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Efficacy of cognitive therapy for depression among women with metastatic cancer: a single-case experimental study

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Abstract

Although depression is frequent among patients with advanced cancer, very few studies have been conducted on its treatment. The objective of this study was to evaluate the efficacy of cognitive therapy for depression in women with metastatic cancer, using a multiple baseline experimental design. Six participants were enrolled in the study and were asked to complete daily and weekly mood assessments. Intervention time-series analyses conducted on daily mood data showed statistically significant improvement of depression symptoms, more importantly anhedonia, and associated features (i.e., anxiety, fatigue) for each participant. These improvements were also found to be clinically significant at post-treatment.

Keywords: Breast cancer; Advanced; Depression; Cognitive therapy

1. Introduction

Despite remarkable progress in cancer care, metastatic cancer remains an incurable condition today. Therefore, it is no surprise that having such a bad prognosis is associated with considerable psychological distress, including

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depression. The prevalence of depression is particularly elevated in patients with advanced cancer (e.g., Bukberg, Penman, & Holland, 1984; Chochinov, Wilson, Enns, & Lander, 1994; Hopwood, Howell, & Maguire, 1991; Kathol, Mutgi, Williams, Clamon, & Noyes, 1990; Plumb & Holland, 1977, 1981) and increases as death approaches (e.g., Fulton, 1997; Pinder et al., 1993). Depression can significantly impair quality of life, treatment compliance, and life satisfaction (Valente, Saunders, & Cohen, 1994). While spontaneous remissions of depression are theoretically possible, they are unlikely in the context of an incurable condition associated with gradual deterioration of functioning and successive treatment failures. Hence the importance of treating depression in this population.

Several psychotherapeutic approaches for depression exist. Among these, cognitive therapy (Beck, Rush, Shaw, & Emery, 1979b) has been identified as one of the very few types of psychotherapy empirically supported for the treatment of depression in the general population (DeRubeis & Crits-Christoph, 1998). In fact, available research data indicate that cognitive therapy is at least as efficacious as antidepressants in the treatment of major depression (e.g., Dobson, 1989; Murphy, Simons, Wetzel, & Lustman, 1984; Robinson, Berman, & Neimeyer, 1990; Rush, Hollon, Beck, & Kovacs, 1977) and this holds even for the treatment of severe major depression (Hollon et al., 1992). Furthermore, it would appear that cognitive therapy is associated with better maintenance of therapeutic gains over time. Indeed, an analysis of four studies (Blackburn, Eunson, & Bishop, 1986; Evans et al., 1992; Kovacs, Rush, Beck, & Hollon, 1981; Simons, Murphy, Levine, & Wetzel, 1986) has established that the risk of relapse was 26% following cognitive therapy compared to 64% among patients treated only with a tricyclic antidepressant (Hollon, 1990).

Cognitive therapy and other cognitive-behavioral therapies (CBT) are the most frequently used interventions in oncology centers, which is due to their well-documented efficacy to treat a variety of psychological disturbances, their short-term format, and their emphasis on increasing patients' self-efficacy (Jacobsen & Hann, 1998). Several studies have assessed the efficacy of CBT in the context of cancer and most of them have found significant benefits, including reduction of depression, anxiety, fatigue, and general psychological distress (Antoni et al., 2001; Bottomley, Hunton, Roberts, Jones, & Bradley, 1996; Cain, Kohorn, Quinlan, Latimer, & Schwartz, 1986; Cruess et al., 2000; Edelman, Bell, & Kidman, 1999; Edgar, Rosberger, & Nowlis, 1992; Evans & Connis, 1995; Fawzy et al., 1990; Greer, Moorey, & Baruch, 1992; Marchioro et al., 1996; Moorey, Greer, Bliss & Law, 1998; Telch & Telch, 1986; Watson, Fenlon, McVey, & Fernandez-Marcos, 1996). In spite of these positive outcomes, CBT with cancer patients still do not satisfy criteria for empirically supported treatments (Compas, Haaga, Keefe, Leitenberg, & Williams, 1998), partly because of the heterogeneity of samples studied in terms of cancer site and stage, precluding generalization of findings (Owen, Klapow, Hicken, & Tucker, 2001).

It is therefore surprising to note that, among studies that have included patients with metastatic cancer as parts of samples mainly composed of patients with loco-regional disease (e.g., Bottomley et al., 1996; Moorey et al., 1998), none has conducted analyses to verify the benefits of CBT specific to this category of patients.

It would have been important to do so, because it is far from certain that an intervention found to be effective in patients with non-metastatic cancer, thus with a much better prognosis, has the same efficacy in patients who have developed distant metastases and who are considered incurable. To our knowledge, only one study has assessed the efficacy of CBT specifically among patients with advanced cancer (Edelman et al., 1999). In this study, 124 women with metastatic breast cancer were assigned either to eight weekly sessions of CBT, administered in a group format, or to standard care (i.e., no CBT). The CBT incorporated a variety of behavioral and cognitive techniques (e.g., relaxation, problem solving, goal setting, communication strategies, cognitive restructuring) and expression of feelings and building of group support were encouraged in the group. Patients who received the CBT showed greater improvements of depression, total mood disturbance, and self-esteem relative to patients of the control group at post-treatment. However, there were no group differences at the 3- and 6-month follow-up assessments. One of the explanations raised by the authors for this lack of maintenance over time is the impossibility, in a group intervention, to individualize the intervention to each patient's specific needs. Accordingly, the authors suggested conducting studies assessing the efficacy of individual CBT in this population.

The aim of this study was to assess the efficacy of cognitive therapy, administered individually, for the treatment of depression among women with metastatic cancer.

2. Method

2.1. Participants

2.1.1. Recruitment

Potential participants were referred by their oncologist from the department of hemato-oncology of the hospital L'Hôtel-Dieu de Québec (CHUQ). In order to be accepted in the study, women had to meet the following inclusion criteria: (a) have metastatic cancer (stage IV); and (b) obtain a score of 17 or greater on the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) or a score of 7 or greater on the depression subscale of the Hospital Anxiety and Depression Scale (HADS-D; Zigmond & Snaith, 1983). A study demonstrated that these cut-off scores were optimal for the screening of clinical depression in the context of HIV (Savard, Laberge, Gauthier, & Bergeron, 1998).

Exclusion criteria for this study were as follows: (a) being in terminal phase defined as a life expectancy of less than 2 months; (b) meeting DSM-IV criteria (American Psychiatric Association, 1994) for a severe major depressive episode or another severe psychiatric disorder (e.g., psychotic, substance use, eating disorders); (c) presenting severe suicidal ideations with a risk of passing to action, as evaluated by the Scale for Suicide Ideation (SSI; Beck, Kovacs, & Weissman, 1979a); (d) starting a new psychotropic medication or changing the dosage or frequency of use of a psychotropic medication during the baseline or treatment phases; and (e) already being implicated in a therapeutic intervention targeting depression. Patients

Table 1
Participants' medical and demographic characteristics

Variables	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6
Age (years)	50	51	66	43	60	42
Type of cancer	Ovary and breast	Breast	Breast	Breast	Breast	Breast
Marriage status	Divorced	Married	Widowed	Married	Married	Married
Education completed	University	University	Elementary	University	College	University
Time since initial cancer dx (months)	53	72	243	143	9	4
Time since metastases dx (months)	16	7	2	7	9	4
Site of metastases	Liver	Bone	Bone	Bone, lung	Liver	Bone, lung, liver, brain
Ongoing treatments	Chemotherapy	Pamidronate	None	Hormone therapy, radio-therapy	None	Chemotherapy, immunotherapy

dx = diagnosis.

excluded from the study were referred to the psycho-oncology service of L'Hôtel-Dieu de Québec.

2.1.2. Sample

Six French-Canadian women with metastatic cancer were enrolled in the study and four of them completed the entire protocol. Participants who abandoned did so at the first (Participant 6) and third treatment (Participant 3) session due to severe medical complications, that made them inapt to participate. In addition, one participant (Participant 1) deceased prior to the 3-month follow-up assessment. The demographic and medical characteristics of the study population are presented in Table 1. The six participants had been treated for breast cancer but metastases were linked to an ovarian cancer in the case of Participant 1. The mean age of participants was 52 years. An average of 87.3 months had elapsed between the time they had received their initial cancer diagnosis and the time they entered the study, while the presence of distant metastases had been known for an average of 7.5 months. All participants but two were receiving some form of palliative medical treatment at the time of study entry.

2.2. Design

A multiple baseline A-B experimental design across participants with replications and follow-ups (Kazdin, 1992) was used to assess the efficacy of cognitive therapy for depression. Phase A corresponded to the baseline phase, of which the duration was determined randomly and varied across participants (from 3 to 8 weeks). During this

phase, no intervention was administered, but participants were asked to complete a daily mood diary and the HADS on a weekly basis. Once the baseline level was completed, the participants received 8-weekly sessions of cognitive therapy (i.e., Phase B). They continued to complete a daily mood diary and weekly mood assessments throughout treatment. Three-and six-month follow-up evaluations were completed in order to assess the maintenance of therapeutic gains.

2.3. Procedure

2.3.1. Pre-treatment

Preliminary screening was conducted using a brief telephone interview. Patients who were found to be potential participants for the study were invited for a clinical interview. During this interview, patients were provided with the detailed information about the study and were invited to read and sign a consent form. A clinical psychologist then administered the Structured Clinical Interview for DSM-IV (First, Spitzer, Gibbon, & Williams, 1996) and the SSI. Participants then completed a questionnaire of medical and demographic information, the HADS and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30; Aaronson et al., 1993). Finally, the Structured Interview Guide for the Hamilton Depression Rating Scale (SIGH-D; Williams, 1988) was administered by an independent evaluator, a resident in psychiatry, who was blind to the procedures and objectives of the study. The clinical interview lasted approximately 120 min. At the end of the interview, several copies of the daily mood diary and the HADS were given to participants for completion as instructed until the beginning of treatment. Participants were reminded each week to complete the mood diary daily, as well as the HADS on a weekly basis

2.3.2. Treatment

Cognitive therapy involved eight individual weekly sessions plus three booster sessions, each lasting approximately 60–90 min. Strategies that were elaborated for the treatment of depression in the general population (Beck et al., 1979b) were adapted in the present study to meet the specific needs of women with metastatic cancer. The ultimate goal of the treatment was to develop an optimistic but realistic attitude towards their situation, as opposed to a negative (e.g., only thinking of death) or overly positive attitude (e.g., hoping to be cured). Cognitive therapy began with the presentation of the cognitive theory of emotions. Then, participants were encouraged to increase their level of daily activities, initially by self-monitoring their activities, then by planning more pleasant and energizing activities every day. This was done sensitively, taking into consideration each participant's energy level. In some cases, the goal was rather to decrease extenuating activities (e.g., house cleaning) to the profit of doing more leisure activities and activities leading to a sense of accomplishment. Participants were then trained to identify their negative thoughts (e.g., "I am going to die alone and in pain"; "Life is no more worth living since I know I am going to die"; "I am of no more use to my family, I am a burden"; "My metastases are progressing, it means that I am going to die within the next two

months'') and to use cognitive restructuring in order to modify dysfunctional or irrational cognitions about cancer and other situations in their life (e.g., ''I know that the most important people to me will be there when I die and my doctor will ensure that I am sufficiently medicated to control pain''; ''No one knows how long I am going to live; I may have enough time to do fun activities with my family and achieve some goals that are important to me''; ''It is true that I can't do as much as I used to, but I'm sure they are happy that I am still alive and to take care of me''; ''My physician told me that there are still a couple of other treatment options that may slow down the progression''). Patients were then encouraged to redefine their life goals. Indeed, patients with metastatic cancer often believe they can no longer have life goals because they have an incurable condition, an attitude that strongly enhances depression. During treatment, participants were encouraged to identify short-, medium- and even long-term new objectives, the rationale being that they are better off to set life goals that they may not have time to achieve than to have no life goals, wait only for death to come, and to feel depressed. Finally, to help prevent relapse, future high-risk situations (e.g., cancer progression, treatment failure, terminal stage of the disease) were identified, as well as strategies to cope with them.

Two licensed psychologists with experience in the application of cognitive therapy (i.e., 5 and 10 years) conducted cognitive therapy sessions. During treatment, patients continued to complete the mood diary daily, as well as the HADS each week. At the fifth session (i.e., mid-treatment) and at post-treatment, the independent evaluator re-administered the SIGH-D.

2.3.3. *Booster and follow-up sessions*

Three booster sessions of cognitive therapy lasting approximately 60–90 min each were administered to participants every 3 weeks following the last intervention session. The goal of these sessions was to review difficulties the participant had experienced since the last session and verify to what extent she used the strategies learned to cope with them and how effective they were. Participants completed the HADS at each booster session. Follow-up assessments were conducted 3 and 6 months after the end of treatment. At this point, participants completed the HADS and the QLQ-C30 once more and the independent evaluator re-administered the SIGH-D. These data are not available for Participant 1 who was deceased at that time.

2.4. *Measures*

Structured Clinical Interview for DSM-IV (SCID): The SCID (First et al., 1996) is a semi-structured interview assessing the most common DSM-IV axis I disorders (American Psychiatric Association, 1994). A French version of the SCID was used in this study.

Scale for Suicide Ideation (SSI): The SSI (Beck et al., 1979a) is a semi-structured interview evaluating the severity of suicidal ideation. The French–Canadian version of the questionnaire used in this study was developed by the second author (J.S.).

Structured Interview Guide for the Hamilton Depression Rating Scale (SIGH-D): The SIGH-D (Williams, 1988) was designed to standardize the depression evaluation of the Hamilton Depression Rating Scale (Hamilton, 1960). The SIGH-D was translated into French by the second author (J.S.).

Beck Depression Inventory (BDI): This self-report scale includes 21 items evaluating the severity of depressive symptoms, each accompanied by four response choices. The French–Canadian version was developed and empirically validated by Gauthier, Morin, Thériault, and Lawson (1982), who found psychometric properties comparable to those of the English version.

Hospital Anxiety and Depression Scale (HADS): The HADS is specifically designed to evaluate and screen anxiety and depression among patients with a physical illness (Zigmond & Snaith, 1983). The main advantage of the HADS is that it contains no somatic items, which could be confused with symptomatic manifestations of the physical illness. The scale includes 14 items, of which seven measure depression (HADS-D) and seven measure anxiety (HADS-A). The French–Canadian adaptation has been shown to have psychometric qualities equivalent to those of the original English version (Savard, Laberge, Gauthier, Ivers, & Bergeron, 1998).

Daily mood diary: The mood diary included four items. The severity of depressed mood and the lack of interest in activities (i.e., anhedonia), the two main symptoms of depression, were evaluated using the following items: (1) ''Today, what was the highest intensity of my depressed mood?''; and (2) ''Today, to what extent did I feel like doing my activities?''. The other two items evaluated anxious mood and fatigue, two symptoms frequently associated with depression: (1) ''Today, what was the highest intensity of my anxiety?''; and (2) ''Today, how tired did I feel?''. The participant determined to what extent she experienced each symptom on a scale ranging from ''0'' (not at all) to ''100'' (extremely).

European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30): The QLQ-C30 (Aaronson et al., 1993) was developed and validated among cancer patients. Only the global health and quality of life scale was used in this study. A seven-point likert scale ranging from ''1'' (very bad) to ''7'' (excellent) is used to answer two questions: (1) ''How would you rate your overall physical condition during the past week?''; and (2) ''How would you rate your overall quality of life during the past week?''. Total scores are transformed so that they vary between 0 and 100. The French version was provided by the authors of the original version.

2.5. Data analyses

2.5.1. Intervention time-series analyses

Daily mood diary data (i.e., depressed mood, interest for activities, anxiety, and fatigue) were analyzed using intervention time-series analyses (ITSA) in order to determine whether the observed changes were statistically significant. The daily mood diary yielded between 17 and 49 ($M = 35.2$) data entries during the baseline phase (i.e., pre-treatment), which is sufficient according to various empirical

investigations to determine with acceptable power and alpha control the statistical significance of subsequent observed changes (Crosbie, 1993; Greenwood & Matyas, 1990).

To do this, ITSA models were developed using the AUTOREG procedure of SAS 8.2 (SAS Institute, 2001), which implements generalized least-squares regression methods with residuals corrected for autocorrelation. As suggested by Wei (1990, pp. 82–84), the Box–Cox transformation (BOXCOXAR macro; SAA Institute, 2001) was used to test whether each time series needed to be transformed before modelling. Since the issue of missing data is controversial in the ITSA literature, missing data were not estimated by projection or any other method and, thus, were simply dropped from the analysis. Level (i.e., abrupt change in the mean level of the data) and slope (i.e., gradual change) effects were estimated following the recommendations of Huitema and McKean (2000). However, non-linear (logarithmic and quadratic) slope changes were also assessed in order to capture more complex relationships between the intervention and subsequent mood improvement. Autocorrelation of observations was studied for the first 12 lags. Because outliers significantly affect autocorrelation estimates and inferential tests for detecting level and slope changes (Chang, Tiao, & Chen, 1988), extreme scores, identified as additive outliers by the SAS ARIMA (SAS Institute, 2001) outlier procedure, were modelled as "unexpected events" (i.e., pulse functions) following suggestions by Wei (1990, pp. 195–204) and their contribution to error variance was subsequently removed by estimating the magnitude of these events. A maximum of five outliers in each series were modelled in order to minimize the loss of degrees of freedom. The residuals of the final models were visually and statistically inspected to ensure they were normally distributed and exhibited linearity, stationarity (tested by augmented Dickey–Fuller tests), homogeneous variance, and no significant auto-correlation. ITSA were performed on data of all participants, except Participant 6 who failed to return her mood diary forms completed during the intervention.

2.5.2. *Visual analysis*

The HADS and the SIGH-D were not administered frequently enough to be submitted to ITSA. Instead, visual inspection of data distributions throughout the study phases, a method commonly used in research using single-case experimental designs (Kazdin, 1992), was used to identify changes. Visual inspection was performed on data of all participants, except Participant 6 for whom no treatment data was available.

2.5.3. *Clinical significance*

When evaluating the efficacy of a treatment, it is useful for clinicians to know whether effects that are statistically significant are also clinically significant. Five criteria of clinical significance were used in this study. As suggested by Foster and Mash (1999), the first criterion concerned participants' satisfaction with treatment effects. At post-treatment, participants self-evaluated to what extent treatment improved their mood. A bi-directional scale varying from 0 to 7 evaluated the degree of change where "0 " meant deterioration, "3–4 " meant no change and "7 " meant

improvement. A minimal score of 6 was established as a cut-off score to indicate the clinical significance of change. The second criterion used was the clinician's evaluation of the level of improvement in participants' mood at post-treatment, which provides an index of social validation (Foster & Mash, 1999). The same response scale was used and once again, the minimal required score was fixed at 6. In addition, scores obtained on the HADS-D and the HADS-A at post-treatment (i.e., the last data of the treatment phase) and 6-month follow-up (i.e., the first data of the 6-month follow-up phase) had to be reduced by at least 50% when compared to pre-treatment scores in order for the change to be considered clinically significant. Finally, participants had to reach a mean score greater than 67 at post-treatment on the global health and quality of life scale of the QLQ-C30, which corresponds to the median score obtained by a group of 150 women with metastatic breast cancer in another study (McLachlan, Devins, & Goodwin, 1998) and could be considered as a normative comparison (Kendall, Marrs-Garcia, Nath, & Sheldrick, 1999). Quality of life has been identified as a useful construct to determine whether the change is clinically significant (Gladis, Gosch, Dishuk, & Crits-Christoph, 1999).

3. Results

3.1. Intervention time-series analyses

Results of ITSA conducted on variables of the daily mood diary are summarized in Table 2. Since the hypotheses were directional, they were tested using a one-tailed 5% alpha level. A statistically significant change (level or slope change) was observed for each of the five participants on anxiety intensity, level of interest in activities (a depressive symptom), and fatigue level following the introduction of the intervention. However, a significant change of depressed mood was observed for only two of the five participants after treatment introduction. Significant slope changes were observed more often than level changes (14/20 vs. 8/20, respectively), indicating that the impact of cognitive therapy on daily mood was generally gradual. The statistical modeling of time series explained on average 50.9%, 60.7%, 61.9%, and 45.8% of the variance for anxious mood, depressed mood, interest in activities, and fatigue, respectively.

3.2. Visual analysis

Figs. 1 and 2 show the data obtained on the HADS-D and HADS-A throughout the study for Participants 1–5.[1] Visual inspection of these figures reveals that data obtained at baseline are generally stable for all five participants. When some change is observed, it is generally a question of aggravation of symptoms, which is not

[1] The evaluation conducted at the first session of cognitive therapy is included in the baseline phase since participants completed the self-report scales before the therapy session began (i.e., on the past week), thereby explaining why there are only seven data in the treatment phase.

Table 2
Summary of results of ITSA performed on daily diary data for each participant

Variable	Participant	DF	Outliers	R^2(%)	Level (t test)	Slope (t test)
Depressed mood						
	1	70	5	70.8	0.71 ns	−1.45.ns
	2	83	2	38.6	0.88 ns	−1.39 ns
	3	35	1	76.9	0.90 ns	−1.09 ns
	4	101	4	55.1	−4.54***	−3.43***
	5	107	3	62.0	1.12 ns	−3.00**
Interest in activities						
	1	74	2	74.8	−0.27 ns	4.65***
	2	86	0	7.2	−1.15 ns	1.82*
	3	34	3	76.4	−1.65*	1.09 ns
	4	103	5	73.5	−1.76*	10.74***
	5	106	4	77.6	2.03*	1.79*
Anxious mood						
	1	71	4	74.4	0.92 ns	−2.92**
	2	86	0	16.4	1.39 ns	−1.68*
	3	35	0	79.4	1.70*	−1.47 ns
	4	107	0	19.5	−2.05*	−1.12 ns
	5	105	5	64.9	0.24 ns	−1.95*
Fatigue						
	1	70	5	68.8	1.59 ns	−2.29*
	2	86	0	18.4	1.07 ns	−2.27*
	3	37	0	61.1	2.35*	−1.71*
	4	107	1	30.5	−1.86*	−2.08*
	5	108	1	50.1	−0.58 ns	−2.46**

*$p<0.05$; **$p<0.01$; ***$p<0.001$; ns = not significant.

problematic for the interpretation of treatment efficacy (Kazdin, 1992). The introduction of cognitive therapy is clearly associated with a progressive reduction in depression scores (HADS-D; Fig. 1) in Participants 1, 2, and 5. In Participant 4, the depression scores began to decline only at the end of the intervention and in Participant 3, no perceptible improvement occurred during her three weeks of participation. In all treatment completers (i.e., Participants 1, 2, 4, and 5), the improvement of depression scores was well maintained at booster sessions (data available for all four completers) and follow-ups (data available for three of the four completers). Cognitive therapy was also clearly associated with a progressive reduction of anxiety scores (HADS-A; Fig. 2) in Participants 2 and 5, an improvement which was maintained at booster and follow-up sessions. Participant 3 was beginning to show some improvement on anxiety scores when she dropped out of the study at the third session. In Participants 1 and 4, the anxiety scores remained fairly stable throughout the intervention and follow-up phases.

Scores on the SIGH-D generally corroborate the overall results obtained with the weekly depression assessments (see Fig. 3). At post-treatment, the mean SIGH-D score was under the clinical cut-off score of 6 ($M = 2$). Although the severity of

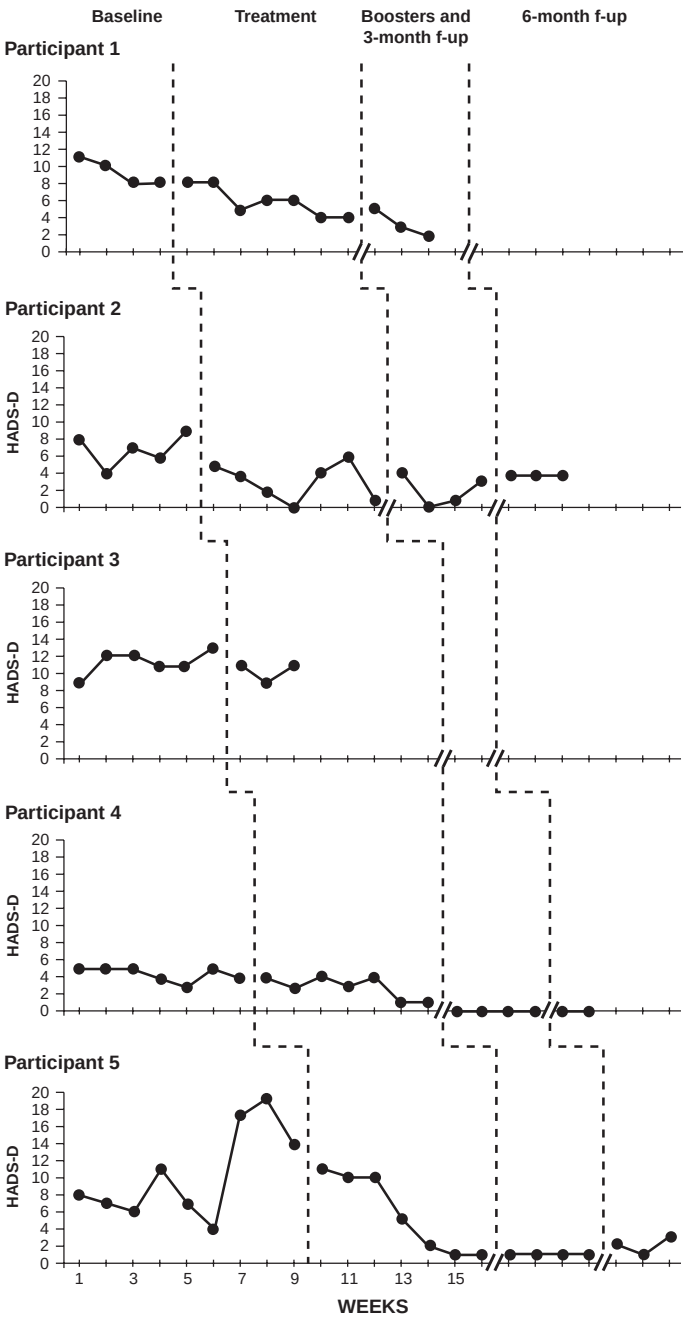

Fig. 1. Scores obtained on the depression subscale of the HADS by each participant at each phase.

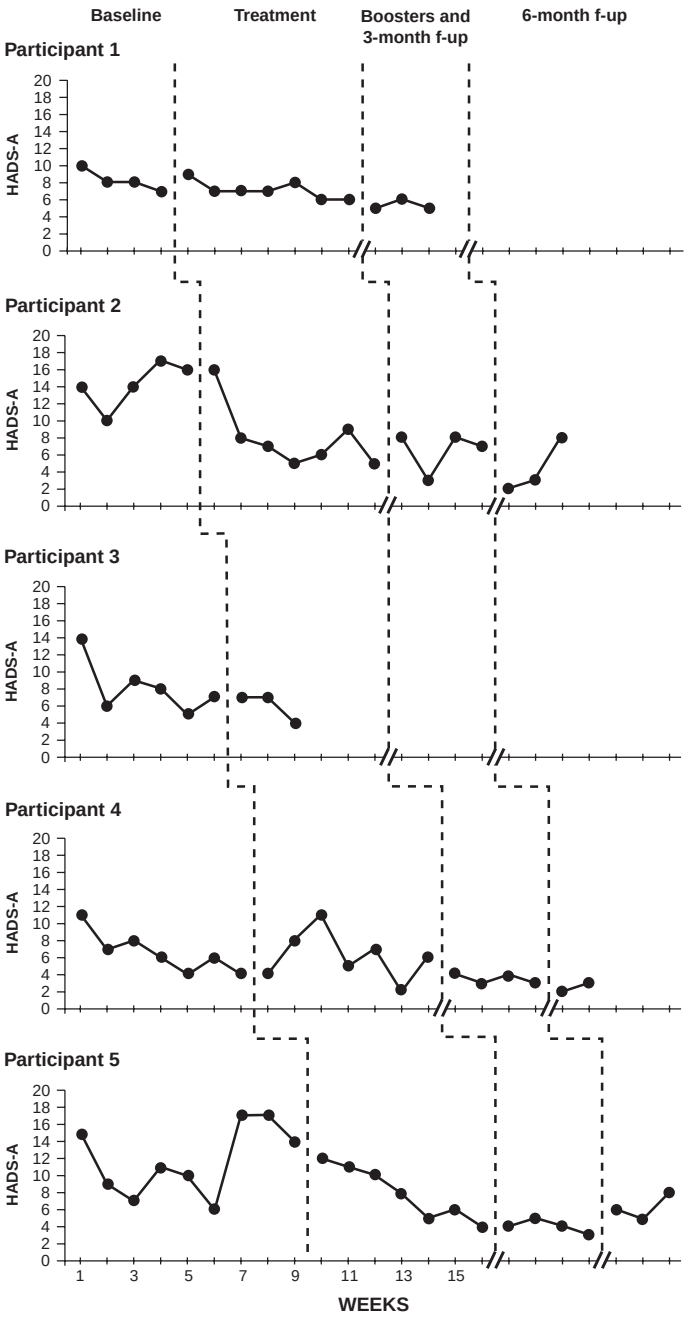

Fig. 2. Scores obtained on the anxiety subscale of the HADS by each participant at each phase.

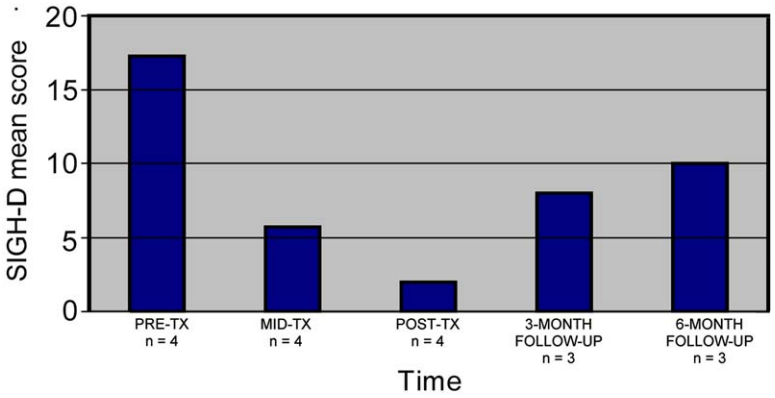

Fig. 3. Mean scores obtained on the Structured Interview Guide for the Hamilton Depression Rating Scale for the four participants at each measurement time.

depressive symptoms measured by the SIGH-D increased at 3-month and 6-month follow-up, it remained well below the pre-treatment score. This increase is mainly attributable to Participants 2 and 4 who were given scores higher than 10.

3.3. Clinical significance

The improvement observed at post-treatment appears to be clinically significant in all four treatment completers (see Table 3). Indeed, except for Participant 1 and 4 who did not meet the criteria for significant change on HADS-A scores, all treatment completers met the five pre-defined criteria determining the presence of clinically significant change. Specifically, all of them reported being satisfied with their mood improvement following cognitive therapy, showed a reduction of at least 50% on HADS-D scores compared to baseline, obtained a quality of life score greater than 67, and received a score of improvement of 6 or higher from the clinician at post-treatment. At 6-month follow-up, all treatment completers showed a reduction of 50% or higher both on the HADS-D and the HADS-A compared to the baseline. However, only 33% of them obtained a quality of life score greater than 67. As could be expected, these percentages were all lower when calculated on the total sample rather than treatment completers only (see Table 3).

4. Discussion

The aim of the present study was to assess the efficacy of cognitive therapy for depression among women with metastatic cancer. Overall, this study supports the utility of cognitive therapy to improve depressive symptoms in this population. Intervention time-series analyses of daily mood data revealed statistically significant improvements of depressive symptoms (i.e., depressed mood, anhedonia) and

Table 3
Criteria of clinical significance of changes met by each participant at post-treatment and 6-month follow-up

Participant		Criteria				
		Participant's Satisfaction $\geqslant 6$	Clinician's Evaluation $\geqslant 6$	Reduction on the HADS-D $\geqslant 50\%$	Reduction on the HADS-A $\geqslant 50\%$	Score > 67 on QLQ-C30
1	Post	Yes	Yes	Yes(64%)	No(40%)	Yes(83)
	F-up	N/A	N/A	m.d.	m.d.	m.d.
2	Post	Yes	Yes	Yes(88%)	Yes(64%)	Yes(83)
	F-up	N/A	N/A	Yes(50%)	Yes(86%)	No(58)
3	Post	m.d.	m.d.	m.d.	m.d.	m.d.
	F-up	N/A	N/A	m.d.	m.d.	m.d.
4	Post	Yes	Yes	Yes(80%)	No(46%)	Yes(75)
	F-up	N/A	N/A	Yes(100%)	Yes(82%)	No(50)
5	Post	Yes	Yes	Yes(88%)	Yes(73%)	Yes(83)
	F-up	N/A	N/A	Yes(75%)	Yes(60%)	Yes(83)
6	Post	m.d.	m.d.	m.d.	m.d.	m.d.
	F-up	N/A	N/A	m.d.	m.d.	m.d.
Percent	On Completers Only (On total Sample)					
	Post $n = 4$ ($n = 6$)	100% (67%)	100% (67%)	100% (67%)	50% (33%)	100% (67%)
	F-up $n = 3$ ($n = 6$)	N/A	N/A	100% (50%)	100% (50%)	33% (17%)

HADS-D = depression subscale of the Hospital Anxiety and Depression Scale; HADS-A = anxiety subscale of the Hospital Anxiety and Depression Scale; QLQ-C30 = Global health and quality of life scales of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; N/A = not applicable; m.d. = missing data; F-up = follow-up.

associated features (i.e., fatigue, anxious mood) in all patients following the introduction of treatment. These findings were further supported, although less consistently, by weekly self-reported assessments of depression and by clinical evaluations of depressive symptoms performed by an independent interviewer. Therapeutic gains were generally gradual and well maintained over time. In addition to being statistically significant, mood changes at post-treatment and six-month follow-up were clinically significant according to criteria used. Finally, results also indicated that cognitive therapy for depression contributed in improving patients' quality of life.

Results of the present study are consistent with prior findings supporting the efficacy of CBT in improving a variety of psychological parameters, including depression, in patients with non-metastatic cancer (Antoni et al., 2001; Bottomley et al., 1996; Cain et al., 1986; Cruess et al., 2000; Edgar et al., 1992; Fawzy et al., 1990; Greer et al., 1992; Marchioro et al., 1996; Moorey et al., 1998; Telch & Telch, 1986; Watson et al., 1996). These results are also consistent with data from the only other study that has specifically assessed the efficacy of CBT in women with advanced cancer (Edelman et al., 1999).

However, Edelman et al.'s study found only short-term benefits and these authors raised the possibility that it could be attributable to the group format of the intervention that might have prevented to individualize the intervention to each patient's needs. In the present study, therapeutic gains were fairly well maintained at three- and six-month follow-up when measured using the HADS-D, which would tend to suggest that individual interventions allow for a better maintenance of gains over time. However, clinical data (i.e., SIGH-D) were less conclusive. The mood deterioration observed at both follow-up evaluations, as evaluated by the SIGH-D, could be accounted for by the fact that this questionnaire contains several somatic items (8 out of 17 items) and, therefore, is more likely to be influenced by the patient's medical condition. In this study, therapeutic gains as assessed by the SIGH-D were noticeably less well maintained over time in Participants 2 and 4, whose follow-up evaluation coincided, respectively, with a progressive attempt to return to work that failed due to physical incapacity and with a treatment failure followed by the initiation of a new line of treatment. It may also be that metastatic cancer is a condition inherently associated with repeated stressors (e.g., illness aggravation, treatment failure) and that it is difficult with a short-term intervention to prevent patients from experiencing any psychological distress when these difficult situations occur. A more realistic goal might be to prevent the psychological distress reaching levels that incapacitate the person. It is noteworthy that although some deterioration was found on SIGH-D scores at both follow-up evaluations, scores remained considerably lower than those observed at pre-treatment, which seems to support that hypothesis. However, because no statistical analysis could be performed on these data, the issue of maintenance of therapeutic gains needs further investigation.

While these results are promising, this study is not without limitations. Firstly, the small sample size does not permit generalization of the results to the entire population of women with metastatic cancer. Our research group has just completed a randomized trial with a larger sample size of which results will be analyzed soon. Moreover, it is possible that those participants who accepted to participate in this study differed from the population of women with metastatic breast cancer on factors such as social and economics status, motivation, and physical capacity, which further limits the generalization of results. The high dropout rate (two of the six participants) is another factor that may affect the generalization of findings although it is a problem inherent to this severely ill population that has been encountered in other studies (e.g., Edelman et al., 1999). In addition, although the use of a multiple baseline experimental design controls for the influence of some non-specific variables (e.g., maturation, passage of time), it is impossible to determine with absolute

certainty whether therapeutic gains observed were due to specific cognitive strategies used or to non-specific ingredients common to all psychological interventions, such as therapeutic alliance and empathy.

Nevertheless, the present study has important clinical implications. Depression is still often perceived as a normal reaction to physical illnesses such as metastatic cancer, an attitude leading to underdiagnosis and undertreatment (Cassem, 1995). The present study shows that it is possible, in a short period of time, to improve depressive symptoms, as well as some factors associated with depression (i.e., fatigue and anxiety) and global quality of life, in spite of the seriousness of this disease. It is therefore imperative to implement systematic screening in this population with the goal of offering an appropriate therapy to those who need and want one. On the other hand, the maintenance of therapeutic gains over time appears challenging in this population. Future investigations could assess the efficacy of several strategies to increase the maintenance of gains that would take into account the evolutive aspect of metastatic disease, such as offering additional booster sessions at fixed time intervals or as needed, the later strategy being closer to the clinical practice.

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