MDMA phase II protocol design: preliminary research report

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THE FOLLOWING is a summary of the preliminary research report begun in March of 1993 at the request of the FDA. In order to determine the usefulness of our instruments and the feasibility of the testing, I have administered the battery of seven written tests to three cancer patients, each having completed three entire test batteries. The original intention was to schedule one test battery per month for three months. I soon discovered that rigid schedules do not apply to people fighting life-threatening diseases and, only in one case was I able to administer the battery of tests in successive months.

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On the basis of these cases, I would make the following recommendations for the Phase II Study. As I reported in my article in the MAPS Newsletter of the Summer, 1993, by far the most challenging element of this preliminary study was securing the subjects. I would like to take this opportunity to thank those who did volunteer as well as Valerie Corral (*see story page 26*) who not only provided a subject for the study but has been courageously helping cancer patients for many years. Presumably, the difficulty of securing subjects will be obviated when the study is carried out at UCLA Harbor Hospital with a much more extensive pool of potential subjects.

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As indicated above, setting up a rigid schedule for monthly follow-up tests may not prove feasible with these subjects. Cancer is an unpredictable illness and often the treatment (e.g. chemotherapy or radiation) is even more debilitating than the disease itself. Some flexibility should be built in to the testing schedule and I see no reason why this should interfere with the statistical viability of the results.

If the intention remains to work only with terminal cancer patients in the upcoming MDMA phase of the protocol, it would be my recommendation that the entire test battery be shortened. Of the four subjects I initially contacted, only one proved terminal in the course of my year of research. She was also able to complete only six of the seven tests and it took her almost twice as long. Not only do some of the existing instruments overlap significantly in content, there are other areas to be assessed for which test(s) need to be added.

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Test instruments

On the basis of this small sample, the following are my recommendations on the efficacy and relevance of each of the seven instruments we tested. Of the seven, by far the most comprehensive, meaningful and relevant to the cancer patient is the Functional Living Index: Cancer (FLIC). This test seems to do a good job targeting quality of life questions specifically related to the cancer patient and includes physical pain and mood as well as attitude, energy and lifestyle changes.

For mood evaluation, I would recommend keeping the Beck Depression Inventory (BDI) as it is widely used and recognized and eliminating the Profile of Mood States - Brief Version, as it overlaps significantly with the BDI. The two remaining mood or psychological instruments, the State-Trait Anxiety Inventory (STAI) and the Brief Symptom Inventory also overlap significantly in content. The latter is longer and far more extensive and specific and includes some physical symptoms as well. If possible, I

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would also recommend eliminating the STAI. These tests also reflect the shortcomings of psychological testing that the field of transpersonal psychology has long recognized. They are geared only to measure pathology and disturbance - at best a subject comes out "neutral". There are no questions which measure ecstasy, revelation, transformation, bliss. I will talk later about adding an instrument in which a section could explore the transpersonal side of wellness.

The two remaining tests measure physical discomfort: The Symptom Distress Scale and the Short Form McGill Pain Questionnaire. The latter explores the kind of pain the subject is experiencing (i.e. "throbbing, shooting, stabbing", etc.), and may not be particularly indicative of the potential pain relief MDMA treatment might provide. The McGill is quite a short test, however, and the only instrument which asks these specific questions. If time permits, I would suggest keeping both these tests in the final battery.

As I discussed in my original article, two instruments we hoped to use proved impractical from the start. The Memorial Sloan Kettering Pain Card needed to be filled out daily and, not only did the subjects fail to follow through, it was an unnecessary additional stressor for them. We also dropped the Questionnaire Measure of Emotional Empathy because, at best it failed to measure our definition of empathy and, at worst, pathologized the quality of empathy.

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It is my very strong recommendation that an instrument be developed for the Phase II Protocol which measures, not only empathy (see discussion in earlier article) but the profound attitudinal and philosophical shifts which can occur as the result of MDMA therapy. As mentioned above, questions might be included which target more "transpersonal" states of wellness. Some of this may be explored through the use of an interview which could potentially identify the more profound sources of emotional and psychological pain in the subject (e.g. family fissures, relationship issues, etc.). Currently, there is no test in the battery which explores the pain of living with an alcoholic or abusive spouse, not talking to your child for ten years, being cut off from a brother or a sister, having a child or a mate die - and these are the kind of difficulties that are frequently discussed in my cancer groups. These are also the kind of stressors which can be addressed in a meaningful way through MDMA therapy. In the psychosocial treatment of cancer, much of the work is based on the theories of psychoneuroimmunology. Consequently, significant life stressors such as these not only impact quality of life, but may play a role in suppressing the immune system as well.

In my work with cancer patients as an MFCC intern, I sometimes see individuals for short-term (six sessions) individual work in addition to weekly support groups. Frequently, these individuals face difficult decisions about treatment, frighteningly poor prognoses and, consequently, precious little time in which to make important decisions both about their treatment and about their lives. It is exactly in these cases that the therapeutic potential for MDMA treatment seems enormous.

The following are two brief case studies which, to me, were excellent examples of individuals who might have benefited greatly from MDMA therapy and illustrate the relevance of the various instruments.

Case 1: Sally

(name and some characteristics changed) is a 28 year old single woman. She is an architect, attractive, poised and well-dressed. Sally studied for and passed the architectural license exams while undergoing chemotherapy for breast cancer. She survived, went into remission, only to be hit several years later with another primary cancer: a particularly virulent ovarian cancer. After one unsuccessful surgery, her doctors were recommending a radical hysterectomy as her only hope of survival. Even with the recommended surgery, her prognosis was not good and the potential complications of the surgery could greatly impair her quality of life. Sally is engaged to be married and her fiance is adamantly in favor of the surgery - as is everyone else in her life.

In the course of our work together I discovered that Sally's refusal to have this operation was infuriating those who loved her and she was feeling increasingly isolated. She also shared with me that her parents enjoyed an open marriage when she was growing up and her reaction to this was to become very "uptight" sexually. She believed that her "overly" repressed sexuality may have ultimately caused her cancer as it manifested in her breasts and ovaries. This is a very powerful belief and one in which we could only scratch the surface in six sessions of "talk therapy". The implications of this belief vis a vis her relationship with her parents and her fiance, not to mention her disease, are enormous. MDMA therapy may have provided a tool for this woman to non-defensively explore this belief and determine if she had other choices about the derivation of her illness.

Case 2: Roberta

(name and some characteristics changed) is a bank president - divorced for many years. One of her two grown sons died in an auto accident a few years ago and the other is a source of constant disappointment and frustration for her. He was due to visit for the holidays and she wanted me to see them together so I could tell him how stressful his behavior was to his mother and how this could negatively impact the course of her cancer. I met with her first alone to discuss the limits of what I could say to her son and to clarify and make realistic our goals for our single session together. The session with her son was volatile at best. Though the love and wish to connect were there, they were buried deep under years of anger, projection, expectations, disappointment and deeply conditioned patterns of behavior with one another. Even the idea that this may have been their last Christmas together was not sufficient to outweigh the years of "button-pushing". As in Sally's case, Roberta was holding the belief that her cancer was certainly exacerbated, if not caused, by the stress her son created in her life. It is just these beliefs - enormous in their potential to tear apart a family and undermine the physical fight for recovery - which have the potential to be illuminated in a deep and transformative way with the use of MDMA assisted therapy.

Of the tools currently available in the psycho-social treatment of cancer, relaxation/visualization has proven very useful and is enjoying greater recognition even among the traditional medical community in the treatment of pain as well as stress reduction. Jon Kabat-Zinn has enjoyed enormous success at his Stress Reduction Clinic at the University of Massachusetts Medical Center as reported in his book, Full Catastrophe Living. There, physicians often send him patients for whom western medicine has nothing further to offer. Jean Achterberg, one of the pioneers of this work has specialized in helping cancer patients through the use of relaxation and visualization for over twenty years. She has also offered her considerable talent and knowledge to support our study.

In light of this, it would be enormously useful to set up an interim study measuring the efficacy of relaxation/visualization in cancer patients to reduce psychological, emotional and physical pain. The same test battery could be used (and further refined, if need be) and comparisons could be made with both the control groups and the MDMA groups when the Phase II research is completed.

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Recommendations

To summarize, my recommendations on the basis of this preliminary research would be to shorten the test battery as much as possible per the suggestions I have made above. A new instrument should be created to measure empathy and "transformation". The authors should also consider its potential application to other psychedelic research which may seek to measure transpersonal states. I would suggest a structured interview, targeting painful life issues, stressors and beliefs about cancer. An interim study, measuring the value of relaxation/visualization should be implemented to further refine the instruments, provide useful comparisons and contribute more research to this new and growing field.•