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How does the Distress Thermometer compare to the Hospital Anxiety and Depression Scale for detecting possible cases of psychological morbidity among cancer survivors?

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ABSTRACT

Purpose: Use of the Distress Thermometer (DT) as a screening tool is increasing across the cancer trajectory. This study examined the accuracy and optimal cut-off score of the DT compared to the Hospital Anxiety and Depression Scale (HADS) for detecting possible cases of psychological morbidity among adults in early survivorship.

Methods: A cross-sectional survey of 1323 adult cancer survivors recruited from two state-based cancer registries in Australia. Participants completed the DT and the HADS at six months post-diagnosis.

Results: Compared to the HADS subscale threshold ≥ 8 , the DT performed well in discriminating between cases and non-cases of anxiety, depression, and comorbid anxiety-depression with an area under the curve of 0.85, 0.84 and 0.87 respectively. A DT cut-off score of ≥ 2 was best for clinical use (sensitivity 87%-95%; specificity 60%-68%); ≥ 4 best for research use (sensitivity 67%-82%; specificity 81%-88%), and ≥ 3 the best balance between sensitivity (77%-88%) and specificity (72%-79%) for detecting cases of anxiety, depression and comorbid anxiety-depression. The DT demonstrated a high level of precision in identifying non-cases of psychological morbidity at all possible thresholds (NPV 77%-99%).

Conclusions: The recommended DT cut-off score of ≥ 4 was not supported for universal use among recent cancer survivors. The optimal DT threshold depends upon whether the tool is being used in the clinical or research setting. The DT may best serve to initially identify non-cases as part of a two stage screening process. The performance of the DT against 'gold standard' clinical interview should be evaluated with cancer survivors.

Keywords: cancer; psychological distress; screening; sensitivity; specificity; survivor

INTRODUCTION

The diagnosis and treatment of cancer has wide-ranging physical, psychosocial and existential effects [1]. Psychological distress is relatively common among oncology populations with estimates of the prevalence ranging from 28% [2] to 43% [3]. Emotional stress has been linked to decreased social functioning, more physical and cognitive impairment, amplified somatic symptoms [4], non-adherence to treatments and health-promoting behaviours [5] and possibly cancer progression and recurrence [6]. Despite the importance of detecting and treating psychological distress, health care providers often fail to accurately recognise distressed patients [7] and many cancer services report providing psychosocial care only to patients in crisis [8]. Consequently, many people with cancer report unmet need for help with psychological issues [9]. Guidelines recommend that all cancer patients should be routinely screened for distress at periods of increased vulnerability during the cancer journey [10, 11]. Screening itself is not diagnostic; rather, those who have a positive result from the screening test require further evaluation to confirm or discount the presence and severity of emotional distress. Routine distress screening is acceptable to people with cancer, feasible to implement [12,13], and estimated to take one-quarter of the time and cost one-third as much as conducting clinical assessments [14].

It is widely accepted that a screening tool should be brief, easy to administer and interpret, reliable, and able to accurately detect most of those with and without the condition of interest based on a cut-off score [15]. Various screening tools such as the Hospital Anxiety and Depression Scale (HADS) [16], Brief Symptom Inventory-18 (BSI-18) [17] and Distress Thermometer (DT) [18] have been developed to quickly identify individuals who may be psychologically distressed. The single-item (DT) is recommended by the National Comprehensive Cancer Network [11]. Potential advantages of the DT over other screening tools are its brevity, and ease of administration and scoring. While the accuracy of the DT to detect psychological distress has been demonstrated against longer criterion measures

including the HADS, BSI-18 and clinical interview, recent reviews have highlighted the DT's lack of specificity to rule-out false positive cases [19-21]. Furthermore, study findings are mixed regarding the optimal DT cut-off score for case-finding with some studies supporting a cut-off score of ≥ 4 and others supporting a cut-off score of ≥ 5 [22].

Despite increased attention to the growing population of individuals transitioning to survivorship, to our knowledge, only two studies have examined the screening performance of the DT among those in survivorship. Merport et al [23] compared the DT to the BSI-18 in a heterogeneous sample of survivors at least two years post-diagnosis while Craike et al [24] compared the DT to the HADS in a sample of recent colorectal cancer survivors. In both studies, the DT demonstrated poor sensitivity relative to the criterion measure for identifying cancer survivors who self-reported symptoms of anxiety and/or depression. These findings highlight the importance of establishing the performance of a screening tool prior to using it with a different population or context to that in which it was validated.

This study aimed to (1) examine the sensitivity and specificity of the recommended DT cut-off score ≥ 4 with the HADS for detecting possible cases of anxiety, depression and comorbid anxiety-depression among a heterogeneous sample of adult cancer survivors six months after diagnosis; and (2) identify the optimal cut-off score on the DT for detecting possible cases of anxiety, depression and comorbid anxiety-depression among adult cancer survivors six months after diagnosis. The HADS was selected as the criterion measure because it is among the most widely used screening tools assessing symptoms of anxiety and depression in oncology populations [21, 22] and was recommended as the tool of choice in recent reviews [25, 26].

METHOD

This paper is based on Time 1 (T1) data collected at six months post-diagnosis from survivors participating in the population-based longitudinal *Cancer Survival Study*. The study protocol and some of the findings have been reported elsewhere [2, 27].

Participants & procedures

The sample was recruited from the two largest state-based cancer registries in Australia which together account for 60% of all new cases of cancer diagnosed [28]. Eligible survivors were (1) diagnosed in the previous six months with their first primary cancer of one of the top eight incident cancer types in Australia (prostate, colorectal, female breast, lung, melanoma, non-Hodgkin's lymphoma, leukaemia, head & neck); (2) aged between 18 and 80 years and living in the state of New South Wales (NSW) or Victoria at diagnosis; (3) considered by their physician to be aware of their diagnosis, physically and mentally capable of participating in the study, and sufficiently proficient in English to complete a questionnaire; and (4) alive.

Eligible survivors who consented to the cancer registry passing on their contact details to the researchers were sent a self-administered questionnaire. Non-responders were sent one reminder questionnaire three weeks later and received one reminder phone call after a further three weeks. Return of the questionnaire indicated voluntary consent to participate. Participants' disease (primary cancer type, spread of disease at diagnosis) and demographic (age, sex) characteristics were obtained from the cancer registries. The study was approved by the appropriate ethics committees.

Measures

Distress was measured by the single item DT [18]. Respondents self-report their level of emotional distress over the past week on a visual analogue scale from 0 (no distress) to 10 (extreme distress). Most studies have identified a cut-off score ≥ 4 indicates clinically

significant distress [13, 29-30]. However, a recent pooled-analysis found that the DT yields high rates of false positives and appears to be better at ruling out possible cases of clinical distress [19], while a systematic review of the psychometric properties of screening instruments for emotional distress rated the DT as only fair [21].

Anxiety and depression were assessed by the HADS, a 14-item screening tool assessing self-reported symptoms of anxiety (HADS-A) and depression (HADS-D). Each item is rated on a Likert scale from 0 to 3 and a score from 0 to 21 is calculated for each subscale. Scores can be kept continuous with higher scores indicating more anxiety or depression, or categorised with scores from 0 to 7 classified as non-case, 8 to 11 as borderline case, and 12 to 21 as probable case [16]. Whilst there is ongoing debate about the optimal HADS cut-off score [31], we used the established subscale cut-off score ≥ 8 to identify 'cases' on HADS-A and 'cases' on HADS-D [16, 32, 33]. In addition, those who scored ≥ 8 on both HADS-A and HADS-D were classified as 'cases' on comorbid anxiety-depression.

Analysis

The HADS was the criterion measure for defining caseness for anxiety, depression and comorbid anxiety-depression. If one item was missing from a HADS subscale, the mean of the remaining six items was imputed in accordance with the recommendations for the measure [34]. To examine the accuracy of the recommended DT cut-off score ≥ 4 to detect cases of psychological morbidity, participants were classified as 'clinically distressed' (DT score ≥ 4) or 'not clinically distressed' (DT score ≤ 3) and as 'cases' (HADS subscale score ≥ 8) or 'non-cases' (HADS subscale score < 8) of anxiety, depression and comorbid anxiety depression. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and the proportion of correctly identified cases and non-cases (based on the HADS classification) was calculated for each outcome with 95% confidence intervals. In this context, sensitivity refers to the proportion of cases identified by the HADS that are correctly

identified as cases by the DT; specificity refers to the proportion of non-cases as identified by the HADS that are correctly identified as non-cases by the DT; PPV is the proportion of cases identified by the DT that are cases according to the HADS, and NPV is the proportion of non-cases identified by the DT that are non-cases according to the HADS.

To identify the optimal cut-point for the DT detecting cases of anxiety, depression and comorbid anxiety-depression, the sensitivity, specificity, PPV, NPV and the proportion of correctly identified 'cases' for each outcome was calculated with 95% confidence intervals for all possible cut-off values for the DT. The optimal DT cut-off score was determined by finding the DT value which achieved the best balance between sensitivity and specificity. Receiver operating characteristic (ROC) curves were used to examine the ability of all possible cut-off values of the DT to detect 'cases' of anxiety, depression and comorbid anxiety-depression as identified by the HADS subscale score ≥ 8 . For each ROC curve, the area under the curve (AUC) estimate was used as an indicator of the overall accuracy of the DT to identify 'cases' of the outcome of interest.

RESULTS

Sample

A total of 3877 potential participants were assessed for study eligibility. Of the 3315 deemed eligible, 1691 consented to contact by the researchers and 1360 returned a T1 questionnaire (41% response rate at T1). Of these, 37 questionnaires were returned more than 9 months after diagnosis and were excluded. The characteristics of the 1323 participants included in these analyses have been reported previously [2]. In summary, participants were surveyed at a median of 6 months after diagnosis (SD = 1 month, range = 4-9 months) and their median age was 63 years (SD = 11 years, range = 18-80). More than half (59%) were male and diagnosed with early stage disease (52%). The most common diagnosis was prostate cancer (26%) followed by breast cancer (16%) and melanoma

(15%). Almost three-quarters of participants (72%) had not received any active cancer treatment in the last month. The sample generally reflected the age and gender profile of the top eight incident cancers diagnosed in Australia in 2005 [27].

Accuracy of the recommended DT cut-off score ≥ 4 for identifying cases of anxiety and depression

Anxiety: A DT cut-off score of 4 correctly identified 67% of HADS cases of anxiety (sensitivity) and 88% of HADS non-cases (specificity). Of the anxiety cases identified by the DT, 62% (PPV) were cases according to the HADS and of the non-cases identified by the DT, 90% (NPV) were defined as non-cases by the HADS. Overall, 83% of survivors were correctly classified as cases or non-cases of anxiety.

Depression: A DT cut-off score of 4 correctly identified 71% (sensitivity) of HADS cases of depression and 82% (specificity) of HADS non-cases. Of the depression cases identified by the DT, 40% (PPV) were cases according to the HADS and of the non-cases identified by the DT, 95% (NPV) were defined as non-cases by the HADS. Overall, 81% of survivors were correctly classified as cases or non-cases of depression.

Comorbid anxiety-depression: A cut-off score of 4 correctly identified 82% (sensitivity) of HADS cases of comorbid anxiety-depression and 81% (specificity) of non-cases. Of the comorbid anxiety-depression cases identified by the DT, 32% (PPV) were defined as cases according to the HADS and of the non-cases identified by the DT, 98% (NPV) were defined as non-cases by the HADS. Overall, 81% of survivors were correctly classified as cases or non-cases of comorbid anxiety-depression.

Optimal DT cut-off score for identifying cases of anxiety and depression

The sensitivity, specificity, PPV, NPV and percent correct for all possible DT cut-off values are presented in Table 1 and ROC curves are graphed in Figures 1-3.

(Table 1 about here)

Anxiety: The DT showed good overall accuracy relative to the HADS-A for discriminating between cases and non-cases of anxiety with an AUC of 0.85 (95% CI: 0.82-0.88). The DT cut-off score for anxiety caseness which achieved the best balance between sensitivity and specificity was 3. A cut-off score of 3 detected 77% of survivors who were true cases and 79% of survivors who were non-cases of anxiety. In addition, half of all survivors who were identified by the DT as cases and 92% who were identified as non-cases of anxiety were classified as such according to the HADS. Raising the cut-off score to 4 decreased sensitivity to 67% but increased specificity to 88%. Lowering the DT threshold to 2 increased sensitivity to 87% but decreased specificity to 68%.

(Figure 1 about here)

Depression: The DT showed good overall accuracy relative to the HADS-D for discriminating between cases and non-cases of depression with an AUC of 0.84 (95% CI 0.81-0.87). The optimal DT cut-off score for depression caseness was 3. A cut-off score of 3 detected 78% of survivors who were true cases and 74% of survivors who were non-cases of anxiety. In addition, one third of all survivors who were identified by the DT as cases and 95% who were identified as non-cases of anxiety were classified as such according to the HADS. Raising the DT threshold to 4 decreased sensitivity to 71% but increased specificity to 82%. Lowering the DT threshold to 2 increased sensitivity to 91% but decreased specificity to 63%.

(Figure 2 about here)

Comorbid anxiety-depression: The DT showed good overall accuracy relative to the HADS for discriminating between cases and non-cases of comorbid anxiety-depression with an AUC of 0.87 (95% CI 0.84-0.90). The optimal DT cut-off score for detecting cases of comorbid anxiety depression was 4. A cut-off score of 4 detected at least 80% of survivors who were true cases and true non-cases of comorbid anxiety-depression. In addition, one third of all survivors who were identified by the DT as cases and 98% who were identified as non-cases of comorbid anxiety-depression were classified as such according to the HADS. Raising the cut-off score to 5 lowered sensitivity to 74% but increased specificity to 86%. Lowering the DT cut-off score to 3 increased sensitivity to 88% but decreased specificity to 72%.

(Figure 3 about here)

DISCUSSION

The DT demonstrated good agreement relative to the HADS to discriminate between cases and non-cases of anxiety, depression, and comorbid anxiety and depression among cancer survivors six months after diagnosis. This is consistent with previous studies which have examined the performance of the DT against criterion measures such as the HADS, BSI-18 and clinical interview to identify psychologically distressed cancer patients and survivors [20-22]. However, at the suggested cut-off score of ≥ 4 , the DT generated a high rate of false negative or 'missed' cases. For instance, the DT failed to identify 96 of 288 HADS cases of anxiety, 50 of 174 HADS cases of depression and 21 of 120 HADS cases of comorbid anxiety-depression. This low level of sensitivity suggests that the recommended DT cut-off score of ≥ 4 may not be ideal for detecting cases of anxiety and depression amongst survivors six months after diagnosis. These findings add to emerging evidence illustrating the DT's lack of sensitivity among individuals in the survivorship phase of care [23, 24] compared to those in the treatment phase [13].

The choice of optimal cut-point is a trade-off between sensitivity and specificity. While lowering the DT cut-off score increased sensitivity and reduced the number of cases that were 'missed', it resulted in a corresponding decrease in specificity and increased the number of false positive cases identified. Conversely, raising the DT cut-off score increased specificity and reduced sensitivity. Our study found that a DT cut-off score of ≥ 3 achieved the best balance between sensitivity and specificity. At this threshold, at least 75% of HADS cases and 72% of HADS non-cases of anxiety, depression and comorbid anxiety-depression were identified as such by the DT. While these rates of sensitivity and specificity are at least as good as those reported in a recent pooled-analysis of the DT compared to the HADS to detect self-reported symptoms of anxiety and depression in oncology populations [19], the optimal cut-point of the DT may depend upon the purpose of using the tool.

For clinical applications, it could be reasoned that optimising sensitivity is desirable in order to not miss possible cases of psychological morbidity that require further assessment and possible treatment. This would lead to over-detection of cases and unnecessary further evaluation which in itself can be stressful. However, it could be argued that in the survivorship context, over-detection is preferable to under-detection given the intermittent nature of contact with health care professionals and thus fewer opportunities for psychological distress to be identified. While a DT threshold of ≥ 2 achieved at least 87% sensitivity for each outcome, the false positive rate was high with 32% to 40% of HADS non-cases misclassified as cases by the DT. These findings suggest that if universal DT screening of cancer survivors in the early stages of survivorship was implemented, a two-stage sequential screening process would be necessary. Survivors who scored ≥ 2 on the DT in the initial screening would need to undergo a second stage of screening, such as completion of a longer and more sensitive screening tool or further discussion with a nurse

or oncologist, to determine if referral to a mental health professional for more comprehensive assessment was warranted.

For research or policy applications however, it could be argued that optimising specificity is desirable in order to not over-detect cases and thereby inflate prevalence rates of psychological morbidity. This is important because decisions about the allocation of limited health care resources are based, in part, on the magnitude of a given problem. In this context, our study found that a cut-off score of ≥ 4 on the DT resulted in a false positive rate of less than 20% for each outcome, yet the false negative rate was high with up to 33% of HADS cases misclassified as non-cases by the DT. Some clinical settings may choose to optimise specificity if there is limited capacity to follow-up people identified as possible cases using a lower threshold.

Overall, the DT demonstrated a high level of precision in identifying non-cases of psychological morbidity with NPV ranging from 77% to 99% for all possible DT thresholds. Using the balanced cut-off score of ≥ 3 , at least 92% of survivors identified by the DT as non-cases of anxiety, depression or comorbid anxiety-depression were also identified as such by the HADS. These data corroborate evidence [19] suggesting that a strength of the DT is its ability to rule out psychological morbidity. These findings, in conjunction with the brevity and ease of scoring the DT, support the conclusion reached by others [19, 35] that the DT may be most useful as the first stage screening instrument for identifying the large number of non-cases of psychological morbidity in a two stage screening process.

Our study is one of the largest to investigate the sensitivity and specificity of the DT among a diverse population-based sample of survivors in the early stages of survivorship. While our findings provide support for the DT as a first stage screening tool in this population, the accuracy of the tool is only one of several criteria that need to be fulfilled prior to

implementing a screening program. One of the key principles underpinning screening is evidence that the early detection and treatment of the condition leads to better outcomes than finding and treating it later when signs or symptoms present [15]. Given the mixed evidence to date [36], well designed studies of the effectiveness of distress screening programs amongst those diagnosed with cancer are urgently needed.

Limitations

The study response rate of 41% may raise concerns about the generalisability of the findings. While the sample was representative of the population from which it was drawn in terms of age and gender, it is possible that the most distressed survivors may not have consented to participate. This may have contributed to the low PPV found in the current study given that this value is directly proportional to the prevalence of the outcome of interest. The HADS was the only criterion measure of anxiety and depression used with a subscale cut-off score of ≥ 8 to identify cases. Although one of the most commonly used short screening measures, recent reviews [21, 30, 33] have revealed a lack of consistency in HADS cut-off scores compared with clinical assessments to identify cases. If we had used the HADS subscale cut-off score of ≥ 11 to identify cases, the sensitivity of the DT at each possible threshold would be higher but the specificity would be lower. Although not possible in the current study, future research should examine the optimal DT threshold against a 'gold standard' clinical interview in this population. This would assist health care professionals in the selection of the most appropriate screening tool, and the most appropriate threshold to use in their setting. For all participants the DT was presented first and the HADS second which may have had an effect on responses. Ideally a cross-over design would be used to negate any order effect of survey administration, however this was not possible in the current study as the two instruments were included within a scannable booklet.

CONCLUSIONS

Compared to the HADS, the DT performed well in discriminating between cases and non-cases of anxiety, depression and comorbid anxiety-depression among cancer survivors in the late treatment to early survivorship phase of care. While appropriate for detecting cases of comorbid anxiety-depression, our findings did not support the recommended DT cut-off score of ≥ 4 to identify cases of anxiety and depression in this population. Our results suggest that the optimal DT threshold varies according to the use of the instrument with a cut-off score of ≥ 2 best for clinical use, ≥ 4 best for research use, and ≥ 3 the best balance between sensitivity and specificity. The high level of precision in correctly identifying survivors who were non-cases indicates that the DT may best serve to initially rule out the substantial number of survivors who are not cases on anxiety, depression or comorbid anxiety-depression as part of a two stage screening process. Future research should evaluate the performance of the DT against 'gold standard' clinical interview with cancer survivors.

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CONFLICT OF INTEREST

Disclosures: None. The authors have full control of all primary data, and agree to allow the journal to review the data relating to this paper if requested.

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Table 1: Performance of Distress Thermometer (DT) scores compared with the Hospital Anxiety and Depression Scale (HADS) for identifying cases of anxiety, depression and comorbid anxiety-depression

	DT score	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	% correctly classified (95% CI)
Anxiety	0	100	0	23 (21-26)		23 (21-26)
(≥8 on HADS-A)	1	93 (90-96)	49 (46-52)	35 (32-39)	96 (94-98)	59 (56-62)
	2	87 (83-91)	68 (65-71)	45 (41-49)	95 (93-96)	72 (70-75)
	3	77 (72-82)	79 (77-82)	53 (48-58)	92 (90-94)	79 (77-81)
	4	67 (61-72)	88 (86-90)	62 (56-67)	90 (88-92)	83 (81-85)
	5	59 (53-64)	91 (90-93)	68 (62-73)	88 (86-90)	84 (82-86)
	6	41 (36-47)	95 (94-96)	71 (64-78)	84 (82-86)	82 (80-85)
	7	29 (24-35)	96 (95-98)	72 (64-80)	82 (80-84)	81 (79-83)
	8	19 (15-24)	98 (98-99)	80 (70-90)	80 (78-82)	80 (78-82)
	9	8 (5-11)	99 (98-99)	81 (66-97)	78 (76-80)	78 (76-80)
	10	4 (2-6)	100 (99-100)	79 (54-100)	77 (75-80)	77 (75-80)
Depression	0	100	0	14 (12-16)		14 (12-16)
(≥8 on HADS-D)	1	95 (92-98)	44 (41-47)	22 (19-25)	98 (97-99)	51 (49-54)

	2	91 (86-95)	63 (60-65)	28 (25-32)	98 (97-99)	66 (64-69)
	3	78 (72-84)	74 (71-76)	33 (28-37)	95 (94-97)	74 (72-77)
	4	71 (64-78)	82 (80-85)	40 (34-45)	95 (93-96)	81 (79-83)
	5	62 (55-69)	87 (85-89)	43 (37-49)	93 (92-95)	83 (81-85)
	6	44 (36-51)	91 (90-93)	45 (37-53)	91 (89-93)	85 (83-87)
	7	35 (28-42)	95 (93-96)	52 (43-61)	90 (88-92)	86 (84-88)
	8	26 (19-32)	98 (97-99)	64 (53-76)	89 (87-91)	88 (86-89)
	9	10 (5-14)	99 (98-100)	63 (43-82)	87 (85-89)	86 (85-88)
	10	5 (1-8)	99 (99-100)	57 (27-87)	86 (85-88)	86 (84-88)
Comorbid	0	100	0	10 (8-11)		10 (8-11)
anxiety-	1	96 (92-99)	43 (40-46)	15 (13-18)	99 (98-100)	48 (45-51)
depression	2	95 (91-99)	60 (58-63)	20 (17-24)	99 (98-100)	64 (61-67)
(≥8 on HADS-A	3	88 (83-94)	72 (70-75)	25 (21-30)	98 (97-99)	74 (71-76)
and HADS-D)	4	82 (76-89)	81 (79-83)	32 (27-37)	98 (97-99)	81 (79-83)
	5	74 (66-82)	86 (84-88)	36 (30-42)	97 (96-98)	84 (82-87)
	6	53 (44-62)	91 (89-93)	38 (31-46)	95 (93-96)	87 (85-89)
	7	42 (34-51)	94 (93-95)	43 (34-52)	94 (92-95)	89 (87-91)

8	33	(25-42)	97	(96-98)	57	(45-69)	93	(92-95)	91	(90-93)
9	12	(6-19)	99	(98-100)	56	(36-76)	91	(90-93)	91	(89-92)
10	6	(2-10)	99	(99-100)	50	(20-80)	91	(89-92)	90	(88-92)

Fig.1 Receiver Operating Characteristic curve of Distress Thermometer scores versus the Hospital Anxiety and Depression Scale anxiety subscale (score ≥ 8)

Fig.2 Receiver Operating Characteristic curve of Distress Thermometer scores versus the Hospital Anxiety and Depression Scale depression subscale (score ≥ 8)

Fig.3 Receiver Operating Characteristic curve of Distress Thermometer scores versus the Hospital Anxiety and Depression Scale (score ≥ 8 on both anxiety and depression subscales)