

Research Update: Can MDMA-Assisted Therapy Reduce Social Anxiety in Autistic Adults?

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Since the launch of our first pilot study of MDMA-assisted therapy for social anxiety in autistic adults in February 2014, calls to the study hotline from potential participants have been steady. Social phobias, fear of speaking on the phone, and other communication challenges have not stopped 228 individuals from across the United States and several other countries from seeking this experimental treatment at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. The high level of interest may be due to the lack of other treatment options that have been proven effective for this group.

As of September 2015, subject eight of 12 has completed their second treatment session and is in follow-up. Nine subjects have been enrolled, with one subject leaving the study after one treatment session. Subject nine of 12 participated in their first treatment session at the end of September. Thus far, no acute or sustained serious adverse events related to study participation have been reported, and there have been no reports of persisting problematic psychological reactions.

The treatment is provided within the context of ongoing therapy over several months, which means that study partici-

pants need to reside within a 30-mile radius of the study location, which has slowed the screening process a bit. However, the widespread interest is encouraging, and we anticipate completing enrollment by winter 2015.

For this pilot study, we are working with an inactive placebo and moderate dose ranges of MDMA, from 75–125 mg with no mid-session “booster” dose. Session lengths average about five to six hours, and participants return to the study site the next day for the first of three integrative therapy sessions. After six months of follow-up, the blind is broken, and participants who were randomized to the placebo group have the option to return for one or two open-label full dose MDMA-assisted therapy sessions.

The treatment method for this study is similar in some ways to MAPS’ studies of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). For example, as in the PTSD studies, there are periods of time when participants are invited to use headphones and eyeshades to support them in reflecting on their inner experience. Also as in the PTSD studies, intention-setting in support of maximizing potential benefits is

a priority during pre-treatment office visits, and participants are encouraged to consider the concept of the “Wise Inner Healer” as the ultimate guide on the healing path. Unlike the PTSD studies, the social anxiety study includes interactions with the researchers that are intended to boost social confidence and provide practice opportunities to try new social skills in a safe setting. Additionally, participants complete a video-based assessment of non-verbal social cues that involves watching actors in various social interactions.

In lieu of requiring an overnight stay in a potentially distressing clinical environment, participants designate a Study Support Partner who does all of the driving on the weekend of the treatment session. The Support Partner also stays at the same location as the participant the night following treatment to be a supportive presence and listen to any insights the participant wants to share. The researchers are gratified that so many excellent Support Partners have volunteered to fulfill this role so well.

One of the key factors contributing to this study running smoothly since it began in April 2014 has been early and ongoing consultation with members of the autism community, and with autistic individuals who provide professional support services for other adults on the autism spectrum. Our primary advisor since the study’s inception has been autism advocate Nick Walker. You can read more about his perspectives on neurodiversity that informed our approach in his blog (neurocosmopolitanism.com). Another excellent resource for those who want to design research that is supportive of autistic individuals, groups, and communities is the Autistic Self-Advocacy Network (ASAN; autisticadvocacy.org).

We also consulted with multiple autistic adults in the planning stage to get their input on how to create a treatment space that would support a diverse group of individuals who were likely to have a wide variety of hypersensitivities. The feedback on the session room has been so positive that we joke about someday raising funds by charging staff from other departments a small fee to take naps in the over-stuffed mechanical recliner.

Some of the best advice we received when we started planning the study is an often-repeated adage in autism circles: “If you’ve met one autistic person, you’ve met *one* autistic person.” Detaching from preconceived notions and stereotypes about autism has been one of the most effective foundations for building therapeutic alliances.

One challenge this study has faced from the start has been inaccurate and sensationalized media reporting. Misleading headlines such as “MDMA in Ecstasy May Soon Be a Treatment for Social Anxiety and Autism” and “Can Ecstasy Combat Autism?” prompted us to publish a Media Tip Sheet to help prevent similar harmful messages from circulating. A few of the essential messages we include are:

- Our research team is not treating autism or seeking a cure for autism. Autism is a genetically based human neurological variant, and it cannot be treated or cured with medication. We are investigating a potential

treatment for social anxiety in adults on the autism spectrum. Social anxiety is common in autistic adults and few effective treatment options are available.

- We work with adults aged 21 and over. We ask that descriptions of our work clearly note this fact to avoid giving the potentially harmful impression that MDMA-assisted therapy is appropriate for autistic children.
- Using the word “Ecstasy” without specifying MDMA is problematic because Ecstasy can be a dangerous street drug that often does not contain MDMA. Our investigational product is pure MDMA used on only two occasions within a psychotherapy model, and we work hard to make that distinction because there are public health and safety issues to consider. Additionally, when referring to the type of treatment we provide, we use “MDMA-assisted therapy” and not simply “MDMA.”

We look to MAPS supporters, the psychedelic community, and media professionals to help us elevate the dialogue in support of harm reduction. In further pursuit of this goal, in March 2015 our team published a peer-reviewed article on the rationale and method for this study in the journal *Progress in Neuro-Psychopharmacology and Biological Psychiatry*. MAPS has made the full text of this article available to view and download free of charge (maps.org/maa2015).

We also wish to express our gratitude for the feedback and guidance that the participants have offered generously at every step in the research process. Their insights have helped the team learn how to work with autistic co-collaborators to explore ways in which MDMA-assisted therapy might bring relief for moderate to severe social anxiety. 🌱

Charles Grob, M.D., is a professor of psychiatry and pediatrics at the UCLA School of Medicine and the Director of the Division of Child and Adolescent Psychiatry at the Harbor-UCLA Medical Center. He is currently leading a MAPS-sponsored phase 2 pilot study on MDMA-assisted therapy for social anxiety in adults on the autism spectrum. His research has included the first FDA-approved Phase 1 study of the physiological and psychological effects of MDMA; a multinational, collaborative study of the Amazonian plant hallucinogen decoction, ayahuasca, in Brazil; and a pilot investigation of the safety and efficacy of psilocybin in the treatment of anxiety in adult patients with advanced-stage cancer.

Alicia Danforth, Ph.D., is the co-investigator for a current MAPS-sponsored phase 2 pilot study looking at the effect of MDMA-assisted therapy on social anxiety in autistic adults. She began her work in clinical research with psychedelic medicines with Dr. Charles Grob at the Los Angeles Biomedical Research Institute, Harbor-UCLA Medical Center in 2004. In 2013, Danforth graduated from the Institute of Transpersonal Psychology (ITP) with a Ph.D. in clinical psychology, with a specialization in Transpersonal Research and Education.