A stepped care stress management intervention on cancer-related traumatic stress symptoms among breast cancer patients—a randomized study in group vs. individual setting

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Abstract

Objective: To evaluate the mode of delivery of a stress management intervention, in a group or individual setting, on self-reported cancer-related traumatic stress symptoms. A secondary aim was to evaluate a stepped care approach.

Methods: All study participants ($n = 425$), who were female, newly diagnosed with breast cancer and receiving standard oncological care were offered Step I of the stepped care approach, a stress management education (SME). Thereafter, they were screened for cancer-related traumatic stress symptoms, and, if present ($n = 304$), were invited to join Step II, a more intense intervention, derived from cognitive behavioral therapy, to which they were randomized to either a group ($n = 77$) or individual ($n = 78$) setting. To assess cancer-related traumatic stress symptoms, participants completed the Impact of Event Scale and the Hospital Anxiety and Depression Scale at the time of inclusion, three-months post-inclusion and approximately 12-months post-inclusion.

Results: The SME did not significantly decrease any of the cancer-related traumatic stress symptoms. No statistically significant differences were found between the group and the individual setting interventions. However, only 54% of the participants attended the group setting compared to 91% for the individual setting.

Conclusion: The mode of delivery had no effect on the cancer-related traumatic stress symptoms; however, the individual setting was preferred. In future studies, a preference-based RCT design will be recommended for evaluating the different treatment effects.
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Background

A cancer diagnosis is acknowledged as a potential traumatic life event in the Diagnostic and Statistical Manual of Mental Disorders—Fourth edition (DSM-IV) [1] and can result in post-traumatic stress disorder (PTSD) [2,3]. Intrusive thoughts and avoidance are two persistent core symptoms of PTSD. The prevalence of intrusive thoughts and avoidance among breast cancer patients varies between 8–48% and 8–46%, respectively [4–6].

Cancer-related traumatic stress symptoms, especially intrusive thoughts, can be a predictor of psychological distress or decreased health-related quality of life (HRQoL) [4,6] and could be used to identify those patients who are at risk of developing psychological distress and decreased HRQoL in the future.

Cognitive-behavioral stress management (CBSM) interventions has proven to be effective in the management of cancer-related traumatic stress symptoms [7–10]. The majority of the reported CBSM interventions utilize group or individual format, which has been compared to a no-therapy control group. There are advantages and disadvantages for CBSM in both group and individual settings. Interventions delivered in a group format offer benefits which include: enabling positive relationships, improved information about their disease and social support from others in the same situation, which could facilitate the therapeutic progression [11–13]. However, some individuals might not want to discuss their problems and feelings with other people in a group and therefore might withdraw from such interventions [14]. Moreover, Osborn *et al.* [15] concluded that group interventions were not as effective as individually based interventions. Therefore, intervention studies investigating the effectiveness of CBSM in a group versus individual format are warranted [16].

Although it is evident that interventions are beneficial, it is not yet well understood how to get the right treatment to the right patient at the right time [17]. One way of doing this is by using the stepped care approaches [18,19], i.e. intervention in several steps, depending on the severity of the disorder. The intervention starts with the least intensive treatment, which is expected to generate effects but does not have

a great impact on the patient in terms of costs and in-convenience [20], i.e. low intensity treatment. Patients who do not respond to the low intensity treatment, or who have more severe symptoms, are offered a more extensive treatment as a second step. There are studies reporting positive effects of stepped care models compared to conventional care [21–23]. Nonetheless, some researchers [24] have called for more research to determine whether stepped care could be an efficient method of delivering, e.g. CBSM.

The present study reports the results from a prospective randomized intervention study with the stepped care approach, the 'Breast cancer and Stress—project' (BAS) [25]. The primary aim was to compare the effects of the two different formats, a Group Stress Management (GSM) intervention to the intervention delivered as an Individual Stress Management (ISM) for patients diagnosed with breast cancer and with cancer-related traumatic stress symptoms. A secondary aim was to evaluate the stepped care approach and to explore if a brief Stress Management Education intervention (SME) in the first step of the stepped care model approach would reduce the number of women who report elevated levels of cancer-related traumatic stress symptoms, thus requiring a more extensive treatment. A non-intervention control group was not applied to the present study since the positive effects of CBT are well-documented [8,16,26,27] and it would not be ethical to withdraw patients in need from a treatment that has been found effective. Furthermore, the aim was not to evaluate the intervention per se but rather to evaluate the mode of delivery by comparing the two intervention arms (group vs individual).

Method

Patients and procedure

During May 2009 and August 2011, female patients over the age of 18 ($n = 821$), newly diagnosed with a stage I–III breast cancer and scheduled for adjuvant treatment at Falun, Gävle, or Uppsala hospital (Sweden), were consecutively informed about the BAS-project and invited by nurses at the clinics to participate in the study. Exclusion criteria were on-going psychiatric illness or inability to speak and understand Swedish. Of those eligible, 395 patients (48%) rejected participation. Of those who stated a reason for not participating ($n = 108$), the most common reason was not distressed (31%), were not able to participate due to other commitments, e.g. a sick spouse (19%) or that they had too far to travel (18%). Some women also said that they were too busy (16%) or too tired (10%) to participate. Furthermore, 4% did not want to be reminded of the breast cancer, and 2% already had the support they needed.

One patient was deceased prior to receiving the questionnaire (Figure 1). Thus, 425 patients (52%) answered the baseline questionnaire along with a signed consent. Participants were included to the BAS-project on average 74 days after receiving their breast cancer diagnosis. Demographic and medical data for the participants are shown in Table 1. The Research Ethics Committee in the Uppsala-Örebro Region approved the project, Dnr 2008/382.

Data collection

Demographic data were collected at baseline using a brief questionnaire. The Regional Cancer Center Register supplied medical data. The cancer-related traumatic stress symptoms were assessed using two instruments:

> The Impact of Event Scale (IES) [28], is a validated [29], 15-item scale, assessing two post-traumatic stress responses, i.e. intrusion and avoidance. Levels of distress above nine were used as the cut-off in the present study.
> The Hospital Anxiety and Depression Scale (HADS) [30] is a validated [31], 14-item questionnaire with two subscales measuring anxiety and depression. Levels of anxiety/depression > 11 were used as the cut-off in the present study.

The questionnaires were mailed to the participants accompanied by written instructions and a prepaid return envelope (Figure 1). In order to secure the points of assessment, the participant was sent a reminder within 14–21 days if the questionnaires had not been returned. After three reminders the participant was excluded from the study.

Stepped care intervention

The goal of the stepped care approach of the intervention program was to provide care at the right level for the participants. Initially, all participants were invited to attend a low intensity treatment, the so-called stress management education (SME), within a three-month period from inclusion. After the SME (T2), all participants were screened in order to find those who reported levels over the cut-off on the IES [28] and/or the HADS [30]. Patients who reported levels over the cut-offs were contacted a second time via telephone by the project personnel and invited to participate in the Step II-intervention, a stress management intervention in a group (GSM) or individual setting (ISM). If participants consented to the second step, they were randomized by a senior researcher, not involved in the recruitment of the patients. Within a week after the randomization, participants in Step II were contacted by mail to receive information about which randomized group they were assigned to, as well as practical details about the
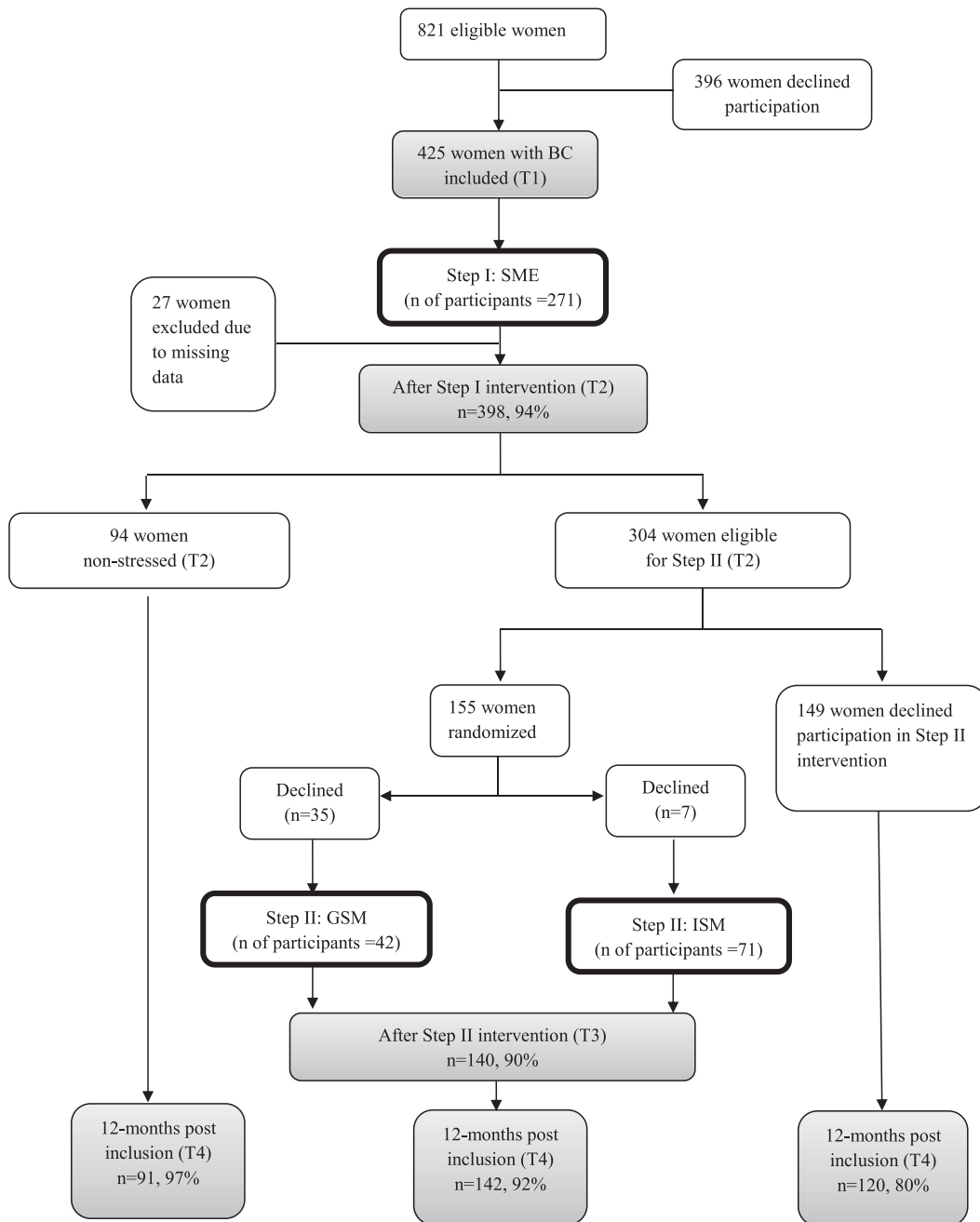
Figure 1. Flowchart of the patients throughout the study

intervention. The interventions were administered by two of the authors (CA and RR) and especially trained oncology nurses at the hospitals and university departments in the different study locations. The training program for the nurses was given prior to the start of the inclusion and has been described in detail elsewhere [32].

Patients were not restricted from participating in the community support groups, such as support groups arranged by the Swedish Breast Cancer Association, or using the standard help line available from the clinics to all cancer patients for health-related questions.

Step I: The stress management education (SME) consisted of a 2-h education, where participants received detailed information about the cancer disease, its treatment options, different stress symptoms and ways to handle the symptoms. Participants were given the

Table 1. Demographic and medical background data at inclusion

| | Total study participants n = 425 (%) | Step I | | Step II | | |
		SME-attendees n = 271 (%)	SME-non attendees n = 154 (%)	GSM n = 77 (%)	ISM n = 78 (%)	Decliners n = 149 (%)
Age, years						
Mean	59	58	58	57	58	59
Minimum–maximum	29–82	29–81	32–82	29–78	37–79	32–81
Residential area						
Dalarna	126 (30)	97 (36)	29 (19)	25 (32)	25 (32)	44 (30)
Gävleborg	158 (37)	119 (44)	39 (25)	30 (39)	29 (37)	54 (36)
Uppsala	141 (33)	55 (20)*	86 (56)*	22 (29)	24 (31)	51 (34)
Social status[a]						
Annual household income (EUR), mean[b]	55,727	53,379	57,248	57,742	55,409	53,769
Living alone	93 (22)	63 (23)	30 (19)	13 (17)	18 (23)	30 (20)
Children (<18 years)	80 (19)	49 (18)	31 (20)	17 (22)	19 (24)	28 (19)
Working	264 (62)	170 (63)	94 (61)	51 (66)	53 (68)	90 (60)
Adjuvant treatment						
Chemotherapy	211 (50)	131 (48)	63 (41)	49 (64)*	40 (51)	69 (47)
Radiation therapy	313 (74)	199 (73)	93 (60)	59 (77)	55 (71)	111 (75)
Hormonal therapy	233 (55)	146 (54)	72 (47)	39 (51)	45 (58)	83 (56)
Other health complaints	87 (20)	56 (21)	25 (16)	13 (17)	24 (31)*	26 (18)

*Statistically significant difference $p < .05$.
[a]n varies depending on number of returned questionnaires.
[b]1 EUR = 8.36 SEK (Exchange rate October 4, 2013).

opportunity to ask questions, and they received written material along with a CD containing relaxation exercises to read and/or practice at home.

Step II: Although the two intervention arms, GSM and ISM, differed in their frequency and setup, both the GSM and the ISM were designed to contain the same core components, the same relaxation techniques and homework assignments and were manual based. Briefly, the core components comprised an introduction to stress and stress responses, both physical and psychological. Furthermore, discussions were held regarding quality of life, focusing on expectations of life post diagnosis. A stress diary, worksheet to monitor one's actions to change inappropriate behaviors/reactions, for example, negative thoughts, and a short relaxation exercise called the 'the stop button' were introduced as techniques to manage stress. These techniques, derived from CBT, were practiced at home between sessions. The home assignments were discussed at the beginning of each session, and time was allocated for feedback.

The group intervention (GSM) consisted of ten 2-h sessions, and each session covered a specific component that was introduced by case illustrations, written texts and exercises tailored for the intervention. Social support within the group was important and allowed us to facilitate the therapeutic progression.

The individual intervention (ISM) consisted of four to eight 1-h sessions, where one to three specific components, similar to the ones in the GSM, were introduced at the beginning of each session. The first four sessions comprised the six components of the intervention. At the end of the fourth session, the nurse and the ISM-participant together decided whether further sessions were warranted. The main reason for continuation was the presence of problems that the individual wanted to address in either of the components covered by the intervention.

Statistical analyses

The effect of the SME (Step I) was evaluated by comparing the participants who attended the SME with the non-attending participants. Since the participants were not randomized to the SME, we applied strata based on the IES- and HADS-subscale scores at T1 for all the participants. Stratification minimizes the confounding bias; moreover, prior to the analysis, a model [33] was proposed to identify covariates, which could increase or reduce the confounding bias, such as demographic variables. The model suggested that strata based on the IES- and HADS-scores would minimize this bias. The first stratum contained participants who scored in the lowest 25%, next strata included participants who scored in the next 25% and so on, dividing participants into four different strata.

The statistical analyses in Step II were made according to the 'intention to treat principle.' Mann–Whitney tests were used to address the main hypotheses. Assessments of differences between the groups were performed with the Chi-2 exact tests for categorical data and with an independent sample t-test or one-way ANOVA for continuous variables. Alpha was set at <0.05. According to the power

calculations for the primary outcome IES [28], based on the data from the Support Project [34], at least 64 patients had to be included in each randomization group (i.e. a total of 128) in order to detect a significant difference for the IES [28]. Missing responses in single items were replaced with the mean response for the participant if at least half of the items were answered on the subscale.

Results

Effects of step I; a brief stress management education intervention (SME)

A total of 62 SME sessions were offered to the 425 participants during August 2009 to October 2011 with a total attendance of 271 (64%). The only statistically significant difference between those who attended the SME and those who did not attend was that fewer participants from Uppsala than from the other residential areas attended the SME $\chi 2$ (2, $N = 425) = 56.1$, $p = .000$.

Elevated levels of cancer-related traumatic stress symptoms were reported by 335 (79%) women at inclusion (T1) and by 304 (72%) women at the three-month post inclusion (T2). There were no statistically significant differences between those who attended the SME and non-attendees (Table 2). Within the different strata, both the attendees and the non-attendees showed the same pattern, that is, a regression to the mean over time (Table 2). Thus, the SME did not significantly reduce the cancer-related traumatic stress symptoms, measured by the IES and the HADS, for those who attended.

Effects of step II; differences in cancer-related traumatic stress symptoms between the GSM vs. ISM randomizations groups

One hundred and fifty-five (51%) individuals agreed to participate in Step II and were randomized in blocks of two into one of the two more intensive treatments: a group stress management (GSM, $n = 77$) or an individual stress management (ISM, $n = 78$). Four statistically significant differences were found between those who declined to participate ($n = 149$) in Step II and those

Table 2. Median (range) and mean differences between T1 and T2 for four different strata evaluating step I

| Subscales | Assessment point | strata | SME-attendees | | | SME-non attendees | | | SME-attendees vs. SME-non attendees p-value |
			Md (range)	Mean differences	n	Md (Range)	Mean differences	n	
IES Avoidance[a]	T1		12 (0–38)		271	14 (0–40)		123	
	T2		11 (0–36)		270	13 (0–36)		122	
	T1–T2	1		−1.826 [d*]	66		−2.438[d]	32	.398
		2		−1.107[d]	76		−1.909[d]	22	.068
		3		2.173**	61		1.595	37	.966
		4		5.154**	67		2.484*	31	.939
Intrusion[b]	T1		14 (0–33)		271	14 (0–33)		123	
	T2		11 (0–35)		270	12 (0–35)		123	
	T1–T2	1		−0.845[d]	71		−1.593[d]	27	.386
		2		0.230	66		0.906	32	.868
		3		1.729**	63		2.000	35	.508
		4		7.214**	70		5.000**	29	.697
HADS Anxiety[c]	T1		5 (0–19)		271	5 (0–19)		123	
	T2		4 (0–16)		271	4 (0–17)		121	
	T1–T2	1		−1.000 [d**]	72		−0.640[d]	25	.200
		2		0.040	65		0.263	33	.065
		3		0.426	64		1.335*	34	.748
		4		3.671**	70		3.304**	29	.507
Depression[c]	T1		2 (0–17)		271	3 (0–16)		123	
	T2		3 (0–19)		271	3 (0–16)		121	
	T1–T2	1		−1.139[d**]	72		−1.000[d**]	25	.570
		2		−0.953[d*]	67		−1.581[d**]	31	.877
		3		−0.742[d]	64		0.299	34	1.000
		4		1.953**	68		0.723	31	.615

Abbreviations Median (Md)

[a]Scores 0–40

[b]Scores 0–35

[c]Scores 0–21

[a-c]A higher value indicates more stress symptoms.

[d]If the mean difference in a strata is negative, it indicates that the strata group has 'increased' stress symptoms from T1 to T2 according to their scores on the subscale.

*$p = <0.05$, difference T1–T2.

**$p = <0.01$, difference T1–T2.

who participated regarding demographical, medical and self-reported variables. The ISM group reported more other health complaints χ^2 (2, $N = 302) = 6.260$, $p = .044$, and participants in the GSM group underwent more chemotherapy χ^2 (2, $N = 301) = 7.050$, $p = .029$. Moreover, those who declined the participation in the intervention reported significantly less anxiety and depression at T2 than those who participated in the intervention (Table 3).

During the study period, three to four GSM interventions were performed at each of the study locations. These GSM were attended by 3–8 participants, who were enrolled 4.5–12.8 months (M = 7.5) post inclusion (T1). The group sessions were spaced approximately one week apart over the course of 3 months. Only 42 (54%) out of 77 randomized participants attended the GSM and completed an average of nine out of the 10 group sessions. The ISM was delivered to 71 (91%) out of 78 randomized participants, who had joined the intervention 4–8.5 months (M = 5.5) post inclusion. The ISM consisted of four to eight 1-h sessions (M = 5.1) over the course of 4.5 months, with approximately one session a month. Twenty-nine (41%) of the ISM-participants had more than four sessions.

Table 3. Mean (SD) and median (range) for the GSM and ISM randomization groups

	Group intervention (GSM)	Individual intervention (ISM)	Decliners
T1	M (SD)/median (range)	M (SD)/median (range)	M(SD)/median (range)
IES			
Avoidance[a]	16 (9)/15 (0–38)	16 (8)/17 (1–36)	15 (8)/15 (0–40)
Intrusion[b]	17 (8)/16 (0–31)	17 (8)/16 (1–33)	16 (8)/15 (0–33)
HADS			
Anxiety[c]	8 (5)/7 (0–18)	7 (5)/7 (0–19)	7 (5)/6 (0–19)
Depression[c]	5 (3)/4 (0–16)	5 (4)/4 (0–16)	4 (4)/3 (0–17)
T2	n = 77	n = 78	n = 148
IES			
Avoidance[a]	16 (8)/14 (2–36)	16 (8)/14 (2–36)	15 (8)/15 (0–36)
Intrusion[b]	16 (6)/16 (4–35)	15 (6)/16 (0–35)	14 (7)/13 (0–35)
HADS			
Anxiety[c]	7 (4)/7 (0–16)	7 (4)/7 (0–16)	5 (4)/5 (0–17) [†]
Depression[c]	5 (4)/4 (0–19)	6 (4)/5 (0–16)	4 (4)/3 (0–16) [††]
T4	n = 70	n = 72	n=120
IES			
Avoidance[a]	13 (10)/11 (0–36)*	14 (8)/12 (0–32)*	13 (8)/12 (0–36)
Intrusion[b]	13 (6)/13 (0–35)*	14 (7)/12 (1–35)*	12 (7)/11 (0–35)
HADS			
Anxiety[c]	6 (4)/6 (0-16)**	6 (4)/5 (0–19)*	5 (4)/4 (0–18)
Depression[c]	4 (4)/2 (0–19)*	4 (3)/3 (0–11)*	3 (3)/2 (0–15)

[a]Scores 0–40
*p = <0.01, difference T2–T4
[b]Scores 0–35
**p = <0.05, difference T2–T4
[c]Scores 0–21
[†]p = <0.05, difference decliners—GSM and ISM
[††]p = <0.05, difference decliners—ISM

Both the GSM and ISM were statistically significantly improved over time on all the end-points (Table 3). However, there were no statistically significant differences in the cancer-related traumatic stress symptoms between the GSM and the ISM randomization groups.

Discussion

Studies evaluating the mode of delivery of stress management interventions are scarce in cancer care, and there has been a call for such studies [16]. To the best of our knowledge, our study is the only study comparing the GSM with the ISM in cancer care. The results showed no statistically significant differences between the GSM and the ISM on any of the main outcomes. However, in the GSM, only 54% of the participants attended the intervention, compared to 91% for the ISM intervention. Thus, based on the experience from our study, the ISM was the more preferred setting for the participants, both during and after the adjuvant treatment. In a review, Moyer et al. [35] argued that because the preference for one type of treatment versus another seems to have important effects, it may be important to include assessments of such preferences and their potential effects on the study outcomes. One possible reason for the lack of statistically significant differences between the GSM and the ISM can be the insufficient statistical power due to the high drop-out rate in the GSM. A majority of the participants who rejected participation in the GSM group stated that they did not know the other group participants and did not want to discuss private matters in a group. Altogether, preference-based randomized controlled studies should be considered when planning new studies trials in the future [35], since the validity and generalizability otherwise might be threatened as it was in our study.

Further, many of the women had gone back to work when the GSM was about to start, which made it difficult for them to attend the ten scheduled GSM sessions. The ISM participants were able to schedule an individual session that suited them, thus, minimizing any delays. The problems of the GSM group were further enhanced by the delays caused by waiting for the new participants. The timing of the intervention might have negatively affected the benefit of the GSM intervention. Previous results from the research group indicate that the timing of the intervention is important to consider. Arving et al. [34] utilized a similar intervention in their study and found significant improvements over time on the outcome variables. The intervention was delivered within a week after the start of the adjuvant cancer treatment.

Also, the brief SME did not result in any clinically significant improvement of the cancer related traumatic stress symptoms. It has been suggested that one brief educational session that teaches problem-solving skills could

be successful [36]. One plausible explanation that the low intensity SME intervention in the present study was not successful could be that medical information has become more easily accessible to patients and the general population, with the use of the Internet and other media [37]; thus, the patients attending the SME were already well informed, which became apparent from the discussions during the SME sessions.

Conclusion

This study suggests that there are no significant benefits in delivering the intervention in a group setting compared with an individual setting. However, there are clinical implications to consider, such as best timing for CBSM and the participants' preferences, which in the present study was in favor of the individual setting. In future studies, the participants' preference for one type of treatment versus another is important to explore, as well as its potential effects on the trials' outcomes since the generalizability otherwise might be threatened.

Conflict of interest

None declared

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