MDMA-assisted Psychotherapy for PTSD: An Update of Completed and Ongoing Research

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Michael Mithoefer, MD, FAPA
Private practice psychiatry & clinical research
Clinical Assistant Professor of Psychiatry Medical University of South Carolina
Outline

• History of MDMA
• MDMA effects
• Why MDMA for PTSD?
• Chronology of MDMA/PTSD research
• Summary of results of completed research
• Design and preliminary results of current studies
• Clinical vignettes
But first a word about drug assisted psychotherapy

Current prevailing wisdom: psychotherapy and medication is the **BEST** treatment.

Problem: What happens when the medication is stopped?
Drug assisted psychotherapy

Medication only effective when taken continuously.

Medication appears to have impeded learning.

Drug assisted psychotherapy

We’re looking for a medication that will **enhance** psychotherapy acutely and not be needed chronically.

MDMA may be just such a medication.
MDMA

- Ring-substituted
  - Phenylisopropylamine
  - Derivative

- Patented in 1914 by Merck - now off-patent

- “Entactogens” - closeness to others, empathy, well-being, and insightfulness, with little perceived loss of control
MDMA (cont’d)

• Classified as a controlled substance in 1985
  – Schedule 1

• Before that, MDMA was used as adjunct to psychotherapy by therapists in the United States and Europe

MDMA (cont’d)

Complex pharmacological profile, dominated by:

- Monoamine release and reuptake inhibition
  - Serotonin (5-HT)
  - Norepinephrine (NE)
  - Dopamine (DA)
  - Greatest effects are on serotonin release

- Some affinity for specific serotonin (5HT2), norepinephrine, acetylcholine, and histamine receptors

Elevates plasma concentrations of a number of hormones:

- **Oxytocin**
- **Vasopressin**
- **Cortisol**
- **Prolactin**
- **Dehydroepiandrosterone (DHEA)**
- **Adrenocorticotropic hormone (ACTH)**

Common Side Effects Reported in Controlled Studies

- Reduced appetite
- Dizziness
- Tight jaw or bruxism (tooth-grinding)
- Difficulty concentrating
- Impaired gait or balance
- Dry mouth
- Anxiety
- Fatigue
- Insomnia
- Lack of appetite

MDMA Toxicity

• Serious acute toxicity occurs in recreational users quite rare given millions of users

• Changes in serotonin neurons in animal models

• Mixed data about the possibility of memory changes in recreational users

• Phase 1 & Phase 2 clinical trials, > 700 people
No unexpected drug-related serious adverse events in medical research settings using pure MDMA

Risk / Benefit

Good safety record in research subjects carefully screened for medical and psychiatric contraindications.

Medical complications, including death have occurred in recreational settings.

62,000 tablets seized by US Coast Guard in Pacific Northwest 2009.
Recent and Current MDMA research

- Lots of pre clinical data and retrospective studies in recreational users

- 1996 Grob published first Phase 1 clinical trial
  - Others followed in US and Europe

- Phase 2 trials completed 2008 (US) and 2011 (Switzerland)
  - Mithoefer et al. published 2010
  - Long-term follow-up published 2012
  - Oehen et al. published 2012
Ongoing MDMA / PTSD research

* Charleston, SC:
  * PTSD in veterans, firefighters, police officers – Phase II
  * MDMA session for therapists - Phase I
  * PTSD relapse study

* Israel:
  * First subject enrolled. Will include PTSD from war and terrorism and other causes

* Boulder, Colorado and Vancouver, Canada:
  * Approved. Will include PTSD from any cause
Timeline – Phase 2 clinical trials of MDMA-assisted psychotherapy for PTSD

- February 2000: Spanish authorities approved first clinical trial
- November 2001: FDA approved first US phase 2 trial
- May 2002: Spanish approval revoked
- September 2003: IRB approval of US study
- February 2004: DEA approval
- March 2004: First participant enrolled
- September 2008: First US Study completed

Timeline – continued

- February 2010: FDA approves “veterans study”
- August 2010: DEA approves “veterans study”
- December 2010: First veteran enrolled
- January 2011: Swiss study completed
- February 2013: first subject enrolled in Israel
- February 2013: final approval in Canada
- February 2013: final approval in Boulder

Need for Additional Treatments for PTSD

• **Existing recognized psychotherapies:**
  – Cognitive-behavioral: Prolonged Exposure Therapy, CPT
  – EMDR
  – Psychodynamic Psychotherapy

• **Pharmacotherapy**
  – (SSRIs only approved drugs, many others used)

  o 25% to 50% of patients/participants **don’t respond adequately** to existing treatments = 2 to 4 million people in the United States

  o 18% (15%-35%) of returning vets
    <10% screening + for PTSD get adequate treatment

CPT, Cognitive Processing Therapy; EMDR, Eye Movement Desensitization and Reprocessing; SSRIs, selective serotonin reuptake inhibitors.

Other therapies – Less Widely Recognized or Experimental

- Psychotherapy models
  - Internal Family Systems (IFS), Voice Dialogue, Psychosynthesis
  - Hakomi
  - Sensorimotor and other body centered therapies
  - Attachment theory, eg. The Attachment, Self-regulation, and Competency (ARC) treatment model

- Drugs or technologies for catalyzing the therapeutic process
  - Holotropic Breathwork
  - Virtual Reality
  - D-cycloserine
  - MDMA

- Drugs given acutely to prevent development of PTSD
  - Beta blockers
  - Morphine
Why Study MDMA for PTSD?

- Obstacles to successful treatment of PTSD
  - Fear
  - Defensiveness / numbing
  - Lack of trust

- MDMA has been reported to:
  - Decrease fear and defensiveness
  - Increase trust and empathy

- Additional therapeutic effect
  - Affirming experiences
  - More realistic perspective about present circumstances/safety

Window of Tolerance

Hyperarousal Zone
- Increased sensation
- Emotional reactivity
- Intrusive imagery
- Disorganized cognitive processing

Hypoarousal Zone
- Relative absence of sensation
- Numbing of emotions
- Disabled cognitive processing
- Reduced physical movement

Additional Therapeutic Effect

• Affirming experiences

• More realistic perspective about present circumstances/safety

• Other factors more difficult to understand
  • Spiritual, energetic, somatic
“Neurocircuitry Model” of PTSD

- Deficit in extinction of fear conditioning

Rauch SL et al. Biol Psychiatry. 2006;60(4):376-382
“Neurocircuitry Model” of PTSD

- Deficit in extinction of fear conditioning
Green = increased cerebral blood flow

Blue = decreased cerebral blood flow
Hormone Release

- Elevates plasma concentrations of a number of hormones:
  - Oxytocin
  - Vasopressin
  - Cortisol
  - Prolactin
  - Dehydroepiandrosterone (DHEA)
  - Adrenocorticotropic hormone (ACTH)

Neuro-molecular model of PTSD
Memory consolidation and reconsolidation

There is substantial evidence that the formation of long-term memories, i.e., consolidation, requires protein synthesis.
Neuro-molecular model of PTSD
Memory consolidation and reconsolidation

A rat placed in a tub of water will quickly learn the location of a hidden platform.
Neuro-molecular model of PTSD
Memory consolidation and reconsolidation

A rat given a protein synthesis inhibitor will struggle to remember the platforms location
Neuro-molecular model of PTSD
Memory consolidation and reconsolidation

- Every time we remember, we may initiate a process called **reconsolidation** which also requires protein synthesis, wherein new memories replace the old versions.

- Reconsolidation offers an opportunity to transform old memories and may explain why exposure therapy works.

- MDMA plus psychotherapy may allow patients to recall haunting memories but reconsolidate them without the intense emotions and physiologic arousal.
Phase 2 Clinical Trial: Safety and Efficacy of MDMA-Assisted Psychotherapy in Patients With Chronic, Treatment-Resistant PTSD

Michael C. Mithoefer, MD, principal investigator
Annie T. Mithoefer, BSN, Mark T. Wagner, PhD, co-investigators
Charleston, SC
Sponsor: MAPS

Phase 2 Clinical Trial:

The safety and efficacy of \( \pm 3,4\)-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: the first randomized controlled pilot study

Michael C Mithoefer\(^1\), Mark T Wagner\(^2\), Ann T Mithoefer\(^1\), Lisa Jerome\(^3\) and Rick Doblin\(^3\)

Abstract
Case reports indicate that psychiatrists administered \( \pm 3,4\)-methylenedioxymethamphetamine (MDMA) as a catalyst to psychotherapy before recreational use of MDMA as ‘Ecstasy’ resulted in its criminalization in 1985. Over two decades later, this study is the first completed clinical trial evaluating MDMA as a therapeutic adjunct. Twenty patients with chronic posttraumatic stress disorder, refractory to both psychotherapy and psychopharmacology, were randomly assigned to psychotherapy with concomitant active drug (\( n = 12\)) or inactive placebo (\( n = 8\)) administered during two 8-h experimental psychotherapy sessions. Both groups received preparatory and follow-up non-drug psychotherapy. The primary outcome measure was the Clinician-Administered PTSD Scale, administered at baseline, 4 days after each experimental session, and 2 months after the second session. Neurocognitive testing, blood pressure, and temperature monitoring were performed. After 2-month follow-up, placebo subjects were offered the option to re-enroll in the experimental procedure with open-label MDMA. Decrease in Clinician-Administered PTSD Scale scores from baseline was significantly greater for the group that received MDMA than for the placebo group at all three time points after baseline. The rate of clinical response was 10/12 (83\%) in the active treatment group versus 2/8 (25\%) in the placebo group. There were no drug-related serious adverse events, adverse neurocognitive effects or clinically significant blood pressure increases. MDMA-assisted psychotherapy can be administered to posttraumatic stress disorder patients without evidence of harm, and it may be useful in patients refractory to other treatments.
Hypothesis: MDMA-Assisted Psychotherapy

• Can be safely administered to people with treatment-resistant PTSD

• Will produce improvement in PTSD symptoms
  – 4 days after each of 2 or 3 experimental intervention sessions
  – At 2 month follow-up

The Protocol

• Double-blind, placebo controlled

• Treatment-resistant – 20 participants
  ∗ SSRI or SNRI + Psychotherapy

• Crime or war related PTSD

Stage 1: Double-Blind

- 60% receive MDMA on 2 or 3 occasions
- 40% receive inactive placebo on 2 occasions
  - Therapy only group

Outcome Measures

- Clinician Administered PTSD Scale (CAPS)
- Impact of Event Scale Revised (IES-R)
- Symptom Checklist 90-revised (SCL-90-R)
- NEO Personality Inventory

Therapeutic Intervention

• MDMA or placebo administered during 8 hour “experimental session”
  – Male and female therapist present
  – Overnight stay after session

• Additional non-drug therapy sessions
  – 11-15 in Stage 1, 9-13 additional in Stage 2

• Blood pressure, pulse q 15 min, temp q hour

ClinicalTrials.gov Identifier: NCT01211405
Therapeutic Approach

Our adaptation of the foundation laid by Stanislav & Christina Grof, George Greer & Requa Tolbert, Ralph Metzner, Leo Zeff and many others

- Non-directive, supporting emerging experience
Experimental Sessions

ClinicalTrials.gov Identifier: NCT01211405
Magnifies Whatever is There

Affirming / Joyful

or

Difficult / Painful
“I don’t know why they call this ecstasy!”
Mean CAPS Scores by Group

Time*Group Interaction $P=0.015$

Stage 2

- Open label MDMA-assisted therapy for participants who originally received placebo-assisted sessions
  - 2-3 MDMA assisted sessions

- Integration non-drug therapy sessions as in Stage 1

- 7 of 8 placebo participants elected to participate

Mean CAPS Scores by Group: Crossover Group

Clinical Response
(>30% Reduction in CAPS)

• **Stage 1**
  - Placebo (psychotherapy only) = **25%**
  - MDMA + psychotherapy = **83%**

• **Stage 2**
  - Placebo → MDMA = **100%**

Neuropsychological Measures

- Repeatable Battery for Assessment of Neuropsychological Status (RBANS)
  - Immediate memory, delayed memory, language, visuospatial/constructional, attention

- Paced Auditory Serial Addition Task (PASAT)

- Rey-Osterreith Complex Figure Test (RCFT)

RBANS: Pre and Post

# Common Side Effects - Day of Session

<table>
<thead>
<tr>
<th>More common with MDMA:</th>
<th>More common with inactive placebo:</th>
</tr>
</thead>
<tbody>
<tr>
<td>✧ Decreased concentration</td>
<td>✧ Anxiety</td>
</tr>
<tr>
<td>✧ Dizziness</td>
<td>✧ Drowsiness</td>
</tr>
<tr>
<td>✧ Dry mouth</td>
<td>✧ Insomnia</td>
</tr>
<tr>
<td>✧ Feeling cold</td>
<td></td>
</tr>
<tr>
<td>✧ Impaired Balance</td>
<td></td>
</tr>
</tbody>
</table>
More common with MDMA:

* Decreased concentration
* Dizziness
* Anxiety

More common with inactive placebo:

* Insomnia
## Blood Pressure, Pulse, Temperature

Maximum values During sessions

<table>
<thead>
<tr>
<th></th>
<th>MDMA</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood Pressure</td>
<td>179</td>
<td>176</td>
</tr>
<tr>
<td>Diastolic Blood Pressure</td>
<td>113</td>
<td>106</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>135</td>
<td>141</td>
</tr>
<tr>
<td>Temperature</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
Study Limitations

• Small sample size (N=20)

• Majority of participants were female and all were white

• Placebo group had a history of more prior psychotherapy than the MDMA group

• Transparency of blinding

• Additional psychotherapy sessions were conducted more often after MDMA-assisted sessions than after psychotherapy-only sessions
Durability of improvement in posttraumatic stress disorder symptoms and absence of harmful effects or drug dependency after 3,4-methylenedioxymethamphetamine-assisted psychotherapy: a prospective long-term follow-up study

Michael C Mithoefer\textsuperscript{1,2}, Mark T Wagner\textsuperscript{3}, Ann T Mithoefer\textsuperscript{1,2}, Lisa Jerome\textsuperscript{4}, Scott F Martin\textsuperscript{5}, Berra Yazar-Klosinski\textsuperscript{6}, Yvonne Michel\textsuperscript{7}, Timothy D Brewerton\textsuperscript{1,8} and Rick Doblin\textsuperscript{9}
Long-Term Follow-up

• 1 year or more after study completion

• Repeat
  – CAPS
  – IES-R
  – NEO
  – Questionnaire
Participants in Data Analysis

- **23** randomized
- **2** dropouts (intent to treat only)
- **21** completed
  - **1** not treatment resistant
  - **20** blinded analysis
    - **1** placebo only
    - **19** received MDMA
      - **19** completed long-term follow-up questionnaire (LTFU)
      - **16** completed LTFU and CAPS

CAPS, Clinician Administered PTSD Scale; LTFU, long-term follow up.
LTFU Mean Global CAPS Scores

17 to 74 Months Post Final MDMA Session
(Mean = 45.4 Months, SD = 17.3)

* Error bars represent SD.
LTFU CAPS

- Of 16 CAPS completers:
  - 12% (2/16) relapsed
  - 88% sustained benefit

- Assuming 3 CAPS non-completers relapsed:
  - 26% relapsed (5/19)
  - 74% sustained benefit

How does MDMA-assisted psychotherapy compare to other methods of psychotherapy for PTSD?

Michael C. Mitroff, M.D.

Revisions:
Version 1: May 30, 2005
Version 2: November 24, 2008
Version 3: October 23, 2010
Version 4: January 16, 2011
Version 5: November 30, 2011
Current Version 6: 4 January 2013

Research Sponsor: Multidisciplinary Association for Psychedelic Studies (MAPS)
309 Cedar Street #2323
Santa Cruz, CA 95060

Sponsor Designee: Rick Doblin, Ph.D.
Phone: 617-484-8711

Amy Emerson
Phone: 510-393-7224

Use of Manual: In accordance with an approved MAPS Study Protocol
Interested parties wishing to copy any portion of this publication are encouraged to do so but are kindly requested to credit MAPS and include our address:

MAPS
309 Cedar Street #2323
Santa Cruz, CA 95060
Phone: 831-429-6362
Web: www.maps.org

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Contributors: Annie Mitroff, B.S.N., Lisa Jerome, Ph.D., June Ruse, Psy.D., Rick Doblin, Ph.D., Elizabeth Gibson, M.S., Marcela Ot’alora G., L.P.C.
Elements of other psychotherapeutic approaches may occur in MDMA-assisted therapy

Often spontaneously with little or no direction from therapists

Not as strange as it sounds!
Elements Shared With Other Therapies

- Cognitive/behavioral – Cognitive Processing (CPT)
  - Cognitive distortions corrected/underlying schema recognized

- Prolonged exposure (PE)
  - Imaginal exposure often happens spontaneously

- Internal Family Systems (IFS)
  - Awareness of parts, self energy increased

- Hakomi and mindfulness based approaches
  - Focus on present moment experience, “beginner’s mind”
Elements Shared With Other Therapies

* **Body oriented therapies (Somatic experiencing etc.)**
  * energy movement, release of body tensions

* **Psychodynamic**
  * transference often addressed, early experiences in life

* **Grof**
  * healing potential of non-ordinary states

* **Jung**
  * powerful archetypal imagery

* **Attachment theory**
  * Awareness and processing of attachment injuries, MDMA may facilitate secure attachment
Elements **NOT** Shared With Some Other Therapies

There were no recovered memories.

“Children often cope with abuse by forgetting it ever happened . . . If you think you were abused and your life shows the symptoms, then you were.”
Ongoing MDMA/PTSD studies in Charleston, SC
Relapse Study

2 subjects from original study who relapsed > 1 year later

ClinicalTrials.gov Identifier: NCT01458327
Training Study

• A Phase I clinical trial
  Profile of mood states (POMS)
  Interpersonal Closeness Scale – L. Jerome
  NEO Personality Inventory
  Brief Symptom Inventory

• Enrollment limited to therapists
  Who have completed our MDMA-assisted psychotherapy training program and will work in MDMA clinical trials

• Three therapists have completed the study thus far
A Randomized, Triple-Blind, Phase 2 Pilot Study Comparing 3 Different Doses of MDMA in Conjunction With Manualized Psychotherapy in 24 Veterans, Firefighters, and Police Officers With Chronic PTSD

Michael C. Mithoefer, MD, Annie T. Mithoefer, BSN, Mark T. Wagner, PhD, Joy Wymer, PhD
Charleston, SC
Sponsor: MAPS

ClinicalTrials.gov Identifier: NCT01211405
Protocol Design: Stage 1

- 24 veterans, firefighters, police officers
  - CAPS scores >50 after medication and/or psychotherapy

- Randomized to low, medium or full dose MDMA (30 mg + 15 mg, 75 mg + 37.5 mg, 125 mg + 62.5 mg)
  - 8-hour MDMA-assisted sessions a month apart with accompanying preparation and integration sessions

- Outcome measures 1 month after 2nd session then blind broken before Stage 2

ClinicalTrials.gov Identifier: NCT01211405
Protocol Design: Stage 2

- Full dose ➞ 3rd full-dose session
- Low or medium dose ➞ 3 full dose sessions
- Follow-up: repeat outcome measures – 2 months and 1 year

ClinicalTrials.gov Identifier: NCT01211405
Screening and Outcome Measures by Psychologists Not Involved in Treatment Phase

Mark T. Wagner, PhD
Director, Neuropsychology Section
Professor of Neurology
Medical University of South Carolina
Charleston, SC

Joy Wymer, PhD
Neuropsychologist/Licensed Clinical Psychologist
Assistant Professor Neurology
Medical University of South Carolina
Charleston, SC

ClinicalTrials.gov Identifier: NCT01211405
Outcome Measures

- Clinician Administered PTSD Scale (CAPS)
- Beck Depression Inventory (BDI-II)
- Global Assessment of Functioning (GAF)
- Posttraumatic Growth Inventory (PTGI)
- Pittsburg Sleep Quality Index (PSQI)
- States of Consciousness Questionnaire (SOCQ)
- NEO Personality Inventory (NEO)

ClinicalTrials.gov Identifier: NCT01211405
Enrollment in “Vet” Study Thus Far

- 11 veterans & 2 firefighters enrolled
  - 9 completed all sessions thus far (2 currently in progress)
  - 2 dropouts
    1 medium dose with good results – completed follow-up
    1 low dose, decided not to continue – completed 2-month follow-up
- 7 males and 1 female with combat trauma (Iraq)
- 3 females with military sexual trauma (MST)
- 2 male firefighters
- >400 veterans have called to ask about participation

ClinicalTrials.gov Identifier: NCT01211405
**CAPS**

**Preliminary:** First 10 Participants (excluding dropouts)

ClinicalTrials.gov Identifier: NCT01211405
Stage 1 CAPS by Individual Subject
Preliminary: 10 subjects (excluding dropouts)

<table>
<thead>
<tr>
<th></th>
<th>Mean CAPS Score</th>
</tr>
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<tbody>
<tr>
<td>Baseline</td>
<td>Full dose</td>
</tr>
<tr>
<td></td>
<td>Medium dose</td>
</tr>
<tr>
<td></td>
<td>Low dose</td>
</tr>
<tr>
<td>Post 2 sessions</td>
<td>801</td>
</tr>
<tr>
<td>Post 3 sessions</td>
<td>809</td>
</tr>
</tbody>
</table>

ClinicalTrials.gov Identifier: NCT01211405
Beck Depression Inventory (BDI-II)

Preliminary: First 10 Participants (excluding dropouts)

ClinicalTrials.gov Identifier: NCT01211405
Global Assessment of Functioning (GAF)
Preliminary: First 10 Participants (excluding dropouts)

1-30 = candidate for inpatient therapy
31-69 = candidate for outpatient therapy
> 70 = functioning very well

ClinicalTrials.gov Identifier: NCT01211405
Posttraumatic Growth Inventory (PTGI)

Preliminary: First 10 Participants (excluding dropouts)

ClinicalTrials.gov Identifier: NCT01211405
Pittsburg Sleep Quality Index (PSQI)

Preliminary: First 6 Participants Tested (excluding dropouts)

Minimum Score = 0 (better); Maximum Score = 21 (worse)
TOTAL < 5 associated with good sleep quality
TOTAL > 5 associated with poor sleep quality

ClinicalTrials.gov Identifier: NCT01211405
States of Consciousness Questionnaire (SOCQ)

- 100 questions, including 57 distractor items
- 43 items: Pahnke-Richards Mystical Experience Questionnaire
- 7 domains of mystical experiences:
  - Internal Unity
  - External Unity
  - Transcendence of Time and Space
  - Ineffability and Paradoxicality
  - Sense of Sacredness
  - Noetic Quality
  - Deeply-Felt Positive Mood

SOCQ: Sub-domains of Mystical-type Experiences

Preliminary: First 11 subjects (excluding dropouts)

Griffiths et al. Psychopharmacology Epub 15 June 2011
ClinicalTrials.gov Identifier: NCT01211405
MDMA From an IFS Perspective

- Increase in Self Energy
  - Often very pronounced
- Curiosity, clarity, compassion, confidence, creativity and connectedness
- Increased awareness of parts
  - And ability to unblend
Parts work/ IFS Occurrence Criteria for MDMA/PTSD studies
Michael Mithoefer, MD  10 October, 2011

Subject # __________________  Session # __________________  Rater: __________________

1) Was the concept of parts brought up by the participant or the therapist?
   Yes ____  No ____
   If yes indicate which brought it up first: participant ____  therapist ____

If the answer to # 1 is "no" then all other questions are NA and should be skipped
with the exception of question # 7 which should be answered in either case.

2) Did the therapist inquire further about the part or parts?
   Yes ____  No ____

3) Did the therapist ask about the participant's feelings or attitude toward the part
   or parts?
   Yes ____  No ____
4) Was there further exploration of the part or information elicited about the part, either spontaneously or prompted by the therapists' questions?
   Yes ____  No ____
   If yes indicate which: therapist's questions ____ , spontaneously ____ , both ____

5) Did the participant's attitude toward the part change in a positive direction?
   Yes ____  No ____

6) Was there a sense that a part released old burdens, either explicitly or implicitly?
   Yes ____  No ____

7) During the session was there an increase in qualities such as calmness, curiosity, clarity, compassion, confidence, creativity, courage, or connectedness.
   Yes ____  No ____ (circle any of the qualities that apply)

8) Did the symptoms or problems related to this part decrease over the course of therapy?
   Yes ____  No ____
Parts Work Scale based on IFS – preliminary results

The chart shows the percentage of yes answers for different questions, with two categories: Full/Medium (N=26) and Low (N=7). The questions are labeled Q1 to Q8, and the chart indicates the response distribution for each question.
Examples of Parts Work During MDMA-assisted Psychotherapy in PTSD Research Sessions

* Arising spontaneously or with very little prompting from the therapists

* 81% of sessions parts brought up by participants
Quotes from Study Participants

ClinicalTrials.gov identifier: NCT01404754
Michael Mithoefer, MD
Annie Mithoefer, BSN
208 Scott Street
Mount Pleasant, SC 29464
843-849-6899
mmithoefer@mac.com
amithoefer@me.com
mdmaptsd.org