Feasibility of real-time monitoring of posttraumatic stress disorder symptoms and sleep quality among patients on medical marijuana

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BACKGROUND

- Medical marijuana (MMJ) is often used to improve Posttraumatic stress disorder (PTSD)- related symptoms including sleep disturbances. But at this point, we lack evidence on its effectiveness as a therapy for PTSD.

- We hypothesized that following MMJ treatment: a) there will be improvements in sleep disturbances, negative affect and daytime PTSD symptoms, and b improved sleep quality and reduction in PTSD symptoms will improve general functioning(Fig1).

- **Goal of Presentation**. Demonstrate the feasibility of recruiting and retaining patients with PTSD on medical marijuana (MMJ) in a prospective study and examine in real-time how MMJ affects PTSD related sleep disturbances and recovery from PTSD symptoms and distress, using Ecological Momentary Assessment (EMA) delivered via smartphone and surveys.
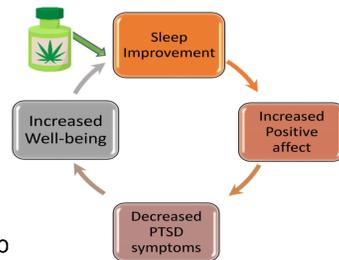
Fig1. Hypothetical model - effects of medical marijuana on sleep quality, decreased PTSD symptoms and improved well-being

METHODS

- **Data collection period:** February 2020 – December 2020. Due to COVID-19 restrictions, all study procedures were conducted virtually and via phone.

- **Primary outcomes.** sleep quality, positive affect, PTSD symptom severity, and general well-being.

- **Secondary outcomes.** willingness to participate in medical marijuana research, adherence to medical marijuana, EMA procedures, and follow-up.

- Recruited 15 patients seeking to start MMJ for their PTSD symptoms from cannabis clinics in Gainesville and Jacksonville, FL.

Eligibility
- Age ≥18 years old
- Provide informed consent
- Not currently on MMJ
- Willing to stop using recreational MJ until State Medical Cannabis Card is obtained
- Currently not in mental health treatment for PTSD
- Not cognitively impaired/psychotic
- Have a smartphone

- **Assessment Protocol** (Fig2).
  - **Pre MMJ-Phase** - baseline and Ecological Momentary Assessment (EMA) 4-times a day (at waking, mid-morning, afternoon and night) for 4-5 days.
  - **Dose-Adjustment Phase** - EMA 4-times a day for one week.
  - **Stable Dose Phase** - 30- day survey + EMA 4-times a day for 7 days, and a 70-day survey.

Assessments
- PTSD Checklist for DSM-5 (PCL-5)
- Pittsburgh Sleep Quality Index (PSQI)
- Positive and Negative Affect Schedule (PANAS)
- PROMIS – Global Health
- MMJ – dose, route, frequency, side-effects – from Dose-Adjustment Phase onwards
- Satisfaction survey – at 70-day follow-up

Ecological Momentary Assessment. mEMA app, illumivu Inc.
- Sleep disturbances
- Positive/Negative Affect
- PTSD symptoms
- MMJ – dose, CBD-THC ratio, route, frequency - from Dose-Adjustment Phase onwards

METHODS (cont'd)

Statistical Analyses
- Descriptive statistics and PROC general linear modeling was used to compare outcomes from baseline to 30- and 70-days using SAS 9.4

Fig2. Study Assessment Plan
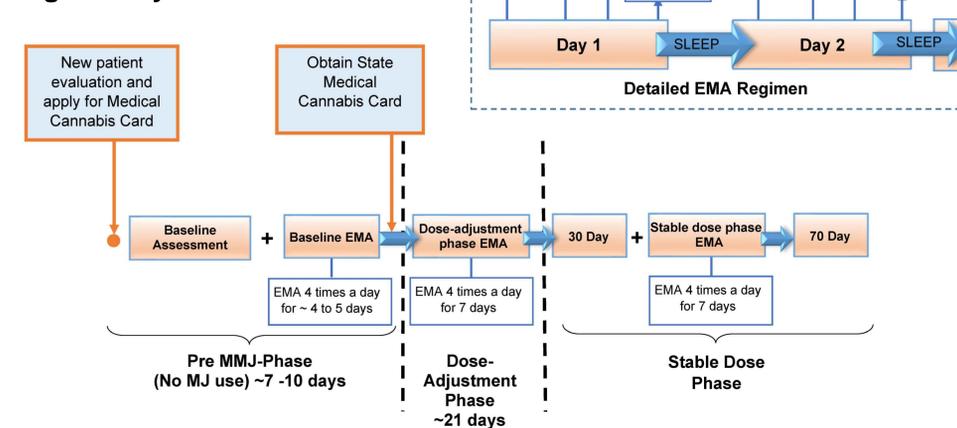
RESULTS

Fig3. Sample Recruitment Log
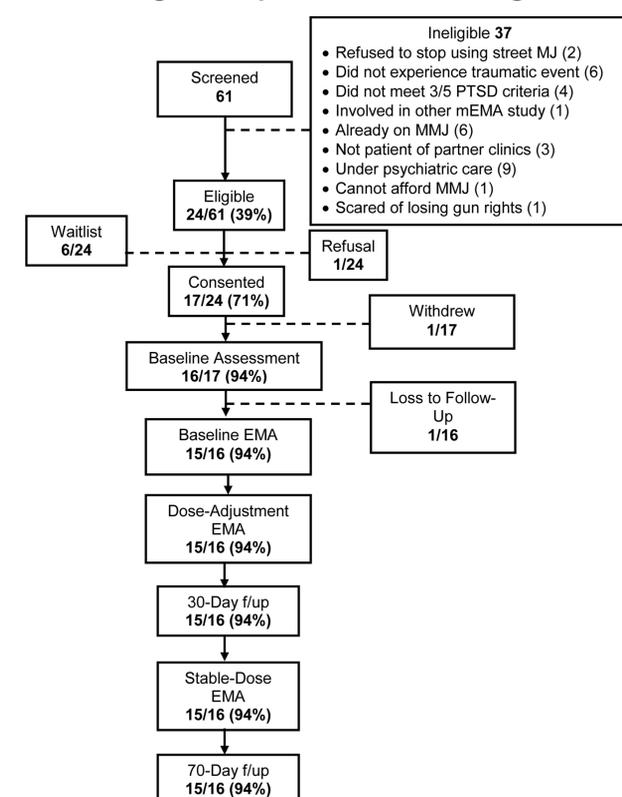
Table 1. Demographics (N=15)

Variable	N	%
Mean age - 44 years, SD 11.9		
Race		
White	12	80.0
Other	3	20.0
Gender		
Male	6	40.0
Female	9	60.0
Education		
Some college, associate's degree, or technical degree	7	46.0
Bachelor's degree	4	27.0
Master's degree	4	27.0
Marital Status		
Never married	4	27.0
Currently employed		
Yes	9	64.0
No	5	36.0
Ever without insurance in the past 12 months		
Yes	4	27.0
No	11	73.0
Cigarette smoking in past 12 months	11	73.0
Alcohol use in past 12 months	10	67.0
Ever injected drugs		
Yes, not in the past 12 months	1	7.0
Never	14	93.0
Ever used other drugs		
Yes, in the past 12 months	8	53.0
Yes, not in the past 12 months	3	20.0
Never	4	27.0

RESULTS (cont'd)

Table 2. . Repeated measure ANOVA on primary outcomes (N=15)

Variables	Mean (SD)			df	Error	F	p Value
	Baseline (T1)	30 – Day (T2)	70 -Day (T3)				
PANAS – Neg. Affect	31.64 (8.1)	24.14 (10.6)	22.93 (9.0)	2	26	9.82	0.0007
PANAS –Pos. Affect	28.86 (9.3)	29.64 (12.4)	32.53 (8.6)	2	26	0.80	0.4618
PCL-5 Total	49.60 (13.2)	30.33 (13.2)	29.0 (15.2)	2	24	13.25	0.0001
PSQI - Total	13.79 (3.5)	10.62 (4.8)	9.13 (2.9)	2	25	16.54	<.0001
Sleep Efficiency	47.2 (25.8)	52.26 (22.2)	49.79 (18.0)	2	27	0.45	0.6401
Sleep Quality	2.27 (0.5)	1.21 (0.5)	1.07 (0.8)	2	27	22.57	<.0001
Sleep Duration-hours	5.03 (1.0)	6.64 (1.7)	6.83 (1.9)	2	27	8.33	0.0015
Nightmares	2.00 (1.1)	1.57 (1.2)	0.87 (1.2)	2	26	13.87	<.0001
Global Health - Physical Health	12.87 (3.3)	13.00 (3.4)	14.40 (3.0)	2	27	2.40	0.1097
Global Health - Mental Health	8.73 (2.8)	10.36 (3.9)	12.13 (2.47)	2	27	8.44	0.0014

EMA data. Our preliminary review of the EMA data shows that most participants have been successful in completing 90% of the EMA surveys during each phase. However, the two participants with Androids have experienced glitches for over half of their allotted surveys.

CONCLUSIONS

- This study demonstrated the feasibility of engaging persons with PTSD on MMJ in a study involving daily EMA assessments and surveys at follow-up.

- Participant recruitment and retention was successful despite COVID-19 restrictions
  - 71% of eligible participants consented
  - 94% of consented completed baseline assessment
  - 94% of participants completed baseline completed all study assessments including 30- and 70-day follow-up

- In this sample of 15 adults with confirmed PTSD who were starting medical marijuana, there were significant improvements in sleep and mental health well-being, and decreases in PTSD symptoms and nightmares, with effects lasting at least 70 days after initiation.

- Follow-up studies with control group and physiological measures of sleep quality are necessary to validate the findings

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