Project New Day

Exclusion Criteria Explanations and References

Project New Day Program Model specifies standards to be met in four different categories: mental health disorders, physiological conditions, current medications, and current life circumstances, such as the presence of a recent traumatic event, active addictions, or the stability of day-to-day living conditions.

Organizations adopting the Project New Day Program Model may choose to accept clients who do not meet all of these standards, in which case the organization is not in compliance with the model.

Medications

The section addresses the use of medications and possible interactions with psilocybin treatments and does not address interactions with other psychedelic compounds. This is not intended to be a fully comprehensive list of all interactions with all possible medicines. Therefore, the Project New Day Program Model highly recommends each client consult with a medical professional regarding possible medicine interactions and the advisability of discontinuation in the weeks or months preceding psilocybin treatments.

Lithium- The use of Lithium significantly increases the risk of seizure and can also increase the likelihood of experiencing a 'bad trip'. It has also been reported that the presence of Lithium in the body while using psilocybin can also increase the likelihood that medical intervention may be required during the psychedelic experience (Nayak, 2021). PND recommendation: Exclude*.

MAOIs- MAOI is an umbrella term used to describe any medication that works to block the actions of monoamine oxidase enzymes. Typically, these drugs are used to reduce symptoms of depression by increasing the concentration of neurotransmitters such as dopamine, norepinephrine, and serotonin by blocking the enzymes that break them down (MAOs).

Psilocin is broken down by monoamine oxidase enzymes. The inhibition of these enzymes through the prescription and administration of MAOIs can increase the potency and length of a treatment in a way that is unpredictable and potentially adverse (Amsterdam, 2011). A list of these drugs can be found below (Pope, 2023).

- Nardil (phenelzine)
- Parnate (tranylcypromine)
- Emsam (selegiline)

- Marplan (isocarboxazid)
- Zelapar (selegiline)
- Eldepryl (selegiline)

While the above list outlines MAOIs that are used to treat depression and anxiety, there are a number of drugs, that while often not listed as MAOIs, inhibit monoamine oxidase enzymes. These can be found below (Pope, 2023).

- Linezolid (Zyvox): An antibiotic used to treat certain bacterial infections that are resistant to other antibiotics.
- Methylene blue (Provayblue): a potent MAOI that is used to treat drug-induced methemoglobinemia (a condition where an inefficient form of hemoglobin [methemoglobin] is present in large quantities in the blood)
- Procarbazine (Matulane): Used in addition to other medications to treat Hodgkin's disease
- Rasagiline (Azilect): Used to treat symptoms of Parkinson's disease
- Selegiline (Eldepryl, Zelapar): May be used for the treatment of Parkinson's disease in addition to other medications.

PND recommendation: Exclude*.

Synthetic Opioids- Methadone, Suboxone, and Buprenorphine are all synthetic opioids used to treat opioid addiction. Information regarding the interaction between psilocybin and this class of drugs is extremely limited. Currently, both Johns Hopkins at the University of Madison Wisconsin are carrying out studies to identify potential interactions and the safety of co-dosing these drugs. With limited knowledge of the potential adverse effects of taking this drug and engaging in the use of psilocybin, the Project New Day Program Model suggests excluding* individuals who are taking these drugs from engaging in the program until more information regarding this topic is made available.

Antidepressants (SSRIs, SNRIs, TCAs, Atypical) - Antidepressants falling under any of these categories are contraindications for two reasons. The first is the dampening effect antidepressants can have on the effects of psilocybin, reducing the therapeutic effect of the psychedelic. The second is the potentially lethal adverse drug reaction, Serotonin Syndrome. (Bahi, 2023) The excessive accumulation of serotonin resulting from the interaction of the two drugs can be avoided by discontinuing the use of antidepressants prior to the administration of psilocybin. PND recommendation: Exclude*.

* An alternative to exclusion is for the client to discontinue the use of the exclusionary medications for a period of time before participating in psilocybin treatments. Current literature generally suggests a few days to three months (see the list below). But these are just

guidelines and may not be appropriate for all individuals. The final decision should be made by a medical professional and the organization adopting the Project New Day Program Model.

- SSRIs: A minimum of two weeks (six weeks for fluoxetine), but ideally an individual would abstain for two months. These drugs have the ability to induce a potentially lethal condition known as serotonin syndrome when combined with psilocybin. Outside of this, they have also been shown to reduce the intensity of the therapeutic psilocybin dose.
- MAOIs: Ideally an individual would abstain for 1 month. These drugs can amplify the effects of psilocybin, increasing the duration and intensity of the therapeutic dose, which can become a safety concern.
- Adderall: Ideally an individual would abstain for 2 to 3 days.
- Vyvanse: Ideally an individual would abstain for 2 to 3 days.
- Ritalin: Ideally an individual would abstain for 2 to 3 days.
- Concerta: Ideally an individual would abstain for 4 days.
- Remeron: Ideally an individual would abstain for 2 to 3 weeks. This drug binds to specific receptors and inhibits the effects of the therapeutic psilocybin dose.
- Trazodone: Ideally an individual would abstain for 3 to 4 days. Trazodone will work to inhibit the effects of the therapeutic psilocybin dose.
- Benzodiazepines: Ideally an individual would abstain for at least 24 hours, but no longer than 2 days in order to avoid placing participants in a state of withdrawal.

Psychological Disorders

Bipolar 1 and 2- Patients diagnosed with Bipolar have described new/increasing symptoms after psilocybin trips, prominently manic symptoms, difficulties sleeping, and anxiety. No differences in rates of adverse events overall were observed between individuals with BD I and those with BD II. While some positive effects have been reported in treating Bipolar I and II with psilocybin treatments, more research needs to be done in this area before the Project New Day Program Model will remove this condition from the exclusionary criteria list. As it stands, data suggest that BD symptoms may emerge or intensify following psilocybin use, creating a potential danger for clients with diagnosed BD (Morton, 2023). Additionally, clients having first-degree relatives with a BD diagnosis will also be excluded.

Schizophrenia- In some individuals, the use of magic mushrooms can exacerbate underlying personality disorders and psychosis-like states (Amsterdam, 2011). While there has been no causal link established between psilocybin and the inducing of psychotic states in healthy populations, there has been data linking schizophrenic patients and acute psychotic state that necessitates hospitalization following the consumption of magic mushrooms (Nielen et al., 2004). Individuals diagnosed with schizophrenia and individuals with first-degree relatives with a positive diagnosis of schizophrenia will also be excluded.

Personality disorders- In some individuals, the use of magic mushrooms can exacerbate underlying personality disorders and psychosis-like states. (Amsterdam, 2011) Individuals with any of the following personality disorders will be excluded:

Group A personality disorders

- Paranoid personality disorder
- Schizoid personality disorder
- Schizotypal personality disorder

Group B personality disorders

- Borderline personality disorder
- Histrionic personality disorder
- Narcissistic personality disorder
- Antisocial personality disorder

Group C personality disorders

- Avoidant personality disorder
- Dependent personality disorder
- Obsessive-compulsive personality disorder

Suicidal Ideation or Prolonged Psychosis Following Previous Use of Psychedelics- To protect the psychological well-being of our clients, it is important to check for a history of psychedelic use and adverse experience following use. It has been recommended that individuals who have experienced suicidal ideations or prolonged psychosis following the use of psychedelics do not engage in psilocybin use in the future. (Aragam, 2022)

Physiological Conditions

Pregnant or Breastfeeding- While there has been almost no research into the potential effects of psilocybin on pregnancy, it is known that high blood pressure during pregnancy also increases the risk of preeclampsia, preterm birth, placental abruption, and cesarean birth. It is also recommended that women refrain from the use of drugs and alcohol to prevent adverse effects during prenatal development. (NIH, 2021)

History of Stroke- An individual who has any history of a condition that indicates an ability to handle an elevation in blood pressure is at a heightened risk for severe adverse effects when ingesting psilocybin (Frecska, 2007). For this reason, those with a history of stroke should be excluded.

Heart Conditions- The tendency for temporarily increased blood pressure may also be a risk factor for users with cardiovascular conditions, especially untreated hypertension (Hasler et al., 2004). Those with cardiovascular conditions are not recommended to engage in the use of psilocybin.

Insulin Dependent Diabetes- Many studies have excluded individuals who require insulin to manage glucose levels. The main risk in these studies for people with insulin-dependent diabetes is the increased likelihood of forgetting to take their insulin or forgetting to eat during the trip (Hicks, 2016). If the insulin dose is missed intermittently, poor glucose levels are usually the result. If glucose levels are not properly monitored and medication is not administered when needed, there is potential for a client to go into diabetic shock.

Epilepsy- classic psychedelic-related seizures were more common among those with a personal or family history of epilepsy (Simonsson, 2022). Due to this increased risk of seizures in those with epilepsy or a history of seizures, PND has determined this to be an exclusionary criteria.

Renal Disease- Renal failure has been reported in the history of research into the relationship between kidney function and consumption of 'magic mushrooms' (Bickel, 2005, Raff, 1992). Anyone with a condition that reduces proper kidney function should be excluded from services that involve prescribed doses of psilocybin.

Unmanaged High Blood Pressure- The tendency for a temporarily increased blood pressure may also be a risk factor for users with cardiovascular conditions, especially untreated hypertension (Hasler et al., 2004). As psilocybin is known to increase heart rate and blood pressure for extended periods of time, it is not recommended that those with high blood pressure consume the drug.

Quality of Life

Addiction- Organizations that adopt the Project New Day Program Model for helping with addiction will typically require a score of at least 1 on both the DAST-10 and the CAGE assessment.

Housing- Organizations that adopt the Project New Day Program Model are encouraged to verify that all participating individuals have relatively stable housing and a quality of life that allows them to participate in the program in a meaningful and consistent manner.

Relationships- The coaching process focuses on increasing the client's quality of life. An important factor in the Project New Day Program Model's efficacy is the immediate relationships in the client's life. If a client describes an environment where a living space is shared with a toxic family member/friend/ or other relationship, the adopting organization may choose to exclude that client.

Access to Wi-Fi- Clients will be expected to meet with life coaches and facilitators during the program. Ensuring clients have access to consistent and reliable transportation helps to ensure the consistent engagement of the client.

Citations

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