SOUTH BAYLO UNIVERSITY

Effect of Auricular Acupuncture for Anxiety and Depression in Post-Acute Withdrawal Syndrome

by

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Effect of Auricular Acupuncture on the Anxiety and Depression Associated with

Post-Acute Withdrawal Syndrome: Case Study

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ABSTRACT

This study was designed to investigate the effectiveness of Auricular Acupuncture on the

Anxiety and Depression associated with Post-Acute Withdrawal Syndrome (PAWS).

Since Auricular Acupuncture is a diagnostic and treatment system focused on normalizing

the body's dysfunction, it has been utilized for pain relief and relaxation among other uses.

This study was to examine the effects of Auricular Acupuncture on PAWS by utilizing

applications on the following five points: Shen Men, Sympathetic, Kidney, Liver, and Lung 2

(National Acupuncture Detoxification Association Protocol). Once a week for 8 weeks, 6 male

participants over the age of 18 who were living in a sober living house, received Auricular

Acupuncture treatments. These treatments consisted of the insertion of needles into five ear point

locations on the left ear for 30 min. These ear points were specifically identified to treat addiction

and withdrawal.

The treatment outcomes were evaluated using the following diagnostic tools: (1) The

Hamilton Rating Scale for Anxiety (HAM-A) and (2) The Hamilton Rating Scale for Depression

(HAM-D)

This study has provided initial evidence of changes in the participants' level of anxiety and

depression after a series of treatments using Auricular Acupuncture. The participants' anxiety and

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depression levels were measured during a baseline assessment prior to treatment (3/21/20), during a follow-up session conducted after week 4 (4/11/20), and during a final assessment conducted at the end of the 8 week treatment (5/9/20).

The mean score of the HAM-A measure of anxiety was reduced from 23.3 ± 6.31 to 7.5 ± 5.82 over the course of 8 treatments. The mean difference before and after treatment was 15.8 ± 5.74 , a p-value of (p=0.0098). The mean score of the HAM-D measure of depression was reduced from 23.5 ± 7.18 to 8.3 ± 5.20 over the course of 8 treatments. The mean difference before and after treatment was 15.2 ± 6.46 , a p-value of (p=0.00484).

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I. INTRODUCTION

Post-Acute Withdrawal Syndrome (PAWS) refers to a set of withdrawal symptoms that can last for months, or even years, when a person with a substance use disorder or someone who is addicted to drugs abstains from substance abuse. The primary symptoms of PAWS are anxiety and depression. According to the Semel Institute for Neuroscience and Human Behavior at UCLA, approximately 90 percent of opioid users who abstain from opioid use and 75 percent of alcoholics who abstain from alcohol suffer from PAWS to at least some extent.¹

The rising rate of substance abuse in the United States in recent years has created an urgent need to find effective means of addiction treatment. According to a study published by the U.S. National Institute on Alcohol Abuse and Alcoholism, the rate of alcoholism among the United States population rose from 8.5 percent, which would mean approximately 18 million people, in 2001-2002 to 13 percent, which would mean approximately 30 million people, in 2012-2013. ² The rise in opioid abuse has become so great in recent years that it is commonly referred to as the "opioid epidemic." According to the U.S. Department of Health and Human Services, in 2018, 10.3 million Americans misused prescription opioids and over 800 thousand Americans used heroin.³

The symptoms of PAWS, which share the symptoms of both mood disorders and anxiety disorders, make it difficult for people with substance use disorder or people who become addicted to drugs to maintain abstinence from the substance that were being abused. Abstinence is widely believed to be the most effective, if not the only effective treatment for substance abuse and drug addiction. Without abstinence, most substance abusers continue to abuse their drug of choice on a chronic basis. Unfortunately, the level of discomfort created by the symptoms of anxiety and depression associated with PAWS is so great that substance abusers and people with addiction, often relapse to temporarily relieve these symptoms of PAWS.

The issue of PAWS is often overlooked when treating those suffering from substance abuse and drug addiction. Many rehabilitation centers and support groups create the expectation that once a substance abuse abstains from all mind-altering substances, life will immediately become better. When the reality of the anxiety and depression associated with PAWS kicks in, substance abusers are often left to their own devices to cope. With the high percentage of substance abusers who quit using drugs and alcohol and then begin to suffer from PAWS, it is vital that effective methods of treatment be utilized to help the patient achieve long-term sobriety.

Given the societal importance of finding more effective methods helping recovering substance abusers to remain abstinent from drugs and alcohol, and given that the discomfort that the symptoms of PAWS creates in recovering substance abusers often lead these substance abusers to give up on sobriety, it is important to study the impact of auricular acupuncture in alleviating PAWS symptoms. Finding more effective methods of treating the anxiety and depression that comes with PAWS is crucial to help those who suffer from addiction and substance abuse issues achieve long-term sobriety.

Auricular acupuncture, which follows the precepts of Traditional Chinese Medicine (TCM), according to which inhibited Qi and Blood have a profoundly negative effect on an individual's physical and mental health, offers the possibility of an improved approach to the treatment of PAWS.

TCM methods aim to restore the flow of qi and blood by resolving the blockages or disruption. Following TCM precepts, acupuncture treatment utilizes points found throughout the body, including the ears. In TCM, the ear is directly or indirectly connected with 12 meridians and stimulating the ear can restore the balance between Qi and Blood. For over 2500 years, people have been using auricular acupuncture for treating diseases. In Europe, auricular acupuncture has been applied systematically and comprehensively since Doctor Nogier

introduced the inverted fetus (Figure 2-2) map in 1957. ⁵ In recent years, auricular acupuncture has utilized a more systemic approach, following the identification and standardization of highly precise points, and auricular acupuncture has subsequently been employed in many clinical applications. The mechanisms of auricular acupuncture are considered to have a close relationship with the autonomic nervous system, the neuroendocrine system, neuro and immunological factors, neuroinflammation, neural reflex, as well as antioxidation.

Auricular acupuncture has been reported in literature to have practical effects on the reduction of anxiety and depression. One primary advantage in utilizing auricular acupuncture to treat the anxiety and depression associated with PAWS is that auricular acupuncture exhibits fewer side effects than treatments employing western medicine.

According to a 2014 study, between 40 and 60 percent of those who have been treated for addiction or alcoholism relapse within a year. Such alarming statistics demonstrate the necessity of helping those who seek treatment for a substance abuse problem to better cope with PAWS symptoms, which are so common among substance abusers and people with drug addiction who begin to abstain from substance abuse. The existing treatment for PAWS relies on outside intervention, often medication such as Disulfiram (sold under the trade name Antabuse) to help the patient to stop drinking or anti-depressants and anti-anxiety medications to help alleviate the symptoms of anxiety and depression. To the extent that there are natural treatments for PAWS, they focus on treating the problem from a psychiatric perspective through such methods as talk therapy, hypnosis, and cognitive behavioral therapy, which are time consuming and expensive.

The purpose of this study is to help determine the efficacy of a naturalistic treatment of PAWS, namely auricular acupuncture, a treatment which helps the body heal itself. This study will therefore help demonstrate whether auricular acupuncture treatment is an effective tool to

help recovering substance abusers who are suffering PAWS, willing to take an active role in their recovery by remain abstinent from all mind-altering substances.

OBJECTIVES

The purpose of this study was to investigate the effectiveness of Auricular Acupuncture treatment for the Anxiety and Depression that are felt by those who suffer from PAWS.

In order to accurately evaluate the effect of auricular acupuncture treatment on anxiety and depression symptoms in patients with PAWS, the patients' levels of anxiety and depression was measured: **before** (a baseline measurement of the patients' level of anxiety and depression before the treatment begins), **during** (measurement of the patients' level of anxiety and depression after the fourth week of treatment) and **after** (measurement of the patients' level of anxiety and depression after the end of the 8 week of treatment) the completion of 8 auricular acupuncture treatments using the HAM-A (Hamilton Rating Scale for Anxiety) and HAM-D (Hamilton Rating Scale for Depression).

The levels of anxiety and depression were measured by HAM-A and HAM-D on 3 different dates (3/21/20, 4/11/20, 5/9/20) and were then compared to each other in order to draw conclusions about the efficacy of auricular acupuncture for treating PAWS.

LITERATURE REVIEW

Addiction & Its Costs

"Addiction is defined as a chronic, relapsing brain disease that is characterized by compulsive drug seeking and use" and "a disease [that] is typically considered chronic, meaning that it lasts a person's lifetime". ⁸ The initial decision to take drugs is voluntary for most people, but repeated drug use can lead to brain changes that challenge an addicted person's self-control and interfere with their ability to resist intense urges to take drugs. These brain changes can be persistent, which is why drug addiction is considered a "relapsing" disease—people in recovery from drug use disorders are at increased risk for returning to drug use even after years of not taking the drug. ⁹

The rates of substance abuse in the United States of America demonstrate that addiction is a major societal problem. According to a study by the National Institute on Drug Abuse, in 2013, 17.3 Million Americans (6.6 percent of the population) were either physically dependent on alcohol or suffered significant consequences due to their alcohol abuse. ¹⁰ The same study showed that another 4.2 Million Americans met the criteria marijuana abuse, another 1.9 Million Americans met the criteria for abuse of prescription pain killers, and another 855 Thousand Americans met the criteria for cocaine abuse. ¹¹ Various studies have been performed to quantify the cost to society from addiction and the cost estimates are massive: \$249 Billion for alcohol abuse, \$193 Billion for illicit drug abuse, and \$78.5 Billion for prescription opioids. ¹²

Treatment

Those who suffer from addiction require treatment. While there are a variety of forms of treatment, the goal of all these forms of treatment are the same. To help the drug abuser to abstain

from using the substance that he or she has been abusing as well as all other mind-altering substances. ¹³ Unfortunately, there is what is known as a "treatment gap" in this United States. The National Institute on Drug Abuse estimates that in 2013, while 22.7 million Americans (8.6 percent of the population) needed treatment for a problem related to drugs or alcohol, only about 2.5 million people (0.9 percent of the population) received treatment at a drug and alcohol rehabilitation facility. ¹⁴ For those who do receive treatment, the success rates are grim: It is estimated that only 13% of those who receive treatment at a residential treatment facility still abstain from drugs and alcohol one year after release from the treatment center. ¹⁵

Post-Acute Withdrawal Syndrome

One of the main stumbling blocks encountered by those who attempt to abstain from drugs and alcohol is Post-Acute Withdrawal Syndrome (PAWS). Post-acute withdrawal can be thought of as a second phase of withdrawal which begins right after the initial phase of detoxification ends. When discussing how PAWS affects alcoholics, The University of Wisconsin School of Medicine and Public Health defines PAWS as "a group of symptoms that happen after acute alcohol withdrawal." ¹⁶ Writing in Psychology Today, Dan Mager identifies the most common symptoms of PAWS as "anxiety, irritability, anger and depression." ¹⁶ The Semel Institute at UCLA estimates that it is estimated that 90 percent of opioid users who abstain from opioid use as well as 75 percent of alcohol and psychotropic drug abusers who abstain from alcohol and psychotropic drug use suffer from PAWS to at least some extent. ¹⁷ Individuals coming out of conventional medical detoxification also often experience post–acute withdrawal syndrome: symptoms of significant cravings for drugs, as well as mental, emotional, and physical symptoms of protracted withdrawal. These cravings are often the trigger for relapse. ¹⁸

Signs and Symptoms

Symptoms of PAWS tend to fluctuate in severity and may disappear altogether only to reappear at another time. Some of the most common symptoms of PAWS include:

- Difficulty with cognitive tasks, such as learning, problem solving, or memory recall
- Irritability
- Feelings of anxiety or panic
- · Depressed mood

Other symptoms may include:

- Obsessive-compulsive behaviors
- Difficulty maintaining social relationships
- Craving originally abused substances
- Apathy or pessimism
- Disturbances in sleep patterns
- Increased sensitivity to stress

These symptoms tend to increase in severity when triggered by stressful situations but might flare up even without any clear stimulus.¹⁷

Causes and Risk Factors

It is thought that PAWS is the result of physiologic changes that occur in the brain due to substance abuse. During drug abuse the brain makes adaptations to accommodate for the changes in available neurotransmitters, and these changes can result in excitability when levels of these neurotransmitters change during abstinence. Scientists hypothesize that that the brain's capacity to deal with stress is reduced with prolonged substance abuse and the related withdrawal experiences. Infants born to mothers who have repeatedly abused substances are also at risk of

developing PAWS. ¹⁷ PAWS can manifest after withdrawal from almost any abusive substance, but those abusing benzodiazepines seem to be the most at risk. There have been reports of benzodiazepine abusers experiencing symptoms of PAWS for years after final cessation of the abuse. ¹⁷

Treatments

Treatment is generally administered over an extended period of times because the symptoms of PAWS can continue for months or years. Acamprosate, a drug commonly used to help recovering alcoholics, has been found to be somewhat effective in managing some PAWS symptoms. Other drugs may also be used. Most patients undergo psychotherapy as well in the form of behavioral therapy, group therapy or both to learn to cope with the symptoms. ¹⁷

PAWS can be challenging to deal with, especially after going through detox and then working to resist relapse. The unpredictable fluctuations of symptoms can be stressful, but a combination of drugs and therapy can help make those symptoms more manageable. ¹⁷

Sober Living Houses

Sober Living Houses are structured in a way that avoids some of the limitations of halfway houses. The essential characteristics include: 1) an alcohol and drug free living environment for individuals attempting to abstain from alcohol and drugs, 2) no formal treatment services but either mandated or strongly encouraged attendance at 12-step self-help groups such as Alcoholics Anonymous (AA), 3) required compliance with house rules such as maintaining abstinence, paying rent and other fees, participating in house chores and attending house meetings, 4) resident responsibility for financing rent and other costs, and finally 5) an invitation for residents to stay in the house as long as they wish provided they comply with house rules (Polcin & Henderson, 2008).¹⁹

Depression

The Diagnostic and Statistical Manual (DSM), which is the published by the American Psychiatric Association, is considered the primary source that practitioners in the psychiatric profession use to diagnose mental illness. The DSM provides the following diagnostic criteria for depressive disorder: "Depressed mood and/or loss of interest or pleasure in life activities for at least 2 weeks and at least five of the following symptoms that cause clinically significant impairment in social, work, or other important areas of functioning almost every day." 20

- 1. Depressed mood most of the day.
- 2. Diminished interest or pleasure in all or most activities.
- 3. Significant unintentional weight loss or gain.
- 4. Insomnia or sleeping too much.
- 5. Agitation or psychomotor retardation noticed by others.
- 6. Fatigue or loss of energy.
- 7. Feelings of worthlessness or excessive guilt.
- 8. Diminished ability to think or concentrate, or indecisiveness.
- 9. Recurrent thoughts of death"

Literature on depression notes discusses the diagnostic challenge that depression presents to health practitioners due to the fact that there are no clear physical markers that signify whether a patient suffers from depression and that the patients themselves are often unaware that they are suffering from depression. ^{21,}

Anxiety

When assessing for General Anxiety Depression (GAD), clinical professionals are looking for the following:

- A. Excessive anxiety and worry (apprehensive expectation), occurring more days than not for at least 6 months, about number of events or activities (such as work or school performance).
- B. The individual finds it difficult to control the worry.
- C. The anxiety and worry are associated with three (or more) of the following six symptoms (with at least some symptoms having been present for more days than not for the past 6 months):

Note: Only one item required in children.

- 1. Restlessness, feeling keyed up or on edge.
- 2. Being easily fatigued.
- 3. Difficulty concentrating or mind going blank.
- 4. Irritability.
- 5. Muscle tension.
- 6. Sleep disturbance (difficulty falling or staying asleep, or restless, unsatisfying sleep).
- D. The anxiety, worry, or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- E. The disturbance is not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication) or another medical condition (e.g., hyperthyroidism).
- F. The disturbance is not better explained by another medical disorder (e.g., anxiety or worry about having panic attacks in panic disorder, negative evaluation in social anxiety disorder [social phobia], contamination or other obsessions in obsessive-compulsive disorder, separation from attachment figures in separation anxiety disorder, reminders of traumatic events in posttraumatic stress disorder, gaining weight in anorexia nervosa, physical complaints in somatic symptom

disorder, perceived appearance flaws in body dysmorphic disorder, having a serious illness in illness anxiety disorder, or the content of delusional beliefs in schizophrenia or delusional disorder). ²²

The DSM IV stipulates two major types of treatment for anxiety: talk therapy and pharmaceutical drugs. Many in the community of medical practitioners believe that combining a regiment of pharmaceutical drugs with talk therapy is the most effective method to combat anxiety. The thought process is that the pharmaceutical drugs can treat the biological portion of the root causes of anxiety while the therapy portion of the equation can treat the behavioral roots of anxiety. ²³

Measurement of Anxiety and Depression

The Hamilton Anxiety Rating Scale (HAM-A) is a rating scale that is used by mental health practitioners to measure the severity of anxiety symptoms. The scale is composed of 14 items, with each item being comprised of a series of symptoms. Each of these items is given a score from 0 (symptom not present) to 4 (symptoms are severe) with the total score of all items ranging from 0 to 56. A score below 17 indicates mild severity, a score between 18 and 24 indicates mild to moderate severity, a score between 25 and 30 indicates moderate to high severity and a score above 30 indicates high severity.²⁴

The Hamilton Depression Rating Scale (HAM-D which is sometimes called the HDRS) is a rating scale used by mental health practitioners to measure the severity of depression symptoms.

The original version of the HAM-D consisted of 17 items but a later version of the HAM-D

consisting of 21 items is available for use by practitioners. Like the HAM-A, each of these items is given a score, though unlike the HAM-A these items can be scored between 0 and 4, which some questions only being scored from 0 to 2 or 0 to 3. A total score on the HAM-D of 0-7 is considered within the normal range (meaning the patient is not currently suffering from depression) whereas a score of 20 indicates moderate severity. ²⁵

Auricular Acupuncture: National Acupuncture Detoxification Association (NADA) Protocol

Auricular acupuncture is a diagnostic and treatment system based on normalizing the body's dysfunction through stimulation of points on the ear. Resulting amelioration of pain and illness is believed to come about through the reticular formation of the sympathetic and parasympathetic nervous systems.²⁶

In 1972, acupuncture for addiction treatment initially discovered by Dr. Hsiang-Lai Wen, Neurosurgeon in Hong Kong found serendipitously that electrical stimulation of 2 ear points and 4 body points used as preoperative anesthetic abated physical withdrawal of opium. Dr. Wen published successfully treating 40 heroin-and opium-addicted individuals. ²⁷

In 1985, Dr. Michael Smith in New York, the head of the National Acupuncture

Detoxification Association (NADA) of the USA, who finalized a protocol, using only ear points without electrical stimulation for the treatment of drug abuse. Dr. Michael Smith and colleagues adopted Dr. Wen's method and over several years, with input from the patients, they added other ear points and dropped the electrical stimulation and found that manual stimulation was more "tonifying", producing a prolonged effect ²⁸

The National Acupuncture Detoxification Association (NADA) was established to promote education and training of clinicians in the NADA ear acupuncture protocol. NADA, a non-for-profit training, and advocacy organization, encourages community wellness through use of a

standardized auricular acupuncture protocol for behavioral health, including addictions, mental health, and disaster and emotional trauma. ²⁴ Auricular acupuncture treatments using this NADA protocol have become increasingly more popular among military and community settings. More than 1,500 clinical sites in the U.S., Africa, Europe, Asia, Canada, Australia, and the Caribbean currently use this protocol.²⁹

The NADA treatment has been shown to significantly decrease cravings for alcohol and drugs, withdrawal symptoms, relapse episodes, anxiety, insomnia, and agitation.³⁰ The points used in NADA protocol are "Shen Men," "Sympathetic" (sometimes noted in the literature as "Autonomic"), "Kidney," "Liver," and "Lung" (Figure 2-1, Table 1)³¹. What also developed from such widespread clinical use of auricular acupuncture was the understanding treatment that auricular acupuncture did not just as relieve acute withdrawal but also offers a long-term, preventative, or "tonification" effect.³²

Traditional Chinese Medicine view for Addiction, Anxiety and Depression

Traditional Chinese Medicine (TCM) has been practiced in China for more than 2000 years, and for the past 200 years it has been used in treatment of opioid addiction. It is a fact that TCM is effective in controlling opiate withdrawal symptoms and preventing opiate relapse with fewer corresponding side effects than western interventions. In Traditional Chinese Medicine (TCM) theory, the common TCM pathological factors that may induce addiction relapse are yang deficiency, blood heat, and phlegm, while it is still an unresolved question about how phlegm induces relapse.³³

TCM is considered a Complementary and Alternative Medicine (CAM) Modality, and TCM principles are applicable to the treatment of psychiatric disorders. References to this practice date to the Su Wen of the Huang Di Nei Jing (Fundamental Questions of the Yellow Emperor's Inner

Classic). 34

Acupuncture and other TCM treatments are dependent on restoration of balance. The Nei Jing asserts that the nature of any entity, living or not, is determined by the intrinsic balance between opposing states, Yin and Yang. Disturbances in balance result in changes in nature, often expressed in living systems in the form of symptoms or signs of disease. TCM treatments are intended to restore balance. Balance is accomplished by influencing the vital energy, the Qi. In the TCM paradigm, Qi flows through channels in the body and in the spaces between muscles and the skin.³⁵

In TCM, psychiatric disorders frequently relate to energetic disharmonies involving the socalled Five Spirits. These are the Hun (the noncorporeal spirit), the Po (the corporeal spirit), the Zhi (the will), the Yi (the intellect) and the Shen (the mind and the connecting spirit).³⁶

II. MATERIALS AND METHODS

2.1.1 Research Design

This research was conducted at Sober Living House, Los Angeles, California between 3/21/20 and 5/9/20. It was designed to research the effect of Auricular Acupuncture for Anxiety and Depression as a case study with thirteen male participants, only six remained and completed the AA treatments (Figure 1).

2.1.2 Materials

- 1) Thirteen participants were selected for the research project treatment after initial screening.
- 2) All participants were over ages 18 years old. In addition, the participants are all male.
- 3) The participants signed an information consent form, explaining the purpose and the method of this research. It will also be fully explained regardless of age, religion, and sex.
- 4) The participants have previously suffered from addiction to drugs, medication and alcohol.
- 5) At the start of the treatment, the participants suffered from the symptoms of PAWS:

 Anxiety and Depression
- 6) Anxiety was measured with Hamilton Rating Scale for Anxiety (HAM-A) and Depression was measured with the Hamilton Rating Scale for Depression (HAM-D)
- For this research, the participants were selected for treatment of anxiety and depression due to PAWS.

2.1.3 Recruitment Criteria

Participants were required to be at least 18 years of age, under no treatment outside of this study for Post-Acute Withdrawal Syndrome (Anxiety and Depression), not currently receiving acupunctural treatments, able to participate for an eight weeks study and willing to sign an Informed Consent Form prior to the beginning of the experiment.

2.1.4 Exclusion Criteria

Potential participants who were receiving acupuncture treatments outside of this research study, pregnant, physically weak, or suffering from severe chronic disease were excluded from consideration for the study.

2.1.5 Ethics

A proposal was first submitted to the Institutional Review Board (IRB) of South Baylo University. The research only began after obtaining approval from the IRB regarding the protocols and Informed Consent Forms (ICF).

2.1.3 Ear Acupuncture Stimulation and Procedure

Auricular acupuncture points on the left ear were selected for acupuncture stimulation (based on Huangdi Nei Jing Su Wen: male is yang and female is yin, left is yang and right is yin). ³⁷

Auricular acupuncture was performed inserting Single-use, sterile, stainless steel needles (DBCTM Spring Ten acupuncture needles, made in Korea). The insertion was performed by utilizing guide tubes. The needles used for auricular acupuncture treatment were sizes of 0.20 mm x 15 mm and

remained inserted for 30min. The needles were used based on Clean Needle Technique (CNT) and were discarded after treatments based on the CA Medical Waste Management Law.

2.2 Methods

2.2.1 Auricular Acupuncture Points

The five points that were utilized in the auricular acupuncture treatment: Shen Men, Sympathetic, Kidney, Liver, and Lung 2 is selected according to the National Acupuncture Detoxification Association (NADA) protocol (Figure 2-1, 2-2) (Table 1),³⁸. The five-points NADA protocol is the most widely adapted for treatment of medical complications. The practice of auricular acupuncture is based on the theory that there are specific points on the auricle which correspond to major organs or systems of the human body and they can be manipulated by acupuncture or acupressure to exert a therapeutic effect upon the corresponding target organ or system. The NADA protocol will help make manipulation of the points on the auricular relevant to the issues of participants in the study.

2.2.2 Statistical Analysis

Statistical Analysis was performed using R software version 3.5.1 (2018-07-02) -- "Feather Spray". After applying a Kolmogorov-Smirnov test and a Shapiro-Wilk test for normalcy, a Paired Samples t-test and an Independent Samples t-test, also known as a Wilcoxon signed rank test and a Mann-Whitney U test, were performed to evaluate the statistical significance. A generalized linear repeated mixed model was employed to analyze missing data, which primarily stemmed from noncompliance. The level set for statistical significance was p < 0.05.

Participant Recruitment N=13Eligibility Assessment & Informed Consent Form Pretest for HAM-A, HAM-D Auricular Acupuncture treatment (once a week) for eight weeks Test after week 4 treatment: HAM-A, HAM-D

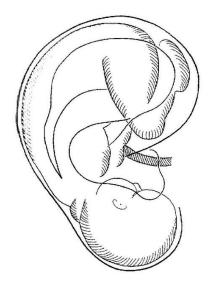
Post Test for HAM-A, HAM-D



Data Collection & Analysis

N=6

Figure 1. Schematic Diagram of Study Design



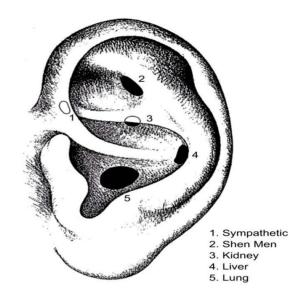


Figure 2-1. Inverted Fetus

Figure 2-2. NADA Protocol

Table 1. Functions of Auricular points (NADA protocol)

Auricular Points

Functions

Shen Men	Reduces stress, anxiety and excessive sensitivity
Snen Men	Enhances the functions of other acupuncture points
G 41 4	Balances sympathetic and parasympathetic nervous systems
Sympathetic	Improves blood circulation
Kidney	Reinforces the function of Kidneys
T.	Promotes smooth flow of Qi and Blood
Liver	Helps the body's detoxification
	Relaxes the muscles and tendon
T 0	Promotes smooth flow of Qi and Blood, nourishes the skin and hair
Lung 2	Treats addiction related lung issues

III. RESULTS

Thirteen residents of a sober living facility were screened for eligibility in this research study

as determined by the manifestation of PAWS symptoms, and all thirteen of the residents' screen

were found to be eligible to participate in the study. All thirteen of these residents initially opted

to participate in this study. Seven of these participants had to drop out of the study for personal

reasons; therefore, data collected from these participants are not included in the study. Six

participants fully participated in the study over the course of the 8-week treatment plan therefore,

the data collected from these participants are included the study.

4.1. HAM- A Results

The Hamilton Anxiety Rating Scale (HAM-A) was used in this study to measure the anxiety

levels of the study participants. Figure 3-1 contains a bar graph showing the study results as

measured by the HAM-A scores for all study participants Before, Middle and After treatment.

Participant 1. 34 years old, Male

Drug of Choice: Opioids

Length of Sobriety: 4 months

Before the first auricular acupuncture treatment the participant's anxiety level as measured

by the HAM-A was 28 (moderate to high severity), after the 4th treatment (middle) the HAM-A

score was 17 (mild severity) and after the last treatment the HAM-A score was 7 (mild severity).

Participant 2. 23 years old, Male

Drug of Choice: Alcohol and Cocaine

Length of Sobriety: 4 months

Before the first auricular acupuncture treatment the participant's anxiety level as measured

by the HAM-A was 20 (mild to moderate severity), after the 4th treatment (middle) the HAM-A

score was 18 (mild to moderate severity) and after the last treatment the HAM-A score was 9

(mild severity).

Participant 3. 28 years old, Male

Drug of Choice: Alcohol

Sober for 1.5 years

Before the first auricular acupuncture treatment the participant's anxiety level as measured by

the HAM-A was 30 (moderate to high severity), after the 4th treatment (middle) the HAM-A

score was 24 (mild to moderate severity), and after the last treatment the HAM-A score was 18

(mild to moderate severity).

Participant 4. 33 years old, Male

Drug of Choice: Heroin

Length of Sobriety: 8 months moderate to high severity

Before the first auricular acupuncture treatment anxiety the participant's anxiety level as

measured by the HAM-A was 27 (moderate to high severity), after the 4th treatment (middle) the

HAM-A score was 20 (mild to moderate severity), and after the last treatment the HAM-A score

was 6 (mild severity).

Participant 5. 28 years old, Male

Drugs of Choice: Opioids and Stimulants

Length of Sobriety: 4 years

Before the first auricular acupuncture treatment the participant's anxiety level as measured

by the HAM-A was 22 (mild to moderate severity), after the 4th treatment (middle) the HAM-A

score was 7 (mild severity), and after the last treatment the HAM-A score was 1(mild severity).

Participant 6. 28 years old, Male

Drugs of Choice: Heroin and Cocaine

Length of Sobriety: 2 months

Before the first auricular acupuncture treatment the participant's anxiety level as measured

by the HAM-A was 13 (mild severity), after the 4th treatment (middle) the HAM-A score was 8

(mild severity) and after the last treatment the HAM-A score was 4 (mild severity).

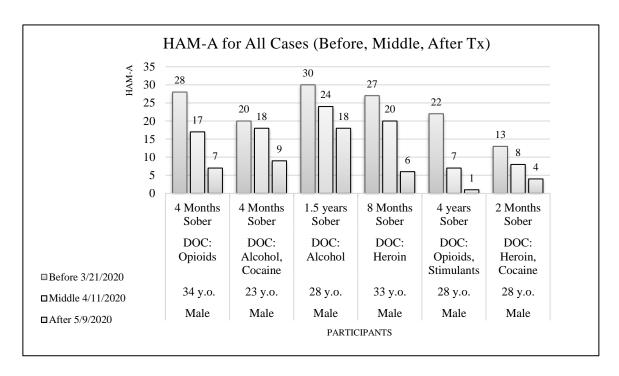
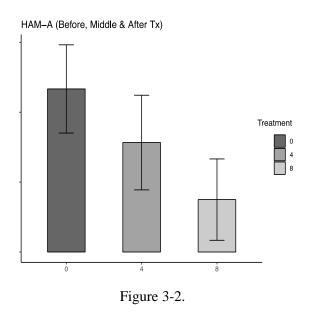
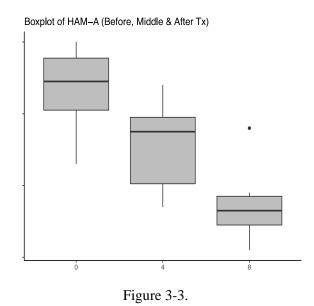


Figure 3-1. Bar graph of HAM-A for All cases Before, Middle and After treatment

	Before	Middle (4th)	After (8th)	
Treatment	(M1±SD1)	(M4±SD4)	(M8±SD8)	p-value*
HAM-A	23.3 ± 6.31	15.7 ± 6.77	7.5 ± 5.82	
Before – Middle (4 th) (M1±SD1 – M4±SD4)		7.7 ± 4.63		0.0252
Before – After (8 th) (M1±SD1 – M8±SD8)			15.8 ± 5.74	0.0098
** Paired Samples t-Test				

Table 2. Mean of HAM-A and its cumulative difference for treatments





Bar graph of mean of HAM-A for the Treatment

Box plot of mean of HAM-A for the Treatment

Table 2. Mean of HAM-A and its cumulative difference for treatments, Figures 3-2. Bar graph of mean of HAM-A for the treatment and 3-3. Box plot of mean of HAM-A for the treatment shows that from the pre-study measurement to the mid-point of the treatments, the HAM-A mean score was reduced from 23.3±6.31 to 15.7±6.77. The mean difference during this period was 7.7±4.63, showing an improvement of (p=0.0252). Over the course of the entire study the HAM-A mean score was reduced from the 23.3±6.31 to 7.5±5.82. The mean difference over the course of the study was 15.8±5.74, showing an improvement of (p=0.0098).

The study results show significant improvements in the levels of anxiety experienced by those who participated in the study. Furthermore, these results show continuous improvements in the levels of anxiety experienced by the participants over the course of study as demonstrated by the fact that the levels of anxiety were higher at the start of the study than at the mid-point of the

study, and the levels of anxiety were higher at the mid-point of the study than at the end of the

study. Therefore, the study results provide statistically significant evidence that the anxiety

experienced by the study participants was decreased by the auricular acupuncture treatment.

4.2. HAM-D Results

The Hamilton Depression Rating Scale (HAM-D) was used in this study to measure the

Depression levels of the study participants. Figure 3-4 contains a bar graph showing the study

results as measured by the HAM-D scores for all study participants Before, During and After

treatment.

Participant 1. 34 years old, Male

Drug of Choice: Opioids

Length of Sobriety: 4 months

Before the first auricular acupuncture treatment the participant's level of depression as

measured by the HAM-D was 30 (moderate severity), after the 4th treatment (middle) the HAM-D

score was 28 (moderate severity) and after the last treatment the HAM-D score was 5 (normal

range).

Participant 2. 23 years old, Male

Drug of Choice: Alcohol, Cocaine

Length of Sobriety: 4 months

Before the first auricular acupuncture treatment the participant's level of depression as

measured by the HAM-D was 17 (moderate severity), after the 4th treatment (middle) the HAM-D

score was 18 (moderate severity) and after the last treatment the HAM-D score was 12 (moderate

severity).

Participant 3. 28 years old, Male

Drug of Choice: Alcohol

Length of Sobriety: 1.5 years

Before the first auricular acupuncture treatment the participant's level of depression as

measured by the HAM-D was 31(moderate severity), after the 4th treatment (middle) the HAM-D

score was 19 (moderate severity) and after the last treatment the HAM-D score was 14 (moderate

severity).

Participant 4. 33 years old, Male

Drug of Choice: Heroin

Length of Sobriety: 8 months

Before the first auricular acupuncture treatment the participant's level of depression as

measured by the HAM-D was 29 (moderate severity), after the 4th treatment (middle) the HAM-D

score was 12 (moderate severity) and after the last treatment the HAM-D score was 13 (moderate

severity).

Participant 5. 28 years old, Male

Drugs of Choice: Opioids & Stimulants

Length Sobriety: 4 years

Before the first auricular acupuncture treatment the participant's level of depression as measured by the HAM-D was 18 (moderate severity), after the 4th treatment (middle) the HAM-D score was 11 (moderate severity) and after the last treatment the HAM-D score was 3 (normal

range).

Participant 6. 28 years old, Male

Drugs of Choice: Heroin, Cocaine

Length of Sobriety: 2 months

Before the first auricular acupuncture treatment the participant's level of depression as measured by the HAM-D was 16 (moderate severity), after the 4th treatment (middle) the HAM-D score was 11 (moderate severity) and after the last treatment the HAM-D score was 3 (normal range).

28

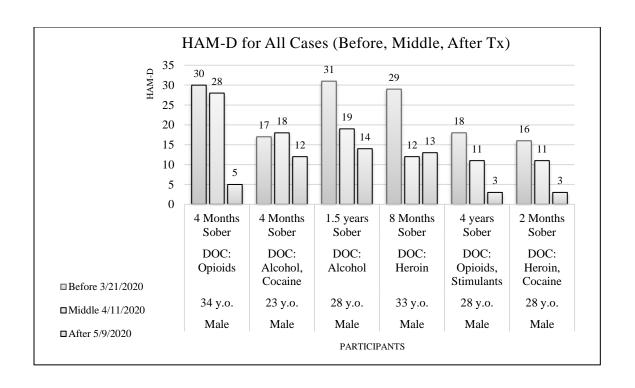


Figure 3-4. Bar graph of HAM-D for all cases before, middle and after treatment

	Before	Middle (4th)	After (8th)	
Treatment	(M1±SD1)	(M4±SD4)	(M8±SD8)	p-value*
HAM-D	23.5 ± 7.18	16.5 ± 6.66	8.3 ± 5.20	
Before – Middle (4 th) (M1±SD1 – M4±SD4)		7.0 ± 6.60		0.0111
Before – After (8 th) (M1±SD1 – M8±SD8)			15.2 ± 6.46	0.0484

^{**} Paired Samples t-Test

Table 3. Mean of HAM-D and its cumulative difference for treatment

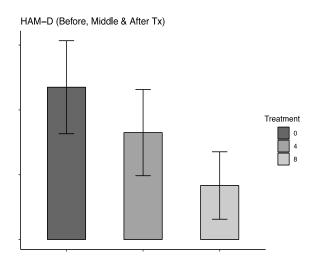


Figure 3-6.

Boxplot of HAM-D (Before, Middle & After Tx)

Figure 3-5.

Box plot of HAM-D for the Treatment

Bar graph of mean of HAM-D for the Treatment

of mean of HAM-D for the treatment and Figure 3-6. Box plot of HAM-D for the treatment shows that from the pre-study measurement to the mid-point of the treatments, the HAM-D mean score was reduced from 23.5±7.18 to 16.5±6.66. The mean difference during this period was 7.0±6.60, showing an improvement of (p=0.0111). Over the course of the entire study the HAM-D mean score was reduced from 23.5±7.18 to 8.3±5.20. The mean difference over the course of the study was 15.2±6.46, showing an improvement of (p=0.00484).

Table 3. Mean of HAM-D and its cumulative difference for treatments, Figure 3-5. Bar graph

The results listed above show significant improvements in the levels of depression experienced by the study participants over the course of the study. Furthermore, these results show continuous improvements in the levels of depression experienced by the studied participants. As demonstrated by the fact that the levels of depression were higher at the start of the study than at the mid-point of the study displaying the levels of depression were higher at the mid-point of the study than at the end of the study. Therefore, the study results provide statistically significant

evidence that the depression experienced by the study participants was decreased by the auricular acupuncture treatment.

IV. DISCUSSION

There is tremendous disagreement on the causes and treatment of substance abuse and addiction; however, there is a consensus that the person with an addiction needs to abstain from mind-altering substances to break the cycle of addiction.

It is common for the people with addictions completing treatment at a residential treatment facility to then stay at another facility known as a "Sober Living House" where they are required to abstain from drugs and alcohol but are not required to reside at the facility for 24 hours a day. It is essential for the course of recovery from addiction that the residents of Sober Living House facilities continue to abstain from drugs and alcohol so they can recover from addiction and fully reintegrate into society. Nevertheless, the residents of Sober Living House facilities often suffer from a variety of additional medical issues, most notably anxiety and depression. Reducing the anxiety and depression (PAWS) at people with addictions experience in the early phases of their recovery can be essential in assisting them to abstain from drugs and alcohol.

Auricular acupuncture, with its emphasis on treatment of points around the ear, provides a powerful and efficient technique for treating a variety of health issues. As this research study demonstrates, auricular acupuncture can be especially effective in treating the symptoms of psychiatric issues like PAWS, and the anxiety and depression associated with PAWS.

Furthermore, discussions with the participants in this study demonstrated that auricular acupuncture itself can help treat insomnia, reduce suicidal ideation and agitation also with non-psychiatric medical issues such as heavy feelings in the abdomen and indigestion. By treating these issues, auricular acupuncture can help generate feelings of general well-being which assist recovering people with addiction related issues to remain abstinent from drugs and alcohol, thereby remaining on the road to recovery.

While the auricular acupuncture treatments given during this study assisted the study participants with a wide range of health issues, the primary focus of the study was on the treatment of PAWS, anxiety, and depression. The study results demonstrated that the auricular acupuncture treatments successfully reduced both the levels of anxiety and depression in the study participants. However, the results also showed that the treatments had greater success in treating anxiety than depression.

Acupuncture is becoming more popular in the United States; however, most Americans are unaware of the ability of acupuncture to treat the anxiety and depression associated with early recovery from substance abuse. One reason for this lack of awareness is that there is not currently enough scientific evidence to demonstrate the efficacy for using acupuncture for this purpose. Nevertheless, the National Acupuncture Detoxification Association (NADA) is trying to rectify this situation by encouraging community wellness through the uses of a standardized auricular acupuncture protocols for behavioral health issues, including addiction, post-traumatic stress disorder and other emotional trauma⁴⁰. Auricular acupuncture treatments using the NADA protocol are now becoming more popular in military and community settings.

In addition to auricular acupuncture, administering regular acupuncture treatments in conjunction with herbal medicine is also an effective treatment modality for anxiety and depression. However, there are no standard protocols (such as NADA protocols) for regular acupuncture treatment or for herbal medicine as there are with auricular acupuncture. This lack of protocols has limited research possibilities with standard acupuncture. Therefore, additional research to determine the efficacy of standard acupuncture treatments in conjunction with herbal medicine on anxiety and depression would be an excellent complement to the study on auricular acupuncture presented here.

This research provided both a valuable opportunity and enlightening experience for the 6 participants. It is recommended that future researchers examine effective methods of acupuncture for PAWS for Anxiety and Depression with a larger sample size for longer period of times preferably at least than one year.

V. CONCLUSION

The conclusions of this study after analyzation for the effect of Auricular Acupuncture treatment on Post-Acute Withdrawal Syndromes for Anxiety and Depression, in participants through a course of eight treatments and using assessment tools measured by, HAM-A as a method of measuring Anxiety and HAM-D as a method of measuring Depression details are as followings:

- 1. The data showed HAM-A means score was reduced from 23.3±6.31 to 15.7±6.77, before and middle treatment. The mean difference was 7.7±4.63, showing improvement of (p=0.0252) and the data showed for Before and After treatment, HAM-A means score was reduced from 23.3±6.31 to 7.5±5.82, The mean difference was 15.8±5.74, showing significant improvement of (p=0.0098).
- 2. The data showed HAM-D means score was reduced from 23.5±7.18 to 16.5±6.66, before and middle treatment. The mean difference was 7.0±6.60, showing improvement of % (p=0.0111) and the data showed for Before and After treatment, HAM-D means score was reduced from 23.5±7.18 to 8.3±5.20, The mean difference was 15.2±6.46, showing significant improvement of (p=0.0484).

In conclusion, this study demonstrates that 8-week auricular acupuncture treatments using NADA Protocol were effective in decreasing Anxiety and Depression (PAWS) as shown by statistically significant improvements in the participants' HAM-A and HAM-D scores which were measure throughout the course of the study.

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APPENDICES

Informed Consent Form

You are invited to participate in a research study about the "Effect of Auricular Acupuncture on anxiety and depression associated with post-acute withdrawal syndrome."

Total goal of this research study is to determine the efficacity of Auricular Acupuncture in treating the anxiety and depression symptoms of Post-Acute Withdrawal Syndrome.

The study design is that the patients' level of anxiety and depression will be measured before the start of treatment, at the end of the first 4 weeks of treatment and at the end of week 8 treatment. The treatment course will consist of 8 treatments performed one time per week over 8 weeks at sober living house.

This study is being conducted by Yoo Jin Kang, L.Ac.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic. You may change your mind later and stop participating even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on Acupuncture and Asian Medicine.

By participating in this research, It is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your condition will not get better and that the new medicine or treatment doesn't work even as well as the old one. If, however, the medicine or treatment is not working, we will give the medication or treatment routinely offered to make you more comfortable. While the possibility of this happening is very low you should still be aware of the possibility.

The information you will share with us if you participate in this study will be kept completely confidential to the full extent of the law. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and only the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Yoo Jin Kang, L.Ac.

If you have any questions about this study, please contact Yoo Jin Kang, L.Ac. at 1-213-820-6015 and ujin0228@gmail.com. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr. Ki Haeng Cho, Chair of the South Baylo University. Institutional Review Board (IRB) at 213-738-0712 or khcho@southbaylo.edu.

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant (Print)

Name of Witness (Print)

Signature of Participant

Signature of Witness

Date: Day/Month/Year

Date: Day/Month/Year

Statement by the researcher/person taking consent:

I have accurately explained the information sheet to the potential participant. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

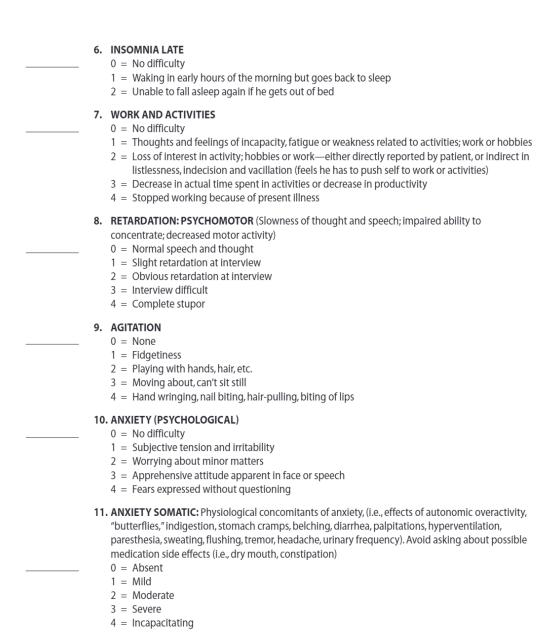
A copy of this ICF has been provided to the participant
Print Name Researcher (Print)
Signature of Researcher
Date: Day/Month/Year

The Hamilton Rating Scale for Depression

(to be administered by a health care professional)

i aliciil 3 ivaiii	ıc	Date of Assessment.
		y of depression in patients who are already diagnosed as depressed, administer this questionnaire. ore, the more severe the depression.
For ea	ach it	tem, write the correct number on the line next to the item. (Only one response per item)
	1.	DEPRESSED MOOD (Sadness, hopeless, helpless, worthless) 0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally—i.e., through facial expression, posture, voice, and tendency to weep 4 = Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and nonverbal communication
	2.	FEELINGS OF GUILT 0 = Absent 1 = Self reproach, feels he has let people down 2 = Ideas of guilt or rumination over past errors or sinful deeds 3 = Present illness is a punishment. Delusions of guilt 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
	3.	SUICIDE 0 = Absent 1 = Feels life is not worth living 2 = Wishes he were dead or any thoughts of possible death to self 3 = Suicidal ideas or gesture 4 = Attempts at suicide (any serious attempt rates 4)
	4.	INSOMNIA EARLY 0 = No difficulty falling asleep 1 = Complains of occasional difficulty falling asleep—i.e., more than 1/2 hour 2 = Complains of nightly difficulty falling asleep
	5.	INSOMNIA MIDDLE 0 = No difficulty 1 = Patient complains of being restless and disturbed during the night 2 = Waking during the night—any getting out of bed rates 2 (except for purposes of voiding)

 $Adapted from \ Hedlung \ and \ Vieweg, The \ Hamilton \ rating \ scale for \ depression, \textit{Journal of Operational Psychiatry}, 1979; 10(2):149-165.$



Adapted from Hedlung and Vieweg, The Hamilton rating scale for depression, Journal of Operational Psychiatry, 1979;10(2):149-165.

12. SOMATIC SYMPTOMS (GASTROINTESTINAL) 0 = None
1 = Loss of appetite but eating without encouragement from others. Food intake about normal 2 = Difficulty eating without urging from others. Marked reduction of appetite and food intake
13. SOMATIC SYMPTOMS GENERAL 0 = None
 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability 2 = Any clear-cut symptom rates 2
 14. GENITAL SYMPTOMS (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances) 0 = Absent 1 = Mild 2 = Severe
15. HYPOCHONDRIASIS 0 = Not present 1 = Self-absorption (bodily) 2 = Preoccupation with health 3 = Frequent complaints, requests for help, etc. 4 = Hypochondriacal delusions
16. LOSS OF WEIGHT A. When rating by history: 0 = No weight loss 1 = Probably weight loss associated with present illness 2 = Definite (according to patient) weight loss 3 = Not assessed
 17. INSIGHT 0 = Acknowledges being depressed and ill 1 = Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc. 2 = Denies being ill at all
 18. DIURNAL VARIATION A. Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none 0 = No variation 1 = Worse in A.M. 2 = Worse in P.M. B. When present, mark the severity of the variation. Mark "None" if NO variation 0 = None 1 = Mild 2 = Severe

 $Adapted from \ Hedlung \ and \ Vieweg, The \ Hamilton \ rating \ scale for \ depression, \textit{Journal of Operational Psychiatry}, 1979; 10(2):149-165.$

 19. DEPERSONALIZATION AND DEREALIZATION (Such as: Feelings 0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating 	of unreality; Nihilistic ideas)
 20. PARANOID SYMPTOMS 0 = None 1 = Suspicious 2 = Ideas of reference 3 = Delusions of reference and persecution	
 21. OBSESSIONAL AND COMPULSIVE SYMPTOMS 0 = Absent 1 = Mild 2 = Severe	
	TOTAL SCORE

HAMILTON ANXIETY RATING SCALE (HAM-A)

Classification of symptoms: 0 - absent; 1 - mild; 2 - moderate; 3 - severe; 4 - incapacitating.

HAM-A score level of anxiety: < 17 mild; 18 - 24 mild to moderate; 25 - 30 moderate to severe.

Symptoms	Date:		
Anxious mood worries anticipates worst	01234	10. Respiratory Symptomschest pressurechoking sensation	0 1 2 3 4
2. Tension • startles • cries easily • restless • trembling	01234	shortness of breath 11. Gastrointestinal Symptoms dysphagia nausea or vomiting constipation	0 1 2 3 4
Fears fear of the dark fear of strangers fear of being alone fear of animal	01234	weight loss 12. Genitourinary Symptoms urinary frequency or urgency dysmenorrhea impotence	01234
Insomnia difficulty falling as leep difficulty with nightma	res	13. Autonomic Symptoms • dry mouth • flushing	01234
 5. Intellectual poor concentration memory impairment 6. Depressed Mood decreased interest in ac 	0 1 2 3 4 0 1 2 3 4	 pallor sweating 14. Behavior at Interview fidgets tremor 	01234
 anhedonia insomnia 7. Somatic complaints - N muscle aches or pains 	Muscular 0 1 2 3 4	• paces	
bruxism Somatic complaints - S tinnitus blurred vision	Sensory 0 1 2 3 4	TOTAL SCORE	i:
9. Cardiovascular Sympto • tachycardia • palpitations • chest pain • sensory of feeling faint			