect sizes favour the active control group (i.e. smaller increases or larger decreases in QLQ-CR29 symptom scales and larger increases or smaller decreases on all other scales); [d]QLQ-CR29 = European Organization for Research and Treatment of Cancer Questionnaire for Colorectal Cancer Patients; [e]equal variances not assumed; *$P<0.05$

is unsurprising given accumulating meta-analytic evidence that it is difficult to detect any difference in efficacy between bone fide therapies in well controlled comparisons for mental health conditions, such as depression.[35] Wampold and Imel[36] contend that common factors across therapies account for much

Table 4. Pre-Treatment Credibility and Post-Intervention Acceptability

	Active control (*n*=19)		Mindfulness (*n*=19)		*P*-value
	n[a]	Mean (Standard Deviation)	*n*	Mean (Standard Deviation)	
Pre-treatment credibility	27	20.04 (5.980)	26	20.85 (5.480)	0.610
1. How valuable was the content of your group therapy sessions?	19	5.89 (1.286)	19	5.47 (1.124)	0.290
2. How valuable was the relationship with your group therapists?	19	6.00 (1.333)	19	5.79 (0.787)	0.557
3. To what extent would you say there has been an improvement in your symptoms since you began group therapy?	19	5.05 (1.393)	19	4.68 (1.003)	0.356
4. To what extent would you say there has been an improvement in your general functioning since you began group therapy?	19	5.21 (1.548)	19	4.58 (0.692)	0.117[b]
6. To what extent did the group therapy programme contribute to your improvement?	19	5.11 (1.969)	18	4.83 (1.249)	0.272
The 2-h group sessions were					
Just right	19 (100.0%)	N/A	16 (94.1%)	N/A	0.284
Too long	0 (0.0%)	N/A	1 (5.9%)	N/A	
The 4-week length of the course was					
Too short	5 (26.3%)	N/A	4 (25.0%)	N/A	0.929
Just right	14 (73.7%)	N/A	12 (75.0%)	N/A	

Notes: [a]One person who only completed 2 (i.e. less than 3) sessions of mindfulness was included in acceptability questionnaire analysis whereas all 19 respondents in the active control group were completers (i.e. completed 3 or more sessions); [b]equal variances not assumed for this *t*-test

of the benefit although proponents of other therapies, such as CBT, continue to dispute the common factors argument which minimises the contribution of therapy-specific strategies based on theorised mechanisms of change in therapies.[37] The mindfulness literature also has strong proponents, however, although there is little doubt on its effectiveness, there are methodological issues in this literature too, including relatively few comparisons with bone fide evidence-based therapies such as CBT.[38] The fact there were MBCT components in mindfulness also meant there were elements of overlap in content between the groups.

Study Limitations

The major limitation was the small sample size in each intervention which was contributed to the low recruitment rate. In addition there was no inactive control group so the extent of spontaneous recovery is unknown. The control arm achieved as much as the mindfulness training, perhaps because patients with cancer often want to know more about their illness.

Of the 175 decliners, participants declined to give reasons on 72 (41.1%) occasions, making an analysis of reasons for declining difficult. Concerns around not having a car or having to travel a large distance (still within the study inclusion criteria) were alluded to on 29 occasions. There were 4 weeks of 2-h sessions, which may be below the minimum dose threshold, and the interventions were performed in groups. Having fewer longer sessions increased the convenience for people who had to travel a long distance to get to the sessions. One-on-one sessions may be more effective for some patients which would be less cost-effective and reduce the impact of peer support. More cost-effective treatment at home on computer/audio has been shown to be feasible and acceptable in several pilot studies, for example, in one study in 41 patients with metastatic CRC receiving chemotherapy[39] and another study in those with late stage cancer.[40]

Conclusion

With increased understanding of what is important for treatment of CRC, it is necessary to explore various management options to try and improve psychosocial as well as medical outcomes. In this study, both brief interventions were similarly effective. Importantly, the limited uptake in this study also underlines the importance of tailoring psychosocial interventions to encourage patients to attend. A major problem was that most patients did not wish to attend sessions for various reasons. The lessons we have learnt from Covid-19 suggest that there may be an increased acceptance (desire) for online learning so app or computer-based treatment models may be an area worth exploring further. E-treatment may be especially important and useful for patients with mobility and transport issues. Moreover,

as computer literacy improves generationally amongst CRC patients, computerised education and mental health interventions are likely to become even more acceptable and feasible.

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Statements and Declarations

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Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

Author Contributions

Andrew McCombie was responsible for the design of the study and ran the statistical analyses and randomization process. Jennifer Jordan, Roger Mulder, Kishion Dee, and Ee Lin Ong helped design the interventions and the study. Ee Lin Ong and Fernanda Zimmerman instructed the mindfulness group and Kishion Dee instructed the active control group. Chris Frampton assisted with statistical analyses. Frank Frizelle provided input to the design and the oncological and surgical aspects of the study. All authors have contributed and critically reviewed the manuscript and approved the final version. All authors have read and agreed to the published version of the manuscript.

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