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Sad and Worried Hearts: A Psychological Treatment for Clinically Significant Depression, Anxiety, and Post-traumatic Stress in Patients with Cardiac Disease

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Abstract

People who suffer from depression, post-traumatic stress, or anxiety following cardiac events and treatment are more likely to have further cardiac complications resulting in death than are people who do not. Although there have been advances in psychological techniques to elicit behavior and lifestyle changes in heart patients [1], there is currently a dearth of information on how to address the psychological sequelae of heart disease effectively. The goals of this pilot study were therefore to develop and test a cognitive-behavioral psychological treatment that was specifically tailored to the needs of people with cardiac disease and symptoms of psychological distress. Fifteen men and 12 women between the ages of 35 and 85 who exhibited clinically significant symptoms of depression, anxiety, or post-traumatic stress following a diagnosis of heart disease participated in a maximum of 20 sessions of cognitive-behavioral therapy. By the end of treatment, there were statistically significant reductions in all symptoms of psychological distress, as measured by the *Beck Depression Inventory Fast Screen for Medical Patients [2]*, the *Beck Anxiety Inventory [3]*, the *Hospital Anxiety and Depression Scale [4]*, and the *Impact of Event Scale, Revised [5]*. We present the treatment protocol in detail and discuss our results in terms of the utility of the integration of psychological services into cardiac care.

Keywords

Heart disease, Depression, Anxiety, PTSD, CBT

Introduction

According to the World Health Organization [6], ischemic heart disease is the leading cause of death worldwide, accounting for 7.2 million deaths or 12.2% of total deaths globally. The decrease in blood flow to the heart that characterizes ischemic heart disease is usually due to blockage of the arteries (known as coronary artery disease or CAD) and can lead to a host of heart problems, including heart attacks, cardiac arrest, and angina pectoris [7].

The psychosocial correlates of cardiac illnesses are both grave and numerous; recent evidence indicates that cardiac diseases and the medical interventions designed to treat them appear to have serious implications for psychological health, which in turn seem to affect long-term physical health outcomes. For example, the results of multiple studies suggest that between 15% and 20% of patients hospitalized for myocardial infarction (heart attack), unstable angina, and cardiac arrhythmia or who undergo invasive treatment procedures in hospital such as angioplasty or coronary bypass surgery are likely to exhibit symptoms of major depression [8,9]. Tedstone and Tarrier [10] suggested in their comprehensive review of the link between heart disease and anxiety that as many as 24% of people who survive a heart attack develop symptoms of post-traumatic stress following the cardiac event, with about 15% meeting criteria for Post-traumatic Stress Disorder (PTSD) in the months following the cardiac event (see Tulloch, Greenman, & Tassé [11] for a review). Cardiac disease and the medical procedures involved in its treatment have also been linked to excessive anxiety and worry that may manifest as Panic Disorder, Acute Stress Disorder, Generalized Anxiety Disorder, and Adjustment Disorder with Anxious Mood [12]. Other reviews have generated similar findings, which testify to the clear link between cardiac illness and subsequent symptoms of depression, post-traumatic stress, generalized anxiety, and panic [13-15].

Although it is possible to employ psychological methods to encourage cardiac patients to engage in the necessary behavioral and lifestyle changes following the diagnosis of heart disease [1], the literature suggests that people who suffer from psychological problems such as depression, post-traumatic stress, or heightened anxiety following cardiac events and treatment are more likely to have further cardiac complications resulting in death than are people who do not [11,16-20] and might therefore be in need of more elaborate psychological interventions that target their mood, anxiety, and potential post-traumatic stress more directly. Unfortunately, there is currently a paucity of information on how to address the

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psychological sequelae of cardiac disease effectively, particularly symptoms of anxiety and post-traumatic stress. The research that does exist in this area is disparate and contradictory [15,17,21-24].

Treating the Psychosocial Aspects of Heart Disease: A Confusing Portrait

Depression

Despite evidence of a clear and consistent relation between cardiovascular disease and depression and of the potentially deadly impact that depression can have on the course of cardiac illness [16,17], the treatment literature remains fragmented and incomplete.

The ENRICHD trials: One of the most ambitious and well-known investigations of the complex interplay among coronary heart disease (CHD), social support, major depression, psychological treatment for depression, and long-term physical and mental health outcomes was the longitudinal, multi-site Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) study, conducted in the United States [25-27]. A striking finding to emerge from this study was that although the cognitive-behavioral treatment employed appeared to help reduce symptoms of depression in patients who had survived heart attacks in the short term, any benefits from psychological treatment seemed to wane after 30 months [27]. In addition, there were no significant differences overall between treatment and control groups in long-term outcomes such as re-hospitalization or death due to subsequent cardiac complications [17,27].

The CREATE trial: In Canada, a different team of researchers completed a large-scale investigation of the effects of a psychological treatment for depression in patients with coronary artery disease (CAD). Similar to the ENRICHD trial, the Canadian Cardiac Randomized Evaluation of Antidepressant and Psychotherapy Efficacy (CREATE) [28,29] study also yielded lukewarm findings concerning the efficacy of psychological treatment for depression in cardiac patients. In this randomized control trial, the authors compared the effectiveness of interpersonal psychotherapy (IPT) for depression to the antidepressant drug citalopram in patients with CAD. They found that IPT was no more effective at alleviating depression in their sample of 284 adults with CAD than was nonspecific, clinical management of depressive symptoms through information, reassurance, and encouragement [29]. On the other hand, citalopram (the antidepressant medication) appeared to reduce patients' symptoms of depression significantly, which led the authors to conclude that antidepressant medication, not psychotherapy, should be the treatment of choice for cardiac patients suffering from major depression [29].

Scattered support for the efficacy of psychological treatment: Despite these findings, other studies indicate a positive impact of psychological treatments for the psychosocial consequences of cardiac illness, including depression. In one such study, albeit conducted on a much smaller scale than the CREATE trial, patients with stable coronary artery disease and major depression who received IPT demonstrated significant reductions in depressive symptoms at the completion of the psychological treatment [30]. In another, patients who had undergone bypass surgery or suffered heart attacks and exhibited symptoms of depression and anxiety had significantly lower scores on standardized measures of these constructs following a cardiac rehabilitation program that included a psycho-educational component [22]. Other studies, whose methods included the integration of cognitive-behavior therapy [31,32], hypnotherapy [33], and Gestalt therapy [34] techniques all yielded similar results: Patients with a variety of cardiac illnesses and comorbid depression appeared to benefit from these psychological treatments. This being said, these reports do not contain information on the impact of these short-term treatments on long-term outcomes such as subsequent cardiac events, re-hospitalization, disability, and death, nor were they well-controlled, large-scale clinical trials.

Questions raised: There are a number of possible explanations for the disparity in findings concerning the efficacy of psychological interventions for depression in cardiac patients. First, in many of the aforementioned studies [25-27,32], the investigators included in their samples cardiac patients with a history of depression, which is a potential confound if one is interested in the effects of treatment on depressive reactions triggered by cardiac events. It is possible that individuals with a history of depression might need more extensive and individualized psychological interventions than the ones provided in these studies. Patients with a pre-MI history of depression, anxiety, or post-traumatic stress may be more appropriate candidates for pharmacotherapeutic approaches or treatments that combine psychotherapy and medication [23]. For these reasons, the presence of previously depressed patients in these samples might have obfuscated findings concerning the efficacy of the treatments employed. Second, there are marked differences in these studies as to what constitutes "therapy." In addition to the different approaches to psychological intervention that have undergone experimental scrutiny (e.g., CBT [31,32], Gestalt therapy [34], IPT [28,29]), the psychological treatments used in these studies vary widely in the degree to which they follow empirically supported treatment protocols with established efficacy for depressed individuals in good physical health [35]. Some studies have featured group therapy sessions and a varying number of individual treatment sessions [25-27], whereas others have examined almost exclusively the effects of psycho-educational interventions [22], which involve a great deal of teaching and dissemination of information but not necessarily any emphasis on other elements crucial to psychotherapeutic success, such as the quality of the therapeutic alliance and attention to changes in the patient's emotional processing [36,37]. In sum, a majority of the interventions provided under the rubric of "psychotherapy" appear to be highly information-based, educational programs delivered by professionals (e.g., nurses, social workers) without extensive training in psychodiagnostics and psychological treatment, which might contribute to some of the confusion about their efficacy.

Anxiety and post-traumatic stress

Similar to the literature on treatment for depression among patients with heart disease, the results of existing studies seem to generate more questions than answers. Despite the substantial amount of evidence of a link between the onset of heart disease and clinically significant symptoms of anxiety and post-traumatic stress [10-14], studies of how to address such symptoms effectively are surprisingly few in number [24]. Preliminary findings in this area are encouraging, however. For example, in a study conducted in Taiwan, patients recovering from heart attacks or coping with unstable angina and cardiac arrhythmias who received relaxation training (a cognitive-behavioral technique for anxiety reduction) demonstrated significant decreases in their symptoms of anxiety, whereas the matched controls in this sample did not [38]. In a different study conducted in Australia, group sessions of cognitive-behavior therapy predicted significant reductions in the self-reported anxiety of cardiac patients who had had stents installed to facilitate cardiovascular blood flow [39]. More recently, a mindfulness-based intervention seems to have contributed to significant reductions in symptoms of depression, anxiety, and stress in cardiac patients under 60 years of age in the Netherlands [40]. Other research has indicated that cognitive-behavioral techniques such as biofeedback, behavioral counseling, behavioral rehearsal, and cognitive restructuring can also effectively reduce symptoms of anxiety in patients with heart disease [41].

Two studies to date have addressed the treatment of PTSD in cardiac patients. In these investigations, patients with PTSD demonstrated significant reductions in their symptoms following 4-5 sessions of CBT that included cognitive reprocessing, relaxation exercises, and exposure [42] and 3-5 sessions of imaginal exposure alone [43].

Questions raised: At this juncture, CBT for PTSD in cardiac patients appears to be promising. However, it is not clear whether the techniques employed in the studies of more general anxiety are applicable to symptoms of anxiety comorbid with heart disease that

are severe enough to warrant a diagnosis of a psychiatric disorder (e.g., panic disorder). This is problematic because cases of diagnosable anxiety disorders appear to result from a number of cardiac illnesses and treatments [10,12]. In addition, it is not clear from the available literature how to address the cognitive symptoms of anxiety disorders and PTSD, which include excessive worry, rumination, and obsessive thoughts [44]. As is the case in the literature on psychological treatments for depression and heart disease, it is also murky at present which specific elements that fall under the rubric of "psychotherapy" would be most helpful to people suffering from anxiety following cardiac illness.

Multimodal behavioral intervention: The Cologne study

A group of German researchers [21] has made a particularly cogent case for the integration of psychosocial components into cardiac care. They analyzed the impact of a multimodal behavioral intervention on the course of patients' cardiac symptoms over a period of seven years. In their randomized, controlled trial of a sample of 76 patients with heart disease, Albus and colleagues found that their intervention reduced the risk of subsequent cardiac events (i.e., myocardial infarction, coronary bypass surgery, percutaneous coronary intervention) by 59% compared to standard cardiac care. In addition, they detected significantly lower levels of myocardial ischemia (i.e., clogged arteries) seven years after the completion of the intervention among the patients who participated in it; there was no such decline among the patients who received standard cardiac care [21].

The multimodal behavioral intervention developed for this study was comprehensive. It included a total of 77.5 hours of treatment, including relaxation training, a weeklong retreat, education on the body and the importance of exercise and proper nutrition for a healthy heart, and, interestingly, what the authors describe as "supportive therapy" in which patients met regularly for 26 sessions over the course of one year, during which they exchanged openly about topics such as their health, their stress associated with health and lifestyle changes, their feelings of depression, and their fears about the future. Although the authors were unable to partial out the specific effects of each component of the intervention, it is noteworthy that this interpersonal, emotion-orientated component of the intervention figured prominently in the program from beginning to end. It might not be enough to simply educate patients about their bodies and the need to change their habits. The authors suggest that the supportive environment in which such education took place and the focus in their intervention on patients' personal, subjective feelings about being ill and trying to recover played a key role in helping patients improve their mental and physical health [21].

In sum, heart disease appears to beget psychological problems, which in turn can exacerbate symptoms of cardiopathy. Clinical manifestations of depression, anxiety, and post-traumatic stress appear to be particularly salient in people suffering from heart disease and their loved ones. Although a number of psychological treatments for symptoms of depression, anxiety, and post-traumatic stress in this population exist, it is not entirely clear at present what works and why.

The Present Study

In light of this state of affairs, the primary goals of this clinical pilot study were 1) to develop a psychological intervention tailored to the specific needs of patients with heart disease as we understood them from our reading of the literature and from our clinical experience, 2) to conduct preliminary tests of the efficacy of the intervention in a pre-post design, and 3) to highlight the specific elements of our treatment protocol that seemed to have positive effects on the symptoms of clinically significant anxiety and depression in patients with cardiac disease.

The cognitive-behavioral treatment manual

After conducting the literature review on the psychological

sequelae of cardiac disease presented above and after working directly with cardiac patients in an outpatient cardiac rehabilitation clinic, we concluded that symptoms of depression, anxiety, and post-traumatic stress would most likely predominate. For this reason, we patterned our intervention after empirically supported treatments for physically healthy patients suffering from mood, anxiety, or adjustment disorders (with depression and anxiety) or PTSD. Given the preponderance of evidence in support of the efficacy of cognitive-behavioral treatments for these conditions [35,45], the treatment that we developed involves a heavy focus on the interplay among patients' thoughts, behaviors, and feelings with regard to their cardiac illness.

Cognitive-behavioral theory: According to cognitive-behavioral theory, psychological distress is the result of problematic interpretations of life events, in conjunction with ineffective behaviors that reinforce these problematic interpretations and exacerbate feelings of fear, sadness, hopelessness, and despair, which with enough intensity and frequency may deteriorate into anxiety, depression, and post-traumatic stress [46-48]. Modern CBT arose out of learning theory, which suggests that the meanings attributed to life events and the emotions that accompany them are the result of both classical and operant conditioning [49], and sociocognitive theories that indicate causal roles of thinking and information-processing in the manifestation of particular behaviors and emotions [50,51].

Treatment progressed in three overlapping stages: 1) psychodiagnostic assessment; 2) socialization to a cognitive-behavioral conceptualization of anxiety and depression co-occurring with cardiac illness; and 3) identification, challenging, and restructuring of the thoughts and behaviors related to the cardiac illness in order to improve mood and reduce stress. Despite the structured nature of the intervention, the manual calls for some flexibility in terms of individual case conceptualizations and the integration of specific therapeutic techniques according to patients' particular needs. For a complete session-by session overview of the treatment protocol, please see Appendix A.

Expertise of service providers: The first author of this paper, a licensed clinical psychologist and expert in individual cognitive-behavior therapy, provided psychotherapy to participants according to the study treatment protocol that he designed in collaboration with the other authors. Advanced, doctoral-level residents in the clinical psychology Ph.D. program at the University of Ottawa with a minimum of two years' experience in supervised psychological practice with CBT also provided services to study participants. Residents who provided psychological services to participants did so under the close clinical supervision of the first author. In addition to the minimum requirement of two years of supervised CBT practice, all residents were briefed on the treatment protocol and participated in five to ten two-hour preparatory supervision sessions in which they reviewed and practiced the main interventions of the treatment protocol. These included cognitive restructuring, exposure, progressive muscle relaxation, and interpersonal behavioral activation.

Implementation of the treatment protocol: All psychotherapy sessions conducted within the context of this study were recorded on audiotape. The first author and principal architect of the treatment protocol listened to and took notes on the recordings of sessions that he conducted as well as those led by doctoral residents working under his supervision. Regular, weekly group supervisions lasting from two to three hours took place throughout the study. During these supervision sessions, clinicians discussed their interventions, gave one another suggestions, and took advice from the supervisor (Dr. Greenman) to ensure that they were faithful to the treatment protocol and were acting in the best interests of their patients.

Hypotheses

Based on our literature review and after having developed our treatment manual, we formulated the following hypotheses:

1) That cardiac patients with symptoms of depression would demonstrate significant decreases in their symptoms over the course of the study;

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2) That cardiac patients with symptoms of anxiety would demonstrate significant decreases in their symptoms over the course of the study; and

3) That cardiac patients with symptoms of post-traumatic stress would demonstrate significant decreases in their symptoms over the course of the study.

Method

This project was approved by the research committee of the Montfort Hospital and by the ethics committees of the Université du Québec en Outaouais and the University of Ottawa. All procedures performed with human participants were in accordance with the ethical standards of these institutional research committees (Montfort Hospital, Université du Québec en Outaouais, and the University of Ottawa) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. As such, all participants gave their informed consent to be involved in the study. They were informed that they could withdraw their consent at any time, freely and without consequence. There were no conflicts of interests on the part of any authors of this paper.

Procedure

Participants were recruited among patients referred for psychological services in the aftermath of their cardiac illness at the Diabetes and Cardiac Rehabilitation Clinic (DCRC) of the Montfort Hospital, located in Ottawa, Ontario, Canada. They were referred for psychological treatment and informed of the opportunity to participate in the study by the team of physicians, nurse practitioners, dieticians, and psychologists at the clinic. These professionals explained to interested patients that they would receive the same psychological interventions, regardless of their decision to participate in the study or not. They signed their consent to participate immediately prior to their first psychotherapy session.

Participants

As per the operating procedures of the DCRC, all patients referred for psychological services first underwent a screening interview conducted by a staff psychologist to determine whether or not the mental health program of the clinic could adequately meet their needs. This initial screening included questions about the severity of psychological distress since the onset of cardiac disease and prior diagnoses of psychiatric illness. The psychologist also administered the *Hospital Anxiety and Depression Scale* (HADS) [4] at the conclusion of each interview. It is important to note that in Canada, the title of "psychologist" is reserved in all jurisdictions to professionals with expertise in psychological diagnosis and treatment. For this reason, clinical psychologists routinely conduct psychological assessments and psychotherapy. The psychologists working on this project were experts in cognitive-behavior therapy.

Men and women between the ages of 35 and 85 who were patients at the DCRC, who had no prior history of psychiatric diagnoses, and who demonstrated clinically significant symptoms of depression or anxiety as indicated during their screening interview and their scores in the clinical range on the HADS were then referred to the first author and his team of residents.

All patients (100%) between March 2007 and March 2009 who were referred for psychological treatment at the DCRC for clinically symptoms of anxiety, depression, or both in the aftermath of their cardiac illness and who met the aforementioned inclusion criteria agreed to participate in the present study (N=15 men and N=12 women). They were offered 20 sessions of CBT as per the treatment protocol in place at the DCRC. Patients were asked to complete a battery of questionnaires (see below) after their first, fourth, eighth, twelfth, sixteenth, and twentieth sessions.

Measures

As the clientele of the Montfort Hospital is predominantly French speaking, validated French-language versions of all instruments were administered to the majority of participants (N=18 native French speakers and N=9 native English speakers). English-speaking participants completed the original versions of the questionnaires, all of which are well-established, psychometrically sound instruments [52,53].

Impact of event scale, revised (IES-R)

The IES-R [5] is a 22-item questionnaire designed to detect symptoms of post-traumatic responses to stressful life events. Participants rate, on Likert scales ranging from 0 (= not at all) to 4 (= extremely), the degree to which they have experienced intrusive ("Pictures about it popped into my mind", "I thought about it when I didn't mean to"), hypervigilant ("I was jumpy and easily startled", "I felt watchful or on guard"), and avoidant ("I tried not to think about it", "I stayed away from reminders about it") symptoms during the past seven days, relative to a specific stressful event. For all participants in the present study, the stressful event was defined as either 1) a heart attack, 2) an angina attack, 3) cardiac arrest, or 4) any surgical intervention designed to treat heart disease or to prevent a cardiac episode from occurring. Examples of the latter included angiograms, angioplasties, and the installation of stents. The French version of the IES-R has good internal consistency (alpha coefficients range from .81 to .93), acceptable test-retest reliability (alpha coefficients range from.71 to .93), and a three-factor structure identical to the original version of the scale [54].

Beck depression inventory, fast screen for medical patients (BDI-FS)

The BDI-FS is a 7-item questionnaire that was developed to detect symptoms of depression in people suffering from physical illnesses [2]. In our view, a key strength of the BDI-FS is that it prevents symptoms of physical illness (e.g., weight loss, difficulty concentrating) from confounding the psychodiagnostic picture, because it only includes the items from the BDI-II that are related to the direct psychological experience of depression. For each question, respondents rate their mood on Likert scales that range from 0 (= "I do not feel sad at all") to 3 (= "I am so sad or unhappy that I can't stand it"). The BDI-FS has excellent internal consistency (Chronbach alpha=.82) and correlates with the depression subscale of the HADS (r=.62) [52].

For the purposes of the present study, the seven items of the BDI-FS were taken from the French version of the BDI-II, which demonstrated satisfactory internal consistency in an administration to 341 French psychiatric patients and 96 control participants and reliably distinguished depressed patients from anxious patients and respondents without any psychiatric symptoms [52].

Beck anxiety inventory

The Beck Anxiety Inventory (BAI) [3] is a 21-item questionnaire intended to gauge the severity of global symptoms of anxiety over the two-week period prior to the administration of the measure. Respondents reply, on a four-point Likert scale (0="not at all", 3="severely—it bothered me a lot") to questions about the intensity of various symptoms related to anxiety that they might have experienced during the month prior to the administration of the questionnaire. These include "numbness or tingling", "heat pounding/racing", and "fear of losing control". Similar to the IES-II and the BDI-FS, the French-language BAI scale has solid internal consistency (Chronbach alphas ranging from .84 to .91) and discriminant validity (r=.25 with the Hamilton Depression Scale) [52].

Hospital anxiety and depression scale

Similar to the BDI-FS, the Hospital Anxiety and Depression Scale (HADS) [4,55] is a 14-item questionnaire designed to detect symptoms of anxiety and depression among patients in hospital settings. The HADS was part of the standard screening procedure at the DCRC; patients were familiar with its questions. We therefore decided to include it as a supplementary measure in our study. Respondents who complete the HADS use Likert scales to indicate their level of agreement with a series of statements that reflect feelings of sadness

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and fear, such as "I feel tense or wound up" (0="never", 3="most of the time") or "I still enjoy things I used to enjoy" (0="definitely as much", 3="hardly at all"). A team of researchers in France [56] investigated the psychometric properties of a French version of the HADS in a population of 2669 outpatients in France across multiple sites. In their study, the HADS demonstrated concurrent validity with the Hamilton Depression Rating Scale.

Results

Of the 27 patients who began the study, nine of them completed all 20 sessions, 12 completed sixteen sessions, and 15 completed at least 12 sessions of CBT. The majority of patients who terminated early did so because they reported in-session that their therapeutic objectives had been met. Preliminary, nonparametric analyses revealed that the first signs of clinically significant change on the HADS, our most general measure of global distress, appeared to take place between sessions one and 12 ($\chi^2(1)=15,00$; $p<.001$). Effect sizes were also noteworthy between sessions one and 12. They were in the small ($d = .43$ for the IES-R), medium ($d=.67$ for the BDI, $d=.65$ for the HADS depression subscale), and large ($d=.97$ for the HADS anxiety subscale, $d=1.19$ for the BAI) ranges. We therefore conducted paired t-tests to compare participants' baseline (TI) scores on all of the measures to their scores after their 12th (T4; n=15), 16th (T5; n=12), and 20th (T6) sessions (n=9). Since patients terminated therapy at different times, we also compared scores after their final session to their initial scores on all instruments, provided that they participated in a minimum of 12 sessions before ending therapy.

Descriptive statistics

Table 1 contains the means and standard deviations of each of the instruments (IES-R, BDI-FS, BAI, HADS) for each time point (baseline, session 12, session 16, session 20, and final session). On average, participating patients were in the moderate-to-clinical range at time 1 on each measure. This reflects the subjective distress that they reported during clinical interviews.

Hypothesis 1: symptoms of depression

Table 1 also contains a summary of the statistical analyses, outlined in detail below.

BDI-FS: We detected significant differences in patient means on the BDI-FS between sessions one and 12 ($t(14)=2.61$, $p=.02$) and between first and final sessions overall $t(14)=3.62$, $p=.003$).

HADS depression subscale: Similarly, there were significant differences in patient means on the HADS between sessions one and 12 ($t(14)=3.05$, $p=.009$), sessions one and 16 ($t(11)=2.66$, $p=.022$), sessions one and 20 ($t(8)=2.56$, $p=.022$), and between their first and final sessions overall ($t(14) = 5.26$, $p<.001$).

Taken together, these results support hypothesis 1, in which we predicted that there would be significant reductions in depressive symptoms over the course of the study.

Hypothesis 2: symptoms of anxiety

BAI: We found significant differences in patient means on the BAI between sessions one and 12 ($t(14)=4.32$, $p=.001$), sessions one and 20 ($t(9)=2.48$, $p=.038$),and between their first and final sessions overall ($t(14)=5.29$, $p<.001$).

HADS anxiety subscale: There were significant differences in patient means on the HADS anxiety subscale between patients' first and final sessions ($t(14)=4.44$, $p=.001$).

The results on the BAI and HADS anxiety subscale support hypothesis 2: Patients' self-reported experience of anxiety decreased over the course of treatment.

Hypothesis 3: symptoms of post-traumatic stress

There were significant differences in patient means on the IES-R between sessions one and 12 ($t(14)=4.45$, $p=.001$), sessions one and 16 ($t(12)=3.14$, $p=.009$), sessions one and 20 ($t(9)=3.62$, $p=.007$), and

between first and final sessions ($t(14)=4.81$, $p<.001$). Overall, there were significant decreases in symptoms of post-traumatic stress between patients' first and final sessions. This supports hypothesis 3, which stipulated significant reduction in symptoms of post-traumatic stress.

Discussion

The results of this pilot study suggest that our CBT intervention for patients suffering from symptoms of depression, anxiety, or post-traumatic stress in conjunction with heart disease was helpful to them. On all measures, their self-reported psychological difficulties decreased significantly between the time they entered treatment and their final session. This corroborates findings from earlier studies that indicate positive effects of psychotherapeutic interventions on symptoms of depression [22,31-34], anxiety [38,39,41], and post-traumatic stress [42,43]. Although the treatment protocol we developed called for 20 sessions of CBT, in most cases patients appeared to make meaningful changes by session 12, which they maintained until termination.

Limitations

Our results must be interpreted with caution for a number of reasons. First, there was no control or comparison group in the present pilot study, which precludes attribution of the changes we observed to our psychological treatment alone. It is possible, for example, that the passage of time or other factors not taken into consideration (e.g., improvements in physical health, favorable socioeconomic conditions) might have contributed to the improvement of patients' psychological functioning. Next, our sample size was small. Of the 27 patients who participated in the study, only nine of them completed all 20 sessions, and only 15 attended the 12 sessions that appeared to be necessary to detect meaningful psychological change. (As previously mentioned, this attrition was due, for the most part, to

Table 1: Descriptive Statistics and t-tests for Outcome Measures at Each Comparison Point

Scale	Time	Mean	SD	t	df	p
IES	T1	33.70	21.90			
	T4	13.73	15.20	4.45	14	0.001
	T5	15.50	16.65	3.14	12	0.009
	T6	14.44	19.87	3.62	9	0.007
	Final	10.13	15.50	4.81	14	0.000
BDI-FS	T1	5.87	4.14			
	T4	3.07	2.99	2.61	14	0.021
	T5	3.83	3.95	2.02	12	0.068
	T6	3.67	4.21	1.14	9	0.280
	Final	2.60	3.00	3.62	14	0.003
BAI	T1	16.80	12.60			
	T4	8.73	6.90	4.32	14	0.001
	T5	11.50	11.71	1.93	12	0.080
	T6	11.11	13.47	2.48	9	0.038
	Final	7.93	9.84	5.29	14	0.000
HADS Anxiety	T1	8.74	4.53			
	T4	6.80	4.92	1.94	14	0.072
	T5	7.17	4.75	1.72	11	0.113
	T6	7.33	5.24	1.49	8	0.175
	Final	4.64	3.43	4.44	14	0.001
HADS Depression	T1	7.26	4.29			
	T4	4.67	3.27	3.05	14	0.009
	T5	5.67	3.80	2.66	11	0.022
	T6	5.22	3.87	2.56	8	0.034
	Final	4.40	3.25	5.26	14	0.000

Note: Separate analyses were conducted comparing T1 to T4, T1 to T5, T1 to T6, and T1 to patients' scores at their final therapy session.

patients stating that their needs had been met.) It is therefore not possible to generalize our findings to the entire population of cardiac patients suffering from depression, anxiety, or post-traumatic stress.

We did not measure in this cross-sectional investigation any long-term outcomes such as the worsening or improvement of psychological or cardiac symptoms, including recurrence, relapse, or death, nor did we examine patients' ability to manage their cardiac symptoms effectively. For these reasons, no conclusions regarding the effects of the psychological treatment employed in this study on the health outcomes of cardiac patients are warranted at this time. However, the results of this study do suggest that our protocol helped improve patients' mental health, which is an important finding vis-à-vis their quality of life.

Finally, as the primary goal of this pilot investigation was to develop and conduct preliminary testing of the potential effectiveness of a new treatment protocol, all of the information about which interventions were used, when, and how was derived from clinicians' reports and from session recordings. The next step in a future project will be to develop a reliable coding scheme to enable systematic treatment fidelity checks by independent observers.

Contributions of the Present Study

Despite the study's limitations, our findings add to the literature because they reveal significant links between a structured, goal-oriented psychological treatment and improvement in a variety of problems in cardiac patients, including symptoms of anxiety and post-traumatic stress that have only been the subject of a handful of scientific investigations. There is some evidence that our treatment worked, which warrants further examination. This positive evidence might be due to a number of factors, including the fact that our sample only included individuals whose psychological symptoms appeared to be directly related to their heart disease, as opposed to others that included patients with a history of psychiatric problems [25-27,32]. The specific elements of the treatment that we designed, and the possibility to adjust the treatment protocol according to patients' needs, might have also played a role in some of the success that we seemed to have.

Details of Psychological Treatment

As per the third and final objective of this paper, we propose to describe in some detail the different components of our intervention. Throughout treatment, therapists provided general information on heart disease, its causes, and its psychological consequences. There were also educational components related to the importance of psychosocial relationships and the usefulness of various interventions, as needed. But information and education were not the bulk of the treatment. This was a specialized intervention, delivered by highly qualified psychological practitioners and residents, with the following specific foci.

Therapeutic relationship

It is difficult to overstate the importance placed on the quality of the therapeutic relationship in the treatment used in the present study. Therapists actively monitored how well their clients were responding to them through active questioning. It is important to note that in addition to providing emotional support, they engaged in active tracking, reflecting, and identifying of patients' thoughts and feelings, which are important aspects of the therapeutic relationship [57].

Cognitive restructuring

Cognitive restructuring was also an essential part of our treatment. This technique involves the systematic identification and challenging of thought patterns or schemas that contribute to the onset and maintenance of symptoms of depression, anxiety, and post-traumatic stress [58]. Some common themes that emerged in our sample, which were related to symptoms of depression and which were the target of cognitive restructuring, included "I'm an invalid and of no use to anyone anymore," "If I ask others for help, I'll become a burden on them and that would be unbearable," "I'm not the person I used to be," "I'm damaged goods," "I'll never be the same anymore and that's unbearable," "Life is not fair and it shouldn't be this way," "It's hopeless, I would have been better off if the heart attack had killed me!", and "I must have done something terrible to deserve this." Thoughts related to symptoms of anxiety in cardiac patients included "I'm having another heart attack!" following innocuous physiological arousal such as sweating or heart palpitations, and "If anything happens to me, no one will be there to care for my loved ones!", also triggered often by signs of physiological arousal.

Patients learned to identify automatic thoughts such as these and to link them to their experience of specific emotions such as fear or sadness in their daily lives. The process of cognitive restructuring then involved teaching them to generate alternative thoughts through Socratic questioning and to transform their perceptions of themselves and the consequences of their illness. As is typical of CBT interventions, clinicians encouraged patients to construe their thoughts and beliefs as hypotheses to be tested through analysis of actual evidence rather than as undeniable truths. For example, we encouraged patients who were convinced that the slightest request for help would lead to complete isolation and abandonment due to the tremendous burden that such a gesture would instill upon their loved ones (i.e., "catastrophizing") [51] to test this belief. We achieved this first through questioning patients about the attitudes and typical behaviors of those close to them and then through behavioral experiments that involved specific attempts at reaching out to loved ones for emotional support. Those who were convinced that they were going to have another heart attack at any sign of physiological reactivity learned to distinguish between dangerous and harmless physical sensations through thorough questioning about their actual experiences both during their heart attack and the often numerous occasions when physiological arousal had no measureable consequence.

It is important to note that the cognitive component to this treatment involved identifying the subjective, personal meanings that patients ascribed to their illness. Although they ultimately worked to help patients alter their subjective perceptions of their illness when these appeared to contribute to feelings of depression or anxiety, therapists were also trained to validate patients' experiences and their suffering in light of their past history and their sense of identity established over a lifetime. We believe that such validation tended to help patients collaborate more effectively with their therapists, most likely because they felt heard and understood.

Behavioral activation

In conjunction with cognitive restructuring, therapists who followed our treatment manual also engaged patients in relationship-oriented behavioral activation. In *all* cases, behavioral activation involved a heavy emphasis on increasing the quality of patients' social networks, given the well-documented effects on physical and emotional health of emotional ties to others [59-62]. Therapists worked to help patients increase not only the number of meaningful social contacts in their daily lives, but also the emotional intimacy characteristic of their social interactions. Cognitive restructuring often revolved around themes of reaching out to others for support in appropriate and effective ways, in an effort to remove obstacles to this interpersonal behavioral activation. These elements were extremely prevalent in treatment, in addition to more typical behavioral activation assignments such as pleasant-events scheduling and the monitoring of enjoyment and mastery of daily activities [63]. In some ways, this type of interpersonal behavioral activation was similar to the supportive components of Albus and colleague's [21] treatment, which was highly successful. Given known links between interpersonal functioning and cardiac health [59], this emphasis on personal relationships might be one of the reasons that the results in the present study were as positive as they seemed to be.

Exposure

For patients experiencing significant anxiety, an important

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component of treatment was exposure, a technique that involves the counter conditioning of acquired responses such as fear in specific situations [64]. For those patients with symptoms of PTSD, exposure involved urging them to tell the story of the anxiety-provoking incident or incidents related to their heart disease in detail, while their therapist inquired as to their subjective units of distress (SUDs) as they did so. Examples included descriptions of the circumstances surrounding their heart attack or surgical intervention for heart disease.

For those patients experiencing anxiety following a diagnosis of heart disease but whose fears were constrained to events they had not actually occurred but that they were convinced would occur (e.g., a return to hospital that would culminate in a complete loss of physical autonomy or death), we incorporated into our treatment protocol a technique known as "the exposure scenario," commonly used in the treatment of Generalized Anxiety Disorder (GAD) [64]. In these instances, cardiac patients wrote a brief script with the help of their therapist that contained detailed images of the imagined scenario, with emphasis on sights, sounds, smells, and physical experiences of difficult emotion. After writing and revising these scenarios with the help of the therapist, patients then completed an exposure exercise similar to the one described above, with the clinician encouraging them to remain in contact with the disturbing scenes until their reported SUDs decreased by half. Patients were then instructed to practice this technique at home on a daily basis in order to gain control over the emotional impact of their thoughts or memories.

Problem-solving techniques and progressive muscle relaxation

Finally, other important components of our treatment included training patients to use effective problem-solving techniques based on quantifiable behavioral goals (e.g., "I want to walk 30 minutes a day for one week") and to engage in progressive muscle relaxation as a way of managing sometimes overwhelming feelings of fear. These techniques, though important, were secondary to the cognitive, interpersonal, and counter conditioning ones.

Conclusion

The results of this pilot study suggest that CBT with a strong cognitive-interpersonal slant might help cardiac patients overcome symptoms of depression, anxiety, and post-traumatic stress related to their heart disease. These results merit further investigation to elucidate potential direct long-term effects on cardiac patients' quality of life, cardiac health improvements, recurrences and relapse, including life expectancy. From a broader health system and health services perspective, the current findings will also be of importance to decision makers and health professionals in specialty care settings such as cardiac rehabilitation clinics, as well as to family physicians and interprofessional teams in primary care clinics, where the majority of cardiac patients with anxiety, depression, or post-traumatic stress are diagnosed and treated.

Ethical Statement

As stated in the body of the text (pp. 13-14):

"All procedures performed with human participants were in accordance with the ethical standards of these institutional research committees (Montfort Hospital, Université du Québec en Outaouais, and the University of Ottawa) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. As such, all participants gave their informed consent to be involved in the study. They were informed that they could withdraw their consent at any time, freely and without consequence. There were no conflicts of interests on the part of any authors of this paper."

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Annex I: Cognitive-Behavioral Treatment (CBT) Protocol

Sessions 1-2: Intake Assessment:

-History of the cardiac event and its psychological consequences (frequency, intensity, duration):

"What does it mean for this person to have this particular illness at this point in time? Is he or she sad? Scared? A combination of both? How do these symptoms manifest themselves?" (e.g., avoidance, clinical depression, etc.).

-Familial, relational, and professional history

-Medical history (experiences with hospitals, physicians, health professionals, experiences with the health-care system in general)

-Socialization to treatment: the interrelation of thoughts, behaviors, and feelings and the CBT focus on modifying thoughts and behaviors in order to modify feeling states

Session 3: Treatment Sessions:

-Presentation to the patient of the cognitive-behavioral conceptualization of his or her presenting problem: links among activating events, thoughts, and behaviors that contribute to the onset and the maintenance of anxious or depressive symptoms

-Revision of the conceptualization in collaboration with the patient

-Establishment of treatment goals in light of the conceptualization

-Discussion of current life stressors that might affect the course of treatment (e.g., financial problems, marital problems)

-Cognitive restructuring: psycho education on the relation between thoughts and feelings

Homework:

Complete a thought record, noting the situations in which the patient experienced strong emotions and the thoughts that accompanied them

Sessions 4-6:

-Pleasant-events scheduling, behavioral activation; identification of barriers to behavioral activation

-Progressive muscle relaxation

-Cognitive restructuring

-Problem-solving exercises

Homework:

Thought record containing alternative thoughts and feelings

Practice relaxation techniques

Evaluation of activities and their effect on mood

Sessions 7-8:

-Behavioral activation (increasing positive interpersonal contacts)

-Cognitive restructuring

-Exposure (primarily for anxiety)

Homework:

Practice exposure

Practice relaxation techniques

Complete thought record replete with alternative thoughts generated by cognitive restructuring. Note impact on emotional experience.

Sessions 9-15:

-Cognitive restructuring: review and integration of different techniques

-Exposure: Continue until the patient is able to discuss the cardiac event or the avoided situations without experiencing significant anxiety

-Problem-solving techniques

-Behavioral activation

Homework:

-*Exposure* (text and *in vivo*)

-*Generate lists of adaptive, alternative thoughts.*

Sessions 16-20:

-Review of therapeutic gains and techniques that the patient found useful

-Preparation for future challenges: reexamination of the specific tools, acquired in therapy, that are now available to the patient in a variety of situations

-Discussion of potential sources of depression or anxiety in the future

-Refinement of coping strategies

-Exposure to any remaining triggers of anxiety