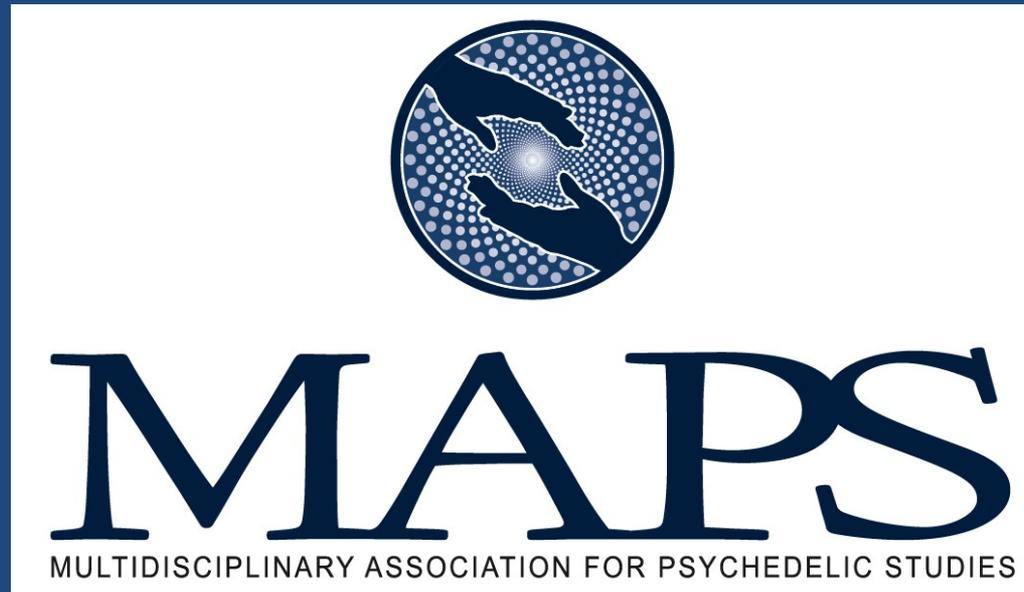


Ibogaine research under a positive legislative regime: Treatment outcomes in a New Zealand observational study

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Substance use and policy analysis

Acknowledgements

In association with



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Ibogaine Aotearoa Charitable Trust (I.ACT)

Researching ibogaine

- Background
 - The Underground
 - Early treatments
 - Legislation
- The study
 - Funding, ethics, recruitment, providers,
 - 3 cases
- Implications

Background— Historical ibogaine treatments in NZ

- Approximately 15 known treatments between 2005-2010
- Others not involving experienced sitters, with ibogaine hcl accessed via the internet
- Principally substance use disorders (SUD's), primarily opiates (e.g. methadone)
- Focus on detox only, not aftercare

Recent legislative changes in New Zealand

- July 2010 – ibogaine gazetted by the government's Medsafe Medicines Classification Committee, under the Medicines Act as a *non-approved prescription medicine*
- Rationale:
 1. potential for therapeutic use, e.g. Mash et al., 2000; Alper et al., 2008
 2. relatively low profile for 'abuse'
 3. mortality rate in treatment similar to that of methadone
 4. will allow therapeutic use while limiting potentially hazardous self-administration
- Implications:
 1. opens way for prescription by a licensed physician
 2. led to possibility of research, i.e. trials / study

But

 3. draws ibogaine into medical control

The Study—

Observational study of the long-term efficacy of ibogaine-assisted therapy in participants with opioid addiction

- Funding
 - MAPS, I.ACT, other
- Ethics
 - Liaising with MAPS, local physicians, others
- Recruitment
 - Providers, Media

Study—objectives

- Primary objective:
 - Using ASI: determine efficacy in reducing use, craving, and withdrawal from opioids, over 12 months post-treatment
- Secondary objectives:
 - Using SOWS: assess severity and reduction of withdrawal symptoms
 - Using BDI-II: assess efficacy in reducing severity of self-reported depression
 - Assess relationship between ASI scores post-treatment and altered consciousness as measured by the SOCQ
 - Assess participants' status/wellbeing; whether post-treatment outcomes have met pre treatment expectations
 - Verify drug use/abstinence via urine screens

Inclusion criteria

1. A minimum of 18 years old
2. Able to communicate in English
3. **Have already received ibogaine treatment or at-home detox treatment for a primary dependence on opioids**
4. Able to provide informed consent on own behalf
5. Prepared to provide contact information of one or two close affiliates whom researcher may contact for corroborating data
6. Must possess a reliable means of contact with the investigators, either through telephone, electronic mail or other electronic means (e.g. Skype)
7. Committed to regular contact with investigators for 12-month period after the treatment

Exclusion criteria

- 1. Persons who underwent ibogaine-assisted therapy for any reason other than opioid drug dependence**
2. Persons who received ibogaine treatment in the past for any reason.
3. Persons who, in the opinion of the investigators, have any personal, health, situational, social or other problem that would prevent them from being able to fully comply with the requirements of this study.
4. Participants who cannot give adequate informed consent.

Study Protocol

1. 12-month follow-up post-treatment
 - a) 14 'visits' (V1-14), 3 drug screens, affiliates
 - b) Face-to-face, Skype, phone
2. V1 1 x pre-treatment 'visit' (Baseline)
 - a) ASI, BDI, SOWS
3. V2 1 x post-treatment 'visit'
 - a) BDI, SOWS, SOCQ
4. Vs 3-14 12 x monthly 'visits'
 - a) ASI @ months 1, 3, 6, 9, 12 post-treatment
 - b) 'random' urine screens @ months 6 & 9
5. Problems, i.e. 'completing' treatment?

Case Series

- 3 x subjects
 - All female
 - All opioid dependent (methadone et al.)
- 2 completed to V3
- 1 completed to V2

Case 1

- 40 yr old female
- Prescribed: Methadone 18 months
- 1 previous detox (2010)
- Recreational drugs
 - 25 years alcohol
 - 5 years morphine / codeine
 - 5 years cannabis
 - 3 years hallucinogens
 - 10 years > 1 substance / day
- Tx @ 70 mg 3 days prior (IV morphine 11 hours prior)
- Dose: 18.6 mg / kg ibogaine hcl.

Case 1

- V1—ASI BDI: 18/63 SOWS: 5/64
 - 1 day alcohol
 - 30 days methadone
 - 20 days other opioids
 - 20 days > 1 substance
 - \$2000 (drugs last 30 days)
 - 6 days experienced 'drug problems' (craving, failing to cease use etc)
 - 4/4 'importance of treatment'
- Dose: 18.6 mg / kg ibogaine hcl.
- V2— 6 daysBDI: 10 SOWS: 13 SOCQ: 12/500
- V3—ASI BDI: 18
 - 1 day alcohol
 - 1 day other opioids
 - 6 days cannabis
 - \$70 (drugs last 30 days)
 - 30 days experienced 'drug problems'
 - 4/4 'importance of treatment'

Case 2

- 44 yr old female
- Prescribed: Methadone 15 years
- 4 previous detox
- Recreational drugs
 - 15 years alcohol
 - 5 years other opioids
 - 18 years barbiturates
 - 28 years sedatives/hypnotics/tranq
 - 3.5 years amphetamines
 - 31 years cannabis
 - 3 years hallucinogens
 - 15 years > 1 substance / day
- Tx @ 100 mg; 500 mg oxycodone (for preceding 2 days)
- Dose: 22 mg / kg ibogaine hcl.

Case 2

- V1—ASI BDI: 26/63 SOWS: 46/64
 - 30 days methadone
 - 10 sedatives/hypnotics/tranq
 - 16 days cannabis
 - 16 days > 1 substance
 - \$300 (drugs last 30 days)
 - 30 days ‘experienced drug problems’ (craving etc.)
 - 4/4 ‘importance of treatment’
- Dose: 22 mg / kg ibogaine hcl.
- V2— 6 days BDI: 6 SOWS: 12 SOCQ: 392/500
- V3—ASI BDI: 4
 - 11 days methadone (prescribed 30 mg, says took 20 mg)
 - 14 days sedatives/hypnotics/tranq
 - 21 cannabis
 - \$40 (drugs last 30 days)
 - 15 days ‘experienced drug problems’ (craving etc.)
 - 0/4 ‘importance of treatment’

Case 3

- 39 yr old female
- Prescribed: Methadone 10 years
- 2 previous detox
- Recreational drugs
 - 8 years alcohol
 - 17 other opioids
 - 6 years sedatives/hypnotics/tranq
 - 23 years cannabis
 - 1 year hallucinogens
 - 18 years > 1 substance / day
- Tx @ 25 mg / day methadone
- Dose: 29.5 mg / kg ibogaine hcl.

Case 3

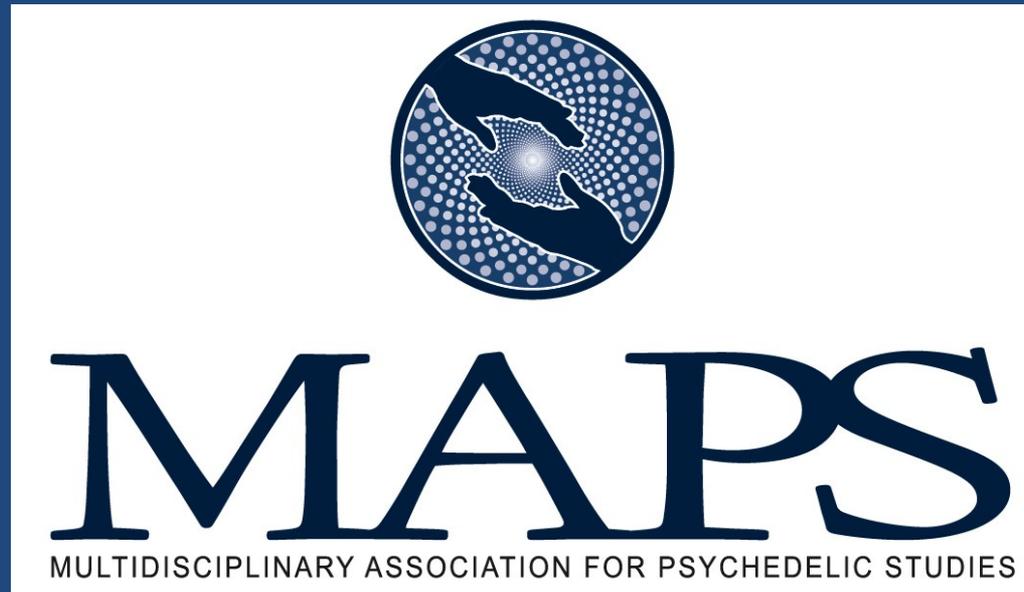
- V1—ASI BDI: 23/63 SOWS: 40/64
 - 30 days methadone
 - 4 days other opioids
 - 30 sedatives/hypnotics/tranq
 - 30 days cannabis
 - 30 days > 1 substance
 - \$200 (drugs last 30 days)
 - 4 days 'experienced drug problems' (craving etc)
 - 4/4 'importance of treatment'
- Dose: 29.5 mg / kg ibogaine hcl.
- V2—8 days BDI: 20 SOWS: 11 SOCQ: 329/500

Summary & Implications

- Legislative changes have led to formalised, medically-supported treatments
- Treatments have opened the door to research
 1. Opportunity to assess efficacy
 2. Awareness of treatment provider variation
 3. Skills, knowledge, 'experience', approach
- Studying ibogaine treatment outcomes a 'complex dance' for providers, researchers, health professionals and clients

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