# Title of Dataset

Psilocybin therapy for females with anorexia nervosa: A phase 1, open label, feasibility study

Reference Information

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Provenance for this README

\* File name: README \_Dataset\_Psilocybin\_AN

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\* Date created: 2022-12-07

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Dataset Version and Release History

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\* Current Version:

\* Number: 1.2.0

\* Date: 2023-06-07

\* Persistent identifier: DOI: 10.5061/dryad.47d7wm3hq

\* Summary of changes: READ\_ME file updated to include additional detail. Exact dates removed, freeform entries unnecessary for data replication removed.

Summary of dataset contents, contextualized in experimental procedures and results.

There are 3 dataset files

1. Clinical laboratory values.This data sheet includes clinical labs that were assessed as a primary safety measure for the study. For this assessment we were looking for changes in laboratory values that were clinically significant or abnormal.

Filename: Clinical\_Lab\_Values.xlsx

There are 2 tabs in this data file.

The “Key” tab denotes how data was coded and uses the following coding formulation to identify categories of laboratory values in the second tab.

|  |  |
| --- | --- |
| yellow | means missing this clinical lab on EPIC |
| grey | means these orders were not required as part of the study layout (note that there are some dosing visit UA lab results summarized, these were part of the study protocol initially but was decided to be redundant and taken out in a later amendement) |
| (A) | Abnormal value |
| (H) | High value |
| (L) | Low value |

The “LABS” tab lists all laboratory values for all subjects at each time point.

Column A: Subject ID

Column B: Study Visit Time point

Columns C-BT: Lists each separate lab value assessed. Data are listed as raw values. Each column is labeled with the standard name used for each clinical laboratory assessment.

Row 60: Includes reference ranges for laboratory assessment.

All study measure time points are included (Baseline, Day 1, Day 7, and Day 28. Lab values for screening assessments are included (to determine eligibility, and lab values for medical stability checks which were needed to ensure medical stability for certain participants PRN.

1. Suicidality. Suicidality was included as a safety measures (primary outcome) and was assessed using the Columbia Suicidality Severity Rating Score. We measured changes in suicidal behaviors, suicidal ideation, and intensity of ideation. The data sheet includes a total tally score for items endorsed as “yes” for items on of 1) suicidal ideation and 2) suicidal behaviors. The intensity of ideation score is a frequency score noting the # of times of ideation.

Filename: CSSRS\_Scoring\_sheet

CSSRS Scoring Sheet: Summarizes responses to each item on the Columbia Suicide Severity Rating Scale for each participant at each time point.

Column A: Represents Subject IDS

Column B: Scores for CSSRS-subscales are clustered by timepoint. i.e. Baseline scores for the 3 subscales of interest are recorded in columns B-D.

The three subscales are suicidal ideation, intensity of ideation, and suicidal behaviors.

-Suicidal ideation scores represent a total tally of “yes” responses to questions 1-5 on the CSSRS.

-Intensity of Ideation scores represent a frequency score, which is the number of times a participant endorsed having had suicidal thoughts.

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-Suicidal behavior represent a tally of “Yes” scores for suicidal behavior items endorsed on the CSSRS which include Yes/NO responses for: Suicide attempts, interrupted attempts, aborted attempts, or an preparatory acts.

1. Preliminary effifacy measures identifying changes in psychopathology. This data file includes scale and subscale scores for all participants on all assessments of psychopathology that are secondary and exploratory measures for this study.

Filename: PAN\_Post-Dosing.Data\_and.CumulativeDataSheet\_FINAL

This file has 3 tabs.

-Tab: Day -1, Day 1: Recorded scale and subscale scores for each assessment of psychopathology for each participant at timepoints Baseline and Day 1.

-Tab: Day 7 Day 28: Recorded scale and subscale scores for each assessment of psychopathology for each participant at timepoints Day 7 and Day 28.

-Tab: Day 84: Recorded scale and subscale scores for each assessment of psychopathology for each participant at timepoint Day 84

For all tabs:

-Column A: Participant numbers

-Column B: Age

-Column C-Diagnosis

-Columns D and on: Scale and subscale scores for each assessment by timepoint. Each column includes the scale abbreviation and the specific timepoint assessed. For example, Tab 1, Column T is labeled Baseline QIDS.

All subscale scores include the Time point assessed, the scale abbreviation, followed by the subscale name in text. Ex. Tab 1,

Column AG: Day 1 Precontemplation RMQ Total Score

Scale abbreviations are used. Here is the key for scale abbreviations:

\*All scores for scales and subscales noted below are continuous unless otherwise specified by an \*.

-5D-ASC- 5 dimensional altered states of consciousness questionnaire (11 subscale scores are listed. Subscales are labeled in each column in text.

\* This score was only administered at Day 1 follow-up, and therefore timepoints are not labeled for in columns.

* QIDS: Represents total scores for Quick Inventory of Depressive Symptomatology scale
* STAI: This is the Spielberger State-Trait Anxiety Inventory

Separate columns are included for STAI Trait and STAI State subscale scores at each timepoint.

* EDE-QS- Represents total scores for the Eating Disorder Examination Short-form questionnaire
* CIA- Total scores for the Clinical Impairment Assessment questionnaire
* BISS- Body Image State scale total score
* RMQ- Readiness and Motivation Questionnaire. All 20 subscale scores are listed by column. Each subscale is labeled RMQ\_ (subscale name in text format).
* PASTAS: Physical Appearance State and Trait Anxiety Scale. Subscale scores for each of 4 subscales is included. Columns are labeled

PASTAS (subscale name in text format)

* EDI: Eating Disorder Inventory. Columns are included for all EDI subscales and the global composite score for the entire scale. Each column is labeled EDI (subscale name)
* YBC-EDS: Yale Brown Cornell Eating Disorder Scale Self Report Questionnaire. We have included subscale scores for all subscales (labeled in each column with text)
* VAS: Visual Analog Scale. These continuous items responses are included in each column, along with the item written in text. Scores are 0-100
* EDE: The Eating Disorder Examination version 17 was out primary efficacy outcome measures. Columns include subscale scores, and global EDE score.
* TCI- Temperament and Character inventory. We administered 2 subscales, the Novelty Seeking subscale, and the Harm Avoidance subscale (noted in the Column name).

## Description of the data and file structure

The data is organized in excel spreadsheets, and separated as referenced above. All scales and subscale scores are recorded independently for each participant.

Assessment measures are abbreviated using standard abbreviations, and

Each item/question is included in a row (item number and description).

## Sharing/Access information

Data is only publicly available via Dryad.

Data was derived from the following sources:

Semi-structured interviews, self report assessments, clinical panels, and physiological asessments.