

MAPS' Clinical Research Monitoring Team Works in Israel



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AS MAPS' NEWEST staff member, I sit here writing in a relatively bleak and 'postmodern' hotel lobby overlooking the citadel of David in the old city of Jerusalem. It has been a long and interesting few days here, days chock full of new information and, albeit, somewhat challenging circumstances. The reason for this visit to Israel was three fold: first and foremost, to perform the initial study initiation visit for Dr. Moshe Kotler's fully-approved MAPS-sponsored study evaluating MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder (PTSD); second, for MAPS President Rick Doblin, Ph.D., to attend a joint Palestinian-Israeli conference on drug policy and the legal regulation of medical marijuana in Israel, coordinated by Israel's progressive Green-Leaf political party; and third, for Rick and MAPS Director of Operations Valerie Mojeiko to conduct the first Israeli Safe-Rave training program about harm-reduction techniques for people using psychedelics in non-therapeutic contexts such as parties and festivals.

Israeli MDMA/PTSD Study Site Initiation Visit

The Israeli MDMA/PTSD study is unique in that it will only be enrolling subjects whose PTSD is primarily a result of war or terrorism. In Israel, PTSD is a particularly salient problem because there are a lot of Holocaust survivors, and also because the country has been in a state of perpetual war since its inception. Furthermore, since almost every Israeli is required to serve in the military upon completion of high school, many young people are exposed to psychologically traumatic events and suffer from their long-term consequences. Thus, since citizens and soldiers have been involved in war- and/or terrorism- related violence, it will unfortunately be relatively easy to recruit subjects.

Like the MAPS-sponsored MDMA/PTSD studies in the US and Switzerland, this study is structured to provide information about two primary objectives: 1)

Improvement in PTSD scores during and after treatment, using the Clinician Administered PTSD Scale (CAPS, the standard measure of PTSD symptoms), and 2) Determination of safety and potential for adverse reactions directly related to the main and/or supplemental dose of MDMA. Based on data already obtained from Dr. Michael Mithoefer's MAPS-sponsored MDMA/PTSD Phase 2 pilot study, and on anecdotal reports, we expect to see reductions in PTSD symptoms for subjects receiving the fully-active dose of MDMA and no serious adverse events. The subjects in this study are required to have a CAPS score of 50 or higher and to have attempted without success at least one other form of clinical treatment for PTSD prior to participation in this study. The goal of our series of Phase 2 pilot studies is to develop data to help us design larger Phase 3 studies. The ultimate goal of these MDMA/PTSD studies is to provide data that is necessary to demonstrate safety and efficacy for approval of MDMA as a prescription medicine from the US FDA and the European Medicines Agency.

As part of my new responsibilities at MAPS, one of my jobs will be to help MAPS Volunteer Clinical Program Manager Amy Emerson and MAPS Director of Operations and Clinical Research Monitor Valerie Mojeiko in the design and creation of Case Report Forms and other study materials for MAPS-sponsored research studies, I've had to learn quickly about several aspects of clinical research monitoring, and the regulations governing study procedures according to both FDA and European Medicines Agency standards. Meanwhile, this has given me a feel for the work flow of initiation visits, monitoring techniques, organizational management, study structure and form creation/evaluation/reporting. To be honest, it's mind-boggling how much work and attention to detail the execution of a pharmaceutical study requires.

The trip from Tel Aviv to Beer Yaakov Mental Hospital, the nearby study site, was breathtaking. On the first day, Tuesday, we traveled from our hotel near the beach in Tel Aviv to the study site in a small town not too far past the outskirts of the city. The campus was initially constructed as army barracks by the British military during their occupation of Israel, and was converted in the 1950s to its present purpose.

After a short tour of the facility, we were met by psychiatrist Rael Strous, M.D., one of the two co-therapists for our study (Dr. Rakefet Rodrigez is the other co-therapist). Dr. Strous is an intense character, vibrant and bustling with positive energy. I could sense immediately upon our introduction that he will make an excellent therapist for this study. After a series of brief introductions, Amy, Valerie, Rick, and myself were led to the office of the hospital director, Moshe Kotler, M.D., the principal investigator for our study. After a short meeting in which some final logistical problems were addressed and a plan of action solidified we were led across the campus to the office of Dr. Strous. to discuss more regulations and logistical plans for the execution of the study over the next year or so. Amy created a helpful power point presentation and an excellent agenda for the meeting. Of course, as usual, there were complications. Some people couldn't make it to the meeting that day, and Amy and Valerie had to rearrange their agenda on the spot. But in the end we all felt that the meetings actually went better because we were able to spend more one-on-one time with the study assistants on the first day, giving them an overview of the structure of the study and making explicit their responsibilities in transcribing the study data from the source records onto the case report forms required by the FDA.

After a short break we were led on a tour of the new research building where the MDMA therapy sessions will take place. Although none of the new furniture had been put into place yet, the building had a pleasant feel, clean and well-organized. We concluded the rest of the day by going over some of the finer points of the study with study assistants Joy and Hadar and their responsibilities.

One interesting aside—we had noticed that in Israel there seemed to be no wild dogs but lots and lots of wild cats—but upon leaving the hospital and walking up the street we noticed two absolutely filthy, tiny, and adorable Rottweiler puppies seemingly abandoned on the side of the road. Needless to say, we couldn't just leave them there to starve so we picked them up (Rick had to climb through some very dense thickets to chase out the smaller of the two puppies) and brought them back to the gate. We were entirely uncertain as to how the staff of the hospital would react to us bringing them inside, but sure enough, they were both understanding and loving to our unexpected deliveries. They brought them milk and food, laughing and cooing all the while. We left the puppies in their care and headed back to the hotel, content that we had done our *mitzvah*, our good deed for the day.

We woke up early the next morning, Wednesday, and traveled by train from Tel Aviv to the hospital, allowing us to further absorb the landscape and architecture of the countryside beyond the city. Rick didn't attend, since he was speaking at a conference in Jerusalem. Again we arrived at the gate and walked over to the office to begin our meeting with co-investigators Rael and Rakefet and the independent assessor Moshe Z. After the mandatory tea and cakes, Amy gave her power-point presentation and led this team through an overview of the regulations for the study and the various requirements for reporting the data. It went wonderfully, and even I finally began to get a handle on all the acronyms and testing requirements for the study.

After Amy concluded, we made our way over to the pharmacy with Rakefet to discuss the protocol for capping and labeling MDMA with the pharmacist. The MDMA had previously arrived in Israel in August, during the war with Lebanon,

There is one major design aspect of the Israeli study's protocol that is different from MAPS' US MDMA/PTSD study, but similar to the Swiss study. Rather than an inactive placebo (with no MDMA or any psychoactive drug) this study uses an active placebo that contains a threshold dose of MDMA (25 mg primary dose, 12.5

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mg supplemental dose). This active placebo may provide a minimal change in blood pressure and some barely perceptible psychological effects to sometimes ‘trick’ the therapists and/or subjects into being unsure of the dose.

Arab-Israeli Joint Conference on Drug Policy

The first Arab-Israeli conference on Drug Policy was held at Hebrew University in Jerusalem. About 60 people attended to hear speeches by MAPS President Rick Doblin, Dr. Lester Grinspoon (US medical marijuana expert recently retired from Harvard Medical School, and author of *Marijuana: The Forbidden Medicine*), former chairman of the Green Leaf Party, Boaz Wachtel, and Dr. Rachel Hamburger, chief scientist of the Israeli Anti-Drug Authority. Unfortunately, with only one Palestinian in attendance, who reported that drugs such as marijuana and MDMA were, in her opinion, forbidden by the Koran since they can produce “unconsciousness”, there was not as much chance for dialogue as the conference organizers had hoped. Nevertheless, several impassioned and data-filled talks with given and the participants exchanged lots of information, primarily about the medical use of marijuana and drug policy in the US and Israel.

Diplomatically, Rick took the opportunity to begin his talk by noting the courage it took for the Palestinian speaker and for Dr. Hamburger to present their views, which in some respects were contrary to those held by most of those in attendance. He also noted the almost decade-long relationship he and MAPS have built with Dr. Hamburger and other officials at the Israeli Anti-Drug Authority and thanked Dr. Hamburger for her support of the Israeli MDMA/PTSD study. He then noted that the Israeli Ministry of Health, as the final condition prior to the

approval of the study, had requested that the Director of the Israeli Anti-Drug Authority put in writing his office’s support for the study, which, amazingly, he did. Rick then outlined MAPS’ psychedelic research studies around the world and noted that our medical marijuana research efforts have been fundamentally obstructed by our lack of an independent source of supply of marijuana that can be used in research (see story on page 13), whereas in contrast MAPS has been able to obtain legal supplies of MDMA, psilocybin and other psychedelics.

Safe Rave Training

Our third task was to conduct an initial training in harm reduction techniques and to facilitate the formation and organization of a core Safe-Rave group in Israel. On Tuesday night we met in East Tel Aviv with a small group of the Green Leaf party members and student activists and two organizers of all-night dance parties in various outdoor locations in natural settings.

As some meetings in Israel go, it was difficult to keep everyone’s attention focused on the task at hand—everyone wants to talk at the same time and no one ever turns off their cell phone. Only when we screened MAPS’ new educational video, “Working With Difficult Psychedelic Experiences,” were we able to hold everyone’s attention. The video, now available on the MAPS website (maps.org/wwpe_vid), received positive responses from everyone at the meeting and we received creative criticism and feedback about what should be changed or incorporated into the next version. In fact, the former chairman of the Green-Leaf Party, Boaz Wachtel, was interested in subtitling and re-editing a version in Hebrew geared toward their specific needs and political climate. Mostly, Valerie explained the principles of psychedelic emergency work

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(create a safe place; sitting, not guiding; talk through, not talk down; difficult isn't necessarily bad), and tried to address concerns about publicly providing Psychedelic Emergency Services at parties, as well as practical advice about establishing a schedule for the team members to work in shifts and creating a safe, comfortable space.

The team mobilized for the first time on the Friday after the training to provide Israel's first Safe Rave space at a party in a remote location in the Negev desert near the Dead Sea. There were three outdoor events that night and that Israeli team chose the event at which they thought they'd be most needed. Rick and Boaz also attended the event. Fortunately, there were no psychedelic emergencies but the dancers and other people in attendance felt safer and more relaxed knowing that help was available should it be needed.

Coincidentally, US political activists Adam Eiding and Robin Bell, in Israel to film the harvesting of Palestinian-grown olives by a team of Arab-Israeli peace activists, for olive oil for use in Dr. Bronner's soaps, were also able to attend the event in the Negev. As sunrise dawned over the Negev, planning was done for a lobby campaign to urge the DEA to approve Prof. Craker's application for a license for a MAPS-sponsored medical marijuana production facility, should the DEA Administrative Law Judge recommend approval of the license.

It is our hope that by reducing the harms that can result from the recreational use of psychedelics, and by changing the ways that individual drug-

users look at taking drugs, we can empower them to transform the politics as well. This is the grassroots level of MAPS' approach to changing drug policy, which protects the advances we are making in the research context from a possible backlash that could be caused by tragedies related to non-medical use.

Upon leaving Israel one has to ask: Is there really hope for peace and resolution to the conflicts that have ravaged this land for millennia? After my first visit to this holy land I have to say—I don't know—there is so much intolerance and hatred embedded in these people, these religions, this land. Personally, I find it hard to conceive of any possibility of lasting peace and healthy coexistence without there first being a radical transformation of the way in which people believe. Critical thinking and rationality must replace the skewed lens of faith. There are three impressions that will always stick with me about my first journey to Israel. First, how I have never seen so many fences in my life—tall wire fences, hard metal fences, chain link fences, barbed and razor wire, opaque plastic fences—every type and variety of fence you can imagine layered and stacked on top of one another. Second, that the sound of an asylum is the sound of cheap rubber sandals scraping across a cement floor. And third, that Israelis love to argue, as one of our Israeli friends put it so succinctly, 'It's in their blood.' In spite of all these things, I believe that change really can occur and that all of the projects that MAPS is coordinating in Israel are movements in the right direction. May we all come and go in peace... •