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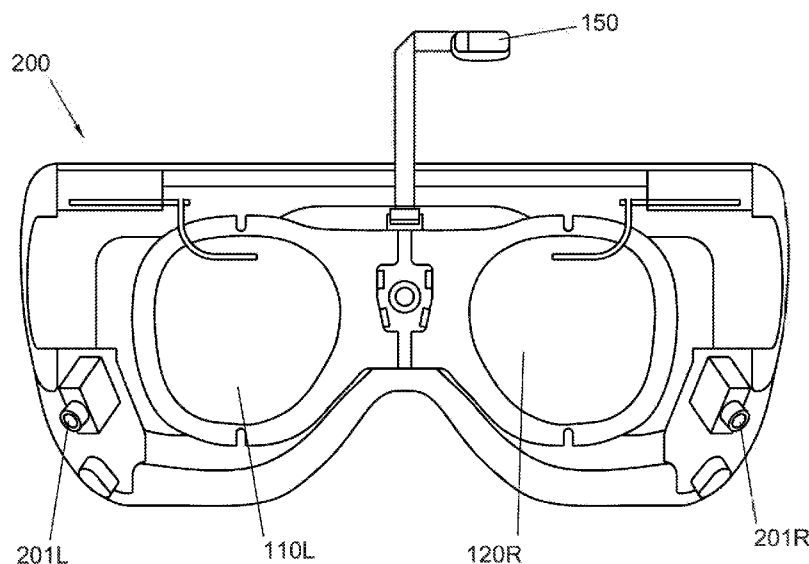


FIG. 3

(57) Abstract: A non-pharmaceutical method of treating the effects of addiction withdrawal is described. The method includes providing a person with stimuli include visual and/or auditory stimuli which are pulsed at the rate of various types of brain waves. The use of the method lessens various withdrawal symptoms, such as anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, bones aching, muscles aching, restlessness, nausea, vomiting, muscle twitching, stomach cramps, pain, the need to use an opioid, the desire to use an opioid, sleep disturbances, and the use of rescue medications.



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NON-PHARMACEUTICAL METHODS OF MITIGATING ADDICTION WITHDRAWAL SYMPTOMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Patent Application No. 16/459,318 filed on July 1, 2019, which claims priority to U.S. Provisional Application No. 62/808,676, filed February 21, 2019, is a Continuation-In-Part of U.S. Patent Application No. 15/910,252 filed on March 2, 2018, which claims the benefit of U.S. Provisional Application No. 62/466,281 filed on March 2, 2017, and is a Continuation-In-Part of U.S. Patent Application No. 16/422,592 filed May 24, 2019, which is a Continuation of U.S. Patent Application No. 15/360,808 filed on November 23, 2016, now U.S. Patent No. 10,328,236, which claims the benefit of U.S. Provisional Application No. 62/258,965 filed on November 23, 2015, the entire disclosures of which are hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention generally relates to assisting those attempting to eliminate addictions, and more particularly to a non-pharmaceutical method of mitigating addictive substance withdrawal symptoms.

BACKGROUND

[0003] The National Survey on Drug Use and Health (NSDUH) estimates that 19.7 million American adults battled a substance use disorder in 2017. Of these Americans, almost 74% of adults struggled with an alcohol use disorder and about 38% of adults battled an illicit drug use disorder. Drug abuse and addiction cost American society more than \$740 billion annually in lost workplace productivity, healthcare expenses, and crime-related costs. Substance use which may result in addiction includes a variety of legal and illegal drugs, and alcohol and nicotine.

[0004] Addictive substances can cause a physical dependence that is usually difficult to overcome and results in a tolerance that requires higher doses over time. It may be extremely difficult for a person to stop taking a substance to which there are addictive. In particular, the human body responds to an abrupt discontinuation or decrease in intake of addictive substances with withdrawal symptoms. Withdrawal symptoms from opiates include anxiety, sweating, vomiting, and diarrhea. Alcohol withdrawal symptoms include irritability, fatigue, shaking, sweating, and nausea. Withdrawal from nicotine can cause irritability, fatigue, insomnia, headache, and difficulty concentrating. Many prescription and legal

nonprescription substances can also cause withdrawal symptoms when individuals stop consuming them, even if they were taken as directed by a physician.

[0005] In addition to withdrawal symptoms, misusing opioids can result in death. Opioids are a class of drugs that include the heroin, synthetic opioids such as fentanyl, and pain relievers available legally by prescription, such as oxycodone (OXYCONTIN[®]), hydrocodone (VICODIN[®]), codeine, and morphine. The number of opioid overdose deaths has increased in recent decades and has reached epidemic proportions.

[0006] Current methods of treating opioid withdrawal symptoms includes providing medications such as methadone, buprenorphine, or naltrexone to a patient. Once treatment is initiated, both a buprenorphine/naloxone combination and an extended release naltrexone formulation are similarly effective in treating opioid addiction. These medications help many people recover from opioid addiction.

[0007] There is a need for tools and methods of addressing addiction. There is also a need for tools and methods of lessening the effects of addiction withdrawal symptoms that do not rely on pharmaceuticals.

SUMMARY

[0008] The present invention overcomes the disadvantages of the prior art by providing a non-pharmaceutical method of treating effects of addiction withdrawal.

[0009] It is one aspect of certain embodiments to provide a method of treating two or more symptoms in a person. The method includes administering a therapeutically effective amount of a sensory stimulus to the person, where the sensory stimulus includes one or more of a visual stimuli and an auditory stimuli. In one embodiment, the symptoms include anxiety, pain, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, aching bones, aching muscles, restlessness, nausea, vomiting, muscle twitching, stomach cramps, pain, the need to use an opioid, the desire to use an opioid, and sleep disturbances.

[0010] It is another aspect of certain embodiments to provide for the use of an apparatus, where the apparatus is characterized for being for the production of sensory stimulus, including one or more of a visual stimuli and an auditory stimuli, for the treatment of symptoms resulting addiction withdrawal. In certain embodiments, the sensory stimulus includes one or more of a visual stimuli and an auditory stimuli. In one embodiment, the symptoms include anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, aching bones, aching muscles, restlessness,

nausea, vomiting, muscle twitching, stomach cramps, pain, the need to use an opioid, the desire to use an opioid, and sleep disturbances.

[0011] It is another aspect of certain embodiments to treat symptoms for a person undergoing addiction withdrawal. In one aspect, the symptoms result opioid addiction. In another aspect, the symptoms result from nicotine addiction.

[0012] It is yet another aspect of certain embodiments to provide a method treating two or more symptoms, where the method includes providing a headset to be worn by the person and administering, with the headset, the therapeutically effective amount of a sensory stimulus to the person.

[0013] In certain embodiments sensory stimulus is provided to a person using devices and methods described in U.S. Patent Application Serial No. 15/360,808 (the '808 patent application) and in U.S. Patent Application Serial No. in 15/910,252 (the '252 patent application). The '808 and '252 patent applications are co-owned with the present patent application and are both herein included by way of incorporation in their entirety.

[0014] These features together with the various ancillary provisions and features which will become apparent to those skilled in the art from the following detailed description are attained by the method of the present invention, preferred embodiments thereof being shown with reference to the accompanying drawings, by way of example only, wherein:

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is a schematic diagram of a system that may be used to provide a therapeutic sensory stimulus to a person;

[0016] FIGS. 2A, 2B, and 2C are a bottom right perspective view, a rear view, and a left view, respectively, and FIG. 3 is an exploded front view of one embodiment of a headset according to the system of FIG. 1;

[0017] FIG. 4 is a flow chart of an exemplary method for providing therapeutic auditory, visual, and/or tactile stimulus; and

[0018] FIGS. 5, 6, and 7 are tables illustrating several treatment stimulus segments of FIG. 4.

[0019] Reference symbols are used in the Figures to indicate certain components, aspects or features shown therein, with reference symbols common to more than one Figure indicating like components, aspects or features shown therein.

DETAILED DESCRIPTION

[0020] Various embodiments described herein are directed to non-pharmaceutical methods of managing pain. The methods include administering a therapeutically effective

amount of a sensory stimulus to the person, resulting in a reduction of the person's perception of pain, and/or an improvement in the person's tolerance for pain.

[0021] The sensory stimulus provided to the person as described herein is provided over a period of time and may, in certain embodiments, comprise two or more simultaneous stimuli, such as a visual stimuli and an auditory stimuli. In addition, each sensory stimuli may include a temporal sequence of sensory stimuli patterns, such as a sequence of stimuli having different frequencies, and/or a stimuli that alternates between sensory organs, as by alternating between the eyes or ears or the person. In various embodiments, the stimulus may include, but is not limited to, one or more of: a visual stimuli to one or both eyes of the person; an auditory stimuli to one or both ears of the person; and/or a tactile stimuli to the skin of the person.

[0022] FIGURE 1 is a schematic diagram of a system **100** that may be used to provide a therapeutic sensory stimulus to a person. System **100** provides one or more stimuli outputs that a person wearing the system may experience as an auditory stimuli, a visual stimuli, and/or tactile stimuli. In one embodiment, system **100** comprises a left light source **110L**, a right light source **110R**, a left vibration source **120L**, a right vibration source **120R**, and a controller **130** for independently controlling and coordinating the action of the light and vibration sources. Thus, for example, system **100** may be positioned on the head of a user with left light source **110L** positioned over the left eye to provide a left visual stimulus, right light source **110R** positioned over the right eye to provide a right visual stimulus, left vibration source **120L** positioned to provide left ear auditory stimuli, and right vibration source **120R** positioned to provide right ear auditory stimuli.

[0023] In one embodiment, left and right light sources **110L**, **110R** may each comprise light-emitting diodes, an incandescent light source having a wavelength filter, a fluorescent light source, a backlit LCD panel, or other light source configured to provide to the user light at a desired, predetermined wavelength or wavelength range.

[0024] In one embodiment, left and right vibration sources **120L**, **120R** may each comprise earbuds, miniature speakers, or other vibration sources that can provide auditory stimuli to a user. In certain other embodiments, left and right vibration sources **120L**, **120R** may comprise bone conduction transducers in the audible frequency range to provide vibrations to the user's skull bone that is sensed as auditory by the user's ear. Optionally, one or more of left and right vibration sources **120L**, **120R** may also produce vibrations that are sensed as tactile stimuli. Thus, for example, controller **130** may provide first signals to bone conduction transducers that vibrate or oscillate at a first frequency that can be interpreted by

the user as auditory stimuli and may provide second signals at a second, lower frequency that can be interpreted as a tactile sensation by the user. In other words, bone conduction transducers may be adapted to provide both auditory and tactile stimulus to the user.

[0025] In certain embodiments, left and right vibration sources **120L**, **120R** provide output at specific one or more frequencies or a range of frequencies. In one embodiment, left and right vibration sources **120L**, **120R** are separately controlled to provide output at certain times and to not provide output at other times. Thus, for example, a vibration source may be programmed to provide an output as an amplitude modulated audio frequency, which may be, for example and without limitation, 141 Hz, 174 Hz, 232 Hz or 256 Hz. Thus, in this example, the vibration source is the product of an audio frequency and a square wave.

[0026] In an alternative embodiment, left and right vibration sources **120L**, **120R** provide signals of slightly different frequencies to the left and right ear. This results in a binaural beats effect, wherein the person perceives a sound at a frequency that is the difference between the frequency in the right ear and the frequency in the left ear. Thus, for example, when a person is provided with a 200 Hz audio frequency to the left ear and a 210 Hz audio frequency to the right ear, the person will perceive 200Hz in the left ear, 210 Hz in the right ear, and $210\text{ Hz} - 200\text{ Hz} = 10\text{ Hz}$ which appear as being provided to both ears. One skilled in the art may use this effect to provide sound at brain wave frequencies separately from, or in combination with, the other methods described herein.

[0027] System **100** also includes a sensor assembly **150** that obtains one or more measurements from the user. Thus, for example and without limitation, sensor **150** may include, or is in communication with, a sensor that measures some property or characteristic of the user, including but not limited to, heart rate, heart rate variability, body temperature, or blood pressure, and includes electronics that provide a signal indicative of the measurement to controller **130**. In other embodiments, the sensors are connected to sensor assembly **150** by wired or wireless connectors. Thus, in various embodiments, the sensors may include one or more: electrodes for sensing electrical activity in the brain, as in a 2 or 4 lead EEG, a temperature sensor, and/or a heartbeat sensor, or one or more EMG sensors positioned, for example and without limitation, to measure eye movement to ascertain when REM sleep is reached, and/or to measure muscle tone to aid in determining states of relaxation. In certain embodiments, controller **130** utilizes the signal from sensor assembly **150** to modify the intensity and/or timing of the light and vibration sources.

[0028] In one embodiment controller **130** includes: an output **131** to provide signals to actuate light sources **110L** and **110R**, vibration sources **120L** and **120R**, and any other

components that provide sensory input to the user; an input **132** to accept signals from sensor assembly **150**; a non-transitory memory **133** for storing programming and data for system **100**; a processor **134**; and a communications module **135**. Memory **133** includes instructions that are accessible to processor **134** for operating the components that provide sensory input to the user, including but not limited to light sources **110L** and **110R**, vibration sources **120L** and **120R**, including accepting input provided to input **132** and modifying signals provided to components that provide sensory input to the user, including but not limited to light sources **110L** and **110R**, vibration sources **120L** and **120R**. Communications module **135** provides for the transfer of information to or from controller **130** by wired or wireless means.

[0029] In an alternative embodiment, system **100** may also provide tactile stimulus to a user by including a left tactile stimulus source and a right tactile stimulus source (not shown), each of which may be individually controlled and coordinated with the controller **130** to provide tactile stimuli to a user of therapeutic system **100**.

[0030] FIGURES. 2A, 2B, and 2C are a bottom right perspective view, a rear view, and a left view, respectively, and FIGURE 3 is an exploded front view headset **200**, which is generally similar to system **100** except as explicitly noted.

[0031] Headset **100** includes sensor assembly **150**, controller **130**, light sources **110L** and **110R**, and vibration sources **120L** and **120R**. Sensor assembly **150** also includes a biometric sensor system, such as that which is sold under the name of VALENCELL BENCHMARK™ (Raleigh, NC), that includes an infrared light source and detector, which can be used to detect heart rate using pulse oximetry, an accelerator, and a processing unit. Sensor assembly **150** includes a sensor module circuit board that contains a digital optical detector system. This detector controls the LEDs and converts the optical signals reflected from the user's skin to digital format and communicates over the internal I2C bus to the PerformTek® processor. The accelerometer is also read via the internal I2C bus for activity signal.

[0032] In one embodiment, controller **130** includes a Nordic Semiconductor ASA (Oslo, Norway) model NRF51822 Multiprotocol BLUETOOTH® low energy/2.4 GHz RF System on Chip, and a VLSI Solution (Tampere, Finland) model VS1000 audio module.

[0033] In one embodiment, light sources **110L** and **110R** are Lite-On, Inc. (Milpitas, CA) Bin G3/W2/AU model LTST-020VSKT LEDs. In one embodiment, vibration sources **120L** and **120R** are Basen Technology Co, Ltd model PN: OEM-E170a earbuds.

[0034] In one embodiment, sensor assembly **150** also includes a PerformTek® processor which polls sensor data over the internal I2C bus and converts the raw measurements into data registers of biometric values (i.e. Heart Rate, Cadence, VO2) and processes those values

further into higher level user assessments (i.e. Calories Burned, Distance, VO2 max, fitness level, and the period between heart rate beats (the Heart Rate Interval, or RR Interval)). The PerformTek® processor runs algorithms to convert the raw signals to a register array of biometric values and high-level assessments. These values are available for reading via the UART or I2C firmware interface. In addition, sensor module diagnostics such as signal quality, error codes, and serial number ID are available.

[0035] Sensor assembly **150** further includes control lines for interfacing controller **130** with the PerformTek® processor include a Power On Self-Test (POST), UART or I2C communication interface, and a wake-from-standby line (WAKE). The host processor can control much of the functionality of the sensor module via a software protocol interface over the UART or I2C interface.

[0036] In one embodiment, sensor assembly **150** determines a current heart rate, and/or an inter-beat R-R interval which is provided to controller **130**. In another embodiment, sensor assembly **150** also provides accelerometer data to controller **130**.

[0037] In yet another embodiment, sensor assembly **150** includes one or more EEG sensors, as are known in the field, and provides brain electrical activity measurements to controller **130**.

[0038] In another embodiment, sensor assembly **150** includes one or more EMG sensors positioned, for example and without limitation, to measure eye movement to ascertain when REM sleep is reached, and/or to measure muscle tone to aid in determining states of relaxation. EMG sensors, as are known in the field, and provides brain electrical activity measurements to controller **130**.

[0039] Headset **200** also includes left and right audio jacks **101L** and **101R** into which left and right earbuds **120L** and **120R**, respectively, may be plugged into. Alternatively, stereo headphones (not shown) may be plugged into one of jacks **101L** or **101R**, where the jacks are appropriately programmed to provide stereo sound to the headphones.

[0040] FIGURE 4 shows a flow chart of an exemplary method **400** for providing therapeutic auditory, visual, and/or tactile stimulus using, for example and without limitation, one of system **100** or headset **200**. In a step **410**, a subject having pain, or who wishes to undergo a treatment for managing pain, is identified. In a step **420**, the subject is provided the therapeutic system or headwear, such as headset **200** as described above, and in step **430**, the subject places the headset on their head. In a step **440**, headset **200** executes programming **450** provided in controller **130** to provide stimuli to the subject. The programming provides two or more of auditory, visual, and/or tactile stimulus to the subject, and thus, for example,

may provide power to activate left light source **110L**, right light source **110R**, left vibration source **120L** and or right vibration source **120R**. The programming also includes modifying the auditory, visual, and/or stimuli in response to measurements obtained by sensor assembly **150** and provided to controller **130**.

[0041] As discussed above and herein, the left vibration source **120L** and the right vibration source **120R** may each comprise bone conduction transducer that may provide both auditory and tactile stimulus.

[0042] In certain embodiments, providing two or more of auditory, visual, and/or tactile stimulus concurrently may provide improved therapeutic benefits as compared to providing only one of auditory, visual, or tactile stimulus at one time. The two or more auditory, visual, and/or tactile stimulus may thus combine to provide the improved therapeutic benefits, for example (i.e., the two or more auditory, visual, and/or tactile stimulus may synergize in a way to provide improved results over providing two of the stimuli individually.)

[0043] Exemplary instructions for providing stimuli may be provided, for example, by programming **450**, which includes one or more subroutines. One such subroutine is subroutine **450e**, which analyzes measurements obtained from sensor assembly **150** and stores the analyzed measurements in memory **113**. Subroutine **450a** includes instructions for the simultaneous activation of all active auditory, visual, and/or tactile stimulus sources. Optionally, the activation of all sources may include the activation of tactile stimulation to run throughout all subsequent auditory and/or visual stimulation. Another exemplary subroutine **450b** may include instructions for alternating the left auditory, visual, and/or tactile stimulus sources with the right auditory, visual, and/or tactile stimulus sources (i.e., the left stimuli and right stimuli take turns being active). Another exemplary subroutine **450c** may include instructions for alternating the visual sources with the auditory and/or tactile sources (i.e., the visual stimuli and the auditory/tactile stimuli take turns being active). Another exemplary subroutine **450d** may include instructions for alternating the left auditory and/or tactile source and the right visual source with the right auditory and/or tactile source and the left visual source (i.e., opposite auditory/tactile stimuli take turns being active).

[0044] In certain optional embodiments, one or more of subroutines **450a**, **450b**, **450c**, or **450d**, access the analyzed measurements from subroutine **450e** and modifies the instructions they provide to the auditory, visual, and/or tactile stimuli depending on real-time or near real-time measurements of the user obtained from sensor assembly **150**. Such programming is further described below.

[0045] In step 440, programming 450, including by not limited to subroutines 450a, 450b, 450c, and 450d, may each be applied one or more times, individually or in combination with one another. The programming may, in addition, provide sequences of output in subroutines 450a, 450b, 450c, and 450d at different frequencies and/or timings. Thus, for example the subroutines may provide output at specific frequencies that change as the subroutine is repeated.

[0046] In certain embodiments, the pulses that determine the amplitude modulation above are essentially square waves and thus, as determined by a Fourier analysis, are formed of sinusoidal components at the pulse frequency and at higher harmonics. As an approximation, an ideal square wave with a pulse frequency of P contains only odd-integer harmonic frequencies at $(2k-1)*P$, where $k = 1, 2, 3 \dots$, which contain a fraction $(2/\pi)/(2k-1)$ of the total power in the square wave. Thus, for example, the signal power in a square wave with a pulse frequency of 4 Hz includes a 63% of the power at 4 Hz, 21% of the power at 12 Hz, 13% of the power at 20, etc., If the square wave does not have equal on and off periods, then the pulse frequency will also contain even-integer harmonic frequencies.

[0047] Thus, for example, subroutine 450a may provide amplitude modulated auditory output to vibration source 120R or 120L at a carrier audio frequency of 256 Hz that is turned on and off, that is it is pulsed, at a pulse frequency of 1 Hz for 2 minutes, or may provide amplitude modulated light output to light source 110R or 110L that produces at a carrier light wavelength 580 nm that is turned on and off, that is it is pulsed at a at a pulse frequency of 1 Hz for 2 minutes. This square pulse auditory or light signal thus generates signals at a frequency of 1 Hz in addition to higher harmonics.

[0048] In certain embodiments, the subroutines described herein generate pulses having sinusoidal components that correspond with certain known brain wave frequencies, which are generally accepted as being delta waves (0.1 to 4.0 Hz), theta brain waves (4 to 7 Hz), alpha brain waves (8 to 15 Hz), beta waves (16 to 31 Hz), and gamma brain waves (32 to 100 Hz). Thus, certain embodiments include pulse frequencies of from 3.75 Hz to 4.25 Hz (theta brain waves), of from 1.25 Hz to 1.75 Hz (delta waves), and/or from 0.25 Hz and 0.75 Hz (delta waves).

[0049] In addition, by alerting the output between left and right channels, the brain may be stimulated in a way that it is forced to communicate between the left and right sides of the brain. This forced communication, for example, can allow PTSD memories to be wired to

both sides of the brain, thereby stopping undesirable flashbacks. It can also create an enhanced relaxation effect, allowing for deeper relaxation and pain management.

[0050] In one embodiment, system **100** provides a stimulus that includes visual and auditory stimuli over three temporally sequential segments – a first segment where stimuli occurs at a first frequency, followed by a second segment where stimuli occurs at a second frequency, which was followed by a third segment where stimuli occurs at a third frequency. Each time segment included sub-segments of visual and auditory stimuli, where each sub-segment was determined by one of the subroutines described above, for example. The visual stimuli were provided by pulsing light at a wavelength of 580 nm at certain pulse frequencies and by pulsing auditory signals at a frequency of 256 Hz at certain pulse frequencies.

[0051] In one embodiment, a treatment stimulus lasted for 16 minutes, and may be understood by reference to Table **500** in FIGURE 5, Table **600** in FIGURE 6, and Table **700** in FIGURE 7, where Table **500** contains specifications for the first segment (“Segment A”), Table **600** contains specifications for the next, second time segment (“Segment B”), and Table **700** contains specifications for the last time segment (“Segment C”). Each of the Segments stimuli patterns at a different pulse frequency. Specifically, Segment A cycles the stimuli through a block of four Segment A stimuli patterns for a total of 2 minutes, Segment B cycles the stimuli through a block of four Segment B stimuli patterns for a total of 2 minutes, and Segment C cycles the stimuli through a block of six Segment C stimuli patterns for a total of 12 minutes.

[0052] More specifically, in the four Segment A stimuli patterns, as shown in Table **500** as Blocks A1, A2, A3, and A4 respectively, the auditory and light outputs cycle 115 or 116 times between being on for 0.1277 seconds and then being off for 0.1277 seconds (that is, at a pulse frequency of 3.9 Hz), followed by no output for 0.5 seconds. In the Segment B stimuli patterns, as shown in Table **600** as Blocks B1, B2, B3 and B4, the auditory and light outputs cycle 44 or 45 times between being on for 0.3333 seconds and then being off for 0.3333 seconds (that is, at a pulse frequency of 1.5 Hz) followed by no output for 0.5 seconds. In the Segment C stimuli patterns, as shown in Table **700** and labeled Blocks C1, C2, C3 and C4, the auditory and light outputs cycle 14 or 15 times between being on for 1 second and then being off for 1 second (that is, a pulse frequency of 0.5 Hz), followed by no output for 1 second. Blocks A1, B1, and C1 pulse the right and left sides of both the light and auditory together, with all outputs are synchronized to be on or off at the same time, as provided by subroutine **450a**. Blocks A2, B2, and C2 synchronize the left side light and auditory output, and the right side light and auditory output to be opposite to one another, as provided by

subroutine **450b**. Blocks A3, B3, and C3 synchronize both lights together to be opposite to both auditory outputs, as provided by subroutine **450c**. Blocks A4, B4, and C4 synchronize the right auditory and light to be opposite to the left auditory and light outputs, as provided by subroutine **450d**.

[0053] In step **440**, subroutine **450e** receives measurements from sensor assembly **150** and stores analyzed measurements. In one embodiment, sensor assembly **150** provides instantaneous, or nearly instantaneous, measurements from the user. Thus, for example and without limitation, sensor assembly **150** provides a sequence of measurements of beat-to-beat intervals of the heart of the user, that is, the time interval between the last two heart beats, which is also referred to, without limitation, as the RR intervals. Controller **130** then computes and stores values of the heart rate variability (HRV), which is a mathematical representation of the physiological phenomenon of variation in the time interval between heartbeats.

[0054] In certain embodiments, a time-domain calculation of RR intervals, as obtained by sensor assembly **150**, is used to compute the HRV. Thus, for example, the sequence of RR intervals (“RR_i”) is accepted from sensor assembly **150** and stored in memory **133**. After the accumulation RR_i for a period of time, T, the HRV is calculated as approximated by the root mean square of successive differences between adjacent RRs, or RMSSD. Thus, at a time T from the beginning of the accumulation of data, if N consecutive RR intervals are stored in memory **133**, the following calculation is performed in processor **134** according to a program stored in the memory:

$$RMSSD = \sqrt{\frac{1}{N-1} (\sum_{i=1}^{N-1} (RR_{i+1} - RR_i)^2)}$$

[0055] The initial value of RMSSD (that is, RMSSD₀) is stored in memory **133** as a baseline. Thereafter, at the end of each period T, the calculation of RMSSD is repeated covering that time period. As a result, a sequence of RMSSD_j values are computed. Next the difference between the current RMSSD value and the baseline RMSSD₀ is computed as ΔRMSSD_j = RMSSD_j - RMSSD₀. ΔRMSSD is a measure of the change between the current HRV and the baseline, initial HRV.

[0056] In general, it is realized by those skilled in the art, that an increased in HRV is associated with a relaxed state, or a sleep state, and that a decrease in HRV is associated with a less relaxed, or stressed, state. For uses of therapeutic system **100** intended to calm a person or to induce sleep, a positive ΔRMSSD indicates that the person is becoming relaxed and that the system is working as intended. A negative ΔRMSSD indicates that the person is not

becoming more relaxed. In one embodiment, an indication that the person is relaxed ($\Delta\text{RMSSD} > 0$) is used to modify the treatment by reducing the treatment time and/or intensity of the stimuli, and an indication that the person is less relaxed ($\Delta\text{RMSSD} < 0$) is used to modify the treatment to increase the treatment time and/or the intensity of the stimuli.

[0057] In certain embodiments, Kubios HRV software (manufactured by Kuopio, Finland) is used to analyze the RR intervals to provide additional HRV related data. Thus, for example, one useful measure for analyzing HRV is the fraction of the power of the HRV signal that occurs in certain frequency ranges. Thus, for example, one measure which is referred to herein as HRV-HFnu is obtained by taking the Fourier transform of the HRV signal and computing the ratio of the power of the HRV signal from 0.15 to 0.40 Hz (“high frequencies”) to the total power of the HRV signal

[0058] The calculations described above are provided by way of explanation and are not meant to limit the scope of the calculations or how the operation of therapeutic system **100** is or is not modified using HRV measurements.

[0059] Although the above steps show method **400** of treating a patient in accordance with embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the treatment.

[0060] One or more of the steps of the method **400** may be performed with the circuitry as described herein, for example, circuitry of the controller **130** or the external control unit **130a** such as one or more of a processor or logic circuitry such as a central processing unit (CPU) or a programmable array logic for field programmable gate array. The circuitry may be programmed to provide one or more of the steps of the method **400**, and the program may comprise program instructions stored on a computer readable memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

MEASURES OF WITHDRAWAL SYMPTOMS

[0061] In the study discussed subsequently, test subjects were provided with a number of sensory stimuli and their response to the treatment was determined using subjective measures of the effect of withdrawal using questionnaires, mostly in the form of Visual Analog Scale (“VAS”) surveys, that the person completed before, during, and after treatment. The measures included the following:

- Subjective Opiate Withdrawal Scale (“SOWS”), in which subjects grade the intensity of 16 opioid withdrawal symptoms on a scale of 0 (not at all) to 4 (extremely). The symptoms measured using SOWS includes, the occurrence of: anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, bones and muscles aching, restlessness, nausea, vomiting, muscle twitching, stomach cramps, and feeling the need of using an opioid. See, for example, <https://www.ncbi.nlm.nih.gov/books/NBK143183/bin/annex10-fm2.pdf>;
- Desire to Use/Need to Use VAS, or VAS-Desire, in which subjects grade the intensity of cravings. See, for example, Kozlowski, L. T., Mann, R. E., Wilkinson, D. A., & Poulos, C. X. (1989). “Cravings” are ambiguous: Ask about urges or desires. *Addictive Behaviors*, 14(4), 443-445;
- VAS-Anxiety, in which subjects rate their perceived level of anxiety as being between “Not at all anxious,” which is assigned a value of zero, and “Very anxious,” which is assigned a value of 10. See, for example, Davey, H. M., Barratt, A. L., Butow, P. N., & Deeks, J. J. (2007). A one-item question with a Likert or Visual Analog Scale adequately measured current anxiety. *Journal of clinical epidemiology*, 60(4), 356-360; and
- VAS-Pain, in which subjects rate their perceived level of pain as being between “No Pain,” which is assigned a value of zero, and “Worst Pain Imaginable,” which is assigned a value of 10.
- Patient-Reported Outcomes Measurement Information System of Sleep Disturbance (PROMIS-Disturbance) is an initiative from the National Institutes of Health to standardize the measurement of common physical and mental diseases, disorders, and conditions. The Sleep Disturbance Scale comprises four separate sub-scales: Quality, Refreshing, Problems, and Difficulty Falling Asleep. The items are then added together, and the resulting estimate can be converted to a standardized measure. Higher scores indicate greater levels of sleep disturbance.

EXAMPLES

ANTIDOTAL EVIDENCE

[0062] Headset **200** has been used in a number of studies, for example, to examine the effects on the headset for improving sleep and in relieving pain. During these studies, the inventor discovered that subjects reported that the use of headset **200** lessened the effects of withdrawal from nicotine addiction.

PILOT STUDY

[0063] A study was conducted on the effectiveness of the inventive method for treating symptoms of opioid addiction withdrawal using a double-blind, randomized, controlled cross-over study of 8 subjects (for a total of 16 subject experiences). The subjects were patients of an inpatient treatment program in which they were receiving daily doses of 60-80 mg of methadone. The demographics of the subjects largely mirroring a methadone-maintained population. There was no attrition and all assessments, as described below, were completed as planned per protocol. The protocol provides for the use of device (headset **200**) at regularly scheduled intervals, as described below.

[0064] In this study, the effectiveness of headset **200** was tested by having each subject undergo two separate treatment regimes. One regime is referred to herein as an “Active Treatment,” in which subjects were provided with sound and light according to the sequences described above. The other regime is referred to herein as a “Sham Treatment,” in which subjects were provided with light and sound using headset **200** which was programmed to provide light and sound at levels that were not therapeutic in nature. Specifically, for the Sham Treatment, headset **200** was programmed to deliver a 232 Hz tone for a short period at the start of 5-minute cycles of the light turning on, then off, then on.

[0065] The pilot study proceeded as follows. On a first day, each patient received their normal dose of methadone and was provided with a headset **200**, along with instructions on its use. The programming of headset **200** was randomly selected to provide the subject with either an Active Treatment or a Sham Treatment, as described above. Baseline scores were collected within 12 hours of taking their methadone, including SOWS, Desire to Use/Need to Use VAS, Anxiety VAS, and Pain VAS scores, and for PROMIS-Disturbance for the night before the first day. During the first day, the subjects used the appropriately programmed headset **200** (either as an Active Treatment or a Sham Treatment) to receive three treatments, at approximately 16:00, 20:00, and 22:00 to 24:00 (prior to bedtime).

[0066] On the following, second day, referred to herein as the “treatment day,” subjects were not allowed to take their normal dose of methadone. The subjects used the appropriately programmed headset **200** to receive five Active Treatments or Sham Treatments over an approximately 16-hour awake period, starting at approximately 8:00 am, with the last treatment prior to bedtime (e.g., at approximately 08:00, 12:00, 16:00, 20:00, and 22:00 to 24:00).

[0067] During the treatment day, scores from each subject was obtained using the SOWS, Desire to Use/Need to Use VAS, VAS-Anxiety, and VAS-Pain on the following schedule: 1) prior to the first morning treatment session; 2) within 5 minutes after each treatment; and 3)

2 hours after the end of the first 4 planned treatments. PROMIS-Disturbance scores were obtained for the night of the treatment day.

[0068] On the morning of day following treatment day, follow-up scores from each subject was obtained using the SOWS, Desire to Use/Need to Use VAS, Anxiety VAS, and Pain VAS and the subjects were permitted to resume their normal methadone treatment. PROMIS-Disturbance scores were obtained for the night of the treatment day. Subjects then continued their normal methadone treatment for at least 7 days to allow for a return to steady-state methadone levels between treatments. Each subject was then provided with the other treatment on the same schedule as described above.

[0069] There were three occasions during the study where subjects needed a dose of rescue medication. For those subjects, there were no measures taken after exposure for the remainder of the treatment day. The use of the Active Treatment resulted in less frequent use of rescue medications as compared to the Sham Treatment.

[0070] Table 1 presents the SOWS scores averaged by treatment condition. A SOWS score of 0-10 is mild withdrawal, 11-20 is moderate, and 21+ is severe. The columns of data in Table 1 are: Baseline mean, presenting SOWS score by condition; Treatment, presenting SOWS score on treatment day per subject, then averaging by condition; Treatment(Max), presenting the largest SOWS score on treatment day per subject, then averaging by condition; and Follow-Up, presenting the mean SOWS score on the day following treatment day per subject, then averaging by condition.

	Baseline	Treatment	Treatment(Max)	Follow-up
Active Treatment	0.5	4.0	9.2	13.9
Sham Treatment	1.0	5.8	12.0	9.5

Table 1: SOWS by Treatment Condition.

[0071] The results in Table 1 indicate that the Active Treatment resulted in a lower average and maximum SOWS scores than the Sham Treatment on the treatment day. Thus, headset **200** provided a therapeutically effective amount of a sensory stimulus for treating, during opioid withdrawal, the combination of anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, bones and muscles aching, restlessness, nausea, vomiting, muscle twitching, stomach cramps, and feeling the need of using an opioid.

[0072] Table 2 presents the VAS-Anxiety score by treatment condition, where the VAS-Anxiety score is used to rate the intensity of anxiety with higher numbers indicate more adverse outcomes. The columns of data in Table 2 are: Baseline mean, presenting VAS-

Anxiety score by condition; Treatment, presenting VAS-Anxiety score on treatment day per subject, then averaging by condition; Treatment(Max), presenting the largest VAS-Anxiety score on treatment day per subject, then averaging by condition; and Follow-Up, presenting the mean VAS-Anxiety score on the day following treatment day per subject, then averaging by condition.

	Baseline	Treatment	Treatment(Max)	Follow-up
Active Treatment	6.7	11.2	18.1	24.2
Sham Treatment	8.7	17.9	29.0	23.5

Table 2: VAS-Anxiety by Treatment Condition.

[0073] The results in Table 2 indicate that the Active Treatment resulted in a lower average and maximum VAS-Anxiety scores than the Sham Treatment on the treatment day. Thus, headset **200** provided a therapeutically effective amount of a sensory stimulus for treating anxiety during opioid withdrawal.

[0074] Table 3 presents the VAS-Need to Use Opioid (or “VAS-N”) scores averaged by treatment condition. Lower scores indicate less need to use, whereas higher scores at the high end indicate a greater need to use. The columns of data in Table 3 are: Baseline mean, presenting VAS-N score by condition; Treatment, presenting VAS-N score on treatment day per subject, then averaging by condition; Treatment(Max), presenting the largest VAS-N score on treatment day per subject, then averaging by condition; and Follow-Up, presenting the mean VAS-N score on the day following treatment day per subject, then averaging by condition.

	Baseline	Treatment	Treatment(Max)	Follow-up
Active Treatment	4.6	12.7	23.6	27.6
Sham Treatment	3.4	21.6	32.7	25.5

Table 3: VAS-N by Treatment Condition.

[0075] The results in Table 3 indicate that the Active Treatment resulted in a lower average and maximum VAS-N scores than the Sham Treatment on the treatment day. Thus, headset **200** provided a therapeutically effective amount of a sensory stimulus for decreasing the need to use an opioid during opioid withdrawal.

[0076] Table 4 presents the VAS-Desire to Use Opioid (or “VAS-D”) scores averaged by treatment condition. Lower scores indicate less desire to use, whereas higher scores at the high end indicate a greater desire to use. VAS- D is conceptually related to the VAS-N, except that it captures the cognitive aspect of addiction compared to the VAS-N, which captures the physical/mental compulsion to use. The columns of data in Table 4 are: Baseline mean,

presenting VAS-D score by condition; Treatment, presenting VAS-D score on treatment day per subject, then averaging by condition; Treatment(Max), presenting the largest VAS-D score on treatment day per subject, then averaging by condition; and Follow-Up, presenting the mean VAS-D score on the day following treatment day per subject, then averaging by condition.

	Baseline	Treatment	Treatment(Max)	Follow-up
Active Treatment	14.0	13.2	2.8	20.8
Sham Treatment	18.0	21.3	9.5	21.0

Table 4: VAS-D scores by Treatment Condition.

[0077] The results in Table 4 indicate that the Active Treatment resulted in a lower average and maximum VAS-D scores than the Sham Treatment on the treatment day. Thus, headset **200** provided a therapeutically effective amount of a sensory stimulus for decreasing the desire to use an opioid during opioid withdrawal.

[0078] Table 5 presents the VAS-Pain scores averaged by treatment condition. Lower scores indicate less desire to use, whereas higher scores at the high end indicate a greater desire to use. The columns of data in Table 5 are: Baseline mean, presenting VAS-Pain score by condition; Treatment, presenting VAS-Pain score on treatment day per subject, then averaging by condition; Treatment(Max), presenting the largest VAS-Pain score on treatment day per subject, then averaging by condition; and Follow-Up, presenting the mean VAS-Pain score on the day following treatment day per subject, then averaging by condition.

	Baseline	Treatment	Treatment(Max)	Follow-up
Active Treatment	12.3	18.0	25.8	26.6
Sham Treatment	20.3	20.0	26.5	23.6

Table 5: VAS-Pain scores by Treatment Condition.

[0079] The results in Table 5 indicate that the Active Treatment resulted in a lower average and maximum VAS-Pain scores than the Sham Treatment on the treatment day. Thus, headset **200** provided a therapeutically effective amount of a sensory stimulus for decreasing pain during opioid withdrawal.

[0080] Table 6 presents the PROMIS Sleep Scale Problems (Disturbance) scores averaged by treatment condition. Higher scores indicate greater levels of sleep disturbance. The columns of data in Table 5 are: Baseline mean, presenting Disturbance score by condition; Treatment, presenting Disturbance score on the evening of treatment day per

subject, then averaging by condition; and Follow-Up, presenting the mean Disturbance score on the day following treatment day per subject, then averaging by condition.

	Baseline	Treatment	Follow-up
Active Treatment	9.6	8.0	10.3
Sham Treatment	9.4	10.0	13.6

Table 6: PROMIS Sleep Scale Problems (Disturbance) scores by Treatment Condition.

[0081] The results in Table 6 indicate that the Active Treatment resulted in a lower average Disturbance score than the Sham Treatment following the treatment day. Thus, headset **200** provided a therapeutically effective amount of a sensory stimulus for improving sleep during opioid withdrawal.

[0082] In summary, the results of the pilot study of the use of headset **200** to treat symptom of opioid withdrawal are: 1) subjects experienced less frequent use of rescue medications when undergoing Active Treatment compared to the Sham Treatment; and 2) SOWS, Desire to Use/Need to Use VAS, Anxiety VAS, Pain VAS and PROMIS-Disturbance scores for Active Treatment all showed improved outcomes relative to Sham Treatments.

[0083] One embodiment of each of the methods described herein is in the form of a computer program that executes on a processing system, e.g., a one or more processors that are part of a system **100**. Thus, as will be appreciated by those skilled in the art, embodiments of the present invention may be embodied as a method, an apparatus such as a special purpose apparatus, an apparatus such as a data processing system, or a carrier medium, e.g., a computer program product. The carrier medium carries one or more computer readable code segments for controlling a processing system to implement a method. Accordingly, aspects of the present invention may take the form of a method, an entirely hardware embodiment, an entirely software embodiment or an embodiment combining software and hardware aspects. Furthermore, the present invention may take the form of carrier medium (e.g., a computer program product on a computer-readable storage medium) carrying computer-readable program code segments embodied in the medium. Any suitable computer readable medium may be used including a magnetic storage device such as a diskette or a hard disk, or an optical storage device such as a CD-ROM.

[0084] Reference throughout this specification to “one embodiment” or “an embodiment” means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases “in one embodiment” or “in an embodiment” in various places throughout this specification are not necessarily all referring to the same embodiment.

Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to one of ordinary skill in the art from this disclosure, in one or more embodiments.

[0085] Similarly, it should be appreciated that in the above description of exemplary embodiments of the invention, various features of the invention are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the claims following the Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment of this invention.

[0086] Consistent with the above disclosure, the examples of systems and method enumerated in the following clauses are specifically contemplated and are intended as a non-limiting set of examples.

[0087] Clause 1. A method of treating effects of addiction withdrawal, said method comprising administering a therapeutically effective amount of a sensory stimulus to the person, where said sensory stimulus includes one or more of a visual stimuli and an auditory stimuli.

[0088] Clause 2. The method of any preceding clause, where said treating reduces one or more symptoms of addiction withdrawal.

[0089] Clause 3. The method of any preceding clause, where said symptoms include anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, aching bones, aching muscles, restlessness, nausea, vomiting, muscle twitching, stomach cramps, pain, the need to use an opioid, the desire to use an opioid, and sleep disturbances.

[0090] Clause 4. The method of any preceding clause, where said addiction withdrawal is opioid addiction withdrawal.

[0091] Clause 5. The method of any preceding clause, where said treating reduces the use of rescue medications.

[0092] Clause 6. The method of any preceding clause, where said addiction withdrawal is nicotine addiction withdrawal.

[0093] Clause 7. The method of any preceding clause, where said visual stimuli includes an amplitude modulated light source.

[0094] Clause 8. The method of any preceding clause, where one of said one or more visual stimuli includes a sinusoidally varying light source.

[0095] Clause 9. The method of any preceding clause, where one of said one or more said auditory stimuli includes an amplitude modulated audio frequency.

[0096] Clause 10. The method of any preceding clause, where said sensory stimulus includes a two or more sensory stimuli patterns including a first stimuli pattern that is different than a second stimuli pattern.

[0097] Clause 11. The method of any preceding clause, where said two or more stimuli patterns includes a first stimuli pattern having a first pulse frequency and a second stimuli pattern having a second pulse frequency.

[0098] Clause 12. The method of any preceding clause, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.

[0099] Clause 13. The method of any preceding clause, where said two or more stimuli patterns includes a third stimuli pattern that is different than said first stimuli pattern and said second stimuli pattern.

[00100] Clause 14. The method of any preceding clause, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said third stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.

[00101] Clause 15. The method of any preceding clause, where said sensory stimulus alternates between

a first sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right auditory stimuli pattern to the right side of the head, and

a second sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a left auditory stimuli pattern to the left side of a head of the user,

wherein one or more of the left auditory stimuli pattern or the right auditory stimuli pattern comprises a sequence of stimuli patterns including the first stimuli pattern, the second stimuli pattern, and the third stimuli pattern.

[00102] Clause 16. The method of any preceding clause, further comprising:

periodically providing a sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user, a right visual stimuli pattern to the right eye of the user, a left auditory stimuli pattern to the left side of the head, and a right auditory stimuli pattern to the right side of a head of the user.

[00103] Clause 17. The method of any preceding clause, further comprising:

alternating sensory stimuli between

a third sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a left auditory stimuli pattern to the left side of the head, and

a fourth sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a right auditory stimuli pattern to the right side of a head of the user.

[00104] Clause 18. The method of any preceding clause, further comprising:

alternating sensory stimuli between

a fifth sensory stimuli including simultaneously providing a left auditory stimuli pattern to the left side of the head and a right auditory stimuli pattern to the right side of the head, and

a sixth sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right visual stimuli pattern to the right eye of the user.

[00105] Clause 19. The method of any preceding clause, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left speaker, and wherein generating the right auditory stimuli pattern comprises generating the right auditory stimuli pattern with a right speaker.

[00106] Clause 20. The method of any preceding clause, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left bone conduction transducer of the headset, and wherein the right auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left bone conduction transducer of a headset.

[00107] Clause 21. The method of any preceding clause, wherein one or more of the left or right auditory stimuli pattern includes an auditory frequency of from 240 Hz to 480 Hz.

[00108] Clause 22. The method of any preceding clause, wherein one or more of the left visual stimuli pattern or right visual stimuli pattern comprises repeatedly pulsing a light at

one or more of a first pulse frequency, a second pulse frequency less than the first pulse frequency, or a third pulse frequency less than the first and second pulse frequencies.

[00109] Clause 23. The method of any preceding clause, wherein the first pulse frequency is between 3.75 Hz and 4.25 Hz, the second pulse frequency is between 1.25 Hz and 1.75 Hz, and the third pulse frequency is between 0.25 Hz and 0.75 Hz.

[00110] Clause 24. The method of any preceding clause, wherein repeatedly pulsing the light comprises pulsing the light for a predetermined time interval.

[00111] Clause 25. The method of any preceding clause, wherein the predetermined time interval is 25-45 seconds.

[00112] Clause 26. The method of any preceding clause, wherein the sequence of stimuli patterns each have a pulse frequency having a pulse period, where a portion of the pulse period includes a stimulus of an auditory frequency of from 240 Hz to 480 Hz.

[00113] Clause 27. The method of any preceding clause, wherein said portion of said pulse period is one half of the pulse period.

[00114] Clause 28. The method of any preceding clause, wherein said first stimuli pattern, said second stimuli pattern, or said third stimuli pattern stimulates for a predetermined time interval.

[00115] Clause 29. The method of any preceding clause, wherein the predetermined time interval is 25-35 seconds.

[00116] Clause 30. The method of any preceding clause, wherein the predetermined time interval is 30 seconds.

[00117] Clause 31. The method of any preceding clause, where said first stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.

[00118] Clause 32. The method of any preceding clause, where said third stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.

[00119] Clause 33. The method of any preceding clause, further comprising
obtaining a measurement of the user using a sensor;
determining a state of the user from the obtained measurement; and

modifying said sensory stimulus according to said determined state of the user.

[00120] Clause 34. The method of any preceding clause, where said sensor is a heart rate sensor, a heart rate variability (HRV) sensor, a temperature sensor, a motion sensor, a galvanic skin response sensor, an accelerometer, an EEG or an EMG.

[00121] Clause 35. The method of any preceding clause, where said determined state of the user is a state of sleep or the level or change in level of relaxation or arousal.

[00122] Clause 36. A method treating two or more symptoms in a person, said method comprising:

providing a headset to be worn by the person; and

administering, with the headset, the therapeutically effective amount of a sensory stimulus to the person of any preceding clause.

[00123] Clause 37. The method of any preceding clause, where said symptoms result from the person undergoing addiction withdrawal.

[00124] Clause 38. The method of any preceding clause, where said symptoms result from the person undergoing withdrawal from opioid addiction.

[00125] Clause 39. The method of any preceding clause, where said symptoms result from the person undergoing withdrawal from nicotine addiction.

[00126] Clause 40. Use of an apparatus, characterized for being for the production of sensory stimulus, including one or more of a visual stimuli and an auditory stimuli, for the treatment of symptoms resulting addiction withdrawal.

[00127] Clause 41. The use of the apparatus of any preceding clause, where the treatment of symptoms includes reducing one or more symptoms of addiction withdrawal.

[00128] Clause 42. The use of the apparatus of any preceding clause, where said symptoms include anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, aching bones, aching muscles, restlessness, nausea, vomiting, muscle twitching, stomach cramps, pain, the need to use an opioid, the desire to use an opioid, and sleep disturbances.

[00129] Clause 43. The use of the apparatus of any preceding clause, where said addiction withdrawal is opioid addiction withdrawal.

[00130] Clause 44. The use of the apparatus of any preceding clause, where said treating reduces the use of rescue medications.

[00131] Clause 45. The use of the apparatus of any preceding clause, where said addiction withdrawal is nicotine addiction withdrawal.

[00132] Clause 46. The use of the apparatus of any preceding clause, where said visual stimuli includes an amplitude modulated light source.

[00133] Clause 47. The use of the apparatus of any preceding clause, where one of said one or more visual stimuli includes a sinusoidally varying light source.

[00134] Clause 48. The use of the apparatus of any preceding clause, where one of said one or more said auditory stimuli includes an amplitude modulated audio frequency.

[00135] Clause 49. The use of the apparatus of any preceding clause, where said sensory stimulus includes a two or more sensory stimuli patterns including a first stimuli pattern that is different than a second stimuli pattern.

[00136] Clause 50. The use of the apparatus of any preceding clause, where said two or more stimuli patterns includes a first stimuli pattern having a first pulse frequency and a second stimuli pattern having a second pulse frequency.

[00137] Clause 51. The use of the apparatus of any preceding clause, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.

[00138] Clause 52. The use of the apparatus of any preceding clause, where said two or more stimuli patterns includes a third stimuli pattern that is different than said first stimuli pattern and said second stimuli pattern.

[00139] Clause 53. The use of the apparatus of any preceding clause, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said third stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.

[00140] Clause 54. The use of the apparatus of any preceding clause, where said sensory stimulus alternates between

a first sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right auditory stimuli pattern to the right side of the head, and

a second sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a left auditory stimuli pattern to the left side of a head of the user,

wherein one or more of the left auditory stimuli pattern or the right auditory stimuli pattern comprises a sequence of stimuli patterns including the first stimuli pattern, the second stimuli pattern, and the third stimuli pattern.

[00141] Clause 55. The use of the apparatus of any preceding clause, further comprising:
periodically providing a sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user, a right visual stimuli pattern to the right eye of the user, a left auditory stimuli pattern to the left side of the head, and a right auditory stimuli pattern to the right side of a head of the user.

[00142] Clause 56. The use of the apparatus of any preceding clause, further comprising:
alternating sensory stimuli between
a third sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a left auditory stimuli pattern to the left side of the head, and
a fourth sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a right auditory stimuli pattern to the right side of a head of the user.

[00143] Clause 57. The use of the apparatus of any preceding clause, further comprising:
alternating sensory stimuli between
a fifth sensory stimuli including simultaneously providing a left auditory stimuli pattern to the left side of the head and a right auditory stimuli pattern to the right side of the head, and
a sixth sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right visual stimuli pattern to the right eye of the user.

[00144] Clause 58. The use of the apparatus of any preceding clause, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left speaker, and wherein generating the right auditory stimuli pattern comprises generating the right auditory stimuli pattern with a right speaker.

[00145] Clause 59. The use of the apparatus of any preceding clause, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left bone conduction transducer of the headset, and wherein the right auditory stimuli pattern comprises generating the right auditory stimuli pattern with a right bone conduction transducer of a headset.

[00146] Clause 60. The use of the apparatus of any preceding clause, wherein one or more of the left or right auditory stimuli pattern includes an auditory frequency of from 240 Hz to 480 Hz.

[00147] Clause 61. The use of the apparatus of any preceding clause, wherein one or more of the left visual stimuli pattern or right visual stimuli pattern comprises repeatedly pulsing a light at one or more of a first pulse frequency, a second pulse frequency less than the first pulse frequency, or a third pulse frequency less than the first and second pulse frequencies.

[00148] Clause 62. The use of the apparatus of any preceding clause, wherein the first pulse frequency is between 3.75 Hz and 4.25 Hz, the second pulse frequency is between 1.25 Hz and 1.75 Hz, and the third pulse frequency is between 0.25 Hz and 0.75 Hz.

[00149] Clause 63. The use of the apparatus of any preceding clause, wherein repeatedly pulsing the light comprises pulsing the light for a predetermined time interval.

[00150] Clause 64. The use of the apparatus of any preceding clause, wherein the predetermined time interval is 25-45 seconds.

[00151] Clause 65. The use of the apparatus of any preceding clause, wherein the sequence of stimuli patterns each have a pulse frequency having a pulse period, where a portion of the pulse period includes a stimulus of an auditory frequency of from 240 Hz to 480 Hz.

[00152] Clause 66. The use of the apparatus of any preceding clause, wherein said portion of said pulse period is one half of the pulse period.

[00153] Clause 67. The use of the apparatus of any preceding clause, wherein said first stimuli pattern, said second stimuli pattern, or said third stimuli pattern stimulates for a predetermined time interval.

[00154] Clause 68. The use of the apparatus of any preceding clause, wherein the predetermined time interval is 25-35 seconds.

[00155] Clause 69. The use of the apparatus of any preceding clause, wherein the predetermined time interval is 30 seconds.

[00156] Clause 70. The use of the apparatus of any preceding clause, where said first stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.

[00157] Clause 71. The use of the apparatus of any preceding clause, where said third stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.

[00158] Clause 72. The use of the apparatus of any preceding clause, where said apparatus includes a sensor to obtains a state of the user and modifies said sensory stimulus according to the state of the user.

[00159] Clause 73. The use of the apparatus of any preceding clause, where said sensor is a heart rate sensor, a heart rate variability (HRV) sensor, a temperature sensor, a motion sensor, a galvanic skin response sensor, an accelerometer, an EEG or an EMG.

[00160] Clause 74. The use of the apparatus of any preceding clause, where the state of the user is a state of sleep or the level or change in level of relaxation or arousal.

[00161] The above discussion is meant to be illustrative of the principles and various embodiments of the present invention. Once the above disclosure is fully appreciated, numerous variations and modifications will become apparent to those skilled in the art. It is intended that the following claims be interpreted to embrace all such variations and modifications.

CLAIMS

What is claimed is:

1. A method of treating effects of addiction withdrawal, said method comprising administering a therapeutically effective amount of a sensory stimulus to the person, where said sensory stimulus includes one or more of a visual stimuli and an auditory stimuli.
2. The method of claim 1, where said treating reduces one or more symptoms of addiction withdrawal.
3. The method of claim 2, where said symptoms include anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, aching bones, aching muscles, restlessness, nausea, vomiting, muscle twitching, stomach cramps, pain, the need to use an opioid, the desire to use an opioid, and sleep disturbances.
4. The method of claim 1, where said addiction withdrawal is opioid addiction withdrawal.
5. The method of claim 4, where said treating reduces the use of rescue medications.
6. The method of claim 1, where said addiction withdrawal is nicotine addiction withdrawal.
7. The method of claim 1, where said visual stimuli includes an amplitude modulated light source.
8. The method of claim 1, where one of said one or more visual stimuli includes a sinusoidally varying light source.
9. The method of claim 1, where one of said one or more said auditory stimuli includes an amplitude modulated audio frequency.
10. The method of claim 1, where said sensory stimulus includes a two or more sensory stimuli patterns including a first stimuli pattern that is different than a second stimuli pattern.
11. The method of claim 10, where said two or more stimuli patterns includes a first stimuli pattern having a first pulse frequency and a second stimuli pattern having a second pulse frequency.
12. The method of claim 11, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.

13. The method of claim 11, where said two or more stimuli patterns includes a third stimuli pattern that is different than said first stimuli pattern and said second stimuli pattern.
14. The method of claim 13, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said third stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.
15. The method of claim 1, where said sensory stimulus alternates between
- a first sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right auditory stimuli pattern to the right side of the head, and
 - a second sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a left auditory stimuli pattern to the left side of a head of the user,
- wherein one or more of the left auditory stimuli pattern or the right auditory stimuli pattern comprises a sequence of stimuli patterns including the first stimuli pattern, the second stimuli pattern, and the third stimuli pattern.
16. The method of claim 15, further comprising:
- periodically providing a sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user, a right visual stimuli pattern to the right eye of the user, a left auditory stimuli pattern to the left side of the head, and a right auditory stimuli pattern to the right side of a head of the user.
17. The method of claim 15, further comprising:
- alternating sensory stimuli between
 - a third sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a left auditory stimuli pattern to the left side of the head, and
 - a fourth sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a right auditory stimuli pattern to the right side of a head of the user.

18. The method of claim 17, further comprising:
alternating sensory stimuli between
a fifth sensory stimuli including simultaneously providing a left auditory stimuli pattern to the left side of the head and a right auditory stimuli pattern to the right side of the head, and
a sixth sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right visual stimuli pattern to the right eye of the user.
19. The method of claim 15, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left speaker, and wherein generating the right auditory stimuli pattern comprises generating the right auditory stimuli pattern with a right speaker.
20. The method of claim 15, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left bone conduction transducer of the headset, and wherein the right auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left bone conduction transducer of a headset.
21. The method of claim 15, wherein one or more of the left or right auditory stimuli pattern includes an auditory frequency of from 240 Hz to 480 Hz.
22. The method of claim 15, wherein one or more of the left visual stimuli pattern or right visual stimuli pattern comprises repeatedly pulsing a light at one or more of a first pulse frequency, a second pulse frequency less than the first pulse frequency, or a third pulse frequency less than the first and second pulse frequencies.
23. The method of claim 22, wherein the first pulse frequency is between 3.75 Hz and 4.25 Hz, the second pulse frequency is between 1.25 Hz and 1.75 Hz, and the third pulse frequency is between 0.25 Hz and 0.75 Hz.
24. The method of claim 15, wherein repeatedly pulsing the light comprises pulsing the light for a predetermined time interval.
25. The method of claim 24, wherein the predetermined time interval is 25-45 seconds.
26. The method of claim 15, wherein the sequence of stimuli patterns each have a pulse frequency having a pulse period, where a portion of the pulse period includes a stimulus of an auditory frequency of from 240 Hz to 480 Hz.
27. The method of claim 26, wherein said portion of said pulse period is one half of the pulse period.

28. The method of claim 15, wherein said first stimuli pattern, said second stimuli pattern, or said third stimuli pattern stimulates for a predetermined time interval.
29. The method of claim 28, wherein the predetermined time interval is 25-35 seconds.
30. The method of claim 29, wherein the predetermined time interval is 30 seconds.
31. The method of claim 11, where said first stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.
32. The method of claim 31, where said third stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.
33. The method of any one of claims 1 through 32, further comprising
obtaining a measurement of the user using a sensor;
determining a state of the user from the obtained measurement; and
modifying said sensory stimulus according to said determined state of the user.
34. The method of claim 33, where said sensor is a heart rate sensor, a heart rate variability (HRV) sensor, a temperature sensor, a motion sensor, a galvanic skin response sensor, an accelerometer, an EEG or an EMG.
35. The method of claim 34, where said determined state of the user is a state of sleep or the level or change in level of relaxation or arousal.
36. A method treating two or more symptoms in a person, said method comprising:
providing a headset to be worn by the person; and
administering, with the headset, the therapeutically effective amount of a sensory stimulus to the person of claim 1.
37. The method of claim 36, where said symptoms result from the person undergoing addiction withdrawal.
38. The method of claim 37, where said symptoms result from the person undergoing withdrawal from opioid addiction.
39. The method of claim 37, where said symptoms result from the person undergoing withdrawal from nicotine addiction.
40. Use of an apparatus, characterized for being for the production of sensory stimulus,

including one or more of a visual stimuli and an auditory stimuli, for the treatment of symptoms resulting addiction withdrawal.

41. The use of the apparatus of claim 40, where the treatment of symptoms includes reducing one or more symptoms of addiction withdrawal.

42. The use of the apparatus of claim 41, where said symptoms include anxiety, sleepiness, sweating, tearing of the eyes, running of the nose, goosebumps, shaking, hot flushes, cold flushes, aching bones, aching muscles, restlessness, nausea, vomiting, muscle twitching, stomach cramps, pain, the need to use an opioid, the desire to use an opioid, and sleep disturbances.

43. The use of the apparatus of claim 40, where said addiction withdrawal is opioid addiction withdrawal.

44. The use of the apparatus of claim 43, where said treating reduces the use of rescue medications.

45. The use of the apparatus of claim 40, where said addiction withdrawal is nicotine addiction withdrawal.

46. The use of the apparatus of claim 40, where said visual stimuli includes an amplitude modulated light source.

47. The use of the apparatus of claim 40, where one of said one or more visual stimuli includes a sinusoidally varying light source.

48. The use of the apparatus of claim 40, where one of said one or more said auditory stimuli includes an amplitude modulated audio frequency.

49. The use of the apparatus of claim 40, where said sensory stimulus includes a two or more sensory stimuli patterns including a first stimuli pattern that is different than a second stimuli pattern.

50. The use of the apparatus of claim 49, where said two or more stimuli patterns includes a first stimuli pattern having a first pulse frequency and a second stimuli pattern having a second pulse frequency.

51. The use of the apparatus of claim 50, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.

52. The use of the apparatus of claim 50, where said two or more stimuli patterns includes a third stimuli pattern that is different than said first stimuli pattern and said second stimuli pattern.
53. The use of the apparatus of claim 52, where said first stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, where said second stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz, and where said third stimuli pattern includes a sinusoidal component that is between 3.75 Hz and 4.25 Hz, is between 1.25 Hz and 1.75 Hz, or is between 0.25 Hz and 0.75 Hz.
54. The use of the apparatus of claim 40, where said sensory stimulus alternates between
a first sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right auditory stimuli pattern to the right side of the head, and
a second sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a left auditory stimuli pattern to the left side of a head of the user,
wherein one or more of the left auditory stimuli pattern or the right auditory stimuli pattern comprises a sequence of stimuli patterns including the first stimuli pattern, the second stimuli pattern, and the third stimuli pattern.
55. The use of the apparatus of claim 54, further comprising:
periodically providing a sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user, a right visual stimuli pattern to the right eye of the user, a left auditory stimuli pattern to the left side of the head, and a right auditory stimuli pattern to the right side of a head of the user.
56. The use of the apparatus of claim 54, further comprising:
alternating sensory stimuli between
a third sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a left auditory stimuli pattern to the left side of the head, and
a fourth sensory stimuli including simultaneously providing a right visual stimuli pattern to the right eye of the user and a right auditory stimuli pattern to the right side of a head of the user.

57. The use of the apparatus of claim 56, further comprising:
- alternating sensory stimuli between
 - a fifth sensory stimuli including simultaneously providing a left auditory stimuli pattern to the left side of the head and a right auditory stimuli pattern to the right side of the head, and
 - a sixth sensory stimuli including simultaneously providing a left visual stimuli pattern to the left eye of the user and a right visual stimuli pattern to the right eye of the user.
58. The use of the apparatus of claim 54, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left speaker, and wherein generating the right auditory stimuli pattern comprises generating the right auditory stimuli pattern with a right speaker.
59. The use of the apparatus of claim 54, wherein the left auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left bone conduction transducer of the headset, and wherein the right auditory stimuli pattern comprises generating the left auditory stimuli pattern with a left bone conduction transducer of a headset.
60. The use of the apparatus of claim 54, wherein one or more of the left or right auditory stimuli pattern includes an auditory frequency of from 240 Hz to 480 Hz.
61. The use of the apparatus of claim 54, wherein one or more of the left visual stimuli pattern or right visual stimuli pattern comprises repeatedly pulsing a light at one or more of a first pulse frequency, a second pulse frequency less than the first pulse frequency, or a third pulse frequency less than the first and second pulse frequencies.
62. The use of the apparatus of claim 61, wherein the first pulse frequency is between 3.75 Hz and 4.25 Hz, the second pulse frequency is between 1.25 Hz and 1.75 Hz, and the third pulse frequency is between 0.25 Hz and 0.75 Hz.
63. The use of the apparatus of claim 54, wherein repeatedly pulsing the light comprises pulsing the light for a predetermined time interval.
64. The use of the apparatus of claim 63, wherein the predetermined time interval is 25-45 seconds.
65. The use of the apparatus of claim 54, wherein the sequence of stimuli patterns each have a pulse frequency having a pulse period, where a portion of the pulse period includes a stimulus of an auditory frequency of from 240 Hz to 480 Hz.
66. The use of the apparatus of claim 65, wherein said portion of said pulse period is one half of the pulse period.

67. The use of the apparatus of claim 54, wherein said first stimuli pattern, said second stimuli pattern, or said third stimuli pattern stimulates for a predetermined time interval.
68. The use of the apparatus of claim 67, wherein the predetermined time interval is 25-35 seconds.
69. The use of the apparatus of claim 68, wherein the predetermined time interval is 30 seconds.
70. The use of the apparatus of claim 50, where said first stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.
71. The use of the apparatus of claim 70, where said third stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency, and where said second stimuli pattern includes a sinusoidal component corresponding to a delta brain wave frequency, a theta brain wave frequency, or an alpha brain wave frequency.
72. The use of the apparatus of any one of claims 40 through 71, where said apparatus includes a sensor to obtains a state of the user and modifies said sensory stimulus according to the state of the user.
73. The use of the apparatus of claim 72, where said sensor is a heart rate sensor, a heart rate variability (HRV) sensor, a temperature sensor, a motion sensor, a galvanic skin response sensor, an accelerometer, an EEG or an EMG.
74. The use of the apparatus of claim 73, where the state of the user is a state of sleep or the level or change in level of relaxation or arousal.

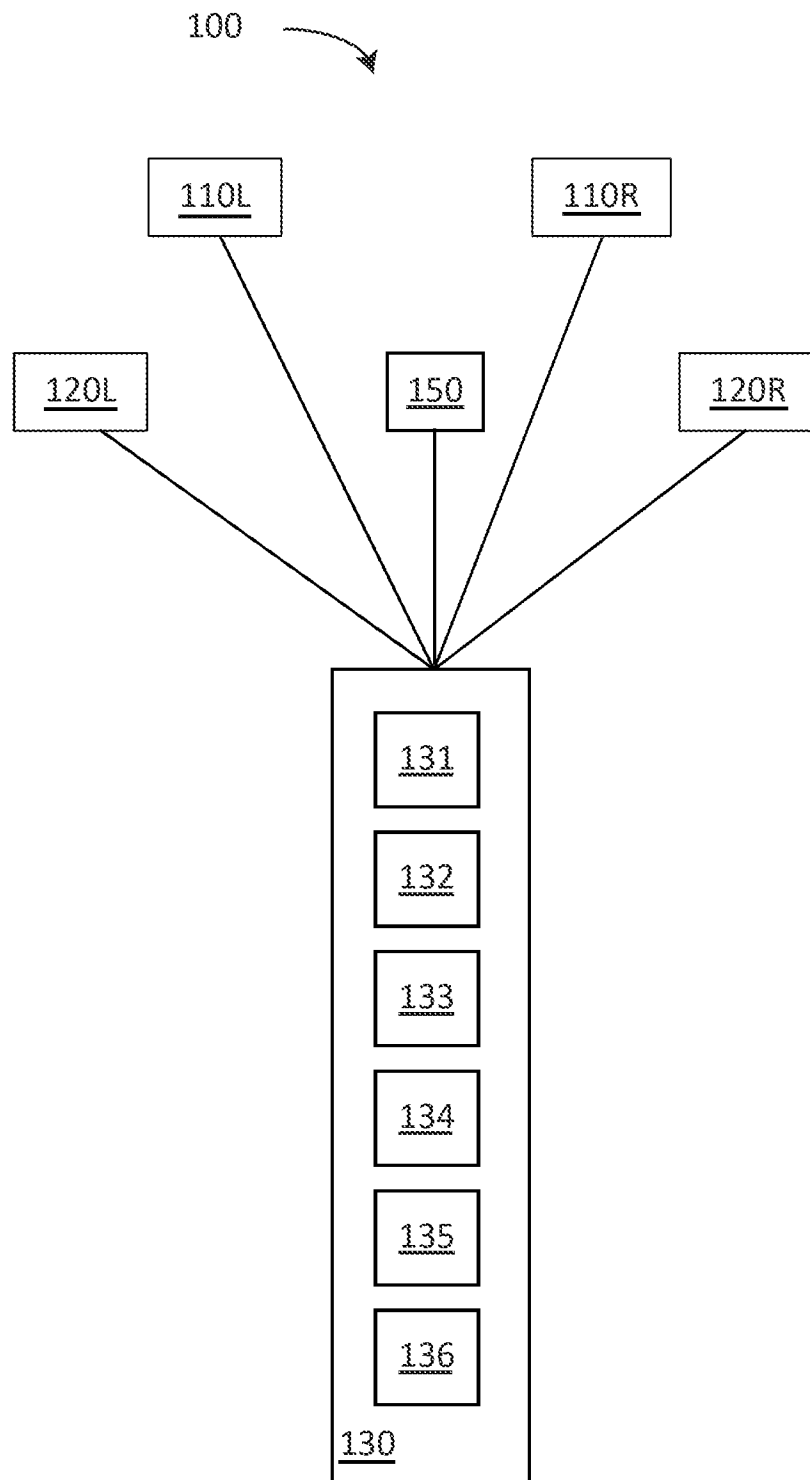


FIG. 1



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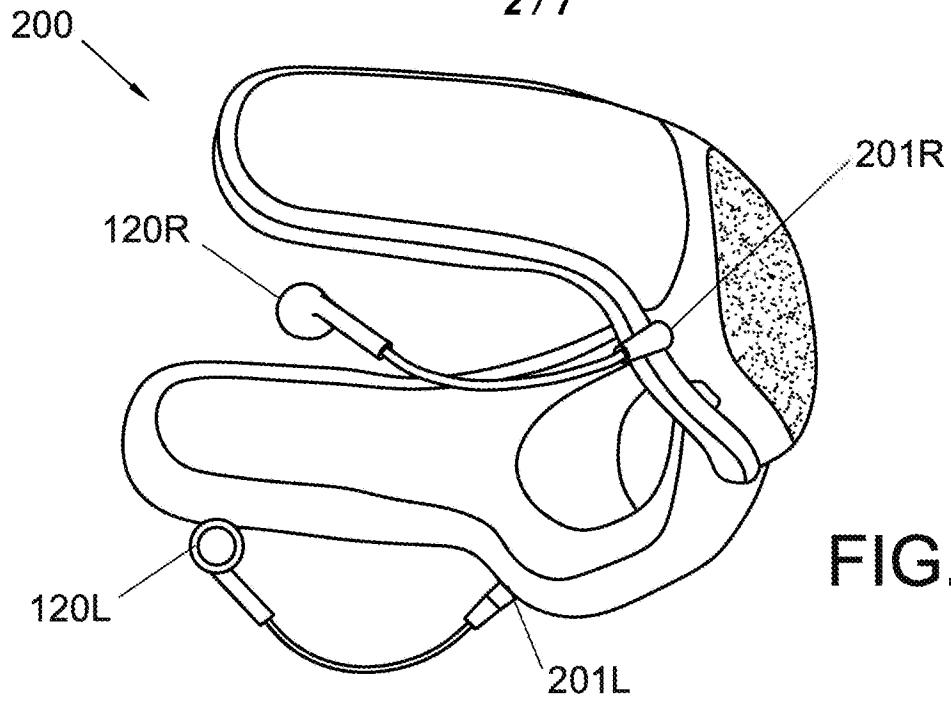


FIG. 2A

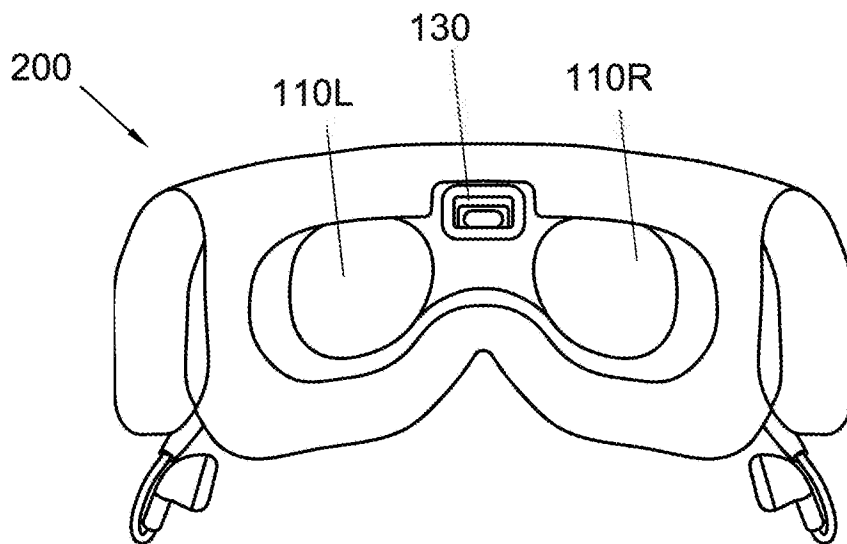


FIG. 2B

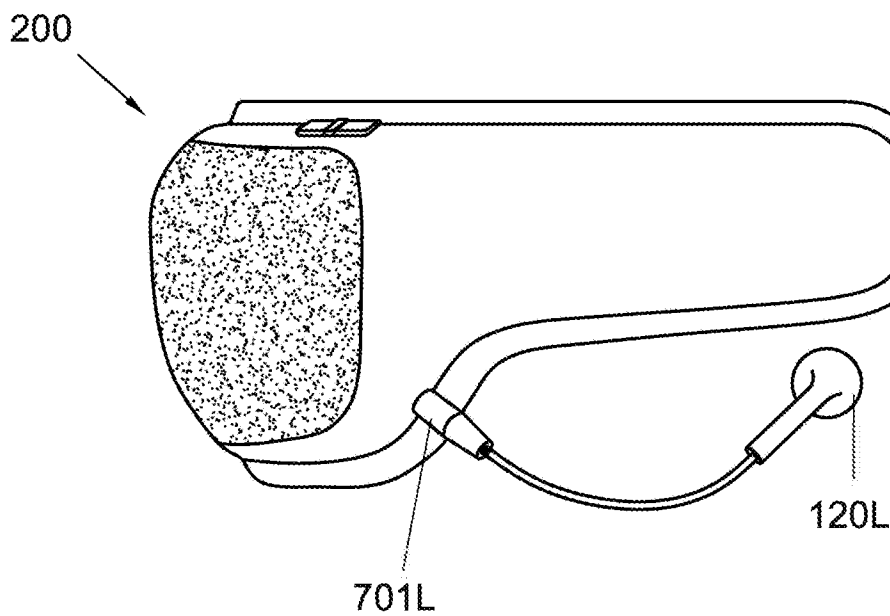


FIG. 2C



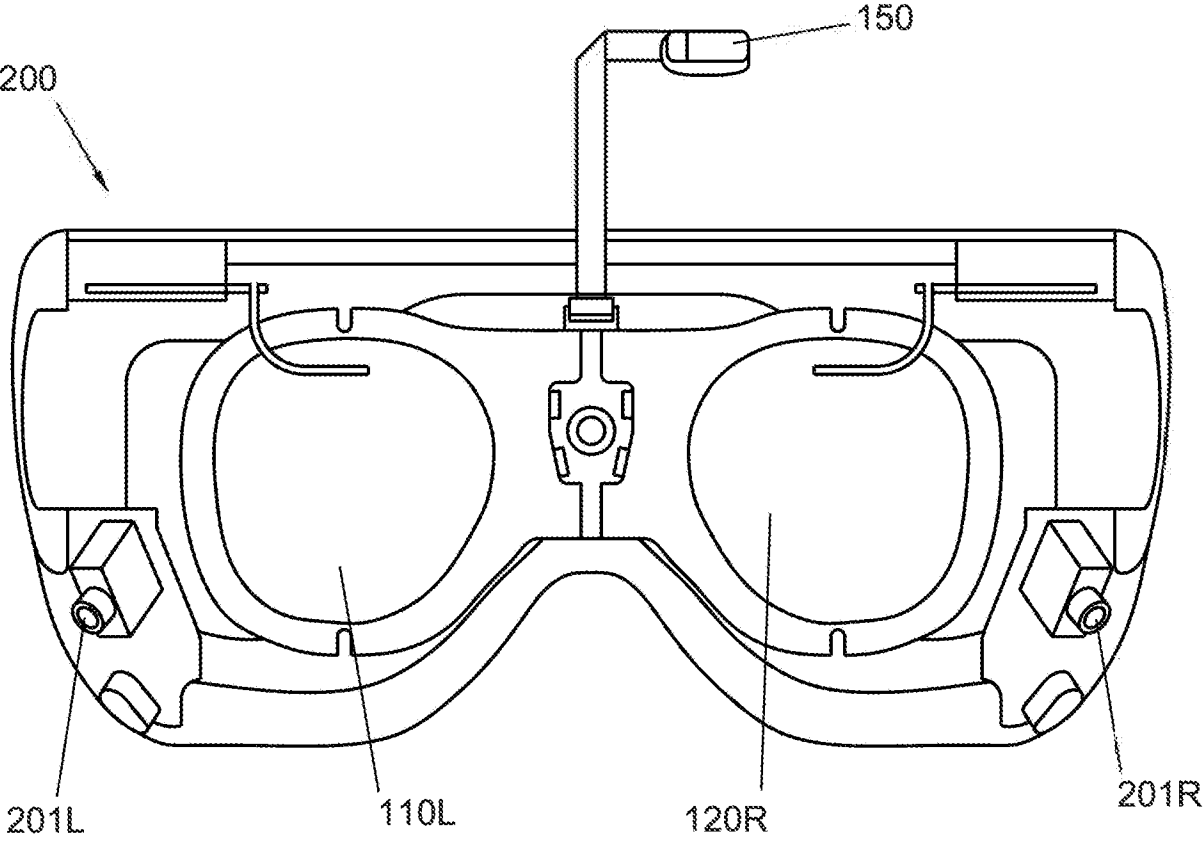


FIG. 3

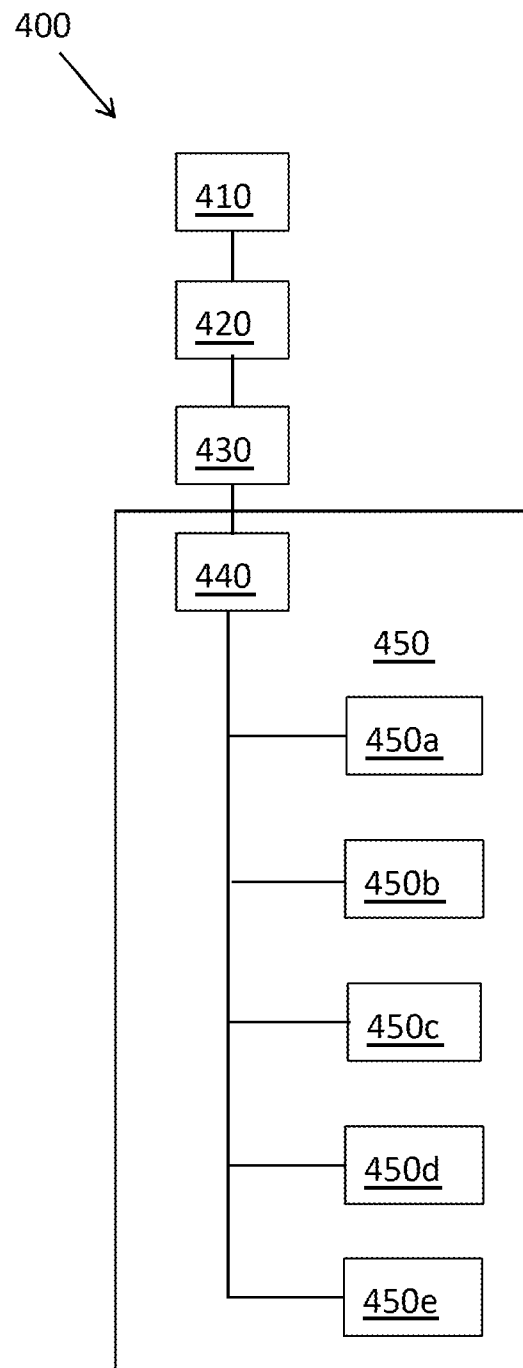


FIG. 4



500 

Segments A1-A4 for 120s	Auditory Left	Auditory Right	Light Left	Light Right
Segment A1 (Light and Auditory both sides pulse together) Repeat 116 times, followed by 0.5 sec gap	On 0.1277 sec	On 0.1277 sec	On 0.1277 sec	On 0.1277 sec
	Off 0.1277 sec	Off 0.1277 sec	Off 0.1277 sec	Off 0.1277 sec
Segment A2 (light and auditory on left side, alternating light and auditory on right). Repeat 116 times, followed by 0.5 sec gap	On 0.1277 sec	Off 0.1277 sec	On 0.1277 sec	Off 0.1277 sec
	Off 0.1277 sec	On 0.1277 sec	Off 0.1277 sec	On 0.1277 sec
Segment A3 (both lights together, alternating with both auditory signals together) Repeat 115 times, followed by 0.5 sec gap	On 0.1277 sec	On 0.1277 sec	Off 0.1277 sec	Off 0.1277 sec
	Off 0.1277 sec	Off 0.1277 sec	On 0.1277 sec	On 0.1277 sec
Segment A4 (auditory left and light right together, alternating auditory right and light left together) Repeat 115 times, followed by 0.5 sec gap	On 0.1277 sec	Off 0.1277 sec	Off 0.1277 sec	On 0.1277 sec
	Off 0.1277 sec	On 0.1277 sec	On 0.1277 sec	Off 0.1277 sec

FIG. 5

600 

Segments B1-B4 for 120s	Auditory Left	Auditory Right	Light Left	Light Right
Segment B1 (Light and Auditory both sides pulse together) Repeat 45 times, followed by 0.5 sec gap	On 0.3333 sec	On 0.3333 sec	On 0.3333 sec	On 0.3333 sec
	Off 0.3333 sec	Off 0.3333 sec	Off 0.3333 sec	Off 0.3333 sec
Segment B2 (light and auditory on left side, alternating light and auditory on right) Repeat 44 times, followed by 0.5 sec gap	On 0.3333 sec	Off 0.3333 sec	On 0.3333 sec	Off 0.3333 sec
	Off 0.3333 sec	On 0.3333 sec	Off 0.3333 sec	On 0.3333 sec
Segment B3 (both lights together, alternating with both auditory signals together) Repeat 44 times, followed by 0.5 sec gap	On 0.3333 sec	On 0.3333 sec	Off 0.3333 sec	Off 0.3333 sec
	Off 0.3333 sec	Off 0.3333 sec	On 0.3333 sec	On 0.3333 sec
Segment B4 (auditory left and light right together, alternating auditory right and light left together) Repeat 44 times, followed by 0.5 sec gap	On 0.3333 sec	Off 0.3333 sec	Off 0.3333 sec	On 0.3333 sec
	Off 0.3333 sec	On 0.3333 sec	On 0.3333 sec	Off 0.3333 sec

FIG. 6



700 

Repeat the following Segments C1-C4 6 times for a total of 12 minutes	Auditory Left	Auditory Right	Light Left	Light Right
Segment C1 (Light and Auditory both sides pulse together) Repeat 15 times, followed by 1 sec gap	On 1 sec	On 1 sec	On 1 sec	On 1 sec
	Off 1 sec	Off 1 sec	Off 1 sec	Off 1 sec
Segment C2 (light and auditory on left side, alternating light and auditory on Right) Repeat 15 times, followed by 1 sec gap	On 1 sec	Off 1 sec	On 1 sec	Off 1 sec
	Off 1 sec	On 1 sec	Off 1 sec	On 1 sec
Segment C3 (both lights together, alternating with both auditory signals together) Repeat 14 times, followed by 1 sec gap	On 1 sec	On 1 sec	Off 1 sec	Off 1 sec
	Off 1 sec	Off 1 sec	On 1 sec	On 1 sec
Segment C4 (auditory left and light right together, alternating auditory right and light left together) Repeat 14 times, followed by 1 sec gap	On 1 sec	Off 1 sec	Off 1 sec	On 1 sec
	Off 1 sec	On 1 sec	On 1 sec	Off 1 sec

FIG. 7



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2020/019091

A: CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 21/00; A61M 21/02; A61N 1/04; A61N 1/36 (2020.01)

CPC - A61M 21/00; A61M 2021/0022; A61M 2021/0027; A61M 2021/0044 (2020.02)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC - 514/810; 514/811; 514/812; 514/813 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2018/0250494 A1 (SANA HEALTH INC) 06 September 2018 (06.09.2018) entire document	1-4, 6-43, 45-74
Y	WO 2012/117343 A1 (KONINKLIJKE PHILIPS ELECTRONICS N V) 07 September 2012 (07.09.2012) entire document	1-4, 6-43, 45-74
A	US 2019/0030279 A1 (NOWLIN) 31 January 2019 (31.01.2019) entire document	1-74
P, A	US 10,328,236 B2 (SANA HEALTH INC) 25 June 2019 (25.06.2019) entire document	1-74
P, A	WO 2019/060598 A1 (THERANOVA LLC) 28 March 2019 (28.03.2019) entire document	1-74

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

12 April 2020

Date of mailing of the international search report

06 MAY 2020

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