Thursday, Aug. 8, 2024 / ECSTASY THERAPY: BAD TRIP

[HALF SECOND OF SILENCE]

[BILLBOARD]

SEAN RAMESWARAM (host): Haleema Shah last week on *Today, Explained* you reported two stories about using MDMA for therapy.

HALEEMA SHAH (senior producer/reporter): That's right. There was an idea that started all the way back in the late 70s, early 80s that MDMA could be useful in therapy. And today we're seeing clinical trials that do just that for people who have PTSD.

SCORING IN – A Smooth Sea Version 1 (no drums)

HALEEMA: So this month, any day now, the FDA is expected to announce whether or not MDMA assisted therapy is a suitable PTSD treatment. And there’s a lot of people, including veterans, who are advocating hard for this. But there are some people who were in trials - who say that this experience traumatized them more.

SARAH MCNAMEE (trial participant): There seems to be a lack of care or curiosity or concern for what happens to the human beings who've been in these trials. Once the trials are over and they've got the data they needed.

SEAN: And we're going to hear from one of them on *Today, Explained.*

[THEME]

SEAN: *Today, Explained*. Sean Rameswaram here with our reporter, Haleema Shah, who, last week, brought us stories featuring people who had positive experiences with MDMA-assisted therapy. But today, Haleema, we're going to hear from someone who had a negative one.

HALEEMA: Yeah. This person was in a late stage clinical trial which reported that participants had a “significant and robust improvement” in PTSD symptoms over the course of the trial. But what this participant says is that she fell apart *after the trial*, and that’s not reported.

SEAN: Hm!

HALEEMA: And she’s saying that not only did the trial harm her, but its design is so flawed that the data from it can't even be trusted. And a heads up to our listeners: this episode discusses suicide and sexual assault.

<COOKING AMBI>

HALEEMA: The participant’s name is Sarah McNamee, and I met her at her home in Montreal.

SARAH: I always enjoyed cooking as a kid. And then after I developed PTSD, I think cooking was, like, the only place where I fit.

SEAN: What’s she cooking?

HALEEMA: She's making tomato soup. And she spent years actually cooking professionally in restaurants, and she told me that kitchens are kind of a safe space for her.

SEAM: Hm!

SARAH: Anyone who's been in the restaurant industry knows, like, the restaurant industry is a place where the misfits fit in.

HALEEMA: But she also found another world where she fit in: trauma research. After six years in the restaurant industry, she decided to go back to school and got a master's degree in social work, focusing on trauma.

<COOKING AMBI OUT>

SARAH: I did end up gravitating towards that, I think in large part to understand myself. I-I think I was diagnosed probably when I was about 22. But the PTSD developed like subsequent to, like, a quite a violent attack. Like, I was having panic attacks. And I was, I was having a lot of nightmares. This is when I was early in the restaurant industry so I was using alcohol and drugs quite a bit to numb. Like I was a mess, honestly.

HALEEMA: In the years that passed, Sarah found ways to cope. Therapy, self care, good friends. But she had a relapse after another traumatic event, and she needed help. So she enrolled in a phase 3 clinical trial. And I want to briefly remind listeners how this works. It’s an 18-week process. She’s assigned to two therapists and for her first experimental session, she gets MDMA or placebo. And then she processes the experience through a series of talk therapy sessions. And the whole sequence repeats itself two more times. The company behind these trials is Lykos, which is the pharma spinoff of a group called the Multidisciplinary Association for Psychedelic Studies, or MAPS. Both are founded by a psychedelic evangelist named Rick Doblin, who has been at this for the last 40 years.

*<CLIP> REASON TV: RICK DOBLIN, MAPS FOUNDER: What we’re talking about is a*

*world of net zero trauma by 2070. So that is the new animating vision for me.*

HALEEMA: Participants like Sarah say that there was pressure in these trials to report positive outcomes so that they could quote “make history.”

SARAH: There was such a strong feeling of it being part of something bigger than me, and like helping to legalize psychedelics. It was like this movement.

HALEEMA: So when Sarah and I talk about this, she mentions several things that alarm her. And some of the big ones were that MDMA sometimes felt good and sometimes it felt agonizing. The second is that, in hindsight, Sarah told me she couldn't always advocate for herself as a trial participant because she was on a lot of drugs and she was kind of advised to trust the process.   
  
SEAN: Hm.  
  
HALEEMA: And the third is that because of how the trial wrapped, Sarah said she fell apart afterwards.

SCORING IN - GRAYAGATE

HALEEMA: So to walk you through her experience: she shows up for her experimental session and takes her pill.

SARAH: And I'm having, like, a lot of anxiety coming up, and I’m trying to breathe through it. It climbs and climbs and climbs to the point where, like, it really, there was no way I didn't have MDMA in my body.

HALEEMA: But the anxiety doesn't last the whole time.

SARAH: And then it shifted. I just felt really peaceful. <voice breaks> It still makes me really emotional to think about it, it was gorgeous. I remember just feeling like I just slept for 100 years, and I felt so rested after maybe 30 minutes of this. And then it was like I got strapped into the trauma roller coaster. And the rest of the session was just intense reliving of trauma.

SCORING BUMP

SARAH: It felt very much out of my control.…it didn't feel like I was making choices.

HALEEMA: She describes it as “motor mouth,” like, her jaw was tense and chattering and she felt like she was almost compulsively telling her story.

SEAN: Hm.

HALEEMA: What are you feeling right now? Talking about this?

SARAH: Um, it's really complicated. There's a lot of mixed emotions. It was difficult, but I think it ultimately did kind of help.

SCORING OUT

SEAN: Wow. I didn't see that coming, actually. Like, I thought…that sounded so negative for her that I thought it was going to be just a negative experience altogether. But she's saying there still was some positive.

HALEEMA: Yeah, and Sarah said in that first session she gets 120 mg of MDMA, which is a high dose, like just for reference, a microdose would be around 40mg or less.

SEAN: Hm.

HALEEMA: But in the second session, participants have the option of taking more MDMA for a potentially more intense, more healing experience. But Sarah told me she felt like she couldn't handle more, and said she told her therapists that too. But she still ends up taking the higher dose.

SARAH: It was, like, brushed off. I don't know how exactly it got communicated, but I understood that they believed that a bigger dose would be better and I would get more out of it, and that I should just sort of like, you know, “surrender” was the key word of the whole trial. I was supposed to just surrender to everything.

SEAN: I've never been part of a psychedelic trial, but this sounds sketchy.

HALEEMA: Yeah, this is what Sarah told me. And I also reached out to her trial therapists and they didn’t respond to my request for comment. So there’s only so much I can know about what happened inside these sessions. They are all recorded, but for patient confidentiality reasons, I obviously can’t see them. Sarah told me she got along with her therapists, and she believes they were trying to help her. But in that second session, she said the trauma rollercoaster was so much worse.

SCORING IN - LATE NIGHT CALL (THEME) - APM

SARAH: It’s so hard to describe, but, like, I felt like I'd been beaten up. I was having, like, really intense physical experiences, a lot of pain. There were like several points in time where I was just writhing on the floor in pain, crying. It didn't feel healing.

HALEEMA: Sarah told me that when this happened, her trial therapist employed what the MAPS therapy manual refers to as “focused bodywork.” The idea is that someone will apply physical pressure to the participant for them to resist against. And this is supposed to release, like, an energy blockage or some type of trauma that's manifested itself as physical pain in the body.

SEAN: Hm.

HALEEMA: And according to the MAPS therapy manual, consent for any kind of touch needs to be obtained before the participant takes MDMA. And that touch can't be sexual and it has to be motivated by the participants’ needs, not the therapists’.

SEAN: I would hope so!

SARAH: You know, they, they were pushing on my stomach, but they put a pillow between their, you know, there was, there were steps taken to mitigate the intimacy of the touch.

HALEEMA: But looking back, she said the ethics of it all are “tricky.”

SARAH: It’s tricky. <laughs> I don’t know the answer. And especially, like, in retrospect, I do think that helped. But I don’t feel good about it.

SCORING OUT

HALEEMA: And she’s not alone in saying that: the whole concept of touch in psychotherapy is controversial even without psychedelics. Given that MDMA famously makes people open to intimacy– how well-equipped is someone who’s rolling to *enforce* boundaries around touch? It’s a question that MAPS has faced before. A couple years ago, a phase 2 participant released a video of herself in distress in an MDMA session. Her therapists are recorded pinning her down and cuddling her. The participant later filed a civil claim alleging that her male therapist sexually assaulted her in follow up treatment after the trial. And the parties agreed to dismiss the lawsuit, but the terms weren’t disclosed. MAPS said the therapists violated protocol and barred them from the trials. But the ethical questions around the use and risk of therapeutic touch in psychedelic-assisted therapy remain, especially because the treatment is still so novel.

SEAN: I mean, this is, this is red flag on red flag, Haleema. And, and you're saying this trip was worse than her first one?

HALEEMA: Yeah. But what she tells me is that her therapists suggested that this really painful stuff that was coming up was stuff that needed to be faced.

SARAH: They really believe that, like, you just need to surrender. And this was always repeated like just, you know, see if you can surrender. Like what's coming up is coming up to be healed. There were these, like, catchphrases almost that they used really regularly.

HALEEMA: There's a concept within the MAPS therapy manual about the “inner healing intelligence.” It's an idea that each person has an innate capacity to heal their own trauma. The MDMA and the therapists are just facilitators. You know what's best for you. You are the key to your own healing.

SARAH: I think it’s a gorgeous clinical concept, but I think it’s getting twisted. There was a point in the trial where it was like, trust the process and trust yourself and trust your inner wisdom very much became trust us and trust the protocol and trust MAPS.

HALEEMA: As a participant, Sarah said she did trust her trial therapists; she even became dependent on them. But that degree of reliance, in retrospect, is troubling to her.

SARAH: You're already taking away a lot of people's agency by giving them drugs that make them super vulnerable. And then you're like taking even more of their agency away by not listening to the boundaries or by framing boundaries as something that needs to be overcome. <sighs> I just like after that second session, like, I was so shattered.

SEAN: Does she continue with this trial or does she bow out?

HALEEMA: She stays. She continues. Sarah said that she and her therapists were pretty convinced that this trial was going the way it was supposed to. Even when it was uncomfortable. Especially because Sarah told me she was reporting a decrease in flashbacks and nightmares on her PTSD assessments. Lykos uses the industry standard measures to assess PTSD symptoms and suicidality. They had independent raters administer it, not therapists, to avoid the bias. But the problem is this instrument doesn't always capture the full picture. And Sarah said it made her look like her PTSD was improving even when she was telling her therapists that she was seriously struggling.  
  
SEAN: Hm.  
  
HALEEMA: And she felt like she was in the middle of her treatment, not at the end.

SARAH: I was feeling like really…like they'd ripped me open and now they were just going to go away and I was going to be left to deal with this. So it was like, as I was contemplating losing their support, that I got very scared and my mental health took a nosedive after that.

HALEEMA: And then after the trial, Sarah told me she was suicidal. She reported it to her trial therapists and Lykos in documents I’ve reviewed.

SEAN: Wow.

SARAH: I'd say in a year and a half after the trial, it was not at all clear to me or my doctor that I was going to survive.

SCORING IN - LATE NIGHT CALL (AMBIENCE VERSION)

SEAN: What does Lykos or MAPS have to say about this?

HALEEMA: That was my question too. And we'll hear from the CEO of Lykos, Amy Emerson, next.

SEAN: On Today, Explained!

[BREAK]

*<CLIP> “EMPIRE STATE OF MIND” - JAY Z*

*“MDMA got you feeling like a champion,*

*City never sleeps better slip you an—”*

SEAN: *Today, Explained* is back with our reporter, Haleema Shah. We've got this organization called MAPS that's doing this assisted therapy with MDMA and the trial is put on by this outfit called Lykos. And Sarah goes to Lykos for the MDMA-assisted trial. What did MAPS or Lykos have to say about what happened to Sarah?

HALEEMA: I spoke to Amy Emerson, whose clinical trial career spans two decades. In the early aughts, she was so compelled by MDMA’s potential to treat PTSD that she worked pro-bono to set up clinical trials. Today, she’s the CEO of Lykos. And I asked her about what we talked about, some of these participant concerns, especially the risk of increased suicidality.

AMY EMERSON (CEO, Lykos Therapeutics): We enrolled a population of people with PTSD that had a high rate of suicidality, like over 90% of our patients in the study had this history. So it was really important to track that throughout our clinical trials. And we used validated measures, one called the Columbia Suicide Severity Rating Scale, at every single visit. So people were asked how they were doing, and they were asked to complete that at every visit. So these were then tracked and reported. And if they went above that baseline, so remember, 90% of the people in the study already had suicidality at baseline, then they were reported as adverse events. So one way or another it was collected in the study as long as they reported it.

HALEEMA: And I’m like, OK, but some said they felt pressured to report positive outcomes to avoid jeopardizing legalization or blocking medical use for other PTSD patients. So how could you know that participants weren’t holding back in their self-reports?

AMY: I can't know what somebody didn't report, right? All we can do is look and ensure that what they did report was there. And we can ensure that the therapists in the sites were trained appropriately for collecting adverse events. All of our studies had a data safety monitoring board oversight, oversight of us doing the monitoring. And then on top of that, FDA coming in to do the inspections that are part of a new drug application.

HALEEMA: But even with all the oversight, how did the study account for people like Sarah who became suicidal after the trial? Amy Emerson said there was a long term follow up study.

AMY: We collected data in the long term follow up six months to a year later that, that we were doing the long term follow up in the second phase three study it was closer to the six month time point.

HALEEMA: In those phase three follow ups, did you find that anybody's suicidality exceeded their baseline?

AMY: I don't, I don’t have individual reports in my head, but for the people that did enroll in the long term follow up study, all of that data is published. And there was not, an increase in suicidality to the point that things were an adverse event or above the baseline.

HALEEMA: Final data from the follow-up study has not been published yet, and participation in that long term follow up wasn’t a requirement. Almost a quarter of phase 3 participants weren’t in it. Including Sarah. In other words, the long term follow up study’s data can’t tell the full story. And I should add that after my interview with Lykos, they announced that *if* the FDA approves their treatment, they’ll add more oversight measures…and collaborate with outside experts on therapy training.

SEAN: But this like, you know, we spent two episodes talking about the potential here this decades long, you know, experimentation and belief that MDMA-assisted therapy can help people, can help our veterans who are experiencing PTSD. But everything you've said so far in this episode makes me feel like there's a lot to still figure out here. Which way is the tide turning? Is it turning towards approving this, or is it turning, you know, back to this is dangerous and should be a schedule one substance or whatever it is.

HALEEMA: I do think that what's happening is that the hype bubble is starting to deflate a little.

There’s still a lot of public pressure from people who feel like this is their own or their loved ones’ last hope for treatment-resistant PTSD.

*<CLIP> FDA ADVISORY COMMITTEE MEETING:*

*JONATHAN LUBECKY: Last year, 50,000 Americans committed suicide, another annual increase. Imagine how many lives your vote could save. Imagine how many will be lost if you vote against this vital therapy.*

HALEEMA: And the FDA can do a couple of things this month. It can wholesale greenlight this, which would be surprising. It can wholesale reject this, or it can say, come back to us with more information.

SEAN: So where does that leave people like Sarah, though, who sounds like she had this awful experience with MDMA-assisted therapy?

HALEEMA: What's interesting is that Sarah did not come away from this experience thinking that MDMA is a bad drug. She came away thinking that she was in a bad trial that left her pretty traumatized. And to work through it all, she's going to therapy.

<SARAH BUTTERING BREAD AND TAKING A BITE>

HALEEMA: She still cooks.

SARAH: <laughing> Mm. I love this.

HALEEMA: And she’s kind of taken matters into her own hands.

SARAH: Paradoxically, what helped me, I think, in really significant ways was MDMA.

HALEEMA: Like taking, taking MDMA after the trial?

SARAH: Yeah. Which feels awkward to talk about.

SEAN: Wait. Hold on. Haleema, is she saying that she's like, now buying MDMA the way, like, ravers are? Or like, you know, college kids at a party are?

HALEEMA: She did say that she got MDMA illegally, and that, for a year, she just waited to take it.

SCORING IN - BEES (Marble beat)

HALEEMA: And then when she was ready, she used it to process her experience in the trial.

SARAH: And I did a session and asked a really close friend of mine to be there just to, like, make sure I didn't have a heart attack. I took a really low dose, and I had the most beautiful session. And like I processed so much of what happened in the MAPS trial during that session. So, like you, you couldn't possibly say that I am anti-drug. Because I do think that the MDMA ultimately really helped me. And it helped me recover from what MAPS did to me.

HALEEMA: What made that experience so different from being in the session?

SARAH: A lot of things. I think, like when I was with someone I knew really well and I trusted, and I already had an established relationship with. I felt in control.

SCORING BUMP

HALEEMA: It's a surprising end after her experience in the trial, isn't it?

SEAN: I'm very surprised.

HALEEMA: Yeah. But it's also not surprising. MDMA might be showing up in a medical framework now with therapists and regulators, but it hasn't shown up that way for most of its existence. MDMA got going with Sasha Shulgin, a chemist in his tool shed in the 1970s.

*<CLIP> SASHA SHULGIN: I looked upon it as a possible low calorie, or no calorie martini.*

HALEEMA: His wife, Anne, thought it was penicillin for the soul.

*<CLIP> ANN SHULGIN: I realized that I was a treasure. I felt as if I were held in the hands of God.*

HALEEMA: But they didn’t take it in therapy themselves! They were self-experimenting. And whether or not the FDA approves MDMA this month, I can't see it taking decades to move the scientific process forward again. I *can* see some serious wrangling with the group bringing this therapy into mainstream and how they do it. But overall, I think MDMA’s reputation as medically useless or poisonous has kind of worn off. It's got a new reputation now as a potential healer, and I don't think that scientists or patients are ready to give up on that just yet.

SCORING OUT

SEAN: Haleema Shah. She's a reporter and a producer here at Today, Explained. This episode was the third in a three part series she made about MDMA-assisted therapy. You can find the other ones in our feed under the title ‘Ecstasy Therapy’.

SCORING IN — Users Lose Drugs (BMC)

SEAN: Our series was edited by Lissa Soep and Mathew Collette, who also fact checked today, with help from Laura Bullard. It was brought to you with support by a grant from the Ferris-UC Berkeley Psychedelic Journalism Fellowship. We thank them for their support. We were mixed by Rob Byers and Andrea Kristinsdottir. And we want to thank our colleagues over at *New York Magazine*, who did a lot of foundational reporting that helped Haleema in a show of *theirs* called *Cover Story: Power Trip*. You can find that show on those devices where you listen to your audio programs. This one's called *Today, Explained*. Thanks for listening to us.

[10 SECONDS OF SILENCE]