

Original paper

Brief psychological intervention to reduce psychological distress among pre-operative cancer patients: A randomized, single-blind, two arm, parallel group-controlled trial in a selected tertiary care hospital in Sri Lanka

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Abstract

Purpose

Psychological distress among pre-operative cancer patients interferes with treatment outcomes. The objective of this study is to determine the effectiveness of a 3-week brief psychological intervention versus routine care on reducing psychological distress among newly diagnosed cancer patients awaiting surgery.

Methods

A randomized, single-blind, two arm, parallel group-controlled trial was conducted among 88 (intervention=46, control=42) newly diagnosed cancer patients awaiting surgery at Colombo South Teaching Hospital. The primary outcome, psychological distress, was assessed using HADS (cut-off 8) at baseline and 3-weeks later. Secondary outcomes assessed were satisfaction on knowledge and care they received and the physical well-being. Comparisons were made using McNemar's Chi-Square at $p < 0.05$ based on intention to treat. Effects measures used are odds ratios (OR) with 95% CI and number needed to treat (NNT).

Results

The prevalence of anxiety and depression at baseline was 90.91% and 89.77%. Intervention significantly

lowered anxiety [intervention 30.43% vs control 69.50%, OR=0.20 (95% CI 0.08, 0.49), $p=0.0004$]. Depression failed to show a significant reduction [67.6% vs 78.4%, OR=0.53 (95% CI 0.22, 1.28), $p=0.1592$]. NNT to avert one case of anxiety is 3 (95% CI 1.73, 5.18). Satisfaction on care received is the only secondary outcome that showed a statistically significant association: intervention 36.96% vs. control 14.28% [OR=0.28 (95% CI 0.10-0.81), $p=0.0057$].

Conclusions

The brief psychological intervention was effective in reducing anxiety among newly diagnosed cancer patients. This simple and brief psychological intervention could be recommended for all new cancer patients awaiting surgical interventions.

This trial was registered in the Sri Lanka clinical trial registry on 14.10.2021. The registration number is SLCTR/2021/028. The protocol is available at the Sri Lanka Clinical Trial Registry website. The Universal Trial Number (UTN) is U1111-1269-2819.

Keywords: psychological intervention, pre-operative cancer patients, psychological distress, HADS, oncology, clinical trial

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Introduction

The diagnosis of cancer is a traumatic event that can have a significant impact on an individual's psychological well-being (1,2). Patients with cancer often suffer from anxiety and depression, with prevalence rates ranging from 40% to 80% (3,4,5,6,7). Psychological distress has been found to interfere with effective coping, treatment

adherence, health-related behaviour, and overall survival (3,4,5,6). Despite the high prevalence of psychological distress among cancer patients, there is a low concordance between the distress ratings of patients and physicians (2). As a result, screening for distress is necessary to identify those patients with high distress (1).

Evidence points towards the potential of improving both psychological and treatment outcomes via provision of psychological support early in the cancer pathway (8). Therefore, routine assessment and treatment of cancer-related distress are recommended by numerous regulatory bodies, including the National Comprehensive Cancer Network and the International Psycho-Oncology Society (9). Most psychological interventions are difficult to be applied in low resource settings due to scarcity of trained professionals, large case load, and lack of integrated cancer care. In such circumstances, brief psychological interventions have been proposed as a potential solution. Though effectiveness of psychological interventions has been studied in different cancer trajectories with promising results (10,11), evidence on the effectiveness of short term, simple multimodal psychological prehabilitation interventions are scarce (12).

In Sri Lanka, the duration from the cancer diagnosis to the surgical intervention takes 4-6 weeks. In the absence of evidence, this study aims to investigate the effectiveness of a brief psychological intervention in reducing psychological distress levels among newly diagnosed cancer patients awaiting surgical intervention in a tertiary care hospital in Sri Lanka.

Material and methods

Trial design

This study utilized a parallel group, two-armed prospective randomized controlled trial design to detect the effect of a brief psychological intervention on psychological distress in preoperative cancer patients. One arm received routine clinical care while the other arm received a brief psychological intervention. The allocation ratio was 1:1 and determined using computer-generated random numbers.

Ethical approval to conduct this study was obtained from the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura. This trial was registered in the Sri Lanka Clinical Trial Registry. The registration number is SLCTR/2021/028.

Participants and recruitment

The study included newly diagnosed cancer patients aged 18-65 years awaiting surgical interventions at the Colombo South Teaching Hospital (CSTH).

Patients were invited to join the trial after a detailed description of the study by a research assistant. Eligibility was assessed by a separate questionnaire. Patients with a past history of cancer, psychiatric diagnosis, cerebral involvement, severe physical pain or travelling difficulties were excluded.

An independent medical officer assessed the psychological distress of the eligible study participants using Hospital Anxiety and Depression Scale (HADS) which captures anxiety and depression separately (13). Patients with HADS scores higher than 11 were referred for an independent psychiatrist for evaluation. Those who required treatment were excluded. Informed written consent was obtained from all study participants at the time of recruitment.

Randomization, allocation concealment, and blinding

The allocation was determined using computer-generated random numbers by an independent medical officer who was not involved with the outcome assessment. Based on the allocation, patients were directed to receive either intervention or control by the medical officer who generated the random numbers. Both data collectors and the analyst were kept blind on treatment allocation throughout the study.

Intervention

This study employed a multimodal prehabilitation with a psychological component: combination of education of their cancer, progressive deep muscle relaxation technique, and problem solving. Two structured intervention sessions took place over a period of three weeks. The first intervention session comprised of half an hour discussion regarding the concerns of the diagnosis, and validating their anxiety by surgical senior registrar, followed by deep muscle relaxation training for half an hour, and an hour of problem-solving technique by the consultant psychiatrist. Patients were instructed to practice 30 minutes of deep muscle relaxation daily and to maintain a diary.

The second stage of the intervention was a two-hour session which included the continuation of answering further queries by the surgical registrar, problem-solving counselling and going through the diary after one week from the first intervention. In addition to the intervention, this group received routine preoperative care. Key points of the intervention are summarised in Figure 1.

The control group was given routine advice regarding investigations and the routine care. These include 10 minutes discussion about surgical procedure, complications, pros and cons of the surgery and hospital stay by a multidisciplinary team including a surgeon, medical officers, and a nurse and the preoperative oncological referral if necessary. In the routine care patients are referred to a nutritionist, endocrinologist, urologist, physician, or psychiatrist depending on the need. Preoperative investigations were arranged to reduce the hospital stay.

Session 1: face to face session – 2 hours

1. Education on diagnosis and management: senior registrar in surgery – 30 minutes
 - Tailored discussion on diagnosis, treatment, care team, and available resources.
 - Ensure patient understanding and allow them to express emotions.
2. Relaxation training practice session on managing stress response: by consultant psychiatrist – 30 minutes.
 - Brief explanation of stress response and its effects on cancer management.
 - Training on progressive deep muscle relaxation technique and encourage daily practice with maintenance of a diary.
 - Validation of distress and explanation of coping needs.
3. Problem solving counseling by consultant psychiatrist – 1 hour.
 - Discuss concerns and stressors, identify, and categorize amenable problems.
 - Prioritize problems and solve through a six-step procedure.
 - Address important but unsolvable problems, such as cancer-related distress.

Session 2: face to face session – 2 hours

- Exclude exposure to other stress reduction programmes.
- Clarification of questions on cancer related problems by surgical registrar – 30 minutes.
- Continued relaxation training and practice session by consultant psychiatrist – 30 minutes.
- Continued problem-solving counselling and addressing negative thoughts related to cancer – 1 hour.

Figure 1. Summary of key points of the intervention

Outcome assessment

Outcomes were assessed 3 weeks after the initiation of the intervention since the average waiting time is 4-6 weeks at the CSTH. Primary outcome was the interviewer administered HADS scores. Sinhala version of HADS, validated locally in similar settings was used for this purpose. Participants were dichotomised as either having or not having anxiety or depression based on the cut-off value of 8 in each sub-scale.

The secondary outcome, patients' perceptions of the intervention, was assessed using a four-item questionnaire in a five-point Likert scale under four domains: patients' satisfaction on knowledge and care they received, general wellbeing during the study period, and support by family. Patients' agreement on satisfaction was measured as strongly agree, agree, neutral, disagree and strongly disagree and dichotomised as 'satisfied' (strongly agree, and agree) and 'not satisfied' (neutral, disagree and strongly disagree).

The psychological distress of participants was assessed at baseline, and at the end of three weeks from baseline using HADS score. In addition, the first assessment

included a questionnaire to assess demographic data, and worries related to their cancer coping methods. The second assessment included HADS score, and patients' perception of the care given preoperatively in both groups. A trained research assistant who was not aware of treatment allocation assessed both types of outcomes. In addition, this included assessment of adherence to the intervention from the intervention group by the psychiatrist who implemented the intervention.

Loss to follow-up participants were contacted via phone to determine the reason for default.

Sample size calculation

The sample size was calculated using the formula for intervention studies with 80% power to detect a 50% reduction in anxiety score three weeks after initiation of the intervention. The calculated sample size was 37 participates for each arm. Considering a lost to follow-up rate of 15% resulting 42 in each arm. To recruit the calculated sample size, 153 potential participants were screened.

Details of the participant flow of the study is given in Figure 2.

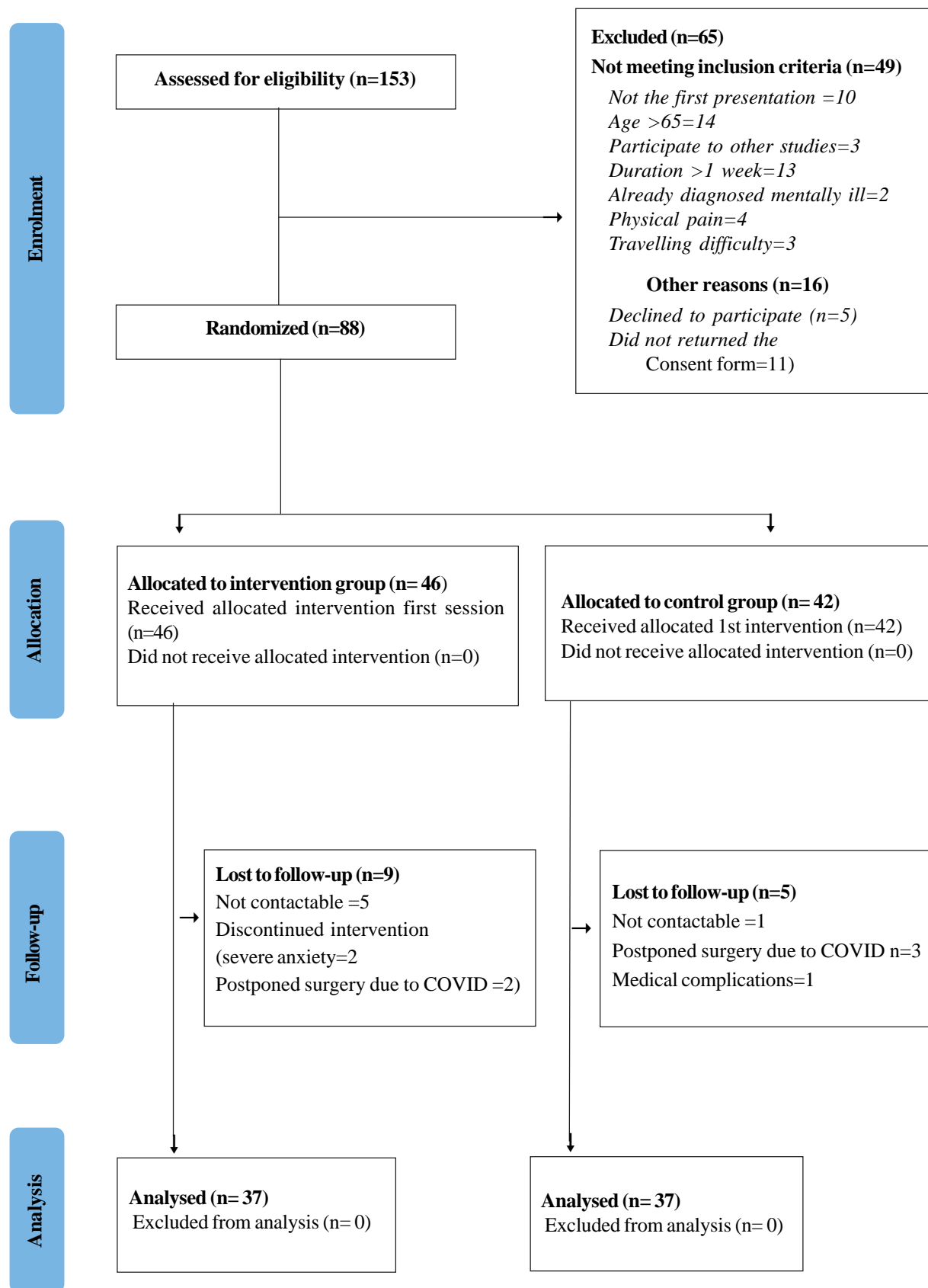


Figure 2. CONSORT Flow Diagram: the participant flow of the study

Data analysis

Data was entered and analysed using Statistical Package for the Social Sciences (SPSS) version 25. Descriptive statistics and frequencies were conducted to obtain prevalence with 95% CI for qualitative variables and means with standard deviations for continuous variables. Baseline variables were compared between intervention and control groups to detect any baseline differences. Intervention group and control group were assessed for their worries related to their cancer diagnosis. Within group comparison of pre and post HADS scores were made using paired sample t test and the % having anxiety and depression using McNemar's Chi Square test. Between groups comparison of both primary and secondary outcomes were made using Chi Square test. Intention to treat analysis was performed when comparing primary and secondary outcomes between the groups. Odds ratios (OR) and the number needed to treat (NNT) with the 95% CI were used as the effects measure. Level of significance was taken as 0.05.

Results

Enrollment and retention

Out of the 88 patients enrolled to this study (46 to intervention and 42 to control arm), at the end of 3-week follow up period, 37 patients were retained in each arm. Fourteen participants were lost to follow up as 9 in the intervention group and 5 in the control group. Participant flow including the reasons for lost to follow up are given in Figure 2.

Baseline data

The mean age of the intervention group was 52.67 (SD=11.77) years while it was 54.86 (SD=8.73) years in the control group. In terms of gender, the intervention group had a higher percentage of females (67.39%) compared to the control group (59.52%). A baseline comparison between the two groups is given in Table 1.

The prevalence of anxiety at baseline was 90.91% (95% CI 83.73-96.27; intervention group 89.13% vs. control group 92.86%). For depression, the baseline prevalence was 89.77% (95% CI 82.46-95.54; intervention group 86.96% vs. control group 92.86%). The baseline mean HADS score of anxiety in the intervention group was 9.70 (SD 2.68) compared to 10.81 (SD 3.02) in the control group. Depression mean HADS score in the intervention group was 9.67 (SD 2.82) compared to 10.88 (SD 2.77) in the control group.

The study evaluated the concerns of patients related to cancer diagnosis in the intervention and control groups at baseline (worries about physical disability, hospitalization, finances, dependents, recurrences, and future treatments). The results showed that the intervention group had lower levels of worry compared to the control group. Specifically, 42.5% of the intervention group and

54.05% of the control group were worried about future treatments, while 40.5% of the intervention group and 43.2% of the control group were concerned about recurrences. The intervention group had lower levels of worry about dependents (53.4% vs. 62.1%). Intervention group had more worries than control group in finances (59.4% vs. 51.3%), and hospitalization (29.7% vs. 25.5%) and worries about disability (70.3% vs. 66.7%) which ranked highest among all. However, there were no significant difference in any of these groups.

Post intervention data

Changes in the HADS scores for anxiety and depression sub-scales following the intervention are given in Table 2. Within group analysis of both arms revealed a significant reduction in both anxiety and depression. For the mean anxiety scores in the intervention group, one tailed (left) results of the paired t test indicated that there is a significant reduction following the brief intervention. Depression scores of the intervention group followed a similar pattern. Control group showed similar results to that of intervention group (Table 2).

However, the magnitude of the reduction is higher among the intervention group compared to control group. For instance, reduction in the prevalence of anxiety in the intervention group is 62.16% (from 78.38% to 37.84%) compared to 9.38% (from 86.49% to 78.38%) in the control group. Similarly, for the depression, the reduction was higher among intervention group (16.67%, from 81.08% to 67.57%) against the control group (14.70%, from 91.89% to 78.38%). Furthermore, the reduction in the prevalence of anxiety in the intervention group is 3.7 times higher compared to the reduction in depression (Table 2).

Post-intervention between group comparison as per the intention to treat analysis showed that anxiety was significantly lower in the intervention group (30.43%) compared to the control group (69.50%) with an OR of 0.20 (95% CI 0.08, 0.49), $p=0.0004$ (Table 3). However, the prevalence of depression failed to show a significant reduction following the intervention [OR=0.53 (95% CI 0.22-1.28), $p=0.1592$] (Table 3). The NNT to avert one case of anxiety is 3 (95% CI 1.73, 5.18).

Secondary outcomes

In both groups, satisfaction about the knowledge and care they received from the healthcare providers and the physical well-being, and the family support was assessed as secondary outcomes (Table 3). The comparison between the groups about their satisfaction on aforementioned four domains showed a higher proportion of satisfied patients in intervention group. However, only the satisfaction on care received showed a statistically significant association: intervention vs. control 39.13%

vs 26.19% on knowledge received [OR= 0.55 (95% CI 0.22-1.37), p=0.0955]; 36.96% vs. 14.28% on care received [OR= 0.28 (95% CI 0.10- 0.81), p=0.0057]; 39.13% vs. 28.57% on physical well-being [OR=0.62 (95% CI 0.25-1.52), p=0.2966]; and 36.96% vs. 23.81% on family support [OR=0.53 (95% CI 0.21-1.35), p= 0.1816].

Table 1. Profile of the study participants at baseline

Characteristic	Intervention (N= 46)		Control (N=42)	
	N	%	N	%
Sex				
Female	31	67.39	25	59.52
Male	15	32.61	17	40.48
Partnership				
Living with partner/ spouse	30	65.2	25	59.5
Lining without partner/ spouse	16	34.8	17	40.5
Employment				
Unemployed-no income	26	56.5	20	47.6
Unemployed-regular income	11	23.9	16	38.1
Employed	9	19.6	6	14.3
Family income				
<20,000	17	37.0	13	31.0
20,000-49,999	21	45.7	23	54.8
50,000-99,999	5	10.9	5	11.9
≥100,000	3	6.5	1	2.4
Insurance				
Yes	18	39.1	6	14.3
No	28	60.9	36	85.7
Family support				
Yes	41	89.1	41	97.6
No	5	10.9	1	2.4
Cancer category				
Breast	12	26.1	12	28.6
Thyroid	5	10.9	13	31.0
Upper GIT	10	21.7	2	4.8
Lower GIT	14	30.4	10	23.8
ENT	2	4.3	0	0.0
Genitourinary	2	4.3	2	4.8
Head and neck	1	2.2	0	0.0
Other ^a	0	0.0	3	7.1
HADS score				
Anxiety ≥8	41	89.13	39	92.86
<8	5	10.87	3	7.14
Depression ≥8	40	86.96	39	92.86
<8	6	13.04	3	7.14

^amelanoma (n=1), hepatobiliary (n=2)

Table 2. Primary and secondary outcomes at the end of 3-weeks^a

	Intervention group (n=37)			Control group (n=37)		
	Test statistics			Test statistics		
HADS score^b	Pre	Post		Pre	Post	
Anxiety	9.70 (2.68)	6.86 (2.48)	t=6.32, p<0.001	10.81 (3.02)	9.14 (2.71)	t=3.87, p<0.001
Depression	9.67 (2.82)	8.65 (2.55)	t=2.63, p=0.007	10.88 (2.77)	9.46 (3.30)	t=3.81, p<0.001
Prevalence of ^c						
Anxiety	29 (78.38%)	14 (37.84%)	p<0.0001	32 (86.49%)	29 (78.38%)	p<0.0001
Depression	30 (81.08%)	25 (67.57%)	p<0.0001	34 (91.89%)	29 (78.38%)	p<0.0001

^acalculations are based on the participants who completed the trial, ^bWithin-group paired sample t-test, ^cMcNemar's Chi-square test, HADS = Hospital Anxiety and Depression Scale, values are expressed as mean (SD) for HADS scores and number (%) for prevalence

Table 3. Primary and secondary outcomes at the end of 3-weeks^a

	Intervention group (n=46) Number (%)	Control group (n=42) Number (%)	OR (95% CI)	p value
Primary outcome				
Anxiety ^b	14 (30.43%)	29 (69.50%)	0.20 (0.08-0.49)	0.0004
Depression ^c	25 (54.35%)	29 (69.05%)	0.53 (0.22-1.28)	0.1592
Secondary outcomes				
Satisfied with				
Knowledge received	18 (39.13%)	11 (26.19%)	0.55 (0.22-1.37)	0.0955
Care received	17 (36.96%)	6 (14.28%)	0.28 (0.10- 0.81)	0.0057
Physical wellbeing	18 (39.13%)	12 (28.57%)	0.62 (0.25-1.52)	0.2966
Family support received	17 (36.96%)	10 (23.81%)	0.53 (0.21-1.35)	0.1816

^aCalculations are based on intention to treat analysis, ^bdefined as HADS anxiety subscale >8, ^cdefined as HADS depression subscale >8, OR = odds ratio

Discussion

In par with the previous studies (14,15,16), our study reported a high prevalence of anxiety (90.91%; 95% CI 83.73,96.27) and depression (89.77%; 95% CI 82.46,95.54). However, the prevalence of depression is higher in our study compared to a recent systematic review of cancer patients in South Asia which reported a prevalence ranging from 3% to 65.5% (17). This difference may be attributed to various factors such as the timing of the measurement and the types of cancer included. We measured the psychological distress one week after

breaking bad news, the time during which the maximum level of anxiety has been reported (15). Furthermore, in contrast to other studies our sample consisted only preoperative cancer patients. The COVID-19 pandemic prevailed may also have contributed to added level of anxiety and depression.

Worries related to physical problems were reported as the major source of distress in cancer patients, followed by emotional problems (18). In par with these findings, worries related to disability ranked first in both groups of our study. This highlights the importance of

addressing patients' concerns about the physical and functional impact of their cancer diagnosis and treatment. While our intervention showed a significant reduction in anxiety, it did not have a significant effect on depression. This is consistent with previous studies on interventions for psychological distress among cancer patients, which have often failed to show an improvement in depression (19).

Theoretically, the observed improvement in the intervention group might have resulted from the additional time spent with the healthcare providers during the intervention sessions rather than the specific intervention itself. However, since the study objective was to assess the effectiveness rather than efficacy of our brief intervention, regardless of the mechanism the clinical benefits are important.

Strengths and limitations

Even though this is a single centred study, since the management remains same during the pre-operative period in government hospitals, findings can be generalized in the country context. Our trial design was pragmatic since we used 'usual treatment' as the comparison group rather than placebo control. Higher anxiety levels due to the COVID pandemic situation prevailed could be a limitation. Another limitation would be the non-inclusion of patients diagnosed with oral, haematological, and lung cancers.

Conclusions

In conclusion, the study revealed the high levels of anxiety and depression among newly diagnosed cancer patients awaiting surgery in Sri Lanka and the effectiveness of our brief psychological intervention on reducing their anxiety levels. However, further research is needed to fully understand the unique psychological needs of this population and to develop effective interventions to address their distress. The study findings highlight the importance of implementing brief interventions to improve the coping skills and mental health of the preoperative cancer patients to improve their psychological status.

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Statements and declarations

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Author contributions

Prasangika Seneviratne Alles (PS), Dushyanthi Alagiyawanna (DA) and Aloka Pathirana (AP) made substantial contributions to the study conception. Sarangi Nanayakkara (SN) and Maneesh Kariyawasam (MK) agree to be accountable for data accuracy. Maheeka Seneviwickrama (MS), PS and DA analysed and interpreted data. The first draft of the manuscript was written by PS and MS. All authors revised the first draft of the manuscript critically for important intellectual content and approved the final manuscript.

Compliance with ethical standards

Disclosure of potential conflicts of interests

The authors declare that they do not have any known competing financial or non-financial interests that could have influenced the findings of the study reported in this paper.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura on 27.07.2021 (Reference number 10/21).

Consent to participate

Informed consent was obtained from all individual participants included in the study.

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