Summary and Conclusions of the SBU Report on:

# **Treatment** of Anxiety Disorders

A Systematic Review

November 2005

### Project Group:

Lars von Knorring (Chair) Viveka Alton Lundberg Vanna Beckman (Participated 1995–2002) Ingrid Håkanson Susanne Bejerot Roland Berg (Participated 1995–2002) (Project Director Cecilia Björkelund Per Carlsson (Participated 1995–1999)

(Participated 1995–2001) Tom Fahlén Mats Fredrikson (Project Assistant) Agneta Pettersson during 2004–2005) Per-Anders Rydelius

Elias Eriksson

Sten Thelander (Project Director during 1995–2004) Helene Törnqvist (Participated 1999–2005) Kristian Wahlbeck (Participated 2002–2005) Hans Ågren

### Scientific Reviewers:

Fredrik Almqvist Per Høglend Alv A. Dahl Raben Rosenberg

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# conclusions

## **SBU's Conclusions**

u	For each anxiety disorder, one or more treatments have prove to be effective (Evidence Grade 1). With the exception of specific phobias, both pharmacological treatment and psycho therapy are moderately effective. The symptoms are alleviated but full remission is rarely achieved. With a few exceptions, the symptoms recur once treatment has been completed.
	The socioeconomic costs – primarily in terms of lower productivity, as well as greater ill-health, death rates and the need for somatic care (treatment for physical symptoms) – are high The cost effectiveness of various treatment options has not been determined.
	There is insufficient scientific evidence for comparing either the efficacy or cost effectiveness of different treatments.
	Studies of psychodynamic therapies are almost totally lacking
	Some benzodiazepines have been shown to be effective in treating certain anxiety disorders. However, it has been well established that the drugs cause significant problems in terms of side-effects, dependence or an exacerbation of symptoms after treatment has proceeded for a certain period of time.
	No study has unequivocally explained why anxiety disorders are associated with raised death rates. Long-term studies on how to reduce raised death rates through some form of intervention are lacking.

Panic disorder (PD), with or without agoraphobia (fear of having a panic attack in a place from which escape would be difficult)
□ The antidepressants sertraline, paroxetine, imipramine and clomipramine (Evidence Grade 1), as well as most likely cita-

4	The antidepressants sertraline, paroxetine, imipramine and
	clomipramine (Evidence Grade 1), as well as most likely cita-
	lopram and moclobemide (Evidence Grade 3), reduce the fre-
	quency of panic attacks. Agoraphobia is only slightly affected
	by antidepressants (Evidence Grade 2).
כ	Exposure to the situations that cause panic alleviates the symptoms of agoraphobia with PD (Evidence Grade 2).
3	Cognitive behavioral therapy (CBT) that includes exposure
	alleviates the symptoms of PD without agoraphobia or with
	mild to moderate agoraphobia (Evidence Grade 1). Its effec-
	tiveness for PD with severe agoraphobia has not been estab-

☐ Psychotherapy has a more longlasting effect than psychotropic drugs (Evidence Grade 2).

of agoraphobia (Evidence Grade 2).

lished. Exposure as a monotherapy alleviates the symptoms

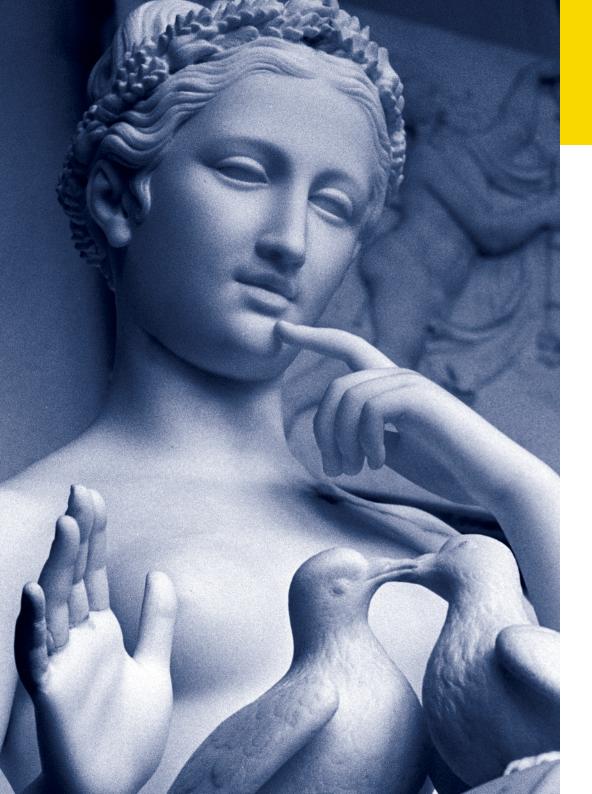
☐ Antidepressants and CBT or exposure have proven to be more effective in combination than as monotherapies (Evidence Grade 2).

Specific Phobias

- ☐ Exposure, modeling and participant modeling, in which the patient learns to handle whatever triggers the fear, has a substantial, long-term impact on specific phobias (Evidence Grade 1).
- ☐ There is no proven pharmacological treatment for specific phobias.

### Social Anxiety Disorder (SAD) ☐ Fluvoxamine, sertraline, paroxetine, venlafaxine and escitalopram alleviate the symptoms of SAD (Evidence Grade 1). ☐ CBT, particularly in a group setting, alleviates the symptoms of SAD (Evidence Grade 1). ☐ Antidepressants and psychological therapies have not proven more effective in combination than when administered separately (Evidence Grade 2). Obsessive-Compulsive Disorder (OCD) ☐ Clomipramine, sertraline, paroxetine, fluoxetine, fluoxamine (Evidence Grade 1) and citalopram (Evidence Grade 2) alleviate the symptoms of both obsessions and compulsions. The drugs are effective as long as they are being administered, but most patients relapse once the treatment has been terminated (Evidence Grade 2). ☐ Behavioral therapy (exposure/response prevention) reduces the symptoms in approximately half of all patients with compulsions (Evidence Grade 1). The effect remains at two-year follow-up (Evidence Grade 2). Post-Traumatic Stress Disorder (PTSD) ☐ Fluoxetine, sertraline and paroxetine alleviate the symptoms of PTSD (Evidence Grade 1). Sertraline remains effective at oneyear follow-up (Evidence Grade 1). ☐ Various kinds of repeated exposure to that which is reminiscent of the traumatic event (Evidence Grade 1) and CBT (Evidence Grade 2) alleviate the symptoms of PTSD.

_	Eye Movement Desensitization and Reprocessing (EMDR), which combines eye movements with behavioral therapy, is effective for PTSD (Evidence Grade 2), but the eye movements lack specific therapeutic value (Evidence Grade 1).
Ge	neralized Anxiety Disorder (GAD)
	Paroxetine, venlafaxine (Evidence Grade 1), sertraline and escitalopram (Evidence Grade 2) alleviate the symptoms of GAD.
	CBT is effective for GAD (Evidence Grade 2).
Tr	eating Children and Adolescents
	CBT alleviates the symptoms of separation anxiety disorder, overanxious disorder, GAD and SAD (Evidence Grade 1). The effect remains at two-year follow-up (Evidence Grade 2). Fluoxetine, paroxetine, sertraline and fluvoxamine have proven to alleviate the symptoms, but none of them has been approved for these disorders in children and adolescents.
	Exposure to the feared object or situation is effective for patients with specific phobias (Evidence Grade 1).
	Clomipramine, sertraline, fluoxetine (Evidence Grade 1), paroxetine and fluvoxamine (Evidence Grade 2) alleviate the symptoms of OCD. Clomipramine, sertraline and fluvoxamine have been approved for treatment in children and adolescents.
	Behavioral therapy, whether CBT or not, is equally effective as antidepressants for treating OCD (Evidence Grade 1). Combination treatment is somewhat more effective (Evidence Grade 1).
	CBT alleviates the symptoms of PTSD (Evidence Grade 2).



# **SBU Summary**

### Introduction

WHO estimates that mental illness accounts for 12 percent of the burden of disease worldwide. Panic disorder is the eleventh most common cause of ill-health in people aged 15–44.

Anxiety disorders entail high socioeconomic costs. According to a 1996 calculation, annual indirect costs – particularly sick leave and early retirement pensions – in Sweden totaled more than SEK 17 billion. Direct healthcare costs came to SEK 1.5 billion, of which SEK 0.3 billion was for drugs.

Anxiety may be defined as apprehension, fear or physical tension as the result of an anticipated danger or misfortune, whether external or internal. Anxiety and apprehension as isolated symptoms are common and occur in connection with a number of mental disorders, including depression and psychoses.

In the case of an anxiety disorder, two or more symptoms of anxiety occur simultaneously in a specific manner and with a certain degree of permanence. To qualify as a disorder, the anxiety must be so severe that it leads to substantial restrictions on the patient's daily life or other functional impairment. The diagnostic classification of a disorder is based on observations rather than knowledge of the underlying mechanisms involved and there are no known biological markers that can be used to make the diagnosis.

### The Assignment

The assignment was to examine various methods of treating the established anxiety disorders. Intervention to alleviate non-specific symptoms of worry, apprehension and anxiety were not part of the assignment. The assessment included the treatment of children, adolescents and adults with:

- Panic disorder (PD)
- Obsessive-compulsive disorder (OCD)
- Post-traumatic stress disorder (PTSD)
- Generalized anxiety disorder (GAD)
- Specific phobias.

Because the course of anxiety disorders is often protracted, a special focus was placed on identifying studies that evaluate the long-term effects of treatment.

The report is based on a systematic perusal of the literature. The review began with an extensive database search to find all publications that deal with the treatment of anxiety disorders. During a step-by-step process, the studies were selected that met the criteria of SBU's quality rating template for psychiatric projects.

The efficacy of a drug was assessed on the basis of randomized studies in which it had been compared with placebo or another active treatment.

For evaluation of psychotherapies, studies in which the control group was on the waiting list for treatment were also accepted. The compilation of the studies, as well as the quality and internal validity of each one, forms the basis of the conclusions that were reached with respect to treatment effects. The total scientific evidence was assigned an evidence grade (see Fact Box 1).

It is important to be aware of the generally known risk of publication bias, i.e., that studies with positive findings are overrepresented in the literature.

### Fact Box 1

### Criteria for Evidence Grading SBU's Conclusions

### Evidence Grade 1 - Strong Scientific Evidence

The conclusion is corroborated by at least two studies with high quality and internal validity, as well as a good systematic overview.

### Evidence Grade 2 - Moderately Strong Scientific Evidence

The conclusion is corroborated by one study with high quality and internal validity, as well as at least two studies with medium quality and internal validity.

### Evidence Grade 3 - Limited Scientific Evidence

The conclusion is corroborated by at least two studies with medium quality and internal validity.

### Insufficient Scientific Evidence

No conclusions can be drawn when there are not any studies that meet the criteria for quality and internal validity.

### **Contradictory Scientific Evidence**

No conclusions can be drawn when there are studies with the same quality and internal validity whose findings contradict each other. The rating presumes that the studies point in the same direction. If the discrepancies are small, the evidence grade may be lowered. A large, well-designed, randomized, controlled study conducted at many centers can replace two small studies.

Regulatory agencies have drawn attention to the problem. For instance, a report of the Swedish Medical Products Agency demonstrated that studies of antidepressants are published on a selective basis.

The project group's perusal of the literature identified large, randomized studies that had only been presented in digest form or summarized for conferences but not published in scientific journals. If that is an indication of publication bias, the efficacy of both drugs and psychotherapies may have been overestimated.

### **Symptoms and Definitions**

Anxiety can manifest in panic attacks, phobias and obsessions/compulsions.

*Panic attacks* may be defined as limited, sudden fits of intense fear, fright or terror. The panic is often associated with a sense of imminent collapse, as well as purely physical symptoms such as extra heartbeats and a choking sensation.

*Obsessions* are recurring, obtrusive thoughts. A compulsion is an act that appears to be goal oriented and that is performed in response to an obsession or in accordance with a rule that the person feels constrained to obey.

*Specific phobias* may be defined as the permanent, irrational fear of a particular stimulus (a precipitating phenomenon, activity or situation). As a result, the person either tries to avoid the stimulus or suffer their way through it.

### **Diagnostic Criteria**

There are two major systems for diagnosing mental disorders: WHO's International Classification of Diseases (ICD) and the APA's Diagnostic and Statistical Manual of Mental Disorders (DSM). Both systems have been revised on a number of occasions. DSM-IV and ICD-10 have been in effect for more than 10 years. The various versions have defined anxiety disorders differently. ICD-10 and DSM-IV usually define them similarly, but limited discrepancies may be significant when it comes to distinguishing among different disorders, the spontaneous course of disease and response to treatment. Comparing studies that use different

versions of the same system may also lead to certain problems. For instance, only DSM-IV requires that a condition last for six months and cause significant suffering before being classified as generalized anxiety disorder. Thus, there is a risk that a selection of patients based on DSM-III criteria will not coincide with one based on DSM-IV.

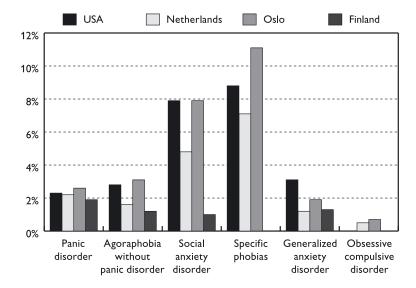
The assessment of treatment effects has taken the classification system and version used into consideration.

Rating scales are often employed to measure the severity of the disorder and the efficacy of treatment. A large number of scales have been developed for each disorder.

# **Anxiety Disorders are Common**

Anxiety disorders are a common phenomenon. The point prevalence, i.e., the number of people who have had an anxiety disorder over a 12-month period, varies between 12 percent and 17 percent in different epidemiological studies. An estimated 25 percent of the population has an anxiety disorder sometime during their lives.

The many epidemiological studies in different countries and cultures generally show similar incidences of the various disorders (see Figure 1). That data is presumably applicable to Sweden as well. Social anxiety disorder, the incidence of which appears to be more dependent on social and cultural conditions, may be an exception.



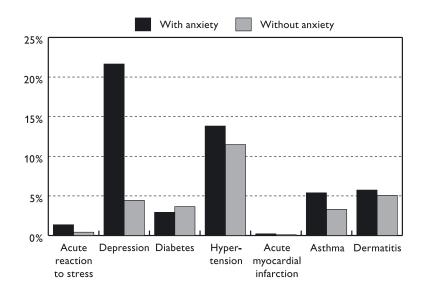
**Figure 1** Incidence of anxiety disorders (percent) in adults (aged 20–60) for one year in the United States (National Comorbidity Survey), the Netherlands (Netherlands Mental Health Survey and Incidence Study), Oslo (Kringlen et al) and Finland (Health 2000 Study).

Women are at higher risk than men of having an anxiety disorder. Studies in the United States and the Netherlands indicate that 13–20 percent of men and 25–30 percent of women have an anxiety disorder sometime during their lives.

The course of certain anxiety disorders has been shown to differ between women and men. That must be taken into consideration when assessing the efficacy of treatment.

### **Comorbidity and Raised Death Rates**

People with an anxiety disorder often have other diseases at the same time. A large epidemiological study found that patients averaged more than two concurrent mental disorders while some had as many as seven. More than 80 percent of people with specific



**Figure 2** Comparison of the incidence of certain mental and physical conditions in 1,900 people with anxiety and 1,900 people without anxiety (Marciniak et al, Depress Anxiety 2004;19:112-20).

phobias, and more than 90 percent with generalized anxiety disorder, had another mental disorder at the same time. Concurrent substance abuse is also common. An American study found that more than 35 percent of subjects with generalized anxiety disorder or specific phobias abused alcohol or drugs.

Physical conditions such as heart trouble, diarrhea, constipation, elevated cholesterol levels and asthma are more common in patients with anxiety disorders than in the general population (see Figure 2).

Many anxiety disorders are associated with significantly raised death rates. For instance, a meta-analysis found that the death rate among people with panic disorder was twice that of the general population and considerably higher than that of people with depression.

Where Are the Patients? Our knowledge of treatment effects and diagnosis is based on studies of specialist care services, where patients generally have more severe problems. However, 70 percent of adult patients are in the primary care system. Often their symptoms are milder and not viewed as typical of anxiety disorders. Many patients turn to primary care not for anxiety, but for physical complaints such as chest pains, palpitations and indigestion. Some patients are examined for other conditions before being diagnosed with and treated for anxiety disorders. A number of Swedish and international studies confirm that fewer than half of patients with anxiety disorders are diagnosed at an early stage. For instance, a major American study entitled PRIME-MD 1000 reported that 61 percent of the patients were not diagnosed despite the fact that they had been seeing a doctor for an extended period of time. Diagnostic quality can be improved through the use of aids such as structured questionnaires and rating scales

Without diagnostic aids With diagnostic aids Prime-MD 1000 Bodlund 1995

Figure 3 Percentage of patients with anxiety disorders detected in primary care

are affected by the way that care is organized. An American study found that the addition of patient training, telephone follow-up and access to a psychiatric consultant produced better results than a control group that received standard treatment only. The implication is that cooperation between primary and specialist psychiatric care can lead to more effective treatment.

### The Social Consequences of Anxiety Disorders

Both health economic studies and official statistics on healthrelated costs confirm that anxiety disorders consume substantial social resources. Because available Swedish statistics are based on der is not known.

(see Figure 3). There are a handful anxiety conditions in a broader sense, the percentage of people of studies that illustrate with "worry, apprehension or anxiety" who have an anxiety disorhow treatment results

Healthcare consumption is high, studies performed on patients with anxiety disorders estimating that nearly 60 percent of the costs are attributable to non-psychiatric care. One study concluded that asthma patients who had a concurrent anxiety disorder generated three times the hospital costs of asthma patients without anxiety.

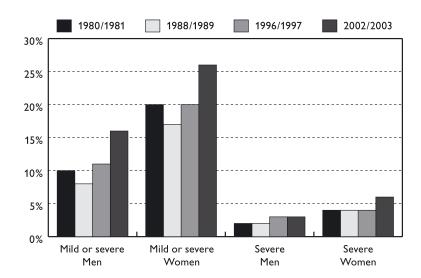
Many patients with anxiety disorders are unable to work for limited or extended periods of time. The data indicates that nearly half of them are completely outside the workforce. Some people, particularly women, may not make it into the job market at all. As indicated by Statistics Sweden's annual Survey of Living Conditions (see Figure 4), mental illness is a growing problem. A five-year follow-up of people who had reported anxiety, worry or apprehension found an elevated relative risk of attempted suicide, as well as hospital stays owing to a psychiatric diagnosis. In 2003, the National Social Insurance Board reported that the number of people on long-term sick leave or early retirement pension due to anxiety conditions or depression rose by 6 percentage points from 1995 to 2002.

### **Treatment of Anxiety Disorders**

The literature generally covers pharmacological treatment or psychotherapy.

### **Pharmacological Treatment**

Most of the literature on pharmacological treatment concerns antidepressants and benzodiazepines, the latter of which have proven to be effective with non-specific anxiety. However, benzodiazepines have been shown to carry major disadvantages. Withdrawal can lead to symptoms such as olfactory and tactile disturbances, disorientation and paresthesia (numbness, dizziness, olfactory changes, etc). Anxiety frequently returns after treatment



**Figure 4** Percentage of the Swedish population with worry, apprehension or anxiety (age-standardized). Source: Swedish National Board of Health and Welfare, Public Health Report 2005.

has proceeded for a while, often with greater severity. There is also a major risk of becoming dependent on the drug.

### **Psychotherapy**

The primary methods used by behavioral therapy for anxiety disorders are exposure and relaxation. Exposure involves confronting the feared situation, either incrementally or directly (what is called implosion therapy or flooding). The idea is to get the patient to endure the phobic stimuli and fear as long as possible without fleeing.

Cognitive therapy focuses on influencing thought patterns. There are a number of methods, some of which have been designed to treat anxiety conditions.

Cognitive Behavioral Therapy (CBT), which incorporates elements of both cognitive and behavioral therapy, relies heavily on homework assignments. The distinction among various therapies is nebulous, and determining which one a study has used is often difficult. Usually a mixture of several, i.e., CBT is involved. Interventions based on psychodynamic theories have received very little attention in studies of anxiety disorders.

### **Efficacy of Various Therapies for Anxiety Disorders**

Tables I–III describe the therapies for which efficacy has been documented.

### Panic Disorder (PD)

PD involves more symptoms than the recurring panic attacks themselves. Dizziness, difficulty breathing and ague (fits of shivering) cause many people to misinterpret the disorder as a physical condition. The symptoms appear suddenly, peak rapidly and last only a few minutes. One attack can give rise to fear of another (apprehensive expectation). Panic attacks often result in agoraphobia as well. Agoraphobics try to avoid places and situations in which a panic attack would be embarrassing or that are not conducive to obtaining assistance. Such a situation might include being alone outdoors, waiting in line or using public transportation

PD occurs twice as frequently in women as in men. Several antidepressants have proven efficacious for panic attacks, but they are of limited value when it comes to agoraphobia. While there is no reliable data on how long pharmacological treatment should last, a large percentage of patients relapse within a year regardless of the length. If agoraphobia is mild or moderate, CBT with exposure has been shown to be effective, and there is limited scientific evidence that it leads to more longlasting remission. However, CBT has not proven efficacious for severe agoraphobia.

### Specific Phobias

As the most common anxiety disorder, specific phobias affect 10 percent of the population sometime during their lives. A phobia involves irrational fear of a particular phenomenon, such as a dental appointment, flying, heights, spiders or the sight of blood. While usually not interfering with daily life to a significant extent, the fear may pose major obstacles and become disabling for some people.

The only intervention that has been shown to be efficacious is behavioral therapy with exposure. The intervention is structured according to the level of anxiety that the patient is able to endure. The approach has proven highly effective, and most patients have recovered fully (or almost fully) at one-year follow-up.

### Social Anxiety Disorder (SAD)

SAD is characterized by acute fear of attracting the attention of others in ordinary social situations by blushing, trembling or standing out. As a result, the person is inordinately mindful of their own behavior, which can be stiff and affected. People with SAD avoid social interactions such as coffee breaks and oral presentations, as well as seeking jobs for which they qualify. In severe cases, SAD is disabling and associated with poorer quality of life.

The line between ordinary shyness and SAD is hard to draw and varies from culture to culture. Most population studies have shown the disorder to be somewhat more common in women than in men.

Several drugs, as well as CBT, have a clinically relevant effect. The therapeutic effects are often inadequate.

### Obsessive-Compulsive Disorder (OCD)

OCD is characterized by obsessions and compulsions. Usually destructive or sexual in nature, obsessions elicit intense anxiety and aversion because they conflict with the person's normal attitudes. Although compulsions often center on staying in control (cleanliness, locking doors, turning off burners, etc.), ritualized

actions and collecting or hoarding useless objects may also be involved. The person perceives the symptoms to be abnormal but experiences deep anxiety if they don't perform the compulsion.

Many people are subject to obsessions and compulsions without suffering from a disorder. OCD affects 2–3 percent of the population. The disorder manifests earlier and is often more severe in men than in women. OCD can be disabling in the sense that the rituals take up all of a person's time and prevent them from working.

Behavioral therapy with exposure/response prevention is the best documented treatment, particularly for compulsions. Through repeated exposure to a situation that brings on anxiety, the patient is gradually able to resist the urge to perform the compulsion. While most patients have residual symptoms, the effects of treatment seem to remain at two-year follow-up.

A number of antidepressants have proven to have a clinically relevant effect but do not usually lead to remission. Most patients relapse once the treatment has been discontinued.

### Post-Traumatic Stress Disorder (PTSD)

PTSD was originally described as a reaction to having engaged in battle or been a prisoner of war. Over time the diagnosis has come to include all types of severe trauma preceded by an event that the person perceived to be life threatening. The main symptoms are flashbacks, insomnia, lack of concentration, irritability and muscular tension.

Women, as well as people with previous mental problems, repeated trauma or personality disorders, are at greater risk of developing PTSD.

A few studies suggest that short-term cognitive therapy starting as soon as the first signs of post-traumatic stress appear can avert the onset of PTSD.

Various types of exposure and two different antidepressants have been shown to have a clinically relevant effect, but the patients rarely recover completely.

Generalized Anxiety Disorder (GAD)

GAD manifests primarily as chronic worry along with physical symptoms such as tension, sweating, indigestion and insomnia. Although the worry is often diffuse, it may also involve exaggerated fears of illness or misfortune. Someone with GAD can never relax.

The disorder generally persists for the rest of the person's life, though its course fluctuates. GAD is commonly concurrent with other anxiety disorders or depression. Patients go to the doctor for physical symptoms. If GAD is diagnosed at all, it is usually in primary or somatic care.

Both CBT and a number of drugs have proven effective with GAD.

# Treating Anxiety Disorders in Children and Adolescents

Anxiety disorders appear to manifest similarly in children and adults. The one exception is separation anxiety disorder, which appears in children only for a limited period of time.

Some antidepressants have proven effective for short-term treatment of GAD and SAD, but pharmacological treatment has been approved for OCD only. Among the various psychotherapies,



behavioral therapy has been shown to be effective with OCD and exposure with specific phobias. CBT is effective for GAD and SAD and moderately effective for PTSD.

A few Australian and American studies have found that preventive psychopedagogical intervention for children with elevated anxiety levels can delay the onset of anxiety disorders by several years, but it is unclear whether that subsequently affects mental health into adulthood.

### **Research Needs**

The review of the existing literature revealed inadequate knowledge about treating anxiety disorders. Additional research is urgent in the following areas.

- There is a lack of clarity about how long pharmacological treatment should last, at what point a new kind of intervention is called for, and the extent to which the combination of an antidepressant and psychotherapy is more effective than monotherapy.
- The scientific evidence is insufficient for assessing which diagnosis and treatment strategies are effective with primary care patients.
- Despite the frequency of comorbidity, few studies have examined the effectiveness of treatments for patients with concurrent depression or multiple concurrent anxiety disorders.
- While a large percentage of anxiety disorders in adulthood first manifest in childhood or adolescence, it is unclear whether the risk to adults can be reduced by means of primary prevention or early intervention among children and adolescents.

- Psychodynamic and family therapy are the most common psychological treatments for anxiety disorders in both children and adults. Due to the lack of well-designed studies, their efficacy cannot be verified.
- There is no scientific evidence for assessing what treatment of people with anxiety disorders is most effective.

SBU SUMMARY AND CONCLUSIONS FROM THE REPORT "TREATMENT OF ANXIETY DISORDERS"

**Table I** Antidepressants that have proven effective for treatment of adults with anxiety disorders (the figures in the table represent Evidence Grades).

Anxiety Disorder	Paroxetine	Sertraline	Fluoxetine	Fluvoxa- mine	Citalo- pram	Escitalo- Venlafaxine Imipramine Clomi- Phen pram pramine	elzine Moclo- bemide
Panic disorder	1	1			3	1 1	3
Specific phobias	·	·					·
Social anxiety disorder	1	1		1		1 1	2 2
Obsessive- compulsive disorder	1	1	1	1	2	1	
PTSD	1	1	1				
GAD	1	2				2 1 2	

PTSD = Post-traumatic stress disorder; GAD = Generalized anxiety disorder

**Table II** Other drugs that have proven effective for treatment of adults with anxiety disorders.

Anxiety Disorder	Buspirone	Hydro- xyzine	Alpra- zolam	Lora- zepam	Clona- zepam	Diaze- pam
Panic disorder			1		1	
Specific phobias						
Social anxiety disorder					3	
Obsessive- com- pulsive disorder						
PTSD						
GAD	3	2	1	1		1

PTSD = Post-traumatic stress disorder; GAD = Generalized anxiety disorder

**Table III** Psychotherapies that have proven effective for treatment of adults with anxiety disorders.

Anxiety Disorder	Cognitive behav- ioral therapy, CBT	Behav- ioral therapy with exposure	Relaxa- tion	Cognitive therapy, CT	Psycho- dynamic therapy	EMDR
Panic disorder	1	2	3			
Specific phobias	1	1				
Social anxiety disorder	1					
Obsessive- com- pulsive disorder		1		3		
PTSD	2	1				2
GAD	2					

PTSD = Post-traumatic stress disorder; GAD = Generalized anxiety disorder EMDR = Eye movement desensitization and reprocessing

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