IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mind Medicine, Inc.
Serial No.: 17/839,374
Filing or 371(c) Date: 06/13/2022
Entitled: SYSTEM AND METHOD FOR MONITORING A CONSCIOUSNESS-ALTERING THERAPEUTIC SESSION

Confirmation No.: 1001
Group No.:
Examiner:

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application:

1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021)
2. U.S. Pat. App. Pub. No. 2017/0172522 "METHOD AND DEVICE FOR AUTOMATIC IDENTIFICATION OF AN OPIOID OVERDOSE AND INJECTION OF AN OPIOID RECEPTOR ANTAGONIST" (Published June 22, 2017)
3. STRAYER (2008) "Adverse events associated with ketamine for procedural sedation in adults". American Journal of Emergency Medicine. 26(9): 985-1028
4. U.S. Pat. App. Pub. No. 2020/0337625 "SYSTEM AND METHOD FOR BRAIN MODELLING" (Published October 29, 2020)
5. PROVIDENCE CARE, "Providence Care Ketamine Clinic; a new hope for treatment resistant depression" January 29, 2020; URL: https://providencecare.ca/providence-care-ketamine-clinic-a-new-hope-for-treatment-resistant-depression/; Retrieved on October 26, 2023

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list of the elements of the presently pending claims.

U.S.S.N. 17/839,374	References
1. A system for monitoring patients during a consciousness-altering therapeutic treatment session comprising: a data collection module in electronic communication with network servers for storage of data on non-transitory computer readable media for monitoring a patient's well-being during and after the treatment session.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0164]** "The invention features methods and systems involving a patient who is undergoing treatment with a psychedelic agent or who is a candidate for treatment with a psychedelic agent. In some embodiments, **the invention involves monitoring patients undergoing treatment with psychedelic agents**, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania." From **[0165]** "The invention features methods related to treatment of psychedelic therapy. **Psychedelic agents useful as part of the invention include any compound capable of inducing an altered state of consciousness**, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Psychedelic agents include 5-HT.sub.2A agonists (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents; e.g., 3,4-methylenedioxymethamphetamine (MDMA)), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine)." From **[0130]** "In some embodiments, **the system passively acquires data (e.g., language data) that indicates that a psychedelic dose is too high** (e.g., as a result of a non-compliant high administration or due to a greater-than-intended influence level of a planned dose). **In any case, a third party may be notified to follow up with the patient, to temporarily suspend treatment, or both."** From **[0134]** "In some embodiments, **a network-connected computerized database** contains a record of clinical support features, such as contact information for specialized treatment facilities, pharmacies, physicians, emergency personnel, and/or other support services. **A system of the invention may include a software application (e.g., a patient-interface application, e.g., a mobile-device application) that accesses such a database conditionally or automatically to send one or more notifications, alerts, reports, or other information to a third party (e.g., to a computing platform (e.g., a remote database) or a clinical professional) for storage or analysis.** From **[0085]** "The methods and systems provided herein feature **automated language analysis to process and analyze one or more language samples obtained from a candidate or patient**. Automated language analysis can be executed as part of a software program (e.g., as part of a software application or accessible to the software application **(e.g., on a remote server in communication with the software application)**)."

2. The system of claim 1, wherein said data collection module includes a patient mobile device, at least one wearable device, a sound system, and a blood pressure monitor.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0103]** "In other instances, **a behavioral sample detected by a sensor.** For example, **physical activity of an individual may be detected or monitored by a sensor**. For example, physical sensors include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, **ultrasonic sensors**, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., **as part of a mobile device**, such as a smartphone or **smart wearable device**), or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or **blood characteristics (e.g., blood pressure**, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))))."
3. The system of claim 2, wherein said patient mobile device is chosen from the group consisting of a smartphone and tablet, and said at least one wearable device is chosen from the group consisting of a smart watch and a fitness band.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0104]** "**Biosensors may be part of a mobile device, such as a smartphone, tablet, or wearable mobile device, such as a watch**, **bracelet, or necklace**. Biosensors include sensors equipped with the capacity to detect the presence or level of one or more biomarkers (e.g., digital biomarkers), such as CO.sub.2 levels (e.g., blood CO.sub.2), glucose levels, expression of genes or proteins that correlate positively or negative with behavior."
4. The system of claim 2, wherein said data collection module includes a facilitator mobile device in electronic communication with said patient mobile device, said at least one wearable device, said sound system, and said blood pressure monitor.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0134]** "In some embodiments, **a network-connected computerized database contains a record of clinical support features,** such as contact information for specialized treatment facilities, pharmacies, physicians, emergency personnel, and/or other support services. A system of the invention may include **a software application (e.g., a patient-interface application, e.g., a mobile-device application) that accesses such a database conditionally or automatically to send one or more notifications, alerts, reports, or other information to a third party (e.g., to a computing platform (e.g., a remote database) or a clinical professional)** for storage or analysis." From **[0103]** "In other instances, **a behavioral sample detected by a sensor.** For example, **physical activity of an individual may be detected or monitored by a sensor**. For example, physical sensors

	include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, **ultrasonic sensors**, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., **as part of a mobile device**, such as a smartphone or **smart wearable device**), or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or **blood characteristics (e.g., blood pressure**, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).” From **[0104]** “**Biosensors may be part of a mobile device, such as a smartphone, tablet, or wearable mobile device, such as a watch**, **bracelet, or necklace**. Biosensors include sensors equipped with the capacity to detect the presence or level of one or more biomarkers (e.g., digital biomarkers), such as CO.sub.2 levels (e.g., blood CO.sub.2), glucose levels, expression of genes or proteins that correlate positively or negative with behavior.”
5. The system of claim 4, wherein said facilitator mobile device provides audio and video feed, ePRO, eCOA, EMA, ClinRO, EHR/EMR, cognitive tasks, and therapy notes.	1. U.S. Pat. App. Pub. No. 2021/0183519 “METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES” (Published June 17, 2021) From **[0103]** “In other instances, a behavioral sample detected by a sensor. For example, physical activity of an individual may be detected or monitored by a sensor. For example, **physical sensors include any device able to detect physical activity or characteristics** (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), **including video sensors (e.g., video cameras)**, motion sensors (e.g., passive infrared sensors, **ultrasonic sensors**, microwave sensors, or tomographic sensors), GPS, accelerometers (**e.g., as part of a mobile device, such as a smartphone or smart wearable device**), or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).” From **[0138]** “In some embodiments, **the server database contains sufficient audio-video link information to establish audio and video communication between the candidate or patient and a clinician**. For example, the server and database may contain both the internet address information for the practitioner, patient, and any third parties as needed, and also act to relay the data packets between the parties. Alternatively, the server and database may contain address links, such as, for example, for Skype or other online video conferencing systems enabling the patient, healthcare practitioner, and third parties to communicate by third party messaging systems. In general, in order to ensure quality and a consistent user interface, often the server will both present the telemedicine user interface (e.g. present one or more web

	pages for telemedicine applications) in addition to relaying the audio and video data packets. Accordingly, a telemedicine session can be suitably encrypted." From **claim 190** "The method of claim 188, further comprising **conducting a cognitive assessment on the patient**." From **[0137]** "Additionally or alternatively, **personal identification information, medical records, and any messages or notes provided by the patient can be sent with a notification, alert, or report to a third party.**"
6. The system of claim 4, wherein said facilitator mobile device includes an application stored on non-transitory computer readable media for guiding the facilitator through the treatment session.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0052]** "In another aspect, the invention **features a software program** configured for assessing a risk of precipitating or exacerbating psychosis, hypomania, or mania **in a patient undergoing treatment with a psychedelic agent or a candidate for treatment with a psychedelic agent, the software program comprising computer-readable instructions for: (i) obtaining one or more language and/or behavioral samples from the user**; (ii) deriving one or more language characteristics from the one or more language samples and/or one or more behavioral characteristics from the one or more behavioral samples; and based on the one or more language and/or behavioral characteristics, determining a measure of risk, wherein the measure of risk correlates with a risk of precipitating or exacerbating psychosis, hypomania, or mania in the candidate; and (iii) reporting the measure of risk to the user and/or a third party." From **[0053]** "In some embodiments, **the software program further includes computer-readable instructions for receiving information regarding the treatment with the psychedelic agent, wherein the information is selected from the group consisting of psychedelic agent composition, a quantity of psychedelic agent prescribed, a dosing schedule, a quantity of psychedelic agent administered per dose, a frequency of doses administered, and a cumulative quantity of psychedelic agent administered.** The computer-readable instructions for receiving information regarding the treatment with the psychedelic agent may be configured to receive the information from the patient, a clinician, or the third party. In some embodiments, the computer-readable instructions for receiving information regarding the treatment with the psychedelic agent are further configured to store and/or report the information regarding the treatment with the psychedelic agent (e.g., all or a portion of the information can be reported to the patient or the third party, e.g., all or a portion of the information can be reported to a clinician or another third party upon detecting non-compliance by the patient, e.g., an increase or decrease in the dose or frequency of psychedelic agent administered)."

7. The system of claim 1, wherein said network servers include a backend with API including a relational database and external storage.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0134]** "In some embodiments, **a network-connected computerized database** contains a record of clinical support features, such as contact information for specialized treatment facilities, pharmacies, physicians, emergency personnel, and/or other support services. **A system of the invention may include a software application (e.g., a patient-interface application, e.g., a mobile-device application) that accesses such a database conditionally or automatically to send one or more notifications, alerts, reports, or other information to a third party (e.g., to a computing platform (e.g., a remote database) or a clinical professional) for storage or analysis.** From **[0197]** "As discussed above, **the computer system includes a mechanism to send a report to a third party and/or to view all or a portion of the results on the application's interface to the subject**."
8. The system of claim 1, wherein said data collection module collects audio and music stream data with a microphone and speakers, motion and actigraphy with an accelerometer, gyroscope, and magnetometer, heart rate and blood pressure with a heart rate sensor and said blood pressure monitor, ePRO, eCOA, EMA, or ClinRO with said facilitator mobile device, and video and image stream with a camera.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0041]** "In some embodiments of any of the preceding methods, the measure of risk is further based on one or more language characteristics derived from a language sample. The language sample may be elicited by a digital prompt, a questionnaire, or a clinician administered interview. In some embodiments, the language sample is, or may be derived from, a dream report, a description of a picture, a thematic apperception test, or a neutral text reading. In some embodiments, the language sample is obtained by passive acquisition (e.g., constant or arbitrary monitoring of outgoing audio data or text data). **In some embodiments, the language sample is a text sample and/or an audio sample**. In some embodiments, the audio sample is analyzed to derive the one or more language characteristics, wherein the one or more language characteristics comprises one or more acoustic features (e.g., a measure of irregular pitch (e.g., standard variance of pitch), zero-crossing rate, kurtosis energy, HNR, mel-frequency cepstral coefficients MFCC, and frame energy). In some embodiments, the audio sample is transcribed into text." From **[0107]** "**Sensors also include non-physical sensors**. For example, systems and methods of the invention may additionally or alternatively access data from programs that track television habits (e.g., frequency of changing channels, genres of programs or movies watched, sound volume, etc.), internet habits (e.g., frequency of opening new webpages, types of sites visited, number of emails sent, frequency of messages sent), **music habits (e.g., genre of music listened to, volume of music, frequency of skipped tracks, number of repeated tracks, etc.)**, and/or eating and/or drinking habits (e.g., as

	measured by a smart refrigerator). Any known software applications and/or hardware systems capable of tracking such habits are suitable for methods and systems of the present invention." From **[0103]** "In other instances, a **behavioral sample detected by a sensor**. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include **any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity**), **including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or smart wearable device)**, or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, **heart rate**, breathing characteristics (e.g., rate or depth), or **blood characteristics (e.g., blood pressure**, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))). From **[0137]** "Additionally or alternatively, **personal identification information, medical records, and any messages or notes provided by the patient can be sent with a notification, alert, or report to a third party.**"
9. The system of claim 1, wherein said consciousness-altering therapeutic is chosen from the group consisting of lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), ibogaine, ketamine, salts thereof, tartrates thereof, solvates thereof, isomers thereof, analogs thereof, homologues thereof, and deuterated forms thereof.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0164]** "The invention features methods and systems involving a patient who is undergoing treatment with a psychedelic agent or who is a candidate for treatment with a psychedelic agent. In some embodiments, **the invention involves monitoring patients undergoing treatment with psychedelic agents**, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania." From **[0165]** "The invention features methods related to treatment of psychedelic therapy. **Psychedelic agents useful as part of the invention include any compound capable of inducing an altered state of consciousness**, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. **Psychedelic agents include 5-HT.sub.2A agonists (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents;** e.g., 3,4-methylenedioxymethamphetamine (MDMA)), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; **e.g., ketamine)**." From **[0166]** "5-HT.sub.2A agonists include **psilocybin, LSD, DOI (±)-1-(2,5-dimethoxyphenyl)-2-aminopropane hydrochloride; (R)-DOI ((R)-1-(2,5-dimethoxy-4-iodophenyl)-2-aminopropane)** (greater

	than 95% R enantiomer); LA-SS-Az (2'S,4'S)-(+)-9,10-Didehydro-6-methylergoline-8β-(trans-2,4-dimethylazetidide); 2C-BCB (4-Bromo-3,6-dimethoxybenzocyclobuten-1-yl) methylamine; **ayahuasca; 3,4,5-trimethoxyphenethylamine (mescaline); 5-methoxy-N,N-dimethyltryptamine (5-meo-DMT); and ibogaine**." From **[0134]** "In some embodiments, **a network-connected computerized database** contains a record of clinical support features, such as contact information for specialized treatment facilities, pharmacies, physicians, emergency personnel, and/or other support services. **A system of the invention may include a software application (e.g., a patient-interface application, e.g., a mobile-device application) that accesses such a database conditionally or automatically to send one or more notifications, alerts, reports, or other information to a third party (e.g., to a computing platform (e.g., a remote database) or a clinical professional) for storage or analysis.**
10. The system of claim 1, wherein said system provides a feature chosen from the group consisting of automatic detection of mood swings, early onset of panic attacks, and other psychological states and behavioral correlates of consciousness altering effects of the administered therapeutic, continuous monitoring and real-time detection of adverse events related to consciousness altering treatment, automatic analysis of the clinician's/facilitator's notes and the ability to automatically identify, extract, and present critical moments, comment, and highlights of the treatment session, automatically create patient specific and/or session-specific statistics, monitoring for signs of abuse or dependence, an automatic drug provisioning system, a dosing administration tracking system, automatic detection of an inappropriate treatment	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0071]** "The invention features a method of **enhancing the safety of the therapeutic application of psychedelic**, empathogenic, and dissociative compounds including: evaluating the suitability of the treatment for the patient given the capacity to **detect a latent, remitted, or active psychosis, hypomania, or mania**. The invention includes a software application delivered via computer, smartphone, or other device (e.g. mobile device), which is capable of **collecting patient data through textual and/or audio recording of responses to automated** and clinician administered **structured interviews and surveys, audio recording of phone conversations, mobile sensors and other psychometric information gathered from a smartphone or other mobile device, and other prompted and unprompted voice, text, keypad, push-button, or other forms of computerized data captures**. The invention is further capable of converting this data into a format capable of being **rapidly analyzed in automated assessments in one or more validated quantitative frameworks capable of identifying prodromal or manifest symptoms of psychosis, hypomania, and mania**. The invention is also capable of recording the results of these **automated quantitative assessments and making them available to supervisory clinicians should they indicate a patient is in need of immediate attention**. The invention is also capable of **alerting clinicians should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition**, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, **and if warranted, emergency medical intervention and/or discontinuation of the associated drug treatment.** In addition, methods of the invention can **trigger clinical assessment (e.g., by a clinician or by**

setting, a digitized clinician, facilitator, and site certification system, a treatment management system, session scheduling, digital medical history, and an audit trail interface, and combinations thereof.	**software) for further review/confirmation and to determine the need to adjust a therapy (e.g., a chronic, acute, or psychotherapy-assisted dosing regimen).** For example, a therapy may be adjusted by **supplementing the therapy, escalating the dose, reducing the dose, retreating the patient, discontinuing treatment, or otherwise modifying a prescribed course of therapy**. A clinical assessment may also trigger contacting a patient's care provider, family, next of kin, etc." From **[0011]** "In some embodiments, the method further includes administering the psychedelic agent (or recommending administration of the psychedelic agent) if the screening indicates that the patient is not experiencing the one or more adverse effects (e.g., presently experiencing one or more adverse effects or has experienced one or more adverse effects during the course of psychedelic treatment), **or if the screening does not indicate that the patient is experiencing the one or more adverse effects (e.g., presently experiencing one or more adverse effects or has experienced one or more adverse effects during the course of psychedelic treatment)."** From **claim 25** "The method of any one of claims 10-24, further comprising **assessing a measure of compliance with, or abuse of, the psychedelic agent**." From **claim 26** "The method of claim 25, wherein the **measure of compliance with, or abuse of, the psychedelic agent is derived from a biomarker**." From **Example 2**. "On-Going **Safety Monitoring of LSD Therapy Patient for Risk of Developing Psychosis**" From **[0184]** "After agreeing to adhere to a smartphone-based screening program as a follow-on component of the complex therapy involving LSD and behavior therapy, a 54-year old patient diagnosed with substance abuse is administered LSD at a treatment center. The patient downloads a software application to her smartphone at the treatment center, is instructed on the proper and regular use of the application, and is **notified via push notifications when her mobile device safety session is scheduled**, e.g., monthly, beginning one day after the complex therapy is administered." From **[0137]** "Additionally or alternatively, **personal identification information, medical records, and any messages or notes provided by the patient can be sent with a notification, alert, or report to a third party**."
11. A method of using a monitoring system in treating a patient, including the steps of: continuously, continually, or at the	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021)

healthcare professionals discretion monitoring the well-being of the patient during a consciousness-altering therapeutic treatment session through one or more wearable devices and a patient mobile device in electronic communication with a facilitator mobile device; and continuously monitoring the well-being of the patient after the treatment session with the wearable device.	From **[0185]** "**Utilizing the smartphone-based safety monitoring application**, the patient is digitally prompted to speak freely about a recent experience and her expectations for the future. Several follow-on prompts are provided to generate a twenty-minute audio recording, which is pre-processed on the smartphone processor and sent to a remote server for language analysis. Using methods such as latent semantic analysis, and by comparing the resulting measure of risk to her own baseline speech previous to treatment administration, **the remote server determines that the subject has a low measure of risk for developing psychosis, hypomania, or mania. The server sends a communication to the patient's smartphone enabling the software application to continue to prompt the patient to provide language samples at the predetermined interval. The patient undergoes adjunctive behavioral therapy through the same smartphone application in parallel with the safety assessment.**" From **[0084]** "In some embodiments, **the language sample is processed in real time, and the software continues to record conversations or the prompt continues to elicit a language sample for the duration of time necessary to achieve a significant result.** For example, the system may iteratively analyze the accumulating language sample until one or more characteristics or **risk measures** reaches a predetermined significance level, at which point the prompt may automatically conclude." From **[0108]** "**A behavioral sample may be acquired for any suitable duration to provide one or more behavioral characteristics**. In some embodiments, the behavioral sample is **processed in real time, and the software continues to acquire the sample for the duration of time necessary to achieve a significant result.** For example, the system may iteratively analyze the accumulating language sample until one or more characteristics or **risk measures** reaches a predetermined significance level, at which point the prompt may automatically conclude." 2. U.S. Pat. App. Pub. No. 2017/0172522 "METHOD AND DEVICE FOR AUTOMATIC IDENTIFICATION OF AN OPIOID OVERDOSE AND INJECTION OF AN OPIOID RECEPTOR ANTAGONIST" (Published June 22, 2017) From **claim 1** "A method for detecting the need for providing assistance to an individual suspected of overdosing on an opiate, the method comprising, **(a) measuring continuously or intermittently one or more physiological parameters of the individual using a device**; (b) **triggering an alarm if the level of at least one of the one or more physiological parameters exceeds a threshold level specific to said parameter;** (c) continuing the measuring, and if the alarm was interrupted, suspending the alarm for a period of time and determining thereafter whether the level of the at least one of the one or more physiological parameters has returned to the threshold level; (d)

	triggering the alarm if, after said period of time, the level of the at least one of the one or more physiological parameters had not returned to the threshold level; (e) repeating steps (c) and (d) if in step (d) the alarm was interrupted, and if the alarm was not interrupted in either step (d) or (b) **within a fixed duration, transmitting a message to one or more contacts** (i) to convey that the individual had overdosed on an opiate and (ii) provide GPS coordinates of the individual."
12. The method of claim 11, wherein said continuously, continually, or at the healthcare professionals discretion monitoring the well-being of the patient during a consciousness-altering therapeutic treatment session step is further defined as collecting baseline data from the patient with a facilitator mobile device, providing the patient with a wearable device, a patient mobile device, and a blood pressure monitor, dosing the patient with a consciousness-altering therapeutic, a facilitator performing a treatment session, continuously monitoring the patient with the wearable device and patient mobile device, and performing a post-session assessment on the patient.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0044]** "In any of the preceding aspects, the measure of risk can be determined using a machine learning algorithm. In some embodiments, the measure of risk is determined using a cluster model (e.g., a supervised cluster model or an unsupervised cluster model). The measure of risk may be determined using a Random Forest classifier or a within-patient Naïve Bayes classifier. In some embodiments, **the measure of risk is determined based on a change of one or more of the characteristics relative to a reference characteristic (e.g., a subject's baseline measurement of the characteristic obtained from the patient at an earlier time point or a cumulative value derived from a plurality of individuals (e.g., healthy individuals)). In some embodiments, the reference characteristic is a predetermined threshold**." From **[0165]** "The invention features methods related to treatment of psychedelic therapy. **Psychedelic agents useful as part of the invention include any compound capable of inducing an altered state of consciousness**, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Psychedelic agents include 5-HT.sub.2A agonists (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents; e.g., 3,4-methylenedioxymethamphetamine (MDMA)), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine)." From **[0185]** "**Utilizing the smartphone-based safety monitoring application**, the patient is digitally prompted to speak freely about a recent experience and her expectations for the future. Several follow-on prompts are provided to generate a twenty-minute audio recording, which is pre-processed on the smartphone processor and sent to a remote server for language analysis. Using methods such as latent semantic analysis, and by comparing the resulting measure of risk to her own baseline speech previous to treatment administration, **the remote server determines that the subject has a low measure of risk for developing psychosis, hypomania, or mania. The server sends a communication to the patient's smartphone enabling the software application to continue to prompt the patient to provide language samples at the predetermined interval. The patient undergoes**

	adjunctive behavioral therapy through the same smartphone application in parallel with the safety assessment." From **[0103]** "In other instances, a **behavioral sample detected by a sensor**. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include **any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity**), **including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or smart wearable device)**, or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, **heart rate**, breathing characteristics (e.g., rate or depth), or **blood characteristics (e.g., blood pressure**, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))). From **[0186]** "**One week after being administered the complex therapy, the patient speech samples are determined to indicate that the patient is at high risk for developing psychosis, based on automated assessments of multiple speech samples taken at varying time points (1 day, 3 days, 7 days) following the complex therapy**. The remote server tasked with assessing speech samples **sends a communication to the patient's smartphone notifying her that a clinician will be in contact to follow up**. A second communication is sent to a clinician, including a summary report of the results of the assessments and the statistical confidence associated with the risk assessment. The clinician would direct the patient to either provide an additional speech sample for further validation, or direct the client to an appropriate mental health clinic for further assessment and or therapy based upon the summary report of safety assessment."
13. The method of claim 12, further including, after said collecting baseline data step, the step of a clinician checking the baseline data and recording a conversation with the patient.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0094] "In some embodiments, the methods and systems of the invention feature a toolkit (e.g., openSMILES), which can be run directly, for example, on a mobile device (e.g., a smartphone or tablet) in real time, as the audio sample is acquired**. In some instances, raw or processed data can be input into a model that is user-specific **(e.g., compared with baseline values of the same user)** or user-independent (e.g., compared with a predetermined threshold or a composite of values obtained by other users). Additional methods of measuring, processing, and characterizing any of the aforementioned acoustic features are known in the art and describe, for example, in Vanello et al., Conf Proc IEEE Eng Med Biol Soc 2012. 2012:2104-2107 and Karam et al., Proceedings of the IEEE International Conference on Acoustics, Speech, and Signal Processing (Conference)

	2014:4858-4862, both of which are incorporated by reference in their entireties." From **[0071]** "The invention features a method of enhancing the safety of the therapeutic application of psychedelic, empathogenic, and dissociative compounds including: evaluating the suitability of the treatment for the patient given the capacity to detect a latent, remitted, or active psychosis, hypomania, or mania. **The invention includes a software application delivered via computer, smartphone, or other device** (e.g. mobile device), **which is capable of collecting patient data through** textual and/or audio recording of responses to automated and clinician administered structured interviews and surveys, **audio recording of phone conversations,** mobile sensors and other psychometric information gathered from a smartphone or other mobile device, and other prompted and unprompted voice, text, keypad, push-button, or other forms of computerized data captures. The invention is further capable of converting this data into a format capable of being rapidly analyzed in automated assessments in one or more validated quantitative frameworks capable of identifying prodromal or manifest symptoms of psychosis, hypomania, and mania. The invention is also capable of recording the results of these automated quantitative assessments and making them available to supervisory clinicians should they indicate a patient is in need of immediate attention. The invention is also capable of alerting clinicians should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, emergency medical intervention and/or discontinuation of the associated drug treatment. In addition, **methods of the invention can trigger clinical assessment** (e.g., by a clinician or by software) for further review/confirmation and to determine the need to adjust a therapy (e.g., a chronic, acute, or psychotherapy-assisted dosing regimen). For example, a therapy may be adjusted by supplementing the therapy, escalating the dose, reducing the dose, retreating the patient, discontinuing treatment, or otherwise modifying a prescribed course of therapy. **A clinical assessment may also trigger contacting a patient's care provider**, family, next of kin, etc."
14. The method of claim 12, wherein said facilitator performing a treatment session step is further defined as an application stored on non-transitory computer readable media on the facilitator mobile device guiding the facilitator through the treatment session.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0052]** "In another aspect, the invention **features a software program** configured for assessing a risk of precipitating or exacerbating psychosis, hypomania, or mania **in a patient undergoing treatment with a psychedelic agent or a candidate for treatment with a psychedelic agent, the software program comprising computer-readable instructions for: (i) obtaining one or more language and/or behavioral samples from the user**; (ii) deriving one or more language characteristics from the one or more language

	samples and/or one or more behavioral characteristics from the one or more behavioral samples; and based on the one or more language and/or behavioral characteristics, determining a measure of risk, wherein the measure of risk correlates with a risk of precipitating or exacerbating psychosis, hypomania, or mania in the candidate; and (iii) reporting the measure of risk to the user and/or a third party." From **[0053]** "In some embodiments, **the software program further includes computer-readable instructions for receiving information regarding the treatment with the psychedelic agent, wherein the information is selected from the group consisting of psychedelic agent composition, a quantity of psychedelic agent prescribed, a dosing schedule, a quantity of psychedelic agent administered per dose, a frequency of doses administered, and a cumulative quantity of psychedelic agent administered.** The computer-readable instructions for receiving information regarding the treatment with the psychedelic agent may be configured to receive the information from the patient, a clinician, or the third party. In some embodiments, the computer-readable instructions for receiving information regarding the treatment with the psychedelic agent are further configured to store and/or report the information regarding the treatment with the psychedelic agent (e.g., all or a portion of the information can be reported to the patient or the third party, e.g., all or a portion of the information can be reported to a clinician or another third party upon detecting non-compliance by the patient, e.g., an increase or decrease in the dose or frequency of psychedelic agent administered)."
15. The method of claim 12, further including the step of notifying the facilitator if any metrics differ significantly from the baseline data.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **claim 21** "**A method of providing a regimen of psychedelic therapy to a patient, the method comprising**: (i) providing a differential measure of risk obtained by comparing two or more measures of risk, each measure of risk derived from one or more language characteristics of a language sample obtained from the patient, wherein the one or more measures of risk correlates with the risk of precipitating or exacerbating psychosis, hypomania, or mania in the patient, and wherein each measure of risk is associated with a different treatment time point; and (ii) **suspending the psychedelic therapy if the differential measure of risk exceeds a predetermined threshold."** **From [0044]** "In any of the preceding aspects, the measure of risk can be determined using a machine learning algorithm. In some embodiments, the measure of risk is determined using a cluster model (e.g., a supervised cluster model or an unsupervised cluster model). The measure of risk may be determined using a Random Forest classifier or a within-patient Naïve Bayes classifier. **In some embodiments, the measure of risk is determined based on a change of one or more of the characteristics relative to a reference characteristic (e.g., a**

	subject's baseline measurement of the characteristic obtained from the patient at an earlier time point or a cumulative value derived from a plurality of individuals (e.g., healthy individuals)). In some embodiments, the reference characteristic is a predetermined threshold." From **[0134]** "In some embodiments, **a network-connected computerized database** contains a record of clinical support features, such as contact information for specialized treatment facilities, pharmacies, physicians, emergency personnel, and/or other support services. **A system of the invention may include a software application (e.g., a patient-interface application, e.g., a mobile-device application) that accesses such a database conditionally or automatically to send one or more notifications, alerts, reports, or other information to a third party (e.g., to a computing platform (e.g., a remote database) or a clinical professional) for storage or analysis.**
16. The method of claim 12, further including the step of the facilitator making notes and tagging critical events in session in the application.	3. STRAYER (2008) "Adverse events associated with ketamine for procedural sedation in adults". American Journal of Emergency Medicine. 26(9): 985-1028 From page **991** "…Hallucinations were noted in 6/32 cases and "nightmares and anxiety" occurred in 2/32 cases…" From page **1009** "67 patients aged 6-43 y undergoing tonsillectomy at a Nigerian hospital received IV diazepam, 0.2 mg/kg (max 10 mg) 5-10 min preinduction. The pharynx was then anesthetized with 3-4 doses of 10% lidocaine spray (10 mg/dose). **Patients then received IM ketamine 5 mg/kg** and were positioned in neck hyperextension with sandbags under the shoulders so that blood would flow anteriorly rather than posteriorly. **An additional dose of IV ketamine, 1 mg/kg, was given just before the commencement of the operation**… **Cardiorespiratory status was continuously monitored by a nurse anesthetist. No psychiatric adverse event reporting methodology is presented**…No cardiorespiratory adverse events occurred; specifically there were no cases of laryngospasm. No "emergency delirium" occurred, but **"patients were rather more restless than usual." The authors note a prolonged recovery time ranging from 40 min to 2 h. Postoperative vomiting occurred in 31% of patients.**" From pages **1014-1015** "**239 patients undergoing 247 assorted operations in a hospital in Guyana received IV ketamine, 2.2 mg/kg, or IM ketamine, 11 mg/kg,** followed by supplemental smaller doses as needed with or without premedicant IM diazepam, 10-15 mg…Adverse event reporting methodology is not presented, however **cardiorespiratory status seemed to be continuously monitored in the anesthesiologist controlled operating room setting. The author reports that he saw all patients postoperatively and reviewed all nursing notes for complications.**"

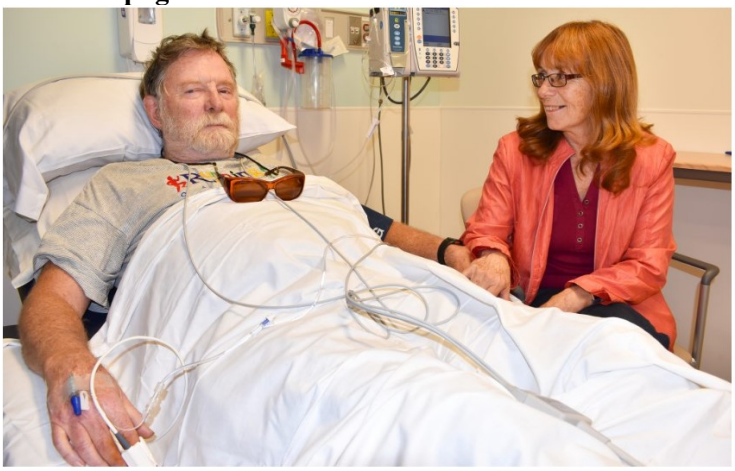
17. The method of claim 12, further including the step of the application providing information about the length of the session, estimated duration of the session, estimated end of the session, estimated intensity of administered therapeutic, and estimated time period for consciousness-altering therapeutic experience stage/phase for early stage, onset, peak and comedown.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0143]** "In some instances, a perceptible dose of a psychedelic therapy is administered as an out-patient procedure, and the patient is monitored before release to ensure that any perceptible psychedelic effects (e.g., influences) have subsided. In this instance, the influence of the psychedelic therapy can be characterized at one or more (e.g., two, three, four, five, or more) time points following administration, e.g., to monitor its kinetics. For example, based on one or more of characteristics of a language sample obtained from a patient, a measure of influence can be derived using any of the methods described above. **In some embodiments, a language sample is taken shortly after administration of the psychedelic agent** (e.g., from 1-10 minutes, from 10-20 minutes, from 20-30 minutes, or within 1 hour, e.g., at 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, 40 minutes, or 50 minutes) **to determine an influence measure at or near the psychedelic agent's peak effect. This peak influence measure may be compared to a reference measure** (e.g., a baseline measure obtained from the same patient, or a measure derived from a plurality of subjects characterized as having a low influence measure or a low risk of developing psychosis, hypomania, or mania, e.g., as determined using any of the methods described herein). A subsequent language sample may be taken after any period of time from administration in which a psychedelic influence may have subsided (e.g., from 1-72 hours, e.g., from 24-72 hours or from 36-48 hours after administration, e.g., from 1-2 hours, from 2-3 hours, from 3-4 hours, from 4-5 hours, from 5-6 hours, from 6-7 hours, from 7-8 hours, from 8-10 hours, from 10-12 hours, from 12-14 hours, from 14-16 hours, form 16-18 hours, form 18-20 hours, from 20-22 hours, from 22-24 hours, from 24-36 hours, from 36-42 hours, from 42-48 hours, from 48-60 hours, or from 60-72 hours after administration, e.g., about 24 hours, about 36 hours, about 48 hours, about 60 hours, or about 72 hours after administration). **The degree to which a psychedelic influence subsides can be characterized, for example, by a decrease from a peak influence measure to a subsequent influence measure**." 4. U.S. Pat. App. Pub. No. 2020/0337625 "SYSTEM AND METHOD FOR BRAIN MODELLING" (Published October 29, 2020) From **[0315]** "**In the case of psychedelic therapy,** for example, the regulation of set, setting, and intensification of experience could be modulated and adjusted by a caregiver receiving outputs from the patient undergoing therapy in real time through which **the patient's experience is modeled predictively in order to understand how their experience and temporal state could be anticipated to alter or vary throughout the course of treatment,** in relation to their

	particular interaction and integration with the therapy. In order to optimize the efficacy of a psychedelic treatment, it is especially important to identify and determine the way in which a patient will experience its corresponding effects, such that success of treatment will vary depending on the specific and particular level of receptivity and comfortability with the therapeutic experience." From **[0028]** "According to a further aspect, there is provided **a non-transitory computer readable medium comprising a computer readable memory storing computer executable instructions thereon that when executed by a computer cause the computer to perform a method as described herein.**"
18. The method of claim 12, wherein said performing a post-session assessment step is further defined as the facilitator assessing the patient's resting state by assessing heart rate, blood pressure, and overall stress levels, digitally processing all notes generated during the session, and automatically extracting and visually presenting highlights and critical events with a timeline on the facilitator mobile device.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0101]** "In some embodiments, a behavioral sample is a telephone record, which contains information related to an individual's social behavior (e.g., a number or frequency of outgoing calls or messages, a number or frequency of incoming calls or messages, a ratio between a number or frequency of outgoing calls or messages and a number or frequency of incoming calls or messages, a duration of one or more calls, a length of one or more messages, a number or frequency of newly added contacts, a number of changes of turns between participants of a telephone call, a number of short turns in conversation, a number of changes in cell tower IDs, and/or a number of unique cell tower IDs). **Systems of the invention may be configured to automatically receive an individual's telephone record upon its preparation (e.g., daily, weekly, biweekly, or monthly)** or in real time." From **[0044]** "In any of the preceding aspects, the measure of risk can be determined using a machine learning algorithm. In some embodiments, the measure of risk is determined using a cluster model (e.g., a supervised cluster model or an unsupervised cluster model). The measure of risk may be determined using a Random Forest classifier or a within-patient Naïve Bayes classifier. **In some embodiments, the measure of risk is determined based on a change of one or more of the characteristics relative to a reference characteristic (e.g., a subject's baseline measurement of the characteristic obtained from the patient at an earlier time point or a cumulative value derived from a plurality of individuals (e.g., healthy individuals))**. In some embodiments, the reference characteristic is a predetermined threshold." From **[0103]** "**In other instances, a behavioral sample detected by a sensor**. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video

	sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers **(e.g., as part of a mobile device, such as a smartphone or smart wearable device)**, or **biosensors** (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, **heart rate**, breathing characteristics (e.g., rate or depth), or **blood characteristics (e.g., blood pressure**, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).” From **[0102]** “A behavioral sample may also be a report of the number and/or frequency of instances in which a **mobile device screen (e.g., a screen of a smartphone or tablet)** is turned on. Such a sample can be detected by **a program running on device being monitored, or the device screen status can be detected remotely**.” From **[0135]** “**Various patient information can be stored on a processing system and/or shared with a third party,** including data obtained from a screening session, such as raw data from a language sample (e.g., audio data, or text data), partially processed data obtained from a language sample **(e.g., representation, summarization**, or integration of a semantic analysis), a characteristic derived from processing a language sample (e.g., a semantic coherence measure, a syntactic complexity measure, a comprehension measure, a lexicon depth measure, or a lexicon breadth measure), a measure derived from one or more or such characteristics (e.g., a composite score derived from two or more of such characteristics (e.g., a composite of semantic coherence and syntactic complexity, or a measure of risk), or a relationship between any of the aforementioned data, e.g., obtained at different screening sessions, e.g., at different time points.” From **[0012]** “Methods of the invention additionally provide means for determining whether the patient is complying with the prescribed regimen of psychedelic therapy. In some embodiments, the method further includes assessing a measure of compliance with the psychedelic agent. In some embodiments, the method further includes assessing a measure of abuse of the psychedelic agent. Measures of compliance and/or abuse can be derived from **one or more digital readouts using the methods and systems of the invention**, e.g., by observing a level of a biomarker, for example, a level of a target molecule present in a body sample obtained from the patient (e.g., a level of the psychedelic agent, a metabolite of the psychedelic agent, or another molecule that correlates positively or negatively with the level of the psychedelic agent in the patient).”
19. The method of claim 18, further including the step of performing a post-session release check with a clinician.	1. U.S. Pat. App. Pub. No. 2021/0183519 “METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES” (Published June 17, 2021) From **claim 96 “The method of any one of claims 90-95, wherein the notification informs a clinician's decision when to release the patient from a supervised facility.”**

	From **[0029]** "In another aspect, **the invention features a method of monitoring a psychedelic agent's effect on a patient's perception, for example, to inform a safe time of release from a supervised facility.** Provided herein is a method of characterizing the influence of a psychedelic agent on the perception of a patient administered therewith, the method including: (i) obtaining a language sample from the patient; (ii) providing one or more language characteristics of the language sample; and (ii) based on the one or more language characteristics, determining a measure of psychedelic influence, wherein the measure of psychedelic influence correlates with the influence of the psychedelic therapy on the perception of the patient. In some embodiments, the psychedelic agent is administered on an in-patient basis. In such instances, the psychedelic agent may be administered in a perceptible dose. In other embodiments, the psychedelic agent is administered on an out-patient basis, and the psychedelic agent may be administered in a sub-perceptible dose or a perceptible dose. In some embodiments, the method further comprises providing a notification based on the influence of a psychedelic agent on the perception of the patient. **In some embodiments, the notification informs a clinician's decision of when drug-induced alterations in perception and cognition of a patient receiving treatment involving a psychedelic agent have returned to baseline or to a sufficiently low level.** In some embodiments, the language sample is analyzed to derive the one or more language characteristics, wherein the one or more language characteristics comprises a measure of semantic proximity to one or more dimensions or facets related to an influence of a psychedelic agent (e.g., as described in the 5D-ASC rating scale). In some embodiments, a measure of semantic proximity to one or more concepts related to an influence of a psychedelic agent is positively correlated with the influence of the psychedelic therapy on the perception of the patient." From **[0190]** "Ketamine and esketamine are used as anti-depressant therapies for use in severe major depression. Use of the invention in the context of using ketamine or esketamine for the treatment of depression involves application as both a screening tool, to exclude patients at risk for psychosis, hypomania, or mania, as well as **in the release interview for the patient, enabling clinicians to confirm the drug effects have subsided and the absence of lingering psychotic or manic symptoms**." From **[0187]** "A 65-year old patient is diagnosed with herpetic encephalitis, is hospitalized due to the life-threatening nature of the condition, and requires immediate treatment with anti-inflammatory therapy. **Following administration of R-DOI, the patient's encephalitis is successfully treated and he is evaluated by doctors for release from the hospital.** Utilizing a mobile device operated by clinicians at the hospital, clinicians instruct the patient to describe a recent dream he has had, or to react to an image or photograph known to elicit a negative emotional response, and **capture his response via**

	the mobile device for pre-processing and transmission to a remote server for analysis. **Using methods described herein, the remote server determines that the patient is at low risk for developing psychosis, hypomania, or mania and is released from the hospital once this result is transmitted back to supervising clinicians at the hospital.** Should the patient have a moderate to high measure or risk for developing psychosis, hypomania, or mania, as determined through statistical confidence interval, **the patient would either be kept at the hospital for further observation by clinicians, or would agree to adhere to a smartphone-based screening program that would allow clinicians to remotely assess the patient's risk for developing psychosis, hypomania, or mania."**
20. The method of claim 11, wherein said continuously monitoring the well-being of the patient after the treatment session step is further defined as continuously monitoring the patient's heart rate and overall activity with the wearable device.	3. STRAYER (2008) "Adverse events associated with ketamine for procedural sedation in adults". American Journal of Emergency Medicine. 26(9): 985-1028 From page **991** "…Hallucinations were noted in 6/32 cases and "nightmares and anxiety" occurred in 2/32 cases…" From page **1009** "67 patients aged 6-43 y undergoing tonsillectomy at a Nigerian hospital received IV diazepam, 0.2 mg/kg (max 10 mg) 5-10 min preinduction. The pharynx was then anesthetized with 3-4 doses of 10% lidocaine spray (10 mg/dose). **Patients then received IM ketamine 5 mg/kg** and were positioned in neck hyperextension with sandbags under the shoulders so that blood would flow anteriorly rather than posteriorly. **An additional dose of IV ketamine, 1 mg/kg, was given just before the commencement of the operation**… **Cardiorespiratory status was continuously monitored by a nurse anesthetist. No psychiatric adverse event reporting methodology is presented**…No cardiorespiratory adverse events occurred; specifically there were no cases of laryngospasm. No "emergency delirium" occurred, but **"patients were rather more restless than usual." The authors note a prolonged recovery time ranging from 40 min to 2 h. Postoperative vomiting occurred in 31% of patients.**" From pages **1014-1015** "**239 patients undergoing 247 assorted operations in a hospital in Guyana received IV ketamine, 2.2 mg/kg, or IM ketamine, 11 mg/kg,** followed by supplemental smaller doses as needed with or without premedicant IM diazepam, 10-15 mg…Adverse event reporting methodology is not presented, however **cardiorespiratory status seemed to be continuously monitored in the anesthesiologist controlled operating room setting. The author reports that he saw all patients postoperatively and reviewed all nursing notes for complications.**" 5. PROVIDENCE CARE, "Providence Care Ketamine Clinic; a new hope for treatment resistant depression" January 29, 2020; URL:

	https://providencecare.ca/providence-care-ketamine-clinic-a-new-hope-for-treatment-resistant-depression/; Retrieved on October 26, 2023 From **webpage** “  Gary and Jan Crawford at **Providence Care’s Ketamine Clinic**. Gary started coming to the clinic in June 2019. … **The ketamine is given by an intravenous (IV) infusion and lasts about 40 minutes, during which their heart rate and blood pressure are monitored.**”
21. The method of claim 11, further including the step of continuously monitoring adverse events.	1. U.S. Pat. App. Pub. No. 2021/0183519 “METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES” (Published June 17, 2021) From **[0011]** “In some embodiments, the method further includes administering the psychedelic agent (or recommending administration of the psychedelic agent) if the screening indicates that the patient is not experiencing the one or more adverse effects (e.g., presently experiencing one or more adverse effects or has experienced one or more adverse effects during the course of psychedelic treatment), **or if the screening does not indicate that the patient is experiencing the one or more adverse effects (e.g., presently experiencing one or more adverse effects or has experienced one or more adverse effects during the course of psychedelic treatment).”** From **[0108]** “**A behavioral sample may be acquired for any suitable duration to provide one or more behavioral characteristics**. In some embodiments, the behavioral sample is **processed in real time, and the software continues to acquire the sample for the duration of time necessary to achieve a significant result.** For example, the system may iteratively analyze the accumulating language sample until one or more characteristics or **risk measures** reaches a predetermined significance level, at which point the prompt may automatically conclude.”

22. The method of claim 11, wherein the one or more wearable devices and patient mobile devices collect passive data continuously chosen from the group consisting of audio, motion, activity, stress level, heart rate, and combinations thereof.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0103]** "In other instances, a **behavioral sample detected by a sensor**. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include **any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity**), **including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or smart wearable device)**, or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, **heart rate**, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))). From **[0094] "In some embodiments, the methods and systems of the invention feature a toolkit (e.g., openSMILES), which can be run directly, for example, on a mobile device (e.g., a smartphone or tablet) in real time, as the audio sample is acquired**. In some instances, raw or processed data can be input into a model that is user-specific **(e.g., compared with baseline values of the same user)** or user-independent (e.g., compared with a predetermined threshold or a composite of values obtained by other users). Additional methods of measuring, processing, and characterizing any of the aforementioned acoustic features are known in the art and describe, for example, in Vanello et al., Conf Proc IEEE Eng Med Biol Soc 2012. 2012:2104-2107 and Karam et al., Proceedings of the IEEE International Conference on Acoustics, Speech, and Signal Processing (Conference) 2014:4858-4862, both of which are incorporated by reference in their entireties."
23. The method of claim 11, wherein the consciousness-altering therapeutic is chosen from the group consisting of lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), ibogaine, ketamine, salts	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0164]** "The invention features methods and systems involving a patient who is undergoing treatment with a psychedelic agent or who is a candidate for treatment with a psychedelic agent. In some embodiments, **the invention involves monitoring patients undergoing treatment with psychedelic agents**, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania." From **[0165]** "The invention features methods related to treatment of psychedelic therapy. **Psychedelic agents useful as part of the invention include any compound capable of inducing an altered state of consciousness**, i.e., a marked deviation in the subjective

thereof, tartrates thereof, solvates thereof, isomers thereof, analogs thereof, homologues thereof, and deuterated forms thereof.	experience or psychological functioning of a normal individual from his or her usual waking consciousness. **Psychedelic agents include 5-HT.sub.2A agonists (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents;** e.g., 3,4-methylenedioxymethamphetamine (MDMA)), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; **e.g., ketamine)**."
24. The method of claim 11, wherein a clinician is monitoring multiple patients at the same time.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0096]** "In some embodiments of any of the methods described above, a measure of any characteristic of a language sample can be derived using a machine learning algorithm, as described, for example, in Bedi. **In some embodiments, a supervised or unsupervised cluster model can be used, e.g., to classify characteristics among a population of candidates or patients**, or to compare one or more characteristics of a candidate or patient with a those of a reference population. The measure of risk may be determined using a Random Forest classifier or a within-patient Naïve Bayes classifier."
25. The method of claim 11, further including a step chosen from the group consisting of automatically detecting mood swings, early onset of panic attacks, and other psychological states and behavioral correlates of consciousness altering effects of the administered therapeutic, continuously monitoring and real-time detecting of adverse events related to consciousness altering treatment, automatically analysing the clinician's/facilitator's notes and automatically identifying, extracting, and presenting critical moments, comments, and highlights of the treatment session, automatically creating patient specific and/or session-specific statistics, monitoring for signs of abuse or dependence, providing an automatic drug	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0149]** "The methods and systems of the present invention relate to **assessment of patients who are undergoing therapy for a condition** (e.g., alleviation of symptoms of a condition) or improvement of mental or physical well-being. Alternatively, the methods and systems of **the invention relate to assessment of candidates for psychedelic therapy for a condition** (e.g., alleviation of symptoms of a condition) **or improvement of mental or physical well-being.** A candidate for psychedelic therapy may be a patient undergoing a non-psychedelic therapy, such as a psychotherapy, who is being screened for suitability as a candidate for a complex therapy (i.e., a drug/non-drug therapy)." From **[0013]** "In some embodiments, methods of the invention include determining a frequency of retreatment of the patient with the psychedelic agent. The frequency of retreatment can be determined by (i) providing a measure of efficacy correlated with a positive therapeutic response in the patient to the psychedelic agent; (ii) providing a measure of risk correlated with a risk of precipitating or exacerbating a disease state associated with stress or a psychopathology; and (iii) based on steps (i) and (ii) (e.g., weighing the measure of risk against the measure of efficacy), determining a frequency of retreatment with the psychedelic agent. **The measure of efficacy, the measure of risk, or both, can be output from (and/or confirmed by) a clinical assessment, e.g., using a software configured to communicate with a mobile device or any of the**

provisioning system, providing a dosing administration tracking system, automatically detecting an inappropriate treatment setting, providing a digitized clinician, facilitator, and site certification system, providing a treatment management system, session scheduling, digital medical history, and an audit trail interface, and combinations thereof.	**methods or systems described herein** (e.g., wherein one or more factors of the clinical assessment include a language characteristic, a **behavioral characteristic**, and/or a biomarker), or directly by a clinician using known methods, such as industry-standard questionnaires. In some embodiments, the frequency of retreatment is from bi-weekly to annually (e.g., bi-weekly, monthly, four times per year, twice annually, or annually). In some embodiments, a patient is retreated or redosed (e.g., to adjust the amount per dose or frequency of dosing) upon detecting a deterioration in mental health. For example, a patient that is undergoing treatment or has been treated for any of the diseases or disorders described herein can be retreated or redosed for the disease or disorder upon detection of an increase in one or more symptoms associated with the disease or disorder. The detection can be by any of the methods described herein, for example, by obtaining a language characteristic, **a behavioral characteristic**, or a digital biomarker indicative of the disease or disorder (e.g., through a digital clinical assessment)." From **[0185]** "**Utilizing the smartphone-based safety monitoring application**, the patient is digitally prompted to speak freely about a recent experience and her expectations for the future. Several follow-on prompts are provided to generate a twenty-minute audio recording, which is pre-processed on the smartphone processor and sent to a remote server for language analysis. Using methods such as latent semantic analysis, and by comparing the resulting measure of risk to her own baseline speech previous to treatment administration, **the remote server determines that the subject has a low measure of risk for developing psychosis, hypomania, or mania. The server sends a communication to the patient's smartphone enabling the software application to continue to prompt the patient to provide language samples at the predetermined interval. The patient undergoes adjunctive behavioral therapy through the same smartphone application in parallel with the safety assessment.**" From **[0084]** "In some embodiments, **the language sample is processed in real time, and the software continues to record conversations or the prompt continues to elicit a language sample for the duration of time necessary to achieve a significant result.** For example, the system may iteratively analyze the accumulating language sample until one or more characteristics or **risk measures** reaches a predetermined significance level, at which point the prompt may **automatically conclude.**" From **[0108]** "**A behavioral sample may be acquired for any suitable duration to provide one or more behavioral characteristics**. In some embodiments, the behavioral sample is **processed in real time, and the software continues to acquire the sample for the duration of time necessary to achieve a significant result.** For example, the system may iteratively analyze the accumulating language sample until one or more characteristics or **risk measures** reaches a predetermined

	significance level, at which point the prompt may automatically conclude." From **claim 25** "The method of any one of claims 10-24, further comprising **assessing a measure of compliance with, or abuse of, the psychedelic agent**." From **[0137]** "Additionally or alternatively, **personal identification information, medical records, and any messages or notes provided by the patient can be sent with a notification, alert, or report to a third party**."
26. The method of claim 11, wherein the patient mobile device is chosen from the group consisting of a smartphone and tablet, and the at least one wearable device is chosen from the group consisting of a smart watch and a fitness band.	1. U.S. Pat. App. Pub. No. 2021/0183519 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published June 17, 2021) From **[0094] "In some embodiments, the methods and systems of the invention feature a toolkit (e.g., openSMILES), which can be run directly, for example, on a mobile device (e.g., a smartphone or tablet) in real time, as the audio sample is acquired**. In some instances, raw or processed data can be input into a model that is user-specific **(e.g., compared with baseline values of the same user)** or user-independent (e.g., compared with a predetermined threshold or a composite of values obtained by other users). Additional methods of measuring, processing, and characterizing any of the aforementioned acoustic features are known in the art and describe, for example, in Vanello et al., Conf Proc IEEE Eng Med Biol Soc 2012. 2012:2104-2107 and Karam et al., Proceedings of the IEEE International Conference on Acoustics, Speech, and Signal Processing (Conference) 2014:4858-4862, both of which are incorporated by reference in their entireties." From **[0104]** "**Biosensors may be part of a mobile device, such as a smartphone, tablet, or wearable mobile device, such as a watch**, **bracelet, or necklace**. Biosensors include sensors equipped with the capacity to detect the presence or level of one or more biomarkers (e.g., digital biomarkers), such as CO.sub.2 levels (e.g., blood CO.sub.2), glucose levels, expression of genes or proteins that correlate positively or negative with behavior."

Electronic Acknowledgement Receipt

EFS ID:	48766705
Application Number:	17839374
International Application Number:	
Confirmation Number:	1001
Title of Invention:	SYSTEM AND METHOD FOR MONITORING A CONSCIOUSNESS-ALTERING THERAPEUTIC SESSION
First Named Inventor/Applicant Name:	Martin MAJERNIK
Customer Number:	48924
Filer:	Sisi Li
Filer Authorized By:	
Attorney Docket Number:	0614.00150
Receipt Date:	26-OCT-2023
Filing Date:	13-JUN-2022
Time Stamp:	13:59:10
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$72
RAM confirmation Number	E20230PD59087391
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