Therapeutic Effect of BR+NAD® on Opioid and Alcohol Withdrawal: Implications for Clinical Populations

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OCTOBER 1, 2019.
Recognition of Substance Use Disorders as public health crises underscores the need for evidence based strategies in treating these chronic conditions.

These conditions cause brain dysfunction, therefore it is imperative to develop treatment protocols that alleviate symptoms associated with acute withdrawal as well as enable successful outcomes in long-term recovery.

A clinic in Springfield, LA developed an alternative protocol using IV administration of Nicotinamide Adenine Dinucleotide (NAD) for acute withdrawal symptoms associated with chronic opioid and alcohol exposure (known as $BR + NAD^{TM}$). Data show that $BR + NAD^{TM}$ significantly reduces symptoms associated with acute withdrawal. Studies are underway to validate these data in order to standardize a protocol for use in similar clinical settings.
Objectives

1. Participants will gain an understanding of how long term exposure to opioids and alcohol compromises brain functioning and the limitations that exist with more traditionally viewed "standard of care" treatment protocols.

2. Participants will be shown statistically significant results from studies utilizing IV BR + NAD® administration protocols in treating symptoms associated with acute withdrawal.

3. Participants will be presented data from ongoing studies evaluating the safety and efficacy of IV BR + NAD® in these and other clinical populations.
Part 1.

Participants will gain an understanding of how long term exposure to opioids and alcohol compromises brain functioning and the limitations that exist with more traditionally viewed "standard of care" treatment protocols.
Defining Substance Use Disorders

Traditional

(DSM-IV-TR; APA 2000)

- Separated between abuse/dependence. Abuse is beyond what is deemed “normal” therapeutic treatment in terms of dose/time.

- Dependence was defined by long-term consequence of abuse behavior; Use is beyond control of social and legal consequences. Often accompanied with development of tolerance/withdrawal symptoms.
Defining Substance Use Disorders

Current
DSM 5; APA 2013

- Substance-use disorders are patterns of symptoms resulting from the use of a substance that you continue to take, despite experiencing problems as a result. (More combined definition using original criteria)

- Substance-induced disorders, including intoxication, withdrawal, and other substance/medication-induced mental disorders, are detailed alongside substance use disorders (ex, methamphetamine psychosis, opioid withdrawal syndrome).
Acute Exposure to substances such as Alcohol, Opioids, Psychostimulants and Benzodiazepines cause increased release of DA in the NA; Amount of dopamine released determines level of reward (i.e., positively reinforcing effects). Also, small increases in stress-induced DA in NACC are a sign of coping with stressors (i.e., negatively reinforcing effects).
Interactions within the Mesolimbic Dopamine Pathway

- LC
- AMYGDA
- BNST
- LSD
- 5HT2a

- PFC
- NMDA
- PCP

- Glu

- NAcc
- NMDA
- PCP

- NAcc
- DAT

- Cocaine, METH
- Dopamine

- VTA
- GABAa
- OPIOID

- ETOH, Opiates and Barbs

- OPIOID
Chronic substance use can cause functional changes in the mesolimbic Dopamine pathway resulting in functional changes in behavior (i.e., operant conditioning) that are resistant to extinction.
Chronic Use Disrupts The Mesolimbic Dopamine Pathway; Interactions with Stress

Previous studies using a chronic meth rat model indicate reduction of basal extracellular DA in Nacc; also noted that chronic use blocks stress induced DA release. This is evidence of chronic effects on behaviors such as mood, cravings, coping response to stress, stress induced drug relapse and drug seeking behaviors.

Long Term Consequences

- **Tolerance** - reduced effects due to repeated administration of the same dose. (Can happen at the cellular level)

- **Withdrawal** - symptoms are both psychological (i.e., cravings) and physiological (i.e., opioid withdrawal syndrome).

- These symptoms can further contribute to the sustainment of substance use disorders due to negatively reinforcing properties.
Long Term Consequences

- On a cellular level, overall function is compromised (example, inflammatory markers increase, energy and metabolism decrease).
- Behaviors associated with high levels of oxidative stress and decreased cellular energy production include:
  - Depression, Anxiety, Sleep Problems and Fatigue
TRADITIONAL TREATMENT FOR SUBSTANCE USE DISORDERS (SUD’S)

- Naltrexone and Naloxone are opioid antagonists and produce immediate reversal of opioid effects. Most commonly administered in opioid overdose.

- Methadone is a synthetic opioid that blocks the effects of heroin and other opioids, eliminates withdrawal symptoms, and relieves drug craving. Methadone reduces severity of opiate withdrawal and allows patients to “taper off”.

- Buprenorphine is a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist. Approved in 2002, it has a longer half-life and less severe withdrawal syndrome. Results mixed regarding effectiveness compared to Methadone.
Limitations

These clinical conditions are perceived as complex brain disorders that are chronic and relapsing in nature; current approaches are lacking in evidence-based approaches that address these issues.

Despite their success at acute detox, these traditional approaches (combined with the associated stigma and treatment as a criminal justice issue) lack support in addressing safety concerns and measurable success in long term positive outcomes (i.e., participation in follow-up, reduced relapse rates, etc).

Limitations

- Traditional methods of detox are undesirable due to issues related to tolerance and abuse liability.
- The stigma associated with these clinical diagnoses (in both hospital and civilian settings) further impedes progress toward the development of successful long-term approaches.
Proposed Solution

- Optimal therapies will maximize therapeutic effects while minimizing abuse liability;
- In other words, these approaches will safely help the brain restore healthy cell function and maintain sobriety over the long term by alleviating cravings and reducing relapse episodes.
- It is also of importance that combinations of approaches particularly focused on after care support will lead to higher success in the long term.
Part 2.

- Participants will be shown statistically significant results from studies utilizing \textit{BR+NAD}® administration protocols in treating symptoms associated with acute withdrawal.
By the early 2000’s, Dr. Hitt collaborated with Paula Norris-Mestayer and other select practitioners in the US on his IV treatment protocol. This was the protocol used in the first retrospective project I presented at SFN 2008 investigating the effects of IV NAD+ on self-reported cravings and additional symptoms associated with acute withdrawal.
The focus of the 2008 retrospective study was to identify quantifiable measures of therapeutic benefit in pre-existing records of patients who sought treatment for withdrawal symptoms associated with SUDs.

We concluded from this study that self reported ratings of overall affect improved significantly over the 10 day treatment protocol.

Significant reductions in cravings, stress, depression and anxiety suggested effectiveness in treating symptoms associated with acute withdrawal and negative affect.

No change in measures of reward indicated minimal abuse potential.
In 2010, a new formulation was derived (BR+NAD®) at Springfield Wellness Center (in collaboration with Archway Apothecary) again identifying NAD+ as the primary ingredient and creating both a proprietary product and IV protocol for use in similar clinical populations and settings.
BR+NAD®

Benefits:

- **Outpatient setting; 8-10 day (short duration)**
- **Safe; uses natural products as opposed to synthetically derived medications that possess abuse potential; descriptive notes from pre-existing patient charts indicate **no serious adverse events.**
- **Efficacy measures collected on both Short and Long Term Outcomes.**
- **Incorporates behavioral therapy and counseling in preparation for success in long term recovery**
For a complete review of the history, development and research from patients treated with the IV BR+NAD® at Springfield Wellness Center
Intravenous Administration of Nicotinamide Adenine Dinucleotide Significantly Reduces Self Report Craving Ratings Associated with Opiate and Alcohol Withdrawal

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¹Dept Psychol, William Carey Univ., Hattiesburg, MS; ²Springfield Wellness Center, Springfield, LA; ³Stullerresettings, LLC; ⁴ABAM.SoberMD,LLC
Objective

This pilot study retrospectively examined the anti-craving properties of NAD+ in a group of 60 patients. Additionally, patients were assessed on severity of cravings and relapse episodes at 12-20 months post treatment.
The patients were adult males and females who sought treatment at SWC for opioid or alcohol use disorders (N=60).

The treatment, Brain Restoration Plus (BR+NAD)® comprised of IV infusions of NAD+ as well as vitamins, oral amino acids, NAC and variable PRN medications for an average of 10 consecutive days ranging from 5 to 10 hours daily at a dose range of 500mg-1500mg each day.

Self-reported craving ratings (0-10 Scale) were collected on Day 1 (before starting treatment), Day 5, and on Day 10 (last day of treatment).

Follow up phone surveys were conducted from 12-20 months post treatment (N= 27).

Patients reported severity of cravings (1-5) and number of relapse episodes at the present time.
NAD Significantly Reduces Craving Ratings Associated With Opiate and Alcohol Withdrawal At Five And Ten Days of Treatment

Pairwise T-tests Conducted on Day 1 vs Day 5 and Day 1 vs Day 10 in Opiate (n=29) and Alcohol (n=24) Groups. * indicates p < 0.01.
Severity of cravings associated with alcohol and opiate withdrawal at 12-20 months post NAD treatment

- OPIATE (n=13)
- ALCOHOL (n=14)

Severity of cravings (+SEM) reported for opiate and alcohol respondents to follow up surveys conducted from 12-20 months post NAD treatment.
Figure 4. Number of Relapse Episodes Reported in Opiate and Alcohol Groups at 12-20 Months Post NAD Treatment

- OPIATE (n = 13)
- ALCOHOL (n = 14)

Number of relapses (±SEM) for Opiate and Alcohol respondents to follow up surveys conducted at 12-24 months post NAD treatment.
Conclusions From Society For Neuroscience (2014)

- BR+NAD® is an effective detox treatment for alcohol and opioid substance use disorders as evidenced by a significant reduction in craving ratings.

- Chart records indicate that 45% of the original sample (27/60) participated in and completed long term follow-up phone surveys.

- BR+NAD® effectively reduces the number of relapse episodes, as well as severity of drug cravings over a 12-20 month follow up period.

- BR+NAD® shows potential as a long-term therapy in maintaining sobriety through minimizing drug cravings and preventing relapse.
The Retrospective Study (2008-2014)

- Expanded population numbers for both groups; still using pre-existing chart information from self report and nurses’ notes as well as standardized assessments.

- Includes additional Short Term Outcome measures (STO’s) in response to IV BR+NAD®. Additional data obtained from SWC population where available included:
  - Demographic information (age and sex) and completion rates (completed minimum of 8 days IV BR+NAD®).
  - Patient Reported Cravings, Anxiety, Depression, Pain, Sleep (also reported on nurses’ notes).
  - First 5 days of COWS/ CIWA scores.
  - Measures of plasma NAD+, NAD/NADH ratios, Inflammatory markers
Part 3.

Participants will be presented data from ongoing studies evaluating the safety and efficacy of $BR+NAD^\text{®}$ in these and other clinical populations.
Current Research in Alcohol and Opioid Clinical Populations

- Continue to identify, quantify and standardize STO’s and LTO’s on measures of efficacy

- Designing an IRB approved prospective outcome study to compare across treatment types on both STO’s and LTO’s measures of efficacy and safety (modeling after the National Association of Addiction Treatment Providers Outcomes Measurement Toolkit 2019)

- Plasma study conducted in 2018 showed Improved Withdrawal Symptoms and Reduced Oxidative Stress and Inflammation Following IV NAD+ in Opiate and Alcohol Abuse Patients (Funded by NAD+Research, Inc.; investigation in additional efficacy measures)

- Prospective Alcohol study

- Standardized Safety Measures (to address NIH and FDA concerns; also to place in clinical outcome study in alcohol patients)

- Animal Studies (Winsaur, P., Lefer, D., Sharp, T., LSUHSC)
Demographics and Descriptive Data for the Alcohol Group

- The average age for alcohol patients was 52 (+/- 2.03). Population comprised 59.46% males and 37.84% females of the total sample (1 unspecified).

- These data represent patients who completed 7-10 days of BR+NAD® and had at least 4 of 5 days of recorded CIWA scores.

- Typical alcohol withdrawal symptoms reported in patients included changes in sleep (mostly insomnia and vivid dreams) and appetite (poor). Patients also reported signs of G. I. distress (i.e., diarrhea), headaches and muscle cramps.
NAD

Test Test 🖤 TEST1234

Birthdate: 10/01/1980 Bed. Chair 301

Allergies: Penicillin, Amoxicillin

Admission: 10/14/2014 Care Team

UR LOC: Detox 10 day

Date/Time

BP systolic BP diastolic Temperature Pulse Respirations Vital Signs O2 Saturation

NAUSEA AND VOMITING Ask "Do you feel sick to your stomach? Have you vomited?" Observation.

TACTILE DISTURBANCES -- Ask "Have you any itching, pins and needles sensations, any burning, any numbness, or do you feel bugs crawling on or under your skin?" Observation.

TREMOR -- Arms extended and fingers spread apart. Observation.

AUDITORY DISTURBANCES -- Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" Observation.

PAROXYSMAL SWEATS -- Observation.

VISUAL DISTURBANCES -- Ask "Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" Observation.

ANXIETY -- Ask "Do you feel nervous?" Observation.

HEADACHE, FULLNESS IN HEAD -- Ask "Does your head feel different? Does it feel like there is a band around your head?" Do not rate for dizziness or lightheadedness. Otherwise, rate severity.

AGITATION -- Observation.

ORIENTATION AND CLOUDING OF SENSORIUM -- Ask "What day is this? Where are you? Who am I?"

Total CIWA-Ar Score 0.0

Maximum Possible Score 67

CIWA-Ar - PRN

Powered by Kipu Systems Page 1 of 1
Preliminary analysis shows a significant decrease in CIWA scores across all days. Statistical differences using Paired T tests for DAY 1 vs DAY 3 and DAY 3 vs DAY 5 were p < 0.01.
Changes in Circulating Oxidative Stress & Pro-inflammatory Markers and Correlations with Affective Measures in Alcohol Patients Following IV NAD+
Demographics and Descriptive Data for the Opioid Group

- The Opioid Group averaged 36 (±1.95) years of age comprised of 81.08% Males and 13.51% Females (2 unspecified).

- The pattern of withdrawal symptoms noted on the COWS assessment form in comparison to the patient reported cravings rating support that patients are experiencing withdrawal defined as LOW severity according to COWS and MODERATE-SEVERE on cravings ratings.

- Three/eighteen patients had a COWS score reported for DAY 6 (scores 2, 5, 9) and one patient had scores reported for days 6 through 10 (scores 9, 7, 9, 3, 4).
COWS ASSESSMENT FORM

Annexes 87
Clinical Opiate Withdrawal Scale (COWS) Clinical Opiate Withdrawal Scale (COWS)
For each item, circle the number that best describes the patient’s signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient’s Name: ___________________ Date and Time ____/____ /_____:_______

Reason for this assessment: ______________________________________________________________

Restina Pulse Rate:_________beats/minute  GI Upset: over last ½ hour
Measured after patient is sitting or lying for one minute  0 no GI symptoms
0  pulse rate 80 or below 1  stomach cramps
1  pulse rate 81-100 2  nausea or loose stool
2  pulse rate 101-120 3  vomiting or diarrhea
4  pulse rate greater than 120 5  Multiple episodes of diarrhea or vomiting

Sweating: over past ½ hour not accounted for by room temperature or patient activity. Tremor observation of outstretched hands
0  no report of chills or flushing 0 No tremor
1  subjective report of chills or flushing 1  tremor can be felt, but not observed
2  flushed or observable moistness on face 2  slight tremor observable
3  beads of sweat on brow or face 4  gross tremor or muscle twitching
4  sweat streaming off face

Restlessness Observation during assessment  Yawning  Observation during assessment
0  able to sit still 0  no yawning
1  reports difficulty sitting still, but is able to do so 1  yawning once or twice during assessment
3  frequent shifting or extraneous movements of legs/arms 2  yawning three or more times during assessment
5  Unable to sit still for more than a few seconds 4  yawning several times/minute

Pupil size  Anxiety or Irritability
0  pupils pinned or normal size for room light 0 none
1  pupils possibly larger than normal for room light 1 patient reports increasing irritability or anxiousness
2  pupils moderately dilated 2 patient obviously irritable anxious
3  pupils so dilated that only the rim of the iris is visible 4 patient so irritable or anxious that participation in the assessment is difficult

Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored
0  skin is smooth
0  not present 3 piloerrection of skin can be felt or hairs standing up on arms
1  mild diffuse discomfort 5 prominent piloerrection
2  patient reports severe diffuse aching of joints/ muscles
4  patient is rubbing joints or muscles and is unable to sit still because of discomfort

Runny nose or tearing Not accounted for by cold symptoms or allergies
0  not present  The total score is the sum of all 11 items
1  nasal stuffiness or unusually moist eyes
2  nose running or tearing  Initials of person
4  nose constantly running or tears streaming down cheeks  completing Assessment: ______________

Total Score __________
Preliminary analysis indicates that these patients were in the MILD range of withdrawal across all 5 days of IV NAD treatment. However, Single factor ANOVA revealed a significant decrease in COWS scores by DAY 5 (p = 0.044). Further, Paired t tests revealed a significant decrease in COWS scores between DAY 1 vs DAY 5 (p = 0.006 one tail; p = 0.011 two tail).
Changes in Circulating Oxidative Stress & Pro-Inflammatory Markers and Correlations with Affective Measures in Opioid Patients Following IV NAD+
Evaluating Safety

The following dependent measures were documented as adverse events (AE) if they were noted in patient record (Alcohol Group) during the initial treatment protocol: histamine response causing congestion, heaviness sensation in chest/core area sometimes dissipating to extremities, tightness in the chest, or general discomfort. These events tended to be more common on days 1-2 and became significantly less frequent throughout the remainder of treatments days.

No serious adverse events were reported from IV BR+ NAD® over the first 3 days in the Alcohol Group.

In the Opioid Group- The nurses’ notes page for patient rated symptoms (scaled 0-10) of cravings, anxiety, depression, irritability and pain are limited; however anxiety, depression, irritability and pain are indicating on average less than 3 (anxiety DAY 1 was 3.4) across the 10 day treatment period, consistent with the COWS scores indicating a less severe withdrawal.

Typical withdrawal symptoms reported in the Opioid group include changes in sleep (insomnia) and appetite (nausea, poor), stomach and muscle cramps, and G.I. distress (diarrhea). It should be noted that these symptoms appear to be dropping off by DAY 7.
NAD Safety Monitoring Form

Chart #: __________ Pt. Initials __________

Date: __________________

Nurse: _________________

NAD Dose: ______mg / ______cc 0.9% NS  Time: ______mg / ______cc 0.9% NS

<table>
<thead>
<tr>
<th>IV Pump Rate (ml/hr)</th>
<th>Time</th>
<th>Reason for adjustment (i.e. increased per pt. request, tolerating well, possible intolerance)</th>
<th>Symptom</th>
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0=NONE
1= Mild, Occasional episodes, infrequent not present most of the time
2= Moderate, but tolerable, Symptoms intermittent, worsening or increasing frequency from mild
3= Severe, Not Tolerable, Constant, more drastic interventions (i.e. stop IV gtt completely for period, IV medication)

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<tr>
<th>Symptom</th>
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<td>Shortness of Breath</td>
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<td>Histamine Response (i.e. nasal congestion, runny nose, watery eyes)</td>
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<td>Dizziness</td>
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Additional Notes:

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Average Symptom Severity Ratings Recorded in Patients Receiving 8hr IV BR+NAD (10 Day) Treatment Protocol (n=21)
Proposed Short Term Outcome Assessment Form

Wellness Self Assessment

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SCALE

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This is a two week journal to mark your progress to health and overall wellness. Here are some guidelines as to how to complete.
Assessment of Long Term Outcomes

Original form used in SFN 2014

Proposed outcome study will measure these and additional measures outlined in the NAATP Addiction Treatment Outcomes Measurement Toolkit (2019)
Other Clinical Applications and Projects


- Broom, S., Mestayer, R. Grant, R., Berg, J., Braidy, N., Bennett, J., Watson, J. (part of the IRB Protocol #2017-12). The effects of IV NAD+ on Cognitive Performance: A Controlled Randomized Pilot Study in Adult Males (manuscript in preparation; see next slide).


Effects of IV NAD+ on Global Cognitive Function and Global Cognitive Processing in Adult Males

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Acknowledgments

- Springfield Wellness Center-Paula Norris-Mestayer, MEd, LPC,
- NAD Research, Inc. – Dr. Richard Mestayer and Science Advisory Board Members
- SWC Staff- James Bennett, Karen Simone, Sherry Summers, Dr. Tyson Olds.
- Australasian Research Institute- Dr. Ross Grant, Dr. Jade Berg, Dr. Naidy Brady
- LSU Health Sciences Center, New Orleans, LA- Dr. Lefer, Dr. Sharp, Dr. Polhemus
- William Carey University Professional Development Committee
- Willam Carey University Institutional Review Board