

Anxiety Sensitivity in Panic Disorder

by

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BY

ANDREA L. HAZEN

A Thesis submitted to the Faculty of Graduate Studies of the University of Manitoba in partial fulfillment of the requirements for the degree of

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Abstract

Along with recent research and clinical advances, there has been a proliferation of biological and psychological theories to account for the development and maintenance of panic disorder. Many of these psychological theories are based on a conceptualization of panic disorder as involving a fear of experiencing panic attacks. Among the more influential of the fear-of-fear theories has been anxiety sensitivity theory. The fundamental premise of this theory is that anxiety sensitivity, or beliefs about the negative consequences of anxiety symptoms, plays a critical role in the genesis of panic attacks and panic disorder. The anxiety sensitivity construct has primarily been operationalized through the Reiss-Epstein-Gursky Anxiety Sensitivity Index (ASI). The first study examined the relationship between anxiety sensitivity and treatment outcome. The sample was comprised of one-hundred-and-seventeen subjects [mean age 36.97 years (range 20-73 years)] with a DSM-III-R diagnosis of panic disorder with or without agoraphobia who were participants in a treatment evaluation study conducted by the Anxiety Disorders Clinic, St. Boniface General Hospital. The results suggest that anxiety sensitivity is responsive to cognitive-behavioral treatment and that individuals who are judged to show improvement by an independent assessor also demonstrate a reduction in anxiety sensitivity. The second study compared subjects with panic disorder and social phobia with

respect to overall level of anxiety sensitivity and response profiles on individual ASI items. The sample consisted of 47 subjects with panic disorder with or without agoraphobia [mean age 38.36 years (range 21-58 years)] and 47 subjects with social phobia [mean age 36.70 years (range 18 to 58 years)]. The results revealed that subjects with panic disorder had significantly higher Anxiety Sensitivity Index scores than subjects with social phobia. Furthermore, the panic disorder group obtained higher scores on items assessing fear of somatic symptoms associated with anxiety and the consequences of those symptoms, whereas the social phobia group obtained higher scores on items relevant to concerns about the social consequences of anxiety. The implications of the findings for research and clinical applications are addressed, and suggestions for future research are provided.

Anxiety Sensitivity in Panic Disorder

Panic disorder is characterized by the occurrence of sudden, intense episodes of anxiety referred to as panic attacks. These attacks are accompanied by a variety of somatic and cognitive symptoms, such as shortness of breath, dizziness, palpitations, nausea, and fear of dying. A diagnosis of panic disorder is made if an individual experiences at least four panic attacks in a four week period or one or more panic attacks are followed by a period lasting at least a month in which the individual is persistently worried about the occurrence of additional attacks (DSM-III-R; American Psychiatric Association, 1987). In cases in which the panic disorder is accompanied by phobic avoidance, the diagnosis of panic disorder with agoraphobia is assigned. Typical agoraphobic situations include being at home alone, standing in line, travelling by bus or car, and being in crowded places, such as shopping malls, restaurants, and churches. The central concern related to these situations is fear of having a panic attack and being incapacitated or unable to escape.

Panic disorder (with or without agoraphobia) is a relatively common syndrome which is frequently encountered in general practice and mental health settings (Boyd, 1986; Katon, 1984). Epidemiologic findings indicate a lifetime prevalence of approximately 4%, and a six-month prevalence of approximately 3% (Wittchen & Essau, 1991). Research has shown that individuals with panic disorder are at increased risk for other mental health

problems, including suicide attempts (Weissman, Klerman, Markowitz, & Ouellette, 1989), affective disorders (e.g., Brier, Charney, & Heninger, 1984; De Ruiter, Rijken, Garssen, Van Schaik, & Kraaimaat, 1989; Stein, Tancer, & Uhde, 1990), and substance abuse (see Cox, Norton, Swinson, & Endler, 1990). The disorder is often complicated by impairment in social, occupational, and family functioning (Markowitz et al., 1989), which serves to underscore its serious and distressing nature. In light of these findings, it is not surprising that the last decade has witnessed a considerable increase in research and clinical interest in what is considered a serious mental health problem.

Along with recent research and clinical advances, there has been a proliferation of biological (see Stein & Uhde, in press) and psychological theories to account for the development and maintenance of panic disorder. Many of the psychological theories which have been advanced are based on a conceptualization of the disorder as involving a fear of experiencing panic attacks (McNally, 1990). Perhaps most influential among these fear-of-fear theories have been interoceptive conditioning theory, cognitive models involving the catastrophic misinterpretation of symptoms, and anxiety sensitivity theory.

Interoceptive Conditioning Theory

An interoceptive conditioning account of the fear-of-fear

was first proposed by Goldstein and Chambless (1978). They suggested that fear-of-fear develops primarily as a result of experiencing panic attacks. It was hypothesized that individuals who tend to misinterpret anxiety symptoms as resulting from illness or disease are particularly vulnerable to developing a fear of anxiety. According to the theory, an individual who experiences panic attacks becomes overly attentive to the bodily sensations of anxiety, fearing that these symptoms signal an impending panic attack. This fear, in turn, leads to higher levels of anxiety, with the cycle culminating in a panic attack. Goldstein and Chambless (1978) suggested that fear-of-fear is acquired through a process of Pavlovian interoceptive conditioning. Essentially, the internal bodily sensations associated with anxiety (e.g., tachycardia, dyspnea) are believed to function as conditioned stimuli for the conditioned response of panic attacks. Through higher order conditioning, other stimuli may also become conditioned stimuli for panic attacks. Thus, agoraphobic avoidance is accounted for by the fact that phobic situations can become higher-order conditioned stimuli that elicit anxiety.

Barlow (1988) recently proposed a model of panic disorder which incorporates Goldstein's and Chambless' (1978) ideas regarding interoceptive conditioning of fear-of-fear responses. The model postulates that individuals who develop panic disorder tend to be neurobiologically sensitive to stressors occurring in

their lives. This genetically-based sensitivity makes them vulnerable to eventually experiencing a panic attack when faced with stressful events. Barlow (1988) proposed that, following the initial panic attack, a process of interoceptive conditioning is likely to occur in which an association is acquired between internal stimuli and panic attacks. In this way, internal (i.e., somatic and/or cognitive) stimuli become cues which signal the possibility of having a panic attack. This interoceptive conditioning process is then followed by the development of anticipatory anxiety regarding the occurrence of future panic attacks and hypervigilance for internal cues which may signal an impending attack.

The interoceptive conditioning model of panic has been subject to criticism on several fronts. The lack of empirical support has been cited as a weakness of the theory (Reiss, 1988). Although Goldstein and Chambless (1978) cited the work of Razran (1961) as illustrating the conditioning process involved in the acquisition of the fear-of-fear response, critics (McNally, 1990; Reiss, 1988) have argued that none of Razran's procedures demonstrate an aversive interoceptive conditioning paradigm which could account for the acquisition of fear responding. Moreover, concern has been expressed that the conditioned stimulus and conditioned response involved in the interoceptive conditioning model of fear-of-fear have been ambiguously defined (McNally, 1990). Because a panic attack is itself defined as a sudden rush

of somatic sensations, the distinction between the conditioned stimuli (internal, bodily sensations) and the conditioned response is blurred. Furthermore, Reiss (1988) has raised an objection to the construal of both the conditioned and unconditioned stimuli as reinforcing stimuli. In Pavlovian conditioning, the conditioned stimulus is generally a nonreinforcing stimulus. Reiss (1988, p.84) has noted that:

The theory holds that a reinforcing stimulus can become "conditioned" to itself, but it is not obvious that this can happen. For example, intense sexual experiences do not seem to condition mild feelings of sexual arousal to peak sexual feelings, and intense feelings of starvation do not seem to condition mild feelings of hunger to peak feelings of starvation. Given these observations, it is not obvious that panic should condition mild feelings of anxiety to peak feelings of anxiety.

Despite these conceptual problems, the interoceptive model has played an important role in the development of effective treatments involving exposure to feared internal stimuli and influenced the development of more recent fear-of-fear conceptualizations of panic disorder.

Cognitive Theories

Several cognitive theories have invoked the fear-of-fear construct in accounting for the occurrence of panic (e.g., Beck & Emery, 1985; Clark, 1986). These models are probably more aptly

described as psychophysiological models since they postulate that a panic attack involves a feedback loop operating between physiological arousal and the cognitive appraisal of somatic symptoms. This feedback loop is believed to be activated when some physiological or cognitive change occurs, which may be due to various causes such as caffeine ingestion or physical exertion (Ehlers, Magraf, & Roth, 1988). These sensations are alarming to the individual because they are interpreted as signals of impending danger, which Clark (1986) refers to as "catastrophic misinterpretation" of symptoms. Generally, the impending threat is related to some physical or mental illness. For example, an "unexplainable" symptom, such as a feeling of depersonalization, may be interpreted as a sign of going crazy. The individual becomes anxious as he or she begins to engage in catastrophic thinking about the impending threat, which leads to an increase in physiological arousal, and this increase in symptoms, in turn, produces additional catastrophic thinking and a further escalation of anxiety. Within a relatively short period of time, this cycle is believed to culminate in the occurrence of a panic attack. The basic premise of this cognitive model of panic has been adapted by anxiety sensitivity theory, which will be considered next.

Anxiety Sensitivity Theory

The concept of anxiety sensitivity was first introduced in the context of Reiss and McNally's (1985) expectancy model of

fear. The theory posited that two factors account for fears: (1) danger expectancy, which refers to expectations of harm or danger evoked by a feared stimulus; (2) the combination of anxiety expectancy and anxiety sensitivity. Anxiety expectancy refers to expectations of becoming anxious which are evoked by a feared stimulus, and anxiety sensitivity refers to fears of becoming anxious. The two fundamental factors, then, which motivate avoidance of feared stimuli are expectations that the stimuli are dangerous and expectations that they are anxiety-arousing. For example, an individual's fear of flying would be said to be motivated by danger expectancy if he or she was afraid of the airplane crashing while in flight. Other fears are motivated by the expectation of becoming anxious when the feared stimuli are encountered (Reiss & McNally, 1985). For instance, a person might be afraid of writing an exam because he or she expects to become extremely anxious to the point of fainting during the exam. The expectancy model of fear was later expanded by Reiss (1991) to include the fear of negative evaluation as another key component involved in fear responding. Thus, three fundamental fears were proposed to account for fearfulness: fear of injury, fear of anxiety (i.e., anxiety sensitivity), and fear of negative evaluation.

Reiss and McNally's (1985) construal of the fear-of-fear was represented by the concept of anxiety sensitivity. Unlike the previously considered cognitive models, the expectancy model of

fear defined anxiety sensitivity as a *dispositional* variable involving beliefs about the negative consequences of anxiety symptoms, rather than a situational variable. The more beliefs an individual holds about the harmful consequences of anxiety, and the more strongly these beliefs are held, the greater the level of anxiety sensitivity. Hence, the theory recognizes that there are individual differences in the fear of anxiety. An individual who has a low level of anxiety sensitivity would be expected to regard anxiety symptoms as uncomfortable but harmless. However, a person with a high level of anxiety sensitivity would hold beliefs that anxiety symptoms are harmful and is likely to become quite anxious upon experiencing any unusual bodily sensations (McNally, 1990). For example, an individual with heightened anxiety sensitivity might be afraid of experiencing heart palpitations, a common somatic symptom of anxiety, because he or she fears that this symptom signals an impending heart attack.

Reiss and McNally's (1985) theory speculated that anxiety sensitivity might be a predisposing factor in the development of anxiety disorders. Theoretically, a person with heightened anxiety sensitivity who begins to experience mild anxiety symptoms as a result of worrying about a stressful life event should also become anxious about potential negative consequences arising from the anxiety symptoms, such as fears of having a heart attack or going crazy. The worry about anxiety symptoms

should, in turn, increase the individual's overall level of anxious arousal. This "vicious cycle" is likely to culminate in a panic attack, and hence, anxiety sensitivity is believed to be a risk factor in the development and maintenance of anxiety disorders in general, and panic disorder in particular (Reiss, 1987). Although the theory suggests that anxiety sensitivity is particularly important in explaining the development of panic attacks and panic disorder, it is not assumed that anxiety sensitivity is uniquely associated with panic disorder. The empirical support for the various hypotheses proffered by anxiety sensitivity theory will be considered in the following sections of this paper.

The Anxiety Sensitivity Index

The anxiety sensitivity construct has primarily been operationalized through the Reiss-Epstein-Gursky Anxiety Sensitivity Index (ASI) (Reiss et al., 1986). (The ASI is presented in Appendix A). It is a self-report measure containing 16 items pertaining to fear of anxiety symptoms and catastrophic consequences resulting from the symptoms (e.g., "It scares me when I feel faint"; "When I notice that my heart is beating rapidly, I worry that I might have a heart attack").

The psychometric properties of the Anxiety Sensitivity Index have been extensively investigated. With regard to internal reliability, alpha coefficients ranging from .82 to .91 have been obtained (see Peterson & Reiss, 1992). In addition, interitem

correlations have been reported for two college samples (Reiss et al., 1986). For the first sample, 41.7% of the interitem correlations were statistically significant, and for the second sample, 73.3% of the interitem correlations were significant. The means for the significant interitem correlations were .42 and .35 for the respective samples. Adequate test-retest reliability of the ASI has also been reported. Test-retest reliability of .75 has been found for a two-week interval (Reiss et al., 1986) and .71 for a three-year interval (Maller & Reiss, 1992).

A brief version of the ASI has recently been developed as a screening measure for panic disorder (Apfeldorf, Shear, Leon, & Portera, 1994). It contains the following four items: "It scares me when I feel shaky"; "It scares me when I feel faint"; "It scares me when my heart beats rapidly"; "It scares me when I become short of breath". The items are scored on the same 5-point Likert scale used in the original measure; thus, the total score can range from 0 to 16. Apfeldorf et al. (1994) have reported a mean score of 12.6 for panic disorder subjects and 7.5 for other anxiety disorders. In their sample, a cut-off score of 11 correctly classified 75% of the panic disorder subjects. Preliminary evidence suggests that this version of the ASI may be a useful screening measure for panic disorder; however, further investigation of its psychometric properties is needed.

Factor structure of the Anxiety Sensitivity Index. Anxiety expectancy theory suggests that anxiety sensitivity is a unitary

construct (Reiss & McNally, 1985). Accordingly, it would be expected that the Anxiety Sensitivity Index would be comprised of a unitary factor structure. Although some findings have supported this prediction, other results have suggested that the ASI has a multifactorial structure. In the first study to investigate the factor structure of the ASI, a principal component analysis conducted on data from two samples of college students derived a single-factor structure, with 13 of the 16 items loading 0.4 or greater on the first factor (Reiss et al., 1986). This factor explained 34% and 35% of the total variance for each respective sample. Taylor, Koch, and Crockett (1991) also obtained a single-factor solution with a clinical sample of outpatients and a non-clinical sample of spider-phobic university students. In this investigation, the single factor solution accounted for 42% of the variance in the clinical sample and 30% in the student sample.

Several studies, however, have reported multifactorial solutions for the ASI. Peterson and Heilbronner (1987) conducted a principal components analysis which yielded a four-factor solution, accounting for 61% of the total variance. The factors were associated with: (a) fear of cognitive symptoms; (b) concerns about maintaining control of symptoms; (c) fear of cardiopulmonary and gastrointestinal symptoms; and (d) fear of fainting and trembling (Peterson, 1990; cited in Taylor, Koch, McNally, & Crockett, 1992). Because only a few items loaded on

each factor, Peterson and Heilbronner (1987) suggested that the factors may be unreliable. Hence, they concluded that the ASI should be viewed as unifactorial, pending further investigation of the factor structure. The results of two subsequent studies also suggested that the ASI is composed of a multifactorial structure. Telch, Shermis, and Lucas (1989), using a principal components analysis with varimax rotation, derived a four-factor solution which accounted for 53.5% of the total variance. The factors pertained to concerns about: (a) physical symptoms (in particular, fainting or nausea); (b) mental/cognitive incapacitation; (c) loss of control; and (d) cardio/pulmonary failure. Using a principal components analysis with varimax rotation, Wardle, Ahmad, and Hayward (1990) also found a four-factor solution for both a sample of outpatients and a sample of normal controls. The four-factor solution accounted for 60% of the variance in the clinical group and approximately 62% of the variance in the control group. The factors derived for the clinical group were: (a) concern about physical sensations, particularly cardiovascular symptoms; (b) concern about loss of mental capacities; (c) concern about gastrointestinal symptoms; and (d) concern about maintaining emotional control. The factor structure for the control sample was less coherent and therefore, difficult to interpret.

A recent study sought to resolve the inconsistencies associated with the factor structure of the ASI by performing a

confirmatory factor analysis (Taylor, Koch, McNally, & Crockett, 1992). This procedure evaluates competing solutions and was used to assess the single-factor as well as the various four-factor solutions obtained in previous research (i.e., Peterson & Heilbronner, 1987; Telch Shermis, & Lucas, 1989; Wardle et al., 1990). Although the four-factor solution derived by Telch, Shermis, and Lucas (1989) was found to provide the best "goodness-of-fit" compared to the competing solutions, the authors (Taylor, Koch, McNally, & Crockett, 1992) noted that this solution was only viable when the factors were forced to orthogonality. If this constraint was not imposed, the factors were highly intercorrelated. Hence, Taylor, Koch, McNally, and Crockett (1992) recommended that the ASI should be considered unifactorial. They found that the single-factor solution explained 42% of the variance in the clinical sample and 30% of the variance in the nonclinical sample.

Given that the majority of available findings support Reiss et al.'s (1986) contention that the ASI is unifactorial, it has been recommended that the total score should be used as the primary score for research and clinical purposes (Peterson & Reiss, 1992). Nevertheless, it is well recognized that certain items do not load very highly on the principal factor of the ASI. Taylor and his colleagues (Taylor, Koch, & Crockett, 1991; Taylor, Koch, & McNally, 1992; Taylor, Koch, McNally, & Crockett, 1992) have conducted factor analyses which have consistently

suggested that the ASI is primarily a measure of the fear of bodily sensations, and items which assess the social consequences of anxiety (i.e., items 7, 13, and to a lesser extent item 1) tend not to load as highly on this factor. Indeed, Taylor, Koch, McNally, & Crockett (1992; p.250) have recommended that "the social-evaluative items of the ASI (e.g., Items 7 and 13) should be deleted from the scale because they blur the distinction between anxiety sensitivity and the fear of negative evaluation". However, this issue is not as clear-cut as it appears. If Items 7 and 13 are actually better measures of the fear of negative evaluation than the anxiety sensitivity construct, then factor analysis should demonstrate that these items do indeed load on a "fear of negative evaluation" factor. However, a factor analysis of the items from the ASI, Fear of Negative Evaluation Scale, and a measure of injury sensitivity failed to verify this prediction (Taylor, 1993a). In fact, items 1 and 5 of the ASI loaded on a "fear of negative evaluation" factor but items 7 and 13 did not (i.e., loadings were $<.30$), suggesting that further investigation of these items is needed before the scale is revised.

Anxiety Sensitivity and the Anxiety Disorders

Since Reiss and McNally (1985) first proposed the expectancy model of fear, a sizeable body of literature has emerged demonstrating a relationship between anxiety sensitivity and various anxiety-related phenomena. This literature has provided support for the validity of both anxiety sensitivity theory and

the ASI.

One of the central tenets of anxiety sensitivity theory is the prediction that fear of anxiety may function as a psychological risk factor in the development of anxiety disorders. Accordingly, considerable attention has focused on investigating anxiety sensitivity among the various anxiety disorders. For instance, research has found that college student samples of blood phobics (Lumley & Melamed, 1992) and individuals with a history of fainting due to blood-injury fears (Kleinknecht, 1988) report greater anxiety sensitivity than control subjects. In addition, anxiety sensitivity has been shown to be related to the severity of generalized anxiety symptoms in college students (Gross & Eifert, 1990).

It has also been demonstrated that individuals with agoraphobia (Ahmad, Wardle, & Hayward, 1992; McNally & Lorenz, 1987; Reiss et al., 1986) and panic disorder (Rapee, Ancis, & Barlow, 1988) score higher than normal controls on the Anxiety Sensitivity Index. Further, subjects with panic disorder report higher levels of anxiety sensitivity than nonclinical panickers, who in turn score higher than non-panickers (Cox, Endler, & Swinson, 1991; Rapee et al., 1988; Telch, Lucas, & Nelson, 1989). Individuals with post-traumatic stress disorder also report heightened anxiety sensitivity, with ASI scores approximating those found with panic disorder subjects (McNally et al., 1987).

To date, four studies have investigated whether anxiety

sensitivity can discriminate panic disorder from other anxiety disorders. Reiss et al. (1986) found that agoraphobics had higher anxiety sensitivity scores than a mixed group of other anxiety disorders (i.e., obsessive compulsive disorder, social phobia, and simple phobia), and in turn, the mixed anxiety disorders group had higher scores than a sample of college students. Two other studies (Apfeldorf et al., 1994; Taylor, Koch, & Crockett, 1991) have also demonstrated that subjects with panic disorder scored significantly higher on the Anxiety Sensitivity Index than a combined group of subjects with other anxiety disorders. Only one paper has reported anxiety sensitivity levels for each of the six anxiety disorders classified by DSM-III-R (Taylor, Koch, & McNally, 1992). This study found that anxiety sensitivity levels were higher for each of the anxiety disorders, with the exception of simple phobia, when compared to normal controls. Subjects with panic disorder reported significantly higher ASI scores than the other anxiety disorder groups, except for the post-traumatic stress disorder group. Although not significant, there was a trend for the panic disorder group to have higher anxiety sensitivity scores than the post-traumatic stress group.

There has also been interest in examining whether particular items of the ASI discriminate panic disorder from the other anxiety disorders. Individuals with panic disorder have been shown to score higher than subjects with other anxiety disorders

on ASI items assessing fear of bodily sensations but not on items assessing fear of social consequences or loss of emotional control (Taylor, Koch, & Crockett, 1991). More recently, Taylor, Koch, & McNally (1992) found that subjects with panic disorder had significantly higher scores than a mixed group of other anxiety disorders (i.e., generalized anxiety disorder, obsessive compulsive disorder, social phobia, and simple phobia) on all ASI items, with the exception of two items assessing the social consequences of anxiety. In addition, panic disorder subjects scored higher than subjects with posttraumatic stress disorder on ASI items assessing fear of cardiopulmonary symptoms, gastrointestinal symptoms, and "unusual" bodily sensations, but they did not differ on items pertaining to concerns about concentration or trembling. Although there are slight discrepancies in the findings of previous research, the results generally indicate that subjects with panic disorder tend to score higher than other anxiety disorders on ASI items assessing the fear of bodily sensations. These findings are not surprising, given that various cognitive theories of panic (e.g., Beck & Emery, 1985; Clark, 1986), including anxiety sensitivity theory, have postulated that misinterpretation of bodily symptoms associated with anxiety plays a central role in the genesis of panic disorder.

Thus, the available research evidence suggests that anxiety disorders, and panic disorder in particular, are characterized by

heightened anxiety sensitivity. The relationship between anxiety sensitivity and panic disorder will be considered further in the following section.

Anxiety sensitivity, panic attacks, and panic disorder.

Anxiety sensitivity theory accounts for the finding of elevations in anxiety sensitivity among subjects with panic disorder by the hypothesized relationship between anxiety sensitivity and the occurrence of panic attacks (McNally, 1990; Reiss & McNally, 1985; Reiss, 1991). Specifically, the theory suggests that an individual with high anxiety sensitivity who experiences unusual bodily symptoms is likely to misinterpret these sensations, fearing that they may be associated with catastrophic consequences such as an impending heart attack. Fear of the anxiety symptoms should heighten the intensity of anxious arousal, thereby increasing the likelihood that the symptoms will spiral into a panic attack. Therefore, a vicious cycle is believed to occur, in which anxiety sensitivity increases the likelihood of experiencing panic attacks, and the occurrence of panic attacks, in turn, increases anxiety sensitivity (Reiss, 1987, 1991). Furthermore, it has been suggested that anxiety sensitivity: (1) is related to the frequency of panic attacks; (2) increases the intensity of panic attacks; (3) interferes with an individual's ability to cope with panic attacks; and (4) is a risk factor for the development of panic attacks and panic disorder (Peterson & Reiss, 1992). The empirical evidence for

each of these hypothesized relationships will be considered in turn.

The prediction of anxiety expectancy theory that anxiety sensitivity is associated with the occurrence of panic attacks has stimulated a considerable body of research. Studies have found that non-clinical subjects who had experienced panic attacks scored higher on anxiety sensitivity than non-panickers (Brown & Cash, 1990; Brown & Deagle, 1992). Anxiety sensitivity has also been found to be related to the occurrence of spontaneous nocturnal panic attacks in a university student sample (Craske & Krueger, 1990).

A series of studies have investigated the relationship between different levels of anxiety sensitivity and the occurrence of non-clinical panic attacks in college students. In the first study to investigate this relationship, subjects were assigned to high, medium or low anxiety sensitivity groups based on their ASI scores and then compared on a number of variables related to panic disorder (Donnell & McNally, 1990). Subjects in the high anxiety sensitivity group were significantly more likely to have received treatment for psychopathology and to have a family history of panic than the subjects in the medium anxiety sensitivity group. The authors also reported that approximately 32.4% of the subjects in the high anxiety sensitivity group had experienced a spontaneous panic attack, as defined by DSM-III-R, in the previous 12 months as compared to 15.6% in the medium

anxiety sensitivity group and 5.1% in the low anxiety sensitivity group. The number of subjects reporting panic attacks in the high anxiety sensitivity group was significantly greater than in the medium anxiety sensitivity group.

Donnell and McNally's (1990) study has been criticized for assessing only spontaneous panic attacks since there is evidence that nonclinical subjects are more likely to experience cued, rather than spontaneous, panic attacks (Cox, Endler, Norton, & Swinson, 1991). To address this limitation, Cox, Endler, Norton, and Swinson (1991) conducted a study which examined the relationship between anxiety sensitivity and both spontaneous and cued non-clinical panic attacks. The results indicated that subjects in the high and medium anxiety sensitivity groups did not significantly differ on the occurrence of spontaneous panic attacks. However, the number of subjects reporting spontaneous or cued panic attacks in the high anxiety sensitivity group was significantly greater than in the medium anxiety sensitivity group (i.e., 50% vs 20%). Meanwhile, Asmundson and Norton (1993) found that a greater proportion of high anxiety sensitive subjects reported experiencing *both* spontaneous *and* cued panic attacks as compared to medium anxiety sensitive subjects. The results of these studies support the relationship between anxiety sensitivity and the occurrence of panic attacks predicted by anxiety sensitivity theory (Reiss, 1991; Reiss and McNally, 1985).

There is also evidence to suggest that anxiety sensitivity is associated with the *frequency* of panic attacks. Studies have found a correlation between anxiety sensitivity levels and frequency of self-reported panic attacks in college student samples (Jasnoski et al., 1990, Jasnoski et al., 1991; cited in Peterson & Reiss, 1992). Anxiety sensitivity scores have also been shown to predict frequency of panic attacks reported at a three-year follow-up assessment (Maller & Reiss, 1992).

To date, only one published study has reported data confirming the prediction that anxiety sensitivity is associated with the *intensity* of panic attacks. Maller and Reiss (1992) found that anxiety sensitivity levels assessed in 1984 predicted the intensity of panic attacks reported in 1987. Frequency and intensity of panic attacks were assessed by self-report questionnaire and structured interview.

Another area that has virtually been ignored by researchers is the relationship between anxiety sensitivity and ability to cope with panic attacks. A review of the current literature found no studies that directly examined this relationship. However, a few studies have investigated the association between anxiety sensitivity and phobic avoidance. Theoretically, the more an individual is afraid of anxiety, the more he or she would be expected to avoid situations that might induce anxiety (or panic attacks in particular) (McNally & Lorenz, 1987). With regard to the relationship between anxiety sensitivity and

avoidance behavior, mixed results have been reported. McNally and Lorenz (1987) reported that the Anxiety Sensitivity Index did not significantly correlate ($r = .20$) with the Agoraphobia subscale of the Fear Questionnaire, a commonly used measure of agoraphobic avoidance. However, as suggested by Taylor (1993a), the lack of a significant relationship may have been due to the fact that a limited range of scores was obtained with the clinical sample. Moreover, anxiety sensitivity has been found to be associated with severity of phobic avoidance in another study (Pollack et al., 1990).

According to anxiety expectancy theory (Reiss & McNally, 1985), heightened anxiety sensitivity may precede the onset of an anxiety disorder and thereby serve as a potential risk factor for its development. One line of research that has been cited in support of this contention is the investigation of anxiety sensitivity in non-clinical panickers. This research has found that between 40 and 70% of subjects with high levels of anxiety sensitivity have never experienced a panic attack (Asmundson & Norton, 1993; Cox, Endler, Norton, & Swinson, 1991; Donnell & McNally, 1990). The implications of these findings are two-fold. First, the results imply that fear of anxiety may be acquired through channels other than direct experience with panic attacks. McNally (in press) has speculated that observational learning and exposure to misinformation about symptoms may be alternative mechanisms through which heightened levels of anxiety sensitivity

can be acquired. Second, because elevations in anxiety sensitivity can occur in the absence of direct experience with panic attacks, it can be inferred that elevations in anxiety sensitivity can precede, and therefore potentially act as a predisposing factor in the development of anxiety disorders in general, and panic disorder in particular.

To date, only one longitudinal study has addressed this issue. In this investigation, subjects were first administered the Anxiety Sensitivity Index in 1984 and then reevaluated three years later (Maller & Reiss, 1992). Results indicated that initial Anxiety Sensitivity Index scores predicted the severity and frequency of panic attacks reported by subjects at the second assessment. The authors also noted that "subjects with high ASI scores in 1984 were five times more likely to have an anxiety disorder during 1984 to 1987 than subjects with low ASI scores in 1984" (p. 245). While the data support the suggestion that elevated anxiety sensitivity may be a risk factor for the development of anxiety disorders, this finding should be regarded as preliminary because of the relatively small sample size (N = 23 in the high ASI group and N = 25 in the low ASI group). Clearly, additional longitudinal research is needed to investigate the role of anxiety sensitivity in the development of anxiety disorders. Ideally, this would involve following subjects (either adults or children) with high and low levels of anxiety sensitivity over an extended time period. Until such

research is conducted, the status of anxiety sensitivity as an etiologic variable in the development of anxiety disorders cannot be resolved. Ultimately, it may be found that heightened anxiety sensitivity represents a vulnerability factor for anxiety disorders but experience with anxiety symptoms (e.g., panic attacks) exacerbates fear of anxiety (Reiss, 1991). If anxiety sensitivity is indeed a risk factor for the development of anxiety disorders, then education about accurate labelling and interpretation of anxiety symptoms and their consequences may be a critical component of prevention efforts (Otto, Pollack, Sachs, & Rosenbaum, 1992). The effectiveness of such an approach is a question for future research.

Anxiety sensitivity and other clinical variables.

Unfortunately, there is little information available about the relationship between anxiety sensitivity and other clinical variables in individuals with panic disorder. One study has presented preliminary data suggesting that anxiety sensitivity is associated with a more persistent course, and with comorbid anxiety, affective, and personality disorders in individuals with panic disorder (Pollack et al., 1990). Additional research is needed to replicate these results and investigate the relationship between anxiety sensitivity and indices of severity in other anxiety disorders.

Recently, studies have investigated the relationship between anxiety sensitivity and other clinical features in individuals

with panic disorder. Otto et al. (1992) examined the relationship between hypochondriacal concerns and several variables, including anxious mood, depressed mood, anxiety sensitivity, number of panic attacks per week, and severity of phobic avoidance. Results from regression procedures indicated that hypochondriacal concerns were most strongly associated with anxiety sensitivity, even after controlling for the effects of anxious and depressed mood.

Stewart, Knize, and Pihl (1992) investigated anxiety sensitivity and dependent personality traits in individuals with panic disorder, nonclinical panickers, and nonpanickers. There were no differences between the non-clinical groups (i.e., panickers versus nonpanickers) with regard to anxiety sensitivity or dependency traits. However, the subjects with panic disorder obtained significantly higher scores on anxiety sensitivity and the "lack of social self-confidence" subscale of the dependency measure used in the study. Moreover, the ASI was found to correlate significantly with overall dependency scores, and with specific subscale scores measuring emotional reliance on others and lack of social self-confidence.

Zeitlin and McNally (1993) investigated the relationship between anxiety sensitivity and alexithymia in individuals with panic disorder and obsessive compulsive disorder. Alexithymia is characterized by difficulties in labelling and expressing feelings and by concrete speech and thought. The authors

hypothesized that subjects with panic disorder may constrict emotional experience in order to avoid feared anxiety symptoms; hence, anxiety sensitivity and alexithymia should be strongly associated. Consistent with this prediction, the results demonstrated that subjects with panic disorder were more alexithymic than individuals with obsessive compulsive disorder, and scores on the alexithymia and anxiety sensitivity scales were highly correlated. Interestingly, Lilienfeld, Turner, and Jacob (1993) recently proposed a theoretical model which relates anxiety sensitivity to the personality variables of negative emotionality and constraint, a concept which appears to overlap with the alexithymia construct. In this model, the anxiety sensitivity construct is viewed as being a composite of negative emotionality and constraint; thus, an individual with heightened anxiety sensitivity is expected to be prone to experiencing negative affect, including anxiety, and to fear these affective states. It remains to be determined by future research whether the Lilienfeld et al. (1993) and other models relating anxiety sensitivity and personality variables can contribute to our understanding of the development and maintenance of panic disorder.

Anxiety Sensitivity and Treatment Outcome

Relatively few studies have investigated the impact of treatment on anxiety sensitivity. A case study reported by McNally (1986) provided the first evidence that anxiety

sensitivity decreases following treatment for anxiety disorders. In this study, a 30-year old man with a choking phobia was successfully treated with behavior therapy, with his ASI scores showing a marked decrease from pre- to post-treatment (i.e., from 40 to 10). In a later study, McNally and Lorenz (1987) found that the mean anxiety sensitivity score for a group of agoraphobic patients significantly decreased to the non-clinical range following behavioral treatment. Although 6 of the 48 subjects did not demonstrate a significant reduction in anxiety sensitivity at post-treatment, their ASI scores continued to decline in the follow-up period. For 4 of the 6 subjects, their 6-month follow-up score was at or below the normative mean (Peterson & Reiss, 1987). Although conclusions are limited by the fact that a wait-list control group was not employed in the study, the results suggest that reductions in anxiety sensitivity can be obtained with cognitive-behavioral treatment. Similarly, Stoler and McNally (1991) demonstrated that untreated agoraphobics had significantly higher ASI scores than recovered agoraphobics, who in turn had significantly higher scores than normal control subjects. Another study (Saviotti et al., 1991) compared levels of anxiety sensitivity in subjects with panic disorder with agoraphobia who had demonstrated improvement in symptoms following participation in a behavioral treatment program and a matched healthy control group. Results indicated that the subjects with panic disorder scored significantly higher

on the Anxiety Sensitivity Index than the controls, with the mean score of the clinical group over one standard deviation above the normative mean (Peterson & Reiss, 1992). The fact that anxiety sensitivity levels were quite elevated in the subjects with panic disorder following successful treatment led the researchers to speculate that anxiety sensitivity may be an enduring personality characteristic that is a risk factor for developing panic disorder. Due to limitations associated with the "post-test only" research design used in the study, this conclusion should be considered with caution. First, the design does not allow a determination of whether elevations in anxiety sensitivity preceded or followed the development of panic disorder; thereby limiting the ability to evaluate the etiologic role of anxiety sensitivity in the development of panic disorder. A longitudinal research design is needed to definitively investigate whether anxiety sensitivity is a risk factor for panic disorder. Second, due to the fact that assessment occurred on only one occasion (i.e., 2 to 3 months post-treatment), it is impossible to make any conclusions regarding the stability of anxiety sensitivity levels. Because baseline levels of anxiety sensitivity were not assessed, treatment effects cannot be definitively evaluated. Clearly, additional research is needed in this area. Future research efforts should be directed towards addressing the methodological limitations of previous studies and investigating new research questions, such as comparing the effects of

cognitive-behavioral and pharmacological treatment on anxiety sensitivity.

The Role of Anxiety Sensitivity in Anxiety Induction Paradigms

With the rise in influence of biological theories of panic disorder in recent years, there has been a great deal of interest in "challenge" paradigms to investigate possible biological markers for the disorder. These challenge tests have involved hyperventilation procedures or the administration of substances such as sodium lactate, caffeine, or isoproterenol (see Magraf, Ehlers, & Roth, 1986; Stein & Uhde, in press; Uhde & Stein, 1988) and have been shown to produce panic attacks in individuals with panic disorder. Biological theorists have argued that the response to challenge tests provides evidence of an underlying biologic abnormality in panic disorder (see Stein & Uhde, in press; Uhde & Stein, 1988). However, researchers have also suggested that cognitive factors may mediate the response to panic-provocation procedures (e.g., Magraf et al., 1986). According to this view, panic is believed to result from the misinterpretation of bodily symptoms produced by the challenge agent. Accordingly, several recent studies have investigated the role of anxiety sensitivity in biological challenge and other anxiety induction procedures. In one study, subjects who were classified as high or low in anxiety sensitivity were required to speak about anxiety-related and neutral material (Maller & Reiss, 1987). The results showed that the subjects in the high anxiety

sensitivity group, compared to subjects in the low anxiety sensitivity group, demonstrated greater anxiety when discussing anxiety related topics but not when discussing neutral topics. Anxiety levels were assessed through self-report and a behavioral measure of speech dysfluencies. Another study (Rapee, Brown, Antony, & Barlow, 1992) examined several potential predictors of affective response to hyperventilation and CO₂ challenge (i.e., anxiety sensitivity, anxious mood, and social anxiety) and found that anxiety sensitivity was the only significant predictor variable. Holloway and McNally (1987) exposed high and low anxiety sensitive college students to 5 minutes of voluntary hyperventilation. At post-test, the high anxiety sensitivity group reported more anxiety and more somatic symptoms than the low anxiety sensitivity group. When pre-test anxiety levels were controlled for, the subjects with high anxiety sensitivity showed a greater increase in self-reported hyperventilation symptoms than the low anxiety sensitivity subjects. In a follow-up study, Donnell and McNally (1989) investigated whether anxiety sensitivity enhances response to biological challenge independent of a history of having experienced panic attacks. Subjects were assigned to one of four groups on the basis of Anxiety Sensitivity Index scores (i.e., high vs low) and history of panic (i.e., panickers vs nonpanickers) and exposed to 5 minutes of voluntary hyperventilation. It was found that high anxiety sensitive subjects, compared to low anxiety sensitive subjects,

reported higher levels of anxiety and somatic symptoms associated with hyperventilation regardless of experience with panic. The greatest response to the challenge test occurred in subjects who had a history of panic and high anxiety sensitivity. However, a history of panic did not affect response to hyperventilation in subjects with low anxiety sensitivity.

The Donnell and McNally (1989) and Holloway and McNally (1987) studies can be criticized for relying on self-report measures of anxiety, thereby emphasizing the subjective experience of symptoms to the exclusion of considering physiological responses to challenge tests. By failing to assess physiological responses, the studies cannot rule out the competing hypothesis that differences in the response to hyperventilation were due to differences in baseline physiological arousal, rather than to the effects of anxiety sensitivity. Indeed, some research has demonstrated that individuals with panic disorder have higher resting arousal levels than control subjects (e.g., Holden & Barlow, 1986). Moreover, because cognitive, physiological, and behavioral responses are often not concordant (Cone, 1977), assessment of all three response systems can provide important information about the effects of anxiety sensitivity in different response systems.

At least two recent studies have included assessment of physiological responses in examining the potential mediating role

of anxiety sensitivity in anxiety-induction paradigms. Shostak and Peterson (1990) exposed 132 undergraduate students to an anxiety-inducing mental arithmetic task. High, medium, and low anxiety sensitive subjects were found to experience similar levels of physiological arousal in response to the experimental task. However, anxiety sensitivity was associated with differences in self-reported anxiety symptoms following the anxiety-inducing task. Because similar levels of physiological arousal (in terms of EMG and systolic blood pressure) were found in the three anxiety sensitivity groups, this factor can be ruled out as a potential explanation for the differences in self-reported anxiety. Thus, the data imply that anxiety sensitivity mediates cognitive appraisal of anxiety but not physiological arousal. In a recent investigation, Koszycki, Cox, and Bradwejn (1993) also found that subjects with a "high" level of anxiety sensitivity experienced more catastrophic cognitions and fear of somatic sensations than subjects with a "low" or "medium" level of anxiety sensitivity in response to a biological challenge task (i.e., CCK-4 challenge). However, subjects in the three anxiety sensitivity groups did not differ in their susceptibility to experiencing panic attacks, suggesting that anxiety sensitivity is not a mediator of response to CCK-4 challenge. Furthermore, the groups did not differ in baseline blood pressure and heart rate, and they demonstrated similar levels of change in cardiovascular data over time. Thus, while the extant literature

generally provides support for the argument that anxiety sensitivity is an important mediator of response to biological challenge, conflicting findings (Koszycki et al., 1993) suggest that replication and further investigation are needed.

Anxiety Sensitivity and Fearfulness

The expectancy theory of fear proposes that there are three fundamental fears: anxiety sensitivity, injury sensitivity, and fear of negative evaluation (Reiss, 1991; Reiss & McNally, 1985). These fundamental fears are believed to account for fear of a wide variety of stimuli and predict individual differences in fearfulness. Therefore, for example, an individual may be afraid of dogs and snakes, which Reiss (1991, p.147) refers to as "ordinary fears", because of a fear of injury, one of the "fundamental fears". Specifically with regard to anxiety sensitivity, it is hypothesized that an individual with a fear of anxiety should be afraid of situations in which there is the possibility of experiencing anxiety. Since there are many situations which are potentially anxiety-inducing, the individual's fear response would be expected to generalize to a broad range of situations or stimuli. It is thought that anxiety sensitivity may facilitate the acquisition of fears by functioning like an aversive unconditioned stimulus (McNally, in press, p.6):

high anxiety sensitivity ought to increase the number and intensity of acquired fears by amplifying the aversiveness

of state anxiety. That is, high anxiety sensitivity ought to function like a high-magnitude unconditioned stimulus (US) in Pavlovian conditioning. Just as highly aversive USs enhance fear conditioning, elevated anxiety sensitivity ought to amplify the negative valence of each episode of anxiety, and thereby increase the number and intensity of learned fears.

Consistent with this prediction, it has been found that anxiety sensitivity accounted for a significant proportion of variance in fears reported by university students (Reiss et al., 1986) and agoraphobics (McNally & Lorenz, 1987). In a follow-up paper, Reiss, Peterson, and Gursky (1988) reanalysed the Reiss et al. (1986) data in order to determine whether the previous findings could be explained by a general tendency for different fears to be related to each other. The results indicated that anxiety sensitivity scores accounted for variance in fear scores beyond that predicted by another fear (i.e., injury sensitivity). Thus, support was provided for the contention that anxiety sensitivity is a distinct fear, which accounts for variance in fearfulness beyond that expected by a general tendency for different fears to be related.

There is also some empirical evidence from factor analytic studies indicating that the three fundamental fears proposed by the expectancy theory of fear are distinct. Reiss et al. (1988) conducted a factor analysis of the pooled items from the Anxiety

Sensitivity Index and the Fear Survey Schedule-II (Geer, 1965) which derived three factors, corresponding to each of the fundamental fears. Quite recently, Taylor (1993a) performed a factor analysis of the pooled items from self-report measures of anxiety sensitivity, fear of negative evaluation, illness/injury sensitivity, and a fear survey schedule completed by community volunteers. Results indicated that the three fundamental fears formed separate factors, with correlations among the factors ranging from .26 to .32. Although these findings support Reiss and McNally's theory (1985), replication with a clinical sample is indicated.

Anxiety Sensitivity and Trait Anxiety

Probably the most contentious issue in the anxiety sensitivity literature concerns the question of whether anxiety sensitivity is distinct from trait anxiety. It has been argued that the findings related to anxiety sensitivity can be accounted for by the construct of trait anxiety and that the ASI is simply another measure of trait anxiety (Lilienfeld, Jacob, & Turner, 1989; Lilienfeld et al., 1993). However, proponents of the ASI have suggested that there are significant conceptual and empirical distinctions between anxiety sensitivity and trait anxiety (e.g., McNally, 1989, in press; Taylor, 1993b). McNally (1989, p.193) has argued that:

anxiety symptoms should not evoke further fear in trait-anxious persons who do not have concurrent high anxiety

sensitivity. Unless one smuggles in the concept of anxiety sensitivity under the rubric of trait anxiety, there is no theoretical basis for predicting that people who respond with excessive fear to threatening stimuli in general should also respond with excessive fear to symptoms that are not inherently stressful.

In addition to this conceptual distinction, there is empirical evidence to suggest that anxiety sensitivity and trait anxiety are distinct constructs. Studies utilizing correlational, multiple regression, and factor analyses have provided evidence for the incremental validity of the ASI, relative to trait anxiety measures (McNally & Lorenz, 1987; Reiss, 1991; Reiss et al., 1986, 1988; Taylor, Koch, & Crockett, 1991).

Purpose of the First Study

The purpose of the present study was to investigate several issues associated with the anxiety sensitivity construct and the Anxiety Sensitivity Index. The first study examined whether anxiety sensitivity changes following cognitive-behavioral treatment for panic disorder. While previous research has suggested that anxiety sensitivity decreases with successful treatment of panic disorder (e.g., McNally & Lorenz, 1987), there have been several methodological limitations associated with this research which this study sought to address. Specifically, the present study examined the relationship between anxiety

sensitivity and treatment outcome via a program which employed a wait-list control group and multi-method assessment of outcome. The inclusion of a wait-list control group allowed for the assessment of change in anxiety sensitivity independent of treatment effects. Moreover, multi-method assessment of outcome permitted the investigation of the relationship between anxiety sensitivity and other self-report measures of anxiety as well as independent assessor ratings of treatment outcome. It was expected that a decrease in anxiety sensitivity would be found for subjects who received active treatment but not for subjects in the wait-list control group.

Another purpose of the first study was to explore the relationship between panic attacks and anxiety sensitivity. As noted previously, anxiety sensitivity theory predicts that frequency of panic attacks is related to level of anxiety sensitivity. Previous research examining this question has solely involved college student samples. The present study sought to extend the existing literature by examining the relationship between anxiety sensitivity levels and self-reported frequency of panic attacks in a clinical sample of individuals with panic disorder. It was expected that higher levels of anxiety sensitivity would be associated with greater frequency of attacks.

Anxiety sensitivity theory also suggests that higher levels of anxiety sensitivity should be associated with lower perceived

ability to cope with panic attacks (Peterson & Reiss, 1992). Thus, in exploring the relationship between anxiety sensitivity and panic attacks, the present study also examined whether anxiety sensitivity was associated with perceived ability to cope with panic attacks. It appears that this is the first study to report data pertaining to this question.

Purpose of the Second Study

The second study addressed several questions related to anxiety sensitivity in panic disorder and another anxiety disorder, namely social phobia. Investigation of anxiety sensitivity in panic disorder and social phobia was of interest because there is considerable overlap between these disorders in terms of symptom profile (Hazen, Walker, Eldridge, Chartier, & Stein, 1993), occurrence of panic attacks, and phobic avoidance (Mannuzza, Fyer, Liebowitz, & Klein, 1990). Both disorders are also characterized by significant attendant disability (e.g., Markowitz et al., 1989; Turner, Beidel, Dancu, & Keys, 1986) and comorbidity with other anxiety (Breier et al., 1986; De Ruiter et al., 1989), affective (Reiter, Otto, Pollack, & Rosenbaum, 1991; Stein, Tancer, Gelerntner, Vittone, & Uhde, 1990; Stein, Tancer, & Uhde, 1990), and substance use disorders (e.g., Himle & Hill, 1991; Schneier, Martin, Liebowitz, Gorman, & Fyer, 1989). Despite these overlapping features, however, certain critical distinctions can be made, particularly with respect to the cognitive features of the respective disorders. In social

phobia, cognitions typically focus on concerns about embarrassment, humiliation, or negative evaluation. In contrast, individuals with panic disorder tend to be primarily concerned with fear of having a panic attack or fear of the potential catastrophic consequences of anxiety, such as having a heart attack or going crazy. Thus, the concerns associated with panic disorder tend to be closely related to the anxiety sensitivity construct, whereas the central concerns associated with social phobia tend to be more closely related to a fear of negative evaluation, humiliation, or embarrassment. Not surprisingly, a previous study found that individuals with panic disorder demonstrated significantly greater levels of anxiety sensitivity than individuals with social phobics (Taylor, Koch, & McNally, 1992). However, another recent study (Harvey, Richards, Dziadosz, & Swindell, 1993) reported elevated ASI scores for both panic disorder and social phobic subjects; the groups did not significantly differ on fear of anxiety symptoms. In view of the conflicting findings and certain limitations associated with the previous research, the present study was interested in examining anxiety sensitivity in panic disorder and social phobia. With regard to the limitations associated with the previous research, it should be noted that the sample sizes of the social phobic groups included in previous studies were relatively small (i.e., $N = 23$ in Taylor, Koch, & McNally, 1992; $N = 12$ in Harvey et al., 1993). Moreover, in the Taylor et al. (1992) study, the sample

was heterogeneous with respect to social phobia subtype in that both specific and generalized subtypes of the disorder were included in the sample. [The generalized subtype refers to a pervasive fear of most social situations, whereas the specific subtype refers to a less generalized form of the disorder in which there is fear of only one or a few social situations, such as speaking in public or eating in front of others (American Psychiatric Association, 1987).] (No information concerning diagnostic subtypes was provided in Harvey et al., 1993.) In view of evidence suggesting that individuals with the generalized subtype of social phobia are more severely impaired and demonstrate greater general anxiety and depression than individuals with the specific subtype (Heimberg, Hope, Dodge, & Becker, 1990), there appears to be merit in utilizing samples which are homogeneous with respect to subtype. Accordingly, the second study compared levels of anxiety sensitivity in subjects with panic disorder and social phobia, using a larger and more homogeneous sample of individuals with social phobia. It was expected that subjects with panic disorder would demonstrate greater overall anxiety sensitivity than subjects with social phobia.

Differences in anxiety sensitivity between panic disorder and social phobia can also be examined at the level of individual ASI items. Previous research has suggested that certain ASI items central to the construct of anxiety sensitivity can

discriminate panic disorder from other anxiety disorders. Specifically, findings have shown that ASI items pertaining to fear of bodily sensations are particularly relevant to panic disorder; items assessing fear of losing emotional control (Taylor et al., 1991) and fear of the social consequences of anxiety (Taylor et al., 1991, Taylor, Koch, & McNally, 1992) have not discriminated panic disorder from other anxiety disorders. However, this issue has primarily been addressed by comparing subjects with panic disorder to mixed groups of subjects with other anxiety disorders, thereby potentially obscuring important differences between panic disorder and specific anxiety disorders. Thus, the second study compared the pattern of responding on individual items of the ASI in subjects with panic disorder and social phobia. It was predicted that the items pertaining to fear of bodily sensations and the catastrophic consequences associated with these sensations (i.e., items 3, 4, 6, 8, 9, 10, 11, 14, 16) would differentiate the panic disorder and social phobia subjects, with the panic disorder subjects endorsing these items to a greater extent. In contrast, the social phobia subjects were expected to demonstrate greater concern about the social consequences of anxiety, as assessed by items 1, 7, and 13.

Study 1

MethodSubjects

The sample was comprised of 117 consecutively accepted participants in a panic disorder treatment evaluation study conducted by the Anxiety Disorders Clinic, St. Boniface General Hospital. The mean age of the subjects was 36.97 years (SD = 9.80; range 20-73 years). Eighty-five females and 32 males participated. Complete subject demographic information is summarized in Table 1. Ten (8.5%) subjects had a primary diagnosis of panic disorder without agoraphobia, and 107 (91.5%) had a primary diagnosis of panic disorder with agoraphobia. The mean duration of panic disorder (with or without agoraphobia) for the sample was 8.47 years. Subjects with comorbid anxiety disorder diagnoses were included in the sample, provided these were secondary to the panic disorder diagnosis. The most common secondary diagnosis was generalized anxiety disorder (34.2%), followed by social phobia (20.5%). Only two subjects (1.7%) had comorbid obsessive-compulsive disorder, and one subject had comorbid post-traumatic stress disorder; however, it should be noted that only 72.6% of the sample were assessed for post-traumatic stress disorder because the version of the clinical interview which was used in the early stages of the evaluation study did not contain a post-traumatic stress disorder module. In addition, subjects were not assessed for simple phobia so

Table 1Sample Demographics for Study I (N = 117)

Mean Age (Years)	36.97
<u>SD</u>	9.80
Sex (% Female)	72.6
Marital Status (%)	
Never Married	24.1
Currently Married	61.2
Divorced/Separated	13.8
Widowed	00.9
Education (%)	
< High school graduate	31.6
High school graduate	35.0
Part college or 2 yr. diploma	13.7
College graduate or beyond	19.7
Ethnicity (%)	
White	95.7
Aboriginal	02.6
Hispanic	00.9

rates for this disorder are not available for the sample.

The purpose of the treatment study was to evaluate the efficacy of a self-help manual for panic disorder, and involved the following four conditions to which subjects were randomly assigned: (1) individual self-administration of the self-help manual; (2) use of the manual in a self-help group; (3) use of the manual in a group led by professional therapists; and (4) a wait-list control group. The treatment manual used in the study was Coping with panic (Clum, 1990). The content of the treatment program included psycho-educational information about anxiety, and cognitive-behavioral treatment strategies, including relaxed breathing, progressive muscle relaxation, cognitive-restructuring, and graduated exposure to feared situations.

Participants in the treatment study were recruited from referrals to the Anxiety Disorders Clinic at St. Boniface General Hospital and from individuals who contacted the Anxiety Disorders Association of Manitoba, a community-based self-help organization. Inclusion criteria for the study were: (1) DSM-III-R diagnosis of panic disorder with or without agoraphobia; (2) minimum of Grade 8 reading and writing ability; (3) 18 years of age or older; and (4) physician agreement regarding participation. Exclusion criteria included: (1) presence of organic disease which might be related to panic disorder or interfere with participation in the study; (2) presence of other serious psychiatric disorders, specifically psychotic disorders,

substance abuse, and current major depressive disorder; (3) presence of significant suicidal risk; (4) involvement in other psychological treatment; and (5) current pharmacological treatment for panic disorder, with the exception of low doses of benzodiazepines (equivalent of 20 mg diazepam or less) or stable doses of antidepressants (prescribed for at least 6 months and stable dose for at least 3 months).

Prior to entering the study, each subject was interviewed by a clinician experienced in assessing anxiety disorders, with the majority of interviews conducted by the author. Diagnosis was determined using a modified version of the Structured Clinical Interview for DSM-III-R (SCID; Spitzer, Williams, Gibbon, & First, 1990). The SCID is a semi-structured interview which provides diagnoses for all of the major Axis I DSM-III-R disorders occurring in adults. Specialized versions of the SCID have been developed for specific research studies. One of these is the SCID-Ro, which was developed by the St. Boniface General Hospital Anxiety Disorders Research Program for use in Hoffmann - La Roche sponsored studies of social phobia and panic disorder (Stein, Hazen, Eldridge, & Walker, 1992). The SCID-Ro provides more detailed information on anxiety disorders, particularly in the panic disorder and social phobia sections. The version of the SCID which was employed in the present study has been found to have satisfactory reliability for diagnosing current panic disorder ($\kappa = .70$; Hazen, Walker, Chartier, Eldridge, &

Stein, 1993).

Measures

The Anxiety Sensitivity Index. The Anxiety Sensitivity Index (ASI) is a 16-item self-report measure which assesses fear of anxiety symptoms and catastrophic consequences resulting from the symptoms (e.g., "It scares me when I am short of breath"). The subject is asked to rate the extent to which he or she agrees with each item using a five-point Likert scale ranging from "very little" to "very much". An individual's ASI score is the total score for the 16 items and can range from 0 to 64. For non-clinical populations, the normative mean is 19.01 (standard deviation = 9.11; Peterson & Reiss, 1992). A minor sex difference has been found, with females scoring slightly higher than males (i.e., mean of 19.75 versus 17.62). As the preceding review indicates, the reliability and validity of the ASI have been well-established.

Fear Questionnaire. The Fear Questionnaire (FQ; Marks & Mathews, 1979) is a frequently used self-report measure of phobic avoidance. It consists of three subscales (i.e., agoraphobia, social phobia, and blood-injury) and a total phobia scale which is derived by summing the subscale scores. Factor analysis has confirmed a three-factor solution corresponding to the subscales proposed by Marks and Mathews (Oei, Moylan, & Evans, 1991). In the present study, the agoraphobia subscale was used to assess agoraphobic avoidance (see Appendix B). This subscale contains 5

items, which are assessed on a 9-point Likert scale (0 = would not avoid it, 8 = always avoid it). The agoraphobia score is derived by summing the ratings for the subscale items, yielding a minimum score of 0 and a maximum score of 40.

Several studies have reported satisfactory reliability for the Agoraphobia subscale of the FQ. Marks and Mathews (1979) reported test-retest reliability of .89 over a 7-day interval. The agoraphobia subscale has also been shown to be stable over longer test-retest intervals. Michelson and Mavissakalian (1983) reported average reliability of .83 across intervals ranging from 4 to 16 weeks. Good internal consistency has been obtained with clinical populations, with alpha coefficients ranging from .69 to .86 (Cox, Swinson, & Shaw, 1991; Oei et al., 1991; Van Zuuren, 1988).

There is also good evidence for the validity of the Agoraphobia subscale. For instance, it has been demonstrated that the subscale is sensitive to treatment effects in patients with panic disorder (Marks & Mathews, 1979; Mavissakalian, 1986). Several studies have also shown that the Agoraphobia subscale, together with the Social Phobia subscale, are able to differentiate subjects with panic disorder and social phobia with a fairly high degree of accuracy (Cox et al., 1991; Oei et al., 1991; Van Zuuren, 1988). Intercorrelations among the subscales are relatively low, suggesting that they are measuring different aspects of phobic avoidance (Marks & Mathews, 1979;

Mavissakalian, 1986).

Sheehan Patient-Rated Anxiety Scale. The Sheehan Patient-Rated Anxiety Scale (SPRAS; Sheehan, 1983) is a 35-item self-report questionnaire which assesses the intensity of anxiety symptoms. Each symptom is rated on a 5-point Likert scale (0 = Not at all distressing; 4 = Extremely distressing). Although the psychometric properties of this instrument have not been extensively investigated, it has been frequently used in pharmacologic and psychological treatment evaluation studies for panic disorder (e.g., Telch et al., 1993). The measure is presented in Appendix C.

Clinical Global Improvement Scale. Subjects' improvement from pre- to post-treatment was evaluated using a clinical global improvement (CGI) scale. This scale is a clinician-rated instrument which is commonly used in anxiety disorders research to evaluate the degree of change exhibited by a subject following treatment. The CGI which was used in the present study contains a 7-point rating scale, ranging from "very much improved" to "very much worse". Ratings of subjects improvement were made at post-treatment by an independent assessor who was "blind" to treatment group membership. A copy of this measure is provided in Appendix D.

Panic attack diary. A panic attack diary developed by the staff of the Anxiety Disorders Clinic, St. Boniface General Hospital was used to determine the number of panic attacks

experienced by subjects during a seven day period prior to beginning treatment. A copy of the diary is provided in Appendix E. Subjects were required to complete a diary for each panic attack experienced during the assessment period. For the present study, the diaries were used to determine the frequency of full-blown panic attacks (i.e., at least 4 panic attack symptoms as defined in DSM-III-R) experienced during the pre-treatment assessment interval.

Panic Self-Efficacy Questionnaire. The Panic Self-Efficacy Questionnaire (Clum, 1990) is an 11-item self-report questionnaire that assesses confidence and perceived ability to cope with panic attacks (see Appendix F). Each item is rated on a 9-point scale that ranges from 1 (Not at all confident) to 9 (Totally confident). Previous research has demonstrated that the Panic Self-Efficacy Questionnaire is sensitive to treatment effects (Borden, Clum, & Salmon, 1991).

Procedure

Approximately one week before beginning treatment, subjects completed a package of self-report questionnaires, which included the measures which were used in this study (i.e., the Anxiety Sensitivity Index, the Fear Questionnaire - Agoraphobia subscale, the Sheehan Patient-Rated Anxiety Scale, and the Panic Self-Efficacy Questionnaire). In addition, subjects were asked to record panic attacks experienced during a seven day period, using the panic attack diary. The questionnaires were mailed to

participants, along with a cover letter which provided instructions for completing the questionnaires. Following assignment to the treatment conditions, a clinician met with each subject to review the self-report measures and the panic attack diaries. All participants in the evaluation study provided written informed consent. A copy of the consent form is provided in Appendix G.

A questionnaire package which included the measures used in this study was again mailed to each subject for completion at post-treatment. Subjects also attended a post-treatment evaluation interview, during which several rating scales, including the clinical global improvement scale, were administered by the author who served as the independent assessor for the evaluation study. Over the course of the study, the independent assessor remained "blind" to subjects' treatment group status in order to ensure that unbiased ratings were made.

Results

Anxiety Sensitivity and Treatment Outcome

The means and standard deviations of the pre- and post-treatment ASI scores for the overall sample and the four treatment groups are presented in Table 2. At pre-treatment, the mean ASI score for the entire sample was 33.27 (SD = 11.11) and the mean scores for the four groups ranged from 31.1 to 36.1, which are similar to the values obtained for panic disorder subjects in other recent studies (e.g., Apfeldorf et al., 1994;

Table 2

Means and Standard Deviations of Anxiety Sensitivity Index Scores

Group	n	Pre-Treatment		Post-Treatment	
		<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>
Professionally-led Group	28	31.1	11.1	17.7 ^a	11.0
Self-help Group	29	33.4	11.3	23.5 ^{a,b}	13.2
Self-help manual	32	32.5	11.7	26.5 ^b	13.7
Wait-list	28	36.1	10.2	35.1 ^c	11.6

Note. Normative mean (for non-clinical populations) = 19.01 (SD = 9.11).

Superscript letters indicate means that are not significantly different in multiple comparisons using the Ryan-Einot-Gabriel-Welsh multiple F test following significant repeated measures ANOVA.

Taylor et al., 1992). An analysis of variance (ANOVA) performed on the pre-treatment ASI scores revealed that the treatment groups did not significantly differ from each other ($F < 2$).

The relationship between anxiety sensitivity and treatment outcome was examined from several perspectives. First, change in anxiety sensitivity was investigated for the four treatment conditions included in the evaluation study. Repeated measures analysis of variance (ANOVA) carried out on the Anxiety Sensitivity Index data showed a significant main effect for Time ($F(1, 102) = 58.52, p < .0001$) and a significant Group by Time interaction ($F(3, 102) = 7.03, p < .0002$). In order to investigate differences between groups, multiple comparisons were conducted using the Ryan-Einot-Gabriel-Welsch multiple F test. This procedure was selected because it controls the familywise error rate while providing adequate statistical power (Seaman, Levin, & Serlin, 1991). Results revealed that subjects in the three active treatment conditions (i.e., the professionally-led and self-help group conditions and the self-help manual used independently) had significantly lower anxiety sensitivity scores than the wait-list control group at post-treatment (See Table 2). Furthermore, only subjects who received the professionally-led group treatment evidenced significantly lower anxiety sensitivity compared to subjects who independently used the self-help manual. There was no significant difference between the professionally-led and self-help groups, nor between the self-help group and the

self-help manual used independently.

At post-treatment, the mean ASI score for the subjects in the professionally-led group treatment condition was slightly below the normative mean for non-clinical populations (see Table 2), and the mean scores for the subjects in the self-help group condition and the self-help manual condition were within one standard deviation of the normative mean. The wait-list control group did not evidence change in mean ASI scores from pre- to post-treatment, which was an interval of approximately four months. The Pearson Product-Moment correlation between pre- and post-treatment scores for this group was .77, which is similar to test-retest reliability results which have been reported in other studies using the ASI. As indicated previously, Reiss et al. (1986) obtained test-retest reliability of .75 for a two-week interval, and Maller and Reiss (1987) reported .71 for a three-year interval.

In order to further assess the relationship between anxiety sensitivity and treatment outcome, subjects were re-grouped according to their Clinical Global Improvement (CGI) ratings. Three groups were formed to represent endstate functioning based on CGI ratings: "Very much or much improved"; "Minimally improved"; "Unchanged or worse". The first group consisted of subjects who obtained ratings ranging from 1 to 2 on the Clinical Global Improvement Scale, the second group included subjects who obtained ratings ranging from 2.5 to 3.5, and the third group

obtained ratings ranging from 4 to 7 on the 7-point rating scale (i.e., 1 = Very Much Improved; 7 = Very Much Worse). It should be noted that these groupings merely reflect independent evaluator assessment of improvement at post-treatment and do not take into account treatment group status. A repeated measures analysis of variance of ASI scores was conducted for the re-grouped data. This analysis revealed a significant main effect for Time ($F(1,103) = 65.77, p < .0001$), and a significant Group by Time interaction ($F(2,103) = 17.66, p < .0001$). ANOVA's performed on the pre- and post-treatment ASI scores revealed that the groups were significantly different at pre- ($F(2,106) = 6.00, p = .0034$) and post-treatment ($F(2,104) = 25.52, p < .0001$). Differences between groups were investigated using the Ryan-Einot-Gabriel-Welsch multiple F test. The subjects categorized in the "Very much or much improved" ($M = 31.81$) and the "Minimally improved" ($M = 29.37$) groups had significantly lower scores on the ASI at pre-treatment than subjects in the "No change or worse" ($M = 38.03$) group. At post-treatment, the subjects in the "Very much or much improved" group had significantly lower anxiety sensitivity ($M = 18.33$) than the subjects in the "Minimally improved" ($M = 24.44$) and "No change or worse" ($M = 37.48$) groups. The difference between the latter two groups was also statistically significant.

The relationship between change in anxiety sensitivity from pre- to post-treatment and independent assessor rating of

improvement was also evaluated by calculating the Pearson Product-Moment correlation between the ASI difference score (i.e., Post-treatment - Pre-treatment) and the Clinical Global Improvement score. The correlation between these variables was significant ($r = .52$, $df = 106$, $p < .0001$). The correlations between the Clinical Global Improvement Scale and the difference scores for the ASI, Fear Questionnaire - Agoraphobia subscale, and the Sheehan Patient-Rated Anxiety Scale are presented in Table 3. The difference scores for the latter two measures were also significantly correlated with the Clinical Global Improvement Scale.

Change in anxiety sensitivity following treatment was also examined with the effect size (ES) statistic which is frequently used in meta-analytic studies investigating the efficacy of psychological and medical treatments (e.g., Lipsey & Wilson, 1993). Effect size was calculated by subtracting the mean posttreatment score of a treatment group from the mean posttreatment score of the control group and dividing the numerator by the standard deviation of the control group posttreatment score (see Gould & Clum, 1993). The effect sizes obtained with the Anxiety Sensitivity Index, Fear Questionnaire - Agoraphobia subscale, and the Sheehan Patient-Rated Anxiety Scale are presented in Table 4. For the ASI, the effect size for the three treatment groups ranged from .74 to 1.50 ($M = 1.08$), for the Fear Questionnaire - Agoraphobia subscale, it ranged from .27

Table 3

Correlations (Pearson r) Between the Clinical Global Improvement Scale and Difference^a Scores of Anxiety Self-Report Measures

Scale	CGI	ASI	FQ-Ag	SPRAS
CGI	—	0.52 [*]	0.39 [*]	0.58 [*]

Note. ^a Difference Score = Post-treatment - Pre-treatment score.

ASI = Anxiety Sensitivity Index

FQ-Ag = Fear Questionnaire - Agoraphobia Subscale

SPRAS = Sheehan Patient-Rated Anxiety Scale

^{*} $p < .0001$.

Table 4**Effect Sizes (ES) for the Anxiety Sensitivity Index and Other Anxiety Self-Report Questionnaires**

Dependent Measure	Treatment Condition	Effect Size
ASI	Professionally-led Group	1.50
	Self-Help Group	1.00
	Self-Help Manual	0.74
FQ-Ag	Professionally-led Group	1.14
	Self-Help Group	0.82
	Self-Help Manual	0.27
SPRAS	Professionally-led Group	0.73
	Self-Help Group	0.48
	Self-Help Manual	0.37

Note. ASI = Anxiety Sensitivity Index

FQ-Ag = Fear Questionnaire - Agoraphobia Subscale

SPRAS = Sheehan Patient-Rated Anxiety Scale

to 1.14 ($M = .74$), and for the Sheehan Patient-Rated Anxiety Scale, the range was .37 to .73 ($M = .53$).

Anxiety Sensitivity and Panic Attacks

The relationship between frequency of panic attacks and anxiety sensitivity was examined using pre-treatment Anxiety Sensitivity Index scores and the number of panic attacks reported in diaries which were completed by subjects for one week prior to beginning treatment. The total number of panic attacks reported by subjects (i.e., the sum of spontaneous and situationally-cued panic attacks) was used in the statistical analyses. Subjects were divided into three groups based on self-reported frequency of panic attacks. The first group ($N = 51$) consisted of subjects who did not experience any panic attacks in the week prior to beginning treatment, the second group ($N = 32$) was comprised of subjects who experienced one to two panic attacks, and the third group ($N = 21$) included subjects who reported three to seven panic attacks. An analysis of variance revealed a significant difference between groups ($F(2, 101) = 7.00, p < .002$).

Multiple comparisons using the Ryan-Einot-Gabriel-Welsch multiple F test indicated that subjects who reported no panic attacks had a significantly lower mean ASI score (29.31, $SD = 10.30$) than subjects who reported either one to two (37.16, $SD = 10.44$), or three to seven (36.90, $SD = 11.34$) panic attacks. The two groups who experienced panic attacks did not significantly differ from each other. In order to further explore the relationship between

anxiety sensitivity and occurrence of panic attacks, the Pearson Product-Moment correlation between pre-treatment ASI scores and total number of panic attacks was calculated. Because a substantial number of subjects had not reported any panic attacks, the frequency distribution for this variable was extremely skewed. As a result, it was decided that only subjects who reported at least one panic attack in the pre-treatment diaries would be included in the analysis. The correlation between anxiety sensitivity and self-reported frequency of panic attacks for this subsample was not significant ($r = 0.04$, $df = 53$, $p = 0.79$).

In order to examine the relationship between anxiety sensitivity and perceived ability to cope with panic attacks, correlations between ASI and Panic Self-Efficacy Questionnaire scores were calculated. The correlation between these measures at pre-treatment was not significant ($r = -0.15$, $df = 109$, $p = .11$), but the correlation between post-treatment scores was significant ($r = -0.48$, $df = 104$, $p < .0001$).

Discussion

The results of the first study suggest that reductions in anxiety sensitivity can be achieved with cognitive-behavioral treatment for panic disorder. As hypothesized, it was demonstrated that subjects who received active treatment evidenced significant decreases in anxiety sensitivity relative to a wait-list control group. Furthermore, this finding was

replicated with treatment outcome groups classified on the basis of independent assessor ratings. It appears that this is the first study to use a non-self-report approach to demonstrate the relationship between anxiety sensitivity and treatment outcome. Interestingly, it was found that subjects who were classified as showing no improvement or having deteriorated at the post-treatment assessment had significantly higher ASI scores at pre- and post-treatment than the subjects who were considered to have improved at least minimally. In terms of their treatment group status, 62.5% of the subjects rated as not improved or deteriorated were in the wait-list condition, 25% were in the self-help manual condition, and 12.5% were in the self-help group condition. It may be that individuals with panic disorder who have higher levels of anxiety sensitivity are less likely to demonstrate improvement in symptoms with self-directed or no treatment. This possibility should be investigated more systematically in future research.

The current results also address the question of whether anxiety sensitivity is a stable, personality variable. While the data indicate that anxiety sensitivity remains relatively stable in the absence to treatment, the present study clearly demonstrates that this phenomenon is responsive to cognitive-behavioral treatment. Therefore, the findings provide support for the view that anxiety sensitivity is a "cross-situational, dispositional" (McNally & Lorenz, 1987, p.9) variable rather than

a stable personality trait (Saviotti et al., 1991).

Furthermore, the findings of this study support the construct validity of the ASI and provide evidence for its efficacy as an outcome measure in panic disorder research. This conclusion is supported by the data demonstrating change in anxiety sensitivity following treatment. It is further supported by the finding that change in anxiety sensitivity scores from pre- to post-treatment was related to independent assessor ratings of improvement. The magnitude of the association between the Clinical Global Improvement (CGI) Scale and change in anxiety sensitivity from pre- to post-treatment (i.e., $r = .52$) is impressive, given that the CGI rating takes into account many areas in which improvement may be evidenced, such as frequency of panic attacks and degree of phobic avoidance. Moreover, the correlation between the CGI and the ASI was similar to that obtained with other widely used anxiety self-report measures (i.e., the Fear Questionnaire - Agoraphobia subscale and the Sheehan Patient-Rated Anxiety Scale). The effect sizes obtained with the ASI were also comparable to those obtained with the Fear Questionnaire and the Sheehan Patient-Rated Anxiety Scale. Moreover, the mean magnitude of effect sizes for the ASI compared favourably to those reported for anxiety disorder treatments in recent meta-analytic studies (e.g., Gould & Clum, 1993; Lipsey & Wilson, 1993). Taken together, these findings suggest that anxiety sensitivity is responsive to cognitive-behavioral

treatment, and the ASI is a sensitive measure of treatment effects.

Another purpose of the present study was to investigate two issues pertaining to the association between anxiety sensitivity and panic attacks. The findings regarding the relationship between frequency of panic attacks and anxiety sensitivity were somewhat equivocal. When subjects were classified into groups according to the frequency of panic attacks reported in diaries, and anxiety sensitivity levels were compared, it was found that subjects who had between one and two and three to seven panic attacks had significantly greater anxiety sensitivity scores than subjects who had no panic attacks. However, subjects who reported fewer (i.e., 1-2) panic attacks did not significantly differ from subjects who reported a greater number (i.e., 3-7) of attacks. Moreover, for subjects who reported at least one panic attack, the frequency of attacks was not significantly related to anxiety sensitivity levels. One interpretation of these data is that anxiety sensitivity is related to the *occurrence* of panic attacks, but not specifically to the actual frequency of attacks. These results, however, should be interpreted with caution given certain limitations associated with the data. It is possible that the correlation between frequency of panic attacks and ASI scores was deflated because of a restricted range and skewed distribution of responses on the measures (Tabachnick & Fidell, 1989). Thus, replication of the results with additional clinical

samples is needed. In order to overcome the problem of obtaining a limited range of responses on panic attack diaries, it is recommended that the assessment period involve a longer time interval, such as two weeks or longer.

Consistent with the prediction of anxiety sensitivity theory (Peterson & Reiss, 1992), it was found that anxiety sensitivity was associated with perceived ability to cope with panic attacks. The results suggest that individuals who have greater fear of anxiety symptoms also tend to have less confidence in their ability to cope with panic attacks. It should be noted that this relationship was found at the post- but not the pre-treatment assessment. Similar to the problem associated with the panic attack data, it is likely that the correlation between the pre-treatment scores on the ASI and the Panic Self-Efficacy Questionnaire was suppressed because a substantial proportion of subjects obtained scores in the pathological range at pre-treatment, thereby resulting in a restricted range and skewed distribution of responses on both measures. While the current results indicate a relationship between anxiety sensitivity and confidence in coping with panic attacks, the nature of this relationship requires further investigation. Future research should examine the direction in which this relationship operates. Borden et al. (1991) have suggested that a sense of personal control as well as catastrophic cognitions play an important role in the occurrence of panic attacks. Moreover, there is some

evidence indicating that change in self-efficacy precedes a shift in catastrophic thoughts (Borden et al., 1991). It would be interesting to address this question with the anxiety sensitivity construct. A future direction may be to investigate whether treatment increases perceived ability to cope with panic attacks, which in turn decreases anxiety sensitivity, or whether anxiety sensitivity decreases first, and lowered fear of anxiety symptoms then leads to greater confidence in handling attacks. The answer to this question has potentially important implications for the selection and sequencing of components in cognitive-behavioral treatments for panic disorder.

Study 2

Method

Subjects

The sample was comprised of 47 subjects with panic disorder (with or without agoraphobia) and 47 subjects with generalized social phobia recruited through the Anxiety Disorders Clinic and the Anxiety Disorders Research Program, St. Boniface General Hospital. Among the subjects with panic disorder, 83% had panic with agoraphobia. The mean duration of disorder was 8.74 years (SD = 9.52) for the subjects with panic disorder and 22.02 years (SD = 11.12) for the subjects with social phobia. All of the subjects with social phobia and 60% of the subjects with panic disorder were participants in pharmacological treatment studies. The remaining subjects with panic disorder participated in the

treatment evaluation study described in Study 1. The demographic characteristics of the two diagnostic groups are presented in Table 5.

In order to be eligible to participate in the present study, subjects had to be between 18 and 65 years of age. The subjects with social phobia were required to have a primary diagnosis of generalized social phobia based on DSM-III-R criteria and could not have comorbid panic disorder, obsessive compulsive disorder, or post-traumatic stress disorder. The subjects with panic disorder were required to have a primary diagnosis of panic disorder with or without agoraphobia according to DSM-III-R criteria and could not have comorbid social phobia, obsessive compulsive disorder, or post-traumatic stress disorder. Individuals with comorbid generalized anxiety disorder or simple phobia were not excluded. Exclusion criteria included: (1) presence of any organic disease related to anxiety disorders; (2) presence of other serious psychiatric disorders, specifically psychotic disorders, substance abuse, and current major depression.

Diagnosis was determined using a modified version of the Structured Clinical Interview for DSM-III-R (SCID; Spitzer et al., 1990) which contained modules for assessing anxiety disorders, affective disorders, psychotic disorders, and substance abuse problems. Acceptable reliability for diagnosing current panic disorder ($\kappa = .70$) and current social phobia

Table 5

Subject Demographics for Study 2

Variable	Diagnostic Group	
	Panic Disorder (N = 47)	Social Phobia (N = 47)
Age (Years)		
Mean	38.36	36.70
SD	9.48	9.77
Sex (% female)	55.32	21.28
Marital Status (%)		
Never married	17.39	42.55
Currently married	76.09	48.94
Divorced/separated	6.52	8.51
Employment Status (%)		
Employed full-time	57.45	59.57
Employed part-time	17.02	6.38
Unemployed	12.77	25.53
Student	4.26	2.13
Homemaker	8.51	2.13
Other	0.00	4.26

(table continues)

Variable	Diagnostic Group	
	Panic Disorder (N = 47)	Social Phobia (N = 47)
Education (%)		
< High school graduate	27.66	17.02
High School Graduate	42.55	27.66
Part college or 2 year diploma	14.89	25.53
College graduate or beyond	14.89	29.79
Ethnicity (%)		
White	89.36	91.49
Aboriginal	6.38	2.13
Asian	0.00	2.13
Missing	4.26	4.26

(kappa = .73) has been obtained with this version of the SCID (i.e., SCID-Ro; Hazen, Walker, Chartier, Eldridge, & Stein, 1993). The interviews were conducted by experienced clinicians employed by the Anxiety Disorders Clinic and the Anxiety Disorders Research Program at St. Boniface General Hospital, including the author.

Measure

Anxiety Sensitivity Index. The Anxiety Sensitivity Index (ASI; Reiss et al., 1986) is a 16-item self-report measure which assesses fear of anxiety symptoms and the consequences associated with the symptoms. (See previous sections of this paper for a description of the measure and a discussion of its psychometric properties.)

Procedure

The Anxiety Sensitivity Index, along with other self-report measures not relevant to the present study, were completed by subjects before beginning treatment. At the time of completion of the ASI, subjects were medication-free, with the exception of two of the subjects with panic disorder. These individuals were using benzodiazepines less than once per week. All participants provided written informed consent prior to entering the studies. A sample consent form for one of the pharmacological treatment studies is provided in Appendix H.

Results

The diagnostic groups were not significantly different with

respect to their mean ages ($t(92) = .84, p = .41$), but there was a significant difference for gender composition ($X^2(1) = 11.53, p < .001$). As a result, gender effects were evaluated in the remaining analyses. The means and standard deviations of the ASI total scores for the two diagnostic groups are presented in Table 6. A 2(Diagnosis) X 2(Gender) ANOVA revealed a significant main effect for diagnosis ($F(1,90) = 7.75, p = .0065$), and a trend towards significance for a gender main effect ($F(1,90) = 3.75, p = .06$). There was no significant diagnosis by gender interaction ($F(1,90) = .32, p = .32$). Subjects with panic disorder had significantly higher anxiety sensitivity scores than subjects with social phobia, with females within each diagnostic group tending to have higher mean scores than the male subjects (see Table 6). Furthermore, the mean ASI score for the male subjects with social phobia was significantly greater than the normative mean (Peterson & Reiss, 1992) for males ($t(36) = 4.45, p < .0005$, and similarly, the mean score for the females with social phobia was significantly elevated relative to the normative mean (Peterson & Reiss, 1992) for females ($t(9) = 3.38, p < .005$).

The means and standard deviations of the item scores for the panic disorder and social phobia groups are presented in Table 7. The overall difference between groups on the ASI items was analyzed using multivariate analysis of variance (MANOVA). The MANOVA revealed a significant effect for diagnosis ($F(16,75) = 7.19, p < .0001$), and a trend towards significance for gender

Table 6

Descriptive Statistics for the ASI Total Score

Group	ASI Total Score		
	<u>n</u>	<u>M</u>	<u>SD</u>
Panic Disorder			
Males	21	32.14	9.57
Females	26	35.12	8.32
Total	47	33.79	8.92
Social Phobia			
Males	37	24.86	9.90
Females	10	30.30	9.88
Total	47	26.02	10.04

Table 7

Descriptive Statistics and Significance Levels for Differences Between Diagnostic Groups on ASI Item Scores

ASI Item	Panic Disorder		Social Phobia		p
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>	
1. It is important to me not to appear nervous	2.66	1.16	3.15	0.75	.0138
2. When I cannot keep my mind on a task, I worry that I might be going crazy	1.02	1.05	0.77	0.98	.5918
3. It scares me when I feel "shaky" (trembling)	2.72	1.02	1.77	1.16	.0023
4. It scares me when I feel faint	2.77	1.32	1.62	1.28	.0009
5. It is important to me to stay in control of my emotions	3.28	0.80	3.30	0.66	.5634
6. It scares me when my heart beats rapidly	3.21	0.75	2.00	1.25	.0001
7. It embarrasses me when my stomach growls	0.94	1.05	2.00	1.30	.0001
8. It scares me when I am nauseous	1.77	1.27	1.28	1.08	.1730

(table continues)

ASI Item	Panic Disorder		Social Phobia		p
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>	
9. When I notice that my heart is beating rapidly, I worry that I might have a heart attack	2.49	1.49	1.30	1.21	.0004
10. It scares me when I become short of breath	2.77	1.22	1.23	1.07	.0001
11. When my stomach is upset, I worry that I might be seriously ill	1.36	1.26	0.53	0.80	.0011
12. It scares me when I am unable to keep my mind on a task	1.55	1.23	1.28	1.16	.4311
13. Other people notice when I feel shaky	1.49	1.12	1.87	1.30	.0473
14. Unusual body sensations scare me	2.49	1.33	1.19	1.09	.0003
15. When I am nervous, I worry that I might be mentally ill	1.26	1.39	0.98	1.07	.7800
16. It scares me when I am nervous	2.02	1.22	1.77	1.15	.7424

($F(16,75) = 1.73, p = .06$). The diagnosis by gender interaction was not significant ($F(16,75) = .76, p = .72$). The significant multivariate test was followed by ANOVA's for each individual ASI item. As table 7 shows, the panic disorder subjects had significantly higher scores ($p < .01$) on 7 of the 16 items, specifically items 3, 4, 6, 9, 10, 11, and 14. The subjects with social phobia scored significantly higher on item 7, and there was a trend towards significance for items 1 and 13. There was no significant diagnosis by gender interaction for any of the items. However, there was a significant gender effect for items 4 and 7, and a marginally significant effect for items 8 and 14. For each of these items, female subjects obtained higher scores than males.

Discussion

As hypothesized, it was found that subjects with panic disorder reported significantly higher anxiety sensitivity levels than subjects with generalized social phobia. In turn, the mean ASI score for the male and female subjects with social phobia was elevated relative to their respective normative means. Thus, the results support the prediction of anxiety sensitivity theory that anxiety sensitivity is an important component of anxiety disorders in general, and panic disorder in particular. The data also replicate previous results reported by Taylor, Koch, and McNally (1992). The mean ASI scores of the subjects with social phobia in the present study and in the Taylor et al. (1992) study

are strikingly similar (ie., 26.02 vs 24.9).

Previous research with the ASI has found a small gender effect for non-clinical populations, with females reporting slightly higher anxiety sensitivity levels than males (Peterson & Reiss, 1992). However, gender differences have not been reported in studies involving clinical samples (e.g., Stewart et al., 1992; Taylor, Koch, & McNally, 1992). The present findings, in contrast, revealed a marginally significant gender effect, with females in each diagnostic group obtaining higher total ASI scores than the male subjects. Unfortunately, the gender composition of the social phobia group was not well balanced, with approximately 79% of the group comprised of males. The proportion of males in the social phobia group was consistent, however, with the overall gender distribution (i.e., 75%) in the pharmacological treatment studies from which the sample was recruited. A possible explanation for the overrepresentation of males may be that there is a gender difference with regard to treatment preference, with males more inclined to attempt pharmacological treatment.

The gender composition of the social phobia group also has implications for the generalizability of the results. Recent epidemiologic findings (see Walker & Stein, in press) suggest that social phobia is more prevalent in females than males, with approximately 60 to 70% of individuals with social phobia being female. Moreover, epidemiologic data have suggested that

individuals with social phobia tend to be disadvantaged with respect to educational attainment relative to individuals without the disorder (e.g., Schneier et al., 1992). Thus, the present sample, which had a relatively high level of educational attainment and a preponderance of males, does not appear to be a representative sample relative to social phobia in community populations.

The hypothesis proffered regarding the ASI items on which the subjects with panic disorder and social phobia would differ was largely supported. As expected, the panic disorder group obtained higher mean scores on items 3, 4, 6, 9, 10, 11, and 14 which describe fear of various bodily sensations related to anxiety. However, contrary to prediction, the subjects with panic disorder did not achieve significantly higher scores on items 8 (It scares me when I am nauseous) and 16 (It scares me when I am nervous). It is difficult to account for the lack of significant differences between the diagnostic groups on these items. Results of factor analyses have suggested that both items load highly on the principal factor of the ASI (e.g., Reiss et al., 1986; Taylor et al., 1991; Taylor, Koch, McNally, & Crockett, 1992), and therefore appear to be good measures of the central construct assessed by the ASI (i.e., fear of anxiety symptoms and the catastrophic consequences of the symptoms).

Not surprisingly, it was found that subjects with social phobia had significantly higher scores on item 7 (It embarrasses

me when my stomach growls), and marginally higher scores on items 1 (It is important to me not to appear nervous) and 13 (Other people notice when I feel shaky). Indeed, concern about the social consequences of anxiety is known to be a central feature of social phobia and is reflected in the DSM-IV diagnostic criteria for the disorder (American Psychiatric Association, 1994). Specifically, the DSM-IV criteria state that the focus of concern in social phobia must be related to doing something or *showing anxiety symptoms* that will be humiliating or embarrassing. The fact that the subjects with social phobia obtained higher scores on these particular items lends further support to the contention (Taylor, Koch, & McNally, 1992) that they are primarily assessing concerns about the social consequences of anxiety.

Similar to the results reported by Taylor et al. (1991) in their comparison of subjects with panic disorder and a mixed group of subjects with other anxiety disorders, the present study found that the diagnostic groups did not differ on items assessing fears of cognitive symptoms or loss of control. This suggests that these concerns are not specific to panic disorder but are also found more generally in social phobia and other anxiety disorders (Taylor et al., 1991). Taken together, the present findings generally replicate previous research (e.g., Taylor et al., 1991; Taylor, Koch, & Crockett, 1992) and confirm that fear of somatic symptoms and the consequences of those

symptoms is particularly relevant to the phenomenology of panic disorder. Further, these concerns differentiate panic disorder from social phobia.

General Discussion

There are several implications of the present results for the assessment and treatment of panic disorder. With regard to assessment, the findings support the use of the Anxiety Sensitivity Index as an outcome measure for treatment evaluation studies and general clinical purposes. However, there are other broader applications of the ASI as an assessment tool which should be explored. For instance, within the constellation of feared anxiety symptoms and catastrophic consequences associated with the anxiety sensitivity construct, there are obviously individual differences across panic disorder patients. A potential application, then, is to use the ASI to identify the specific symptoms and consequences which are relevant to individual patients and tailor treatment to these concerns. Given the concerns about somatic symptoms expressed by panic disorder patients with elevated anxiety sensitivity levels, these individuals are likely to be good candidates for interoceptive exposure, and the ASI could be used to identify the particular symptoms which should be targeted by treatment. Similarly, the ASI could be used to assess the specific cognitive content which should be the focus of cognitive interventions for individual patients.

The results of the present study point to a number of directions for future research. While the findings suggest that anxiety sensitivity is responsive to cognitive-behavioral treatment, it remains to be seen whether similar effects are achieved with successful pharmacological treatment. Additional studies investigating the maintenance of change in anxiety sensitivity following treatment are also needed. A previous study (McNally & Lorenz, 1987) reported that elevated anxiety sensitivity levels at post-treatment did not predict relapse at follow-up assessment when agoraphobic avoidance was used as the indicator of relapse. These findings should be replicated in order to determine if change in anxiety sensitivity is maintained over time, and also to examine whether ASI scores predict relapse on other clinical indicators, such as frequency of panic attacks and agoraphobic avoidance.

It has previously been suggested that the items on the ASI (i.e., items 1, 7, and 13) which appear to be assessing social concerns arising from anxiety symptoms should be removed in order to make the instrument more homogeneous. While the current findings lend further support to the suggestion that these items are measuring concerns of a social-evaluative nature, additional factor analytic studies with clinical samples are required. Another future direction for research is to examine the concordance between anxiety symptoms and fear of symptoms. In other words, is severity of specific symptoms, such as cardiac or

respiratory symptoms, related to fear of those symptoms? Answers to such questions may provide important insights into the acquisition and maintenance of fear of anxiety symptoms.

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Appendix A

Your Initials _____

Date _____

Please circle the number below which best describes you.

	very little	a little	some	much	very much
It is important to me not to appear nervous	0	1	2	3	4
When I cannot keep my mind on a task, I worry that I might be going crazy	0	1	2	3	4
It scares me when I feel 'shakey' (trembling)	0	1	2	3	4
It scares me when I feel faint	0	1	2	3	4
It is important to me to stay in control of my emotions	0	1	2	3	4
It scares me when my heart beats rapidly	0	1	2	3	4
It embarrasses me when my stomach growls	0	1	2	3	4
It scares me when I am nauseous	0	1	2	3	4
When I notice that my heart is beating rapidly, I worry that I might have a heart attack	0	1	2	3	4
It scares me when I become short of breath	0	1	2	3	4
When my stomach is upset, I worry that I might be seriously ill	0	1	2	3	4
It scares me when I am unable to keep my mind on a task	0	1	2	3	4
Other people notice when I feel shakey	0	1	2	3	4
Unusual body sensations scare me	0	1	2	3	4
When I am nervous, I worry that I might be mentally ill	0	1	2	3	4
It scares me when I am nervous	0	1	2	3	4

Appendix B

FEAR QUESTIONNAIRE: Your Initials: _____ Date: _____

1. Describe in your own words on the line below the major fear that you want treated:

2. Circle a number from the scale below to indicate how distressing this fear is to you.

0 1 2 3 4 5 6 7 8

Not at all distressing Slightly distressing Definitely distressing Moderately distressing Very severely distressing

Choose a number from the scale below to indicate how much you would avoid each situation listed below because of fear or other unpleasant feelings. Then, write the number you chose in the space opposite each item.

0 1 2 3 4 5 6 7 8

Would not avoid it Slightly avoid it Definitely avoid it Markedly avoid it Always avoid it

- 1. Your major fear that you described above
2. Injections or minor surgery
3. Eating or drinking with other people
4. Hospitals.....
5. Travelling alone by bus
6. Walking alone in busy streets ..
7. Being watched or stared at
8. Going into crowded stores
9. Talking to people in authority
10. Sight of blood
11. Being criticized
12. Going alone far from home
13. Thought of injury or illness
14. Speaking or acting to an audience
15. Large open spaces
16. Going to the dentist
17. Visiting a person who is seriously ill or dying
18. Encountering things which remind you of death.....

List any other situations you avoid because of fear or other unpleasant feelings and rate as above:

- 19.
20.

over...

Appendix C

SHEEHAN PATIENT RATED
ANXIETY SCALE
(SPRAS)

*Instructions: Below is a list of problems that people sometimes have. Circle the number to the right that best describes how much that problem bothered or distressed you during the past week. Circle only one number for each problem and do not skip any items.

0 = Not at all 1 = A little bit 2 = Moderately 3 = Markedly 4 = Extremely

DURING THE PAST WEEK, HOW MUCH WERE YOU BOTHERED BY:

- | | |
|--|-----------|
| 1. Lightheadedness, faintness or dizzy spells. | 0 1 2 3 4 |
| 2. Sensation of rubbery or "jelly" legs. | 0 1 2 3 4 |
| 3. Feeling off balance or unsteady like you might fall. | 0 1 2 3 4 |
| 4. Difficulty in getting your breath or overbreathing. | 0 1 2 3 4 |
| 5. Skipping or racing of your heart. | 0 1 2 3 4 |
| 6. Chest pain or pressure. | 0 1 2 3 4 |
| 7. Smothering or choking sensation or lump in throat. | 0 1 2 3 4 |
| 8. Tingling or numbness in parts of your body. | 0 1 2 3 4 |
| 9. Hot flashes or cold chills. | 0 1 2 3 4 |
| 10. Nausea or stomach problems. | 0 1 2 3 4 |
| 11. Episodes of diarrhea. | 0 1 2 3 4 |
| 12. Headaches or pains in neck or head. | 0 1 2 3 4 |
| 13. Feeling tired, weak, and exhausted easily. | 0 1 2 3 4 |
| 14. Spells of increased sensitivity to sound, light or touch. | 0 1 2 3 4 |
| 15. Bouts of excessive sweating. | 0 1 2 3 4 |
| 16. Feeling that things around you are strange, unreal, foggy, or detached from you. | 0 1 2 3 4 |

DURING THE PAST WEEK, HOW MUCH WERE YOU BOTHERED BY:

- | | |
|--|-----------|
| 17. Feeling outside or detached from part or all of your body. | 0 1 2 3 4 |
| 18. Worrying about your health too much. | 0 1 2 3 4 |
| 19. Feeling you are losing control or going insane. | 0 1 2 3 4 |
| 20. Having a fear that you are dying or that something terrible is about to happen. | 0 1 2 3 4 |
| 21. Shaking or trembling. | 0 1 2 3 4 |
| 22. Unexpected waves of depression occurring with little or no provocation. | 0 1 2 3 4 |
| 23. Emotions and moods going up and down a lot in response to changes around you. | 0 1 2 3 4 |
| 24. Being dependent on others. | 0 1 2 3 4 |
| 25. Having to repeat the same action in a ritual, e.g. checking, washing, counting repeatedly, when it's not really necessary. | 0 1 2 3 4 |
| 26. Recurrent words or thoughts that persistently intrude on your mind and are hard to get rid of, e.g. recurrent unwanted aggressive sexual or poor impulse control thoughts. | 0 1 2 3 4 |
| 27. Difficulty in falling asleep. | 0 1 2 3 4 |
| 28. Waking up in the middle of the night or restless sleep. | 0 1 2 3 4 |
| 29. Avoiding situations because they frighten you. | 0 1 2 3 4 |
| 30. Tension and inability to relax. | 0 1 2 3 4 |
| 31. Anxiety, nervousness, restlessness. | 0 1 2 3 4 |
| 32. Sudden unexpected panic spells that occur with little or no provocation, e.g. anxiety attacks with three or more of the symptoms listed above occurring together. | 0 1 2 3 4 |
| 33. Sudden unexpected spells of symptoms like those listed above, without full panic that occur with little or no provocation (e.g. attacks associated with only one or two symptoms). | 0 1 2 3 4 |
| 34. Anxiety episodes that build up as you anticipate (before) doing something and that are more intense than most people experience in such situations. | 0 1 2 3 4 |
| 35. Surges of panic that occur while you are in the phobic situation. | 0 1 2 3 4 |

Appendix D

Clinical Global Improvement Scale - Change

Compared to the patient's condition at the time of entry to the study (baseline), how has the patient's illness changed? Rate the extent to which the patient has changed regardless of whether or not, in your judgement, it is entirely due to treatment.

CGI - Overall illness

- 1 Very much improved
- 2 Much improved
- 3 Minimally improved
- 4 No change
- 5 Minimally worse
- 6 Much worse
- 7 Very much worse

Appendix E

 Panic Attack Diary

INITIALS: _____ DAY: _____ DATE: _____

A panic attack is sudden, unexpected onset of intense apprehension, fear, or terror. Fill in the form immediately after your panic attack ends.

Please circle the numbers of the bodily sensations or symptoms that occurred during your attack.

1. shortness of breath or smothering sensations
2. choking
3. palpitations or accelerated heart rate
4. chest pain or discomfort
5. sweating
6. faintness
7. dizziness, lightheadedness, or unsteady feelings
8. nausea or abdominal distress
9. feeling that you or your surroundings are strange or unreal
10. numbness or tingling sensations
11. flushes (hot flashes) or chills
12. trembling or shaking
13. fear of dying
14. fear of going crazy or doing something uncontrolled
15. desire to flee or escape
16. difficulty thinking

other symptoms:

17. _____
18. _____

List in order the numbers of the first three symptoms that you experienced:

Did you expect that you might panic in this situation? yes _____ no _____

6. Experiencing symptoms as strong as you have ever felt.

						yes		no
1	2	3	4	5	6	7	8	9
not at all confident						moderately confident		totally confident

7. Having thoughts as intense, scary, and real as you have ever had.

						yes		no
1	2	3	4	5	6	7	8	9
not at all confident						moderately confident		totally confident

8. Having a full-fledged attack that lasts 15 minutes.

						yes		no
1	2	3	4	5	6	7	8	9
not at all confident						moderately confident		totally confident

9. Having a full-fledged attack that lasts 30 minutes.

						yes		no
1	2	3	4	5	6	7	8	9
not at all confident						moderately confident		totally confident

10. Having a full-fledged attack that lasts several hours.

						yes		no
1	2	3	4	5	6	7	8	9
not at all confident						moderately confident		totally confident

11. Having a full-fledged attack that lasts all day and seems as though it will not subside.

						yes		no
1	2	3	4	5	6	7	8	9
not at all confident						moderately confident		totally confident

Appendix G

CONSENT FORM

Voluntary Participation

I understand that my participation is voluntary and that I may withdraw at any time that I wish with no penalty. If I chose not to participate or withdraw I will remain on the list for participation in Anxiety Disorders Association of Manitoba programs. If I wish, information will be provided about alternative treatment resources available in Winnipeg. I agree not to start any other self-help book or program while I am participating in this study. In addition, I agree to inform the staff of the project of any other medical or psychological treatment initiated during the course of this program.

Confidentiality

I have been further informed that personal information regarding my assessment and treatment is confidential and may only be shared with the staff involved with the study. The evaluation information gathered during the program will be used for research purposes, however, any details that may reveal my identity will be excluded from any research reports.

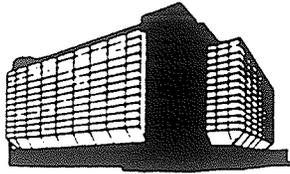
I, _____, have been informed of the nature of the self-administered treatment manual study by _____ and consent to participate in it. A copy of this agreement has been provided to me.

SIGNATURE

DATE

WITNESS

Appendix H

**St. Boniface General Hospital Research Centre**
Hôpital Général St. Boniface Centre de Recherche**INFORMATION AND CONSENT FORM**

A double-blind randomized study to compare the efficacy and safety of Moclobemide with placebo in patients with panic disorder with or without agoraphobia (Protocol N13357B)

Nature and Purpose of the Study

Panic disorder is an illness marked by recurrent panic attacks, and, in some cases, the occurrence of agoraphobia. It afflicts approximately 1% of the general population. While several effective pharmacologic and nonpharmacologic treatments have recently become available, there remains the need to develop new medications which will be effective with fewer side-effects.

This is a study of the usefulness of a new medication, moclobemide, in the treatment of panic disorder. The University of Manitoba is one of 14 Canadian centres participating in this multi-centre trial. The medication being tested in this study, moclobemide, is from a new class of medications known as "reversible inhibitors of monoamine oxidase type A" (RIMAs). This medication is available in several European countries for the treatment of depression, but is an investigational medicine here because it has not yet been approved for general use in Canada by the Health Protection Branch.

The purpose of this study is to evaluate the effectiveness of moclobemide in the treatment of panic disorder with or without agoraphobia. Two doses of moclobemide will be compared to placebo (an inert medication). You will be randomly assigned to receive moclobemide (300 mg/day), moclobemide (600 mg/day) or placebo for 8 weeks. In addition, there will be a one week period during which you will receive placebo, making the total duration of the study 9 weeks. This is a "double-blind" study which means that neither you nor your psychiatrist know which of the medications you have been assigned to receive. This procedure is common in scientific research and assures that there is no bias in the results. A sealed code, with the information as to which medication you are receiving, is available in the case of an emergency.

Study Procedures

You will be interviewed to determine whether drug therapy is recommended for your symptoms. You will undergo a routine physical examination, electrocardiogram (EKG), blood and urine tests, and a pregnancy test (for women of childbearing potential). If the results of these tests and examinations indicate that you are in good physical health, you will be gradually discontinued from previous medications for your panic disorder. You will also be given a supply of medication for one week. At the end of the week, you will be evaluated again. If you still continue to meet all of the study criteria, you will be given an additional supply of medication. You will also be asked to return to the clinic for six (6) visits over an eight (8) week period. At

Moclobemide in Panic Disorder

each visit you will be interviewed by a psychiatrist to determine whether the medication is working and to ensure that it is not causing you any significant problems. You will also be asked to fill out questionnaires asking about how you are feeling. At every visit, your blood pressure and heart rate will be checked and you will be asked for a urine sample. You will also be given a diary to record the occurrence of your panic attacks between visits. During the study routine blood tests (twice) and another physical examination will be performed. The purpose of these tests is to monitor the effects of the medication. There will also be one (1) additional time during the study when blood will be drawn to monitor the levels of moclobemide in your blood.

As with all investigational medications, your reactions to the medication will be carefully monitored. It is extremely important that the psychiatrist or research assistant be informed of all drugs in addition to the study medication you are using while participating in the study. This also includes over-the counter (non-prescription) medications.

If you respond to whatever medication you receive in this study, you will be offered the opportunity to enter a double-blind, follow-up study for up to one year. Your participation in this twelve-month extension will be purely optional, and is not a prerequisite for taking part in this briefer 9-week study.

Potential Benefits of the Study

You may potentially benefit from the study by experiencing the possible elimination or relief of your anxiety symptoms. Your participation in the study may be of help in the future treatment of patients with panic disorder. However, it is possible that you may not derive any benefit from participation in this study.

Possible Risks of the Study

Moclobemide has been given to over 2000 patients and volunteers. No systematic clinical or laboratory abnormalities of a significant nature were detected with dosages of up to 600 mg daily. The most common side-effects reported were, in order of decreasing frequency: dry mouth, headache, sleep disturbances, nausea, dizziness, restlessness/nervousness, constipation, tiredness, tremor, and increased agitation. Overall, the rate of side-effects associated with the use of moclobemide has been lower than with most other antidepressants.

This family of medications may also interact with substances in food and beverages to cause elevations in blood pressure. Moclobemide appears to possess less potential to cause this problem and therefore you will not have a restricted diet. However should you experience symptoms of elevations in blood pressure such as severe headaches, palpitations or neck stiffness you should contact the study psychiatrist immediately, or if he/she is not readily available, go to the nearest emergency room to have your blood pressure checked.

There may be some pain or bruising associated with the drawing of blood, but this is expected to be minor.

Moclobemide in Panic Disorder

Precautions

Women of childbearing potential should avoid getting pregnant by using a proven and reliable method of contraception. If you are unsure about whether or not your current method of birth control is good enough, please discuss this with the study physician.

Alternative Treatments

There are other drugs used to treat panic disorder. These include antidepressants and anxiolytics. Also, specific kinds of psychotherapies are used to treat panic disorder. Each of these treatments has recognized advantages and disadvantages which will be explained to you by the study psychiatrist.

Study Sponsor

The sponsor of this study is Hoffmann-La Roche Limited.

Confidentiality

Every effort will be made to keep your medical records confidential. Your name will not appear in any reports which may be published based on this research. Only authorized study personnel at St. Boniface Hospital and the University of Manitoba will have access to information obtained from this study. In addition, authorized representatives from the Canadian Health Protection Branch or other government agencies, and the sponsor, Hoffmann-La Roche, will be allowed to inspect your medical records. Each of these agencies has strict policies regarding the protection of confidentiality.

Participation

Your participation in this study is entirely voluntary. You are free to decline to participate, or to withdraw your consent to participate at any time during the study. Your participation may also be discontinued without your consent, if in the opinion of the study psychiatrist it is in your best interest, if you fail to comply with the study procedures, or if the project is withdrawn by the sponsor.

If Problems Arise

Should you have an adverse reaction or injury as a result of this study or should you have any questions concerning this study you should contact the research physician at the phone number you have been given. The principal investigator for this study is Dr. Murray Stein, who may be reached at Outside of the hours of 9 AM - 5 PM, you should contact the psychiatrist on-call for St. Boniface Hospital, who may be reached by calling

Moclobemide in Panic Disorder

**CONSENT FORM FOR PARTICIPATION IN STUDY
MOCLOBEMIDE IN THE TREATMENT OF PANIC DISORDER**

I, _____ have been informed of the nature and purpose of the study as well as the potential risks and benefits of participation in the study. I have had an opportunity to ask questions about the study, and all of my questions have been answered to my satisfaction.

I give my voluntary and informed consent to participate in this study. I understand that I am free to withdraw my consent at any time.

I have received a copy of the information and consent for this study.

Subject Signature

Date

Witness Signature

Date

Investigator Signature

Date