

# A Randomised Control Trial in High-Risk Children of Depressed and Anxious Individuals to Prevent Mood and Anxiety Problems in Youth

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## ABSTRACT

**Background:** A great burden is placed on patients by the increased rate of being anxious and mood abnormalities. In this group, there is a clear need to halt the prevention of psychopathology because their offspring are more likely to have these diseases themselves. Due to the substantial coexisting disorders, preventative programs should concentrate on both anxiety and depression. Furthermore, although increased sensations are frequently a sign of preventative actions, resilience-based prevention programs may also be advantageous for children with other high risk profiles.

**Method:** A randomized control clinical trial is used in the current study. It is designed for high-risk people who are symptomless as well as those who have sub-syndrome symptoms. Two among the criteria of the High Risk are met by individuals who do not exhibit any symptoms (attempt). Among a previous study, this measure was created, and it correlates with a higher risk in children of depressed individuals. Children between the ages of 8 and 17 ( $n = 204$ ) who exhibit sub threshold symptoms or who meet the requirements on the HRI are randomly assigned to either (a) 10 sessions every week for child with CBT (b) limited information.. The main result is when a child's anxiety or mood condition first manifests itself. Secondary end factors include the number of days spent feeling depressed or anxious, the severity of symptoms in children and parents, living quality and financial efficiency. Researchers has chosen coping, parent-child relationship, personal attachments , optimism/pessimism, therapies, and emotion processing as potential mediators of treatment outcome based on the etiology of mood and anxiety disorders as well as processes of change during therapies.

**Results:** The happy and Negative Affect Schedule (PANAS) is a 20-item self-report scale used to assess both happy and negative affect. Positive and negative affect both reflect dispositional characteristics; high negative affect is characterised by unpleasant engagement and subjective distress, whereas low NA is characterised by the lack of these feelings. PA, on the other hand, is a measure of how much an adult enjoys engaging with their surroundings. The Attentional Breadth Task, a computer task that was preprogrammed in e-prime, was also used to measure mother-child attachment. The task is based on the supposition that persons with insecure attachment may process information differently when it comes to data that is pertinent to attachments,

**Practical Implication:** Using a quick and focused intervention aimed at strengthening the family unit, the present intervention trial seeks to drastically lower the chance of passing mood and anxiety disorders down the generations and resiliency in youngsters who could be at risk. We intend to determine the mechanisms of change and assess the efficacy and the intervention's efficacy and cost.

**Conclusion:** Positive and negative affect both reflect dispositional features, according to the study's findings. High negative affect is marked by subjective anguish and unpleasant engagement, whereas low negative affect is marked by the absence of these emotions.

**Keywords:** Anxiety, Mood disorders, Depressed, Youth, teenagers, Pakistan

## INTRODUCTION

With estimates of 11.6% annual prevalence in teenagers alone for anxiety disorders and 3.8% annual prevalence in adolescents for depression, these diseases are very common in children and adolescents. In addition to having a significant detrimental influence on current functioning<sup>2, 3</sup>, infancy and adolescence anxiety and mood disorders are also linked to long-term unfavorable outcomes [4, 5]. According to estimates, 37.400 adolescents (3.8%) in the Netherlands alone are thought to have a depressive disorder<sup>1</sup>. This leads to the mortality rate of 7900 Disability according to "Gezond Verstand"<sup>6</sup>.

Epidemiological data show that mood and mood related disorders frequently runing in families. Children with such issues are more likely to experience by a factor, sadness and anxiety of 2–6, respectively.<sup>7, 8</sup>. Etiologically and phenomenological, mood and anxiety disorders are very similar. The age at which depression first appears is often 5 to 10 years later than the age at which anxiety disorders, such as<sup>10</sup>, first appear. The need to prevent anxiety and mood problems is very important in adolescence given the high frequency of these conditions, their severe personal effects, and the accompanying social costs. Since these problems run in families, preventative efforts may be successful if they begin with the family. Numerous initiatives have been created over the past 20 years to shield kids and teenagers from melancholy or anxiety disorders overview:<sup>2, 11</sup>. Universal prevention initiatives have yielded unsatisfactory outcomes in

terms of both anxiety and mood symptomatology<sup>2, 12</sup>. Results are more encouraging targeted high risk groups) and individuals with subclinical symptoms. Despite the relatively substantial risk in offspring, there have been a small number of randomized control trials that evaluates the effectiveness of indicated prevention: The progeny of depressed patients have been the focus of four randomized trials<sup>13–16</sup>. One study discussed anxiety disorder prevention in kids of anxious parents.

In the first trial, adolescents who were the offspring of depressed parents were subjected to a cognitive group training program called "Coping with Stress" to determine its efficacy (15-sessions) 13. Teenagers ( $N = 94$ ) with symptoms and history of depression were ages 13 to 17. The treatment included cognitive restructuring techniques designed to alter dysfunctional thinking about having a depressive parent in particular as well as maladaptive thoughts generally. In addition to lowering depressive symptomatology, the intervention significantly reduced the depression or panic attacks compared with standard care. Additionally, the program was economical<sup>18</sup>. Almost 316 children between the ages of 13 and 17 were enrolled in the trial by Garber and colleagues. They had experienced depression or mentioned depressed symptoms, and they were children of parents who currently or in the past had a depressive condition.

Teenagers were randomly assigned to receive standard care or a group CBT program consisting of 8 sessions of problem-solving and cognitive restructuring. Parents were welcome to

attend one of the two parent information meetings. The third trial looked at a family program for kids aged 8 to 15 whose parents had a depressive episode during the preceding 18 months to see how successful it was.<sup>16</sup> The family needed at least one child who was free of a depressive condition. It was likened to two plenary parent group lectures and the 6- to 11-session family program. Both therapies promoted candid communication regarding the parental sickness and aimed to alter the dynamics of the family. Based on 105 families, both therapies were effective in improvement of family relationships and reduction of in appropriate behaviors up to 4.5 years after the intervention<sup>18</sup>.

Trial looked at family intervention's effectiveness for households where depression had a history in at least one parent. 19. it's possible that the children will participate in the trial without divulging their own ailments. A group based on 12-session cognitive behavioral family intervention or written material was randomly given to 111 families with 155 children between the age groups of 9 and 15<sup>19</sup>. Children in the family intervention program appeared to gain more from internalizing and externalizing symptoms, according to both parent and child reports, according to the results. At the two-year follow-up, these gains were still present<sup>20</sup>.

The current study advances earlier research while also making several new contributions to it. In order to find out the high risk individuals among the children of patients who had anxiety disorders, we first used additional risk variables. Researcher concentrated on to improvement and strength while easing symptoms. Predicting anxiety and mood issues in offspring of depressed patients

**Objective of the Study:** The primary objective of this study is to determine the effect of cognitive behavioral treatment program in reduction of symptom and lowered the development of depression or anxiety disorder in high risk children of patients with unipolar depression or anxiety disorder..

**METHODS/DESIGN**

The current research is set up as a chosen and indicated preventative program, with the goal of identifying and treating children who are at high risk of developing affective disorders. An effective design is produced by such a method<sup>24</sup>. A limited information condition and an intervention condition are both included in the study's randomized controlled trial (RCT) design.

**Participants:** Children of patients with anxiety or mood illness are participants. Researcher wanted to screen 554 kids (T0) and enroll 204 kids in the study's intervention phase. For parents and kids, we've created inclusion and exclusion standards that are:

Parents' inclusion requirements:

Informed permission; at least one biological parent receiving treatment for an anxiety or unipolar mood illness currently or within the last five years;

Requirements for exclusion (both parents):

Being extremely at risk in developing a mood or anxiety disorder between the ages of 8 and 17 is a requirement for inclusion in the intervention phase (offspring). There are two approaches to satisfy the "extremely high risk" standard: (1).

Exclusion criteria (offspring): mental retardation, a lack of proficiency in Dutch, a serious alcohol addict, a mental disease requiring on going care.<sup>36</sup>

**Procedure:** Screening and intervention are the two phases of the study. The flow diagram provides specifics about the process (Figure 1).

**Referral and Recruitment:** General practitioners, mental health services, and the media all seek for adult patients. Participating in the recruitment are adult and pediatric mental health services. Parents are included to child mental health care if they also suffer from anxiety or a mood illness. These parents' entire offspring are eligible to take part in the study..

Next, we conduct a quick telephone interview to assess the status parent's psychopathology in the past and present. Note that a structured diagnostic interview is used to obtain the precise

diagnosis for each parent during the exams (CIDI). At any point during the evaluation or intervention, participants are always free to withdraw from the research without providing a reason

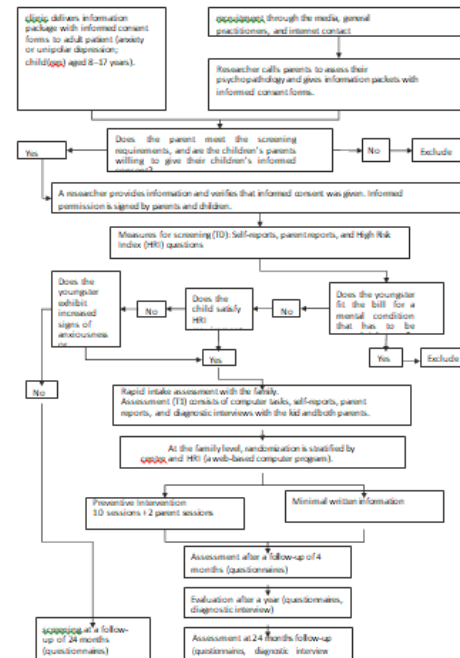


Figure 1. Flow diagram.

**RESULTS**

10 sessions for the children and 2 sessions for the parents made up intervention. Family functioning and social networks are discussed, as well as how to focus on good feelings and events, solve problems, and break the pattern of avoidance behavior. The latter will either emphasize exposure workouts or behavioral activation (a sign of depression symptoms)<sup>35</sup>.

The youngster selects 10 stages to work on throughout the sessions in consultation with the parents. These actions, which are consistent with the aforementioned concepts, could include participation in certain activities, and strengthening exercises. The youngster kept a close eye on the frequency and nature of activities throughout the sessions. Children had enjoyable and playing activities. Parents attended only one session. Additionally, parents were informed about potential effects on children and preventative measures against future child psychology.

**Assessment:** Evaluation includes health questionnaires for parent child assessment (Table 1). The high-risk study population is identified by this initial screening. At T4, the same measurements will be used to reassess all of the parents' participating children. The latter is crucial to determining whether the initial selection of high risk people was valid. The selection technique for future preventative initiatives may need to be reevaluated if a sizable fraction of the low-risk group still exhibits signs of a mood or anxiety problem. ( Figure 1).

Table 1: Assessment schedule for screening (T0) and 24 months follow-up screening

Measures	Child	Parent 1	Parent 2
Demographics (+ HRI)		X	
Child anxiety and depression (RCADS)	X	X	
Child impairment (BIS)		X	
Child externalizing symptoms (SNAP)		X	
Parent positive and negative affect (PANAS)		X	X
Optimism (LOT/YLOT)	X	X	X

Structured interviews of children and parents are part of the pre-intervention assessment, which also includes a variety of other pertinent measurements (Table 2). The intervention phase will

include assessments in first month (T1, the beginning of the intervention), 4 (T2), 12 (T3), and 24 (T4) (T4). A portion of the devices are also planned to be used in months 6 and 18.

Table 2: Assessment schedule for intervention phase

Measures	T1	T2	T3	T4	Child	Parent1	Parent2
Child diagnoses (DISC)	X	-	X	X	X	X	-
Child anxiety and depression (RCADS)	X	X	X	X	X	X	-
Child impairment (BIS)	X	X	X	X	X	-	-
Child externalizing symptoms (SNAP)	X	X	X	X	X	-	-
Child attachment (IPPA)	X	X	X	X	X	-	-
Implicit child attachment (ABT)	X	-	-	-	-	-	-
Child coping (CSLK)	X	X	X	X	X	-	-
Child attributions (CASQ)	X	X	X	X	X	-	-
Child optimism (YLOT)	X	X	X	X	X	-	-
Child self-esteem (RSES)	X	X	X	X	X	-	-
Expressed emotion (FMSS)	X	-	-	-	-	X	X
Implicit Self-associations (EAST)	X	-	-	-	-	-	-
Child executive functions (BRIEF)	X	-	-	-	-	X	-
Child temperament (EATQ)	X	X	X	X	-	X	-
Parent positive and negative affect (PANAS)	X	X	X	X	-	X	X
Parent depression (BDI)	X	X	X	X	-	X	X
Parent anxiety (BAI)	X	X	X	X	-	X	X
Parent substance misuse (AUDIT)	X	X	X	X	-	X	X
Parent optimism (LOT)	X	X	X	X	-	X	X
Parent psychopathology (CID)	X	-	-	-	-	X	X
Cost Effectiveness*	X	X	X	X	-	X	X
Quality of life (EQ-5D)*	X	X	X	X	X	X	X

primary outcome based on the Diagnostic procedures, Version IV. A computer is used to administer the DISC, which is scored using algorithm. The DISC-C is utilized in the current study to evaluate depression, anxiety disorders, and a brief evaluation of alcohol and drug use. Parents can report on their children's symptoms of anxiety and depression using the DISC, which also asks about symptomatology throughout life. The interviewer discusses the previous 12 months during the 12- and 24-follow-up examinations. The interviewer makes an educated guess as to when the disease started and how long it lasted if one was present.

Change Using moderators and mediators, evaluated the following measures that were centered on both child and parent characteristics in order to look into potential mediators and moderators of change: measures based on the child's personality The 12-item Youth Life Orientation (YLOT; was created as a kid-friendly version of the popular Life Orientation Test. It measures dispositional optimism and pessimism. A 24-item abridged questionnaire called the Children's Attributional Style Questionnaire - Revised CASQ-R; is used to evaluate children's causal justifications for both good and bad events. The 15-item Rosenberg Self-Esteem Scale (RSES), which has been translated into other languages, was created for use by both adults and children.

There are 14 subscales in the Children's Coping Strategies Checklist CCSCR1 (CSLK in Dutch) including a number of cognitive coping techniques. Differentiating between coping at home and coping in general may be essential outside, according to earlier study in children <sup>28</sup>. As a result, we used two coping questionnaire versions. Five coping dimensions are included on the scale: "Seeking insight," "Control," "Optimism," "Wishful thinking," "Support for feelings," and "Support for actions."

The Brief Impairment instrument (BIS) is a multidimensional instrument assessing functional impairment for children and adolescents. The 23-item BIS evaluates three functional domains: interpersonal connections, school/work performance, and self-care/self-fulfillment. Children's executive functions are assessed at home and at school using the Behavior Rating of Executive Functioning BRIEF, an 86-item standardized rating scale. To evaluate a child's self-regulation-related temperamental traits, the Early Adolescent Temperament Questionnaire - Revised version (EATQ- R) was developed as a parent-report questionnaire. The 44 items in the present study were divided into three factors: high

intensity pleasure/surgency and effortful control.

The SNAP-IV Parent Rating Scale has 8 items for ODD symptoms and 18 items for ADHD symptoms (inattention and hyperactivity/impulsivity). The Inventory of Parent and Peer Attachment is an 11-item self-report questionnaire (IPPA) in Dutch is used to measure a person's attachment to one significant other and each of their parents. The Attention Breadth Task, a computer task that was preprogrammed in e-prime, was also used to measure mother-child attachment. The task is based on the supposition that persons with insecure attachment may process information differently when it comes to attachment-relevant information.

The father and mother's perceived expressed emotion is evaluated using the Five Minute Speech Sample. Five minutes will be allotted for each parent to discuss their child and their interaction with them. Criticism (CRIT) and emotional over involvement are two components that can be obtained from the text once it has been coded (EOI).

Measures to address psychopathology and parental well-being. The CID 3.0 version of the World Health Organization (WHO) Composite International Diagnostic Interview (WMH-CIDI) is a comprehensive, completely structured interview created for use by trained lay interviewers to evaluate mental disorders in accordance with the diagnoses and criteria of DSM-IV. In a computerized version with the following components, we used the Dutch translation Obsessive Compulsive Disorder, Depression, Mania, Panic Disorder, Social Phobia, Separation Anxiety Disorder, Specific Phobia, and Generalized Anxiety Disorder. A 20-item self-report scale for measuring positive and negative affect is called the Positive and Negative Affect Schedule (PANAS) . Positive Affect and Negative Affect both reflect dispositional traits; high NA is characterized by subjective distress and unpleasant engagement, whereas low NA is characterized by the absence of these emotions. PA, on the other hand, is a measure of how much an adult enjoys engaging with their surroundings.

**DISCUSSION**

In the current STERK study, high-risk kids of anxious and depressed patients (aged 8–17) are the subjects of a randomized controlled preventative intervention. Depending on whether symptoms are worsening or the High Risk Index we created in a prior study of epidemiological offspring (ARIADNE), we select young people. Due to the frequent co-occurrence of these

disorders, the current study is the first to concentrate on both of them. Symptoms of anxiety and depression are pervasive for offspring of patients with anxiety disorders 30 and in those of patients with unipolar depression 31 according to epidemiological data in offspring. With this study, we hope to make progress in our understanding of the factors that influence change as well as the mitigation of mental health issues in future generations.

It takes time to develop prevention research, secure money, obtain ethical approval, and include people. The grant application we applied for funding for the current study/project. Participant integration into the project is still continuing. We were unable to include some of the most recent research into our design because of the time constraints. Actually, the current layout is a modification of an older layout. Only adult patients who were undergoing treatment were included in the study's initial phase; every child who had any kind of history of mental illness was excluded. However, we noticed that quite a few qualified and eager volunteers were thereby left out. In addition, the 2009 publication of the Garber research 14 demonstrated that preventative efforts might only be successful if parents were free of their own mental health issues. As a result, we made the decision to expand the trial's inclusion criteria, which was accepted by the Medical Ethical Committee and government funding agency.

While training in positive traits and fostering resilience may be of highest value in prevention, many programs have concentrated on symptom control. Some children at risk may not yet be exhibiting any symptoms, and they may benefit significantly from treatments that emphasize strengths over weaknesses. As a result, the offspring intervention comprises training in problem-solving skills as well as psycho education for both parents and children. In terms of the risk factors, we are aware that children may be cognitively vulnerable while processing information since they report making more negative and few positive statements<sup>29</sup>. Regular behavioral therapies, such as anxiety exposure exercises and depressive symptom behavioral activation, target these symptoms. Since participating in activities and interactions outside of the home setting has been demonstrated to be an essential protective factor in adolescent children, behavioral activation may be especially relevant<sup>25</sup>. Preventive measures have, up until now, been focused on either mood disorders or anxiety disorders. Studies on prevention should concentrate on both conditions due to the large overlap in symptoms between depression and anxiety disorders.<sup>13,14,15,20</sup>

Studying the economic costs associated with mental diseases and potential outcomes of prevention initiatives is crucial from a social perspective in order to inform future resource allocation and policy decisions. A social viewpoint has been used to perform the study<sup>32</sup>. Methods to investigate the treatment procedures as well as the modifiers of treatment result ("for what groups does the therapy work") are frequently included in treatment outcome studies<sup>33</sup>. Regarding the mediating elements in the current study, the intervention's goals will be to alter coping mechanisms<sup>34</sup>, increase activities<sup>35</sup>, and increase confidence in the presence of attachment figures (in the social network). Even though cognitive restructuring does not directly treat cognitions, we nevertheless want to find out if the child's attributional style changed as a result of our behavior intervention.

Such a prophylactic measure shouldn't be used as a stand-alone in clinical practice. Many youth departments focus exclusively on the psychopathology of the youth and virtually ever recognize parental psychopathology. Similarly, facilities that treat adult patients may not always take their children's mental health into account. We discovered while carrying out this study that therapists frequently aren't aware if the adult patient has kids. The age and emotional health of children are typically not mapped in the electronic patient files. In clinical treatment, it would be beneficial to focus on the psychopathology of the family as a whole and to increase cross-referral collaboration between the juvenile and adult departments. According to Garber's results, it might be beneficial to address the children's mental health during the

remitted period of the parent's condition than the acute phase. Within such an infrastructure, the STERK-study may offer useful resources, including a method of identifying children at high risk and an intervention aimed at symptom reduction and resilience.

**Practical Implication:** The present intervention trial seeks to drastically lower the chance of passing mood and anxiety disorders down the generations and resiliency in youngsters who could be at risk. We intend to determine the mechanisms of change and assess the efficacy and cost-effectiveness of such an intervention.

## CONCLUSION

Positive and negative affect both reflect dispositional features, according to the study's findings. High negative affect is marked by subjective anguish and unpleasant engagement, whereas low negative affect is marked by the absence of these emotions.

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