TSM Protocol for Physicians

Dear, fellow physicians:

I am a medical physician much like you, probably. I have volunteered to concisely detail how I use The Sinclair Method (TSM), a refined version of using naltrexone to create pharmacological extinction, to help my own patients who have alcohol addiction. When I first heard one may cure alcoholics by merely persuading them to take a 50mg pill of naltrexone each day one hour before they drink alcoholic beverages, I thought, "That can't work. That is too good to be true." But I tried it and it did work. And it worked again. And again. I find it works in up to 75% of all alcoholics when they are monitored at one year or longer. Studies show it works 40-78% of the time, depending on which international expert you follow. Perhaps how it is specifically used would explain the range of 40-78%. Regardless, 40-78% is extraordinarily effective by medical standards. Many people are taking some sort of antidepressant medication for depression. In outcome studies, placebos may appear to help depression scores 40%, while antidepressant pills may improve depression scores about 43%. 40-78% (TSM) beats the heck out of 43% (antidepressants)! That is why you should use naltrexone as your "treatment of first choice." That, and because it is tens of thousands of dollars less expensive in the first year than the traditional method of rehab. The traditional methods we have used up until now only work, in my estimation, about 20% of the time when patients are monitored at one year. Why do that, when you can get 40-78% results with TSM?

Here is how I use the Sinclair Method:

1. **Diagnosis**. *Diagnosis should precede treatment.—William Osler.* At the first visit I diagnose the patient. It is usually obvious if a patient has alcoholism. I take special care that they are not also addicted to narcotics, because TSM involves giving naltrexone to the patient. If a narcotic addicted person takes naltrexone, it will result in narcotic withdrawal. Most patients are reluctant to admit to narcotic addiction. To cover this possibility I explain to EVERY patient, "I tend to believe you, but for your own good I am going to tell you that if you are addicted to narcotics and are too embarrassed to admit it, DO NOT TAKE THIS PILL. Because if you do, it will throw you into narcotic withdrawal and there is nothing I can do about that until the medicine gradually wears off over the next 24 hours. If you are not addicted to narcotics there is no problem. Do you understand?"

   One may rule out narcotic addiction in other ways. You could do a urine screen for narcotics. You could do a naltrexone challenge with a micro dose of naltrexone to observe for withdrawal. I also determine by history and exam, if possible, (many alcoholics are too poor to afford unnecessary lab tests) that the patient is not in liver failure. All alcoholics have some liver damage. That is to be expected. So long as it is mild or moderate, I proceed with TSM. Although major liver disease is a contraindication to naltrexone, it is still up to each physician to balance the benefits against the risks on a case by case basis. I prefer for pregnant women (again, by history) to not use naltrexone. And, of course, an allergy to naltrexone is a contraindication.

2. **Family**. It is very easy to use TSM to treat alcoholics who have no family. It is often challenging to treat patients who have a family because the family can be quite prone to

resist this new idea of TSM. When they are introduced to this they think, as I did, that it can't possibly work. It often sounds to them like the wrong thing to do. The physician has the challenge of attempting to change the belief system of each family member about what alcoholics must do to overcome alcoholism. Gaining their trust is critical or else they will sabotage TSM, believing they are helping. I bring the patient into my office, drunk or sober, with at least one family member (if they still have a family) so the family can hear the explanation of TSM from me, the physician. The family will seldom believe the patient if the patient explains TSM to them on their return home. Often the patient tells the family incorrect information and everyone just gets confused. Confusion in the beginning gets everything off on a sour note. I try hard to get both the family and the patient compliant and optimistic in the beginning. I find it helpful to show the family the U.S. Department of Health and Human Service's book on treating alcoholism with medication which has an entire chapter on using Naltrexone. I may show them Roy Eskapa, Ph.D.'s book, *The Cure for Alcoholism*'s graphs showing how, in studies, the alcohol use diminished over the weeks on TSM. I may show them medical research literature vouching for naltrexone's use in treating alcoholics.

3. **Advantages**. Then I explain TSM to the patient. I tell them in the presence of family that this method has been verified to be between 40-78% effective, depending on which international expert you follow, when alcoholics are checked on one year after starting treatment. I see TSM working gradually over a period of up to 9 months. I tell them it is like having a baby. It takes time. More of the improvement occurs in the first 4 months than the last 5 months. I explain that it is not necessary for them to be admitted to an expensive hospital to "dry out" or "be detoxed." Since they quit drinking gradually, there

is no alcohol withdrawal with TSM. I also explain that with TSM it is not necessary to stay in an expensive hospital for weeks of a "program" of educational and counseling nature. I explain that TSM, in fact, has been shown in one study to work better without counseling than with counseling. Another study showed it worked even better with cognitive behavior therapy. There are no public meetings to attend. I tell them that I just require one thing, "Take your naltrexone pill one hour before drinking alcohol over several months. 'Alcohol + Naltrexone = Cure.'"

4. Antebuse (**disulfiram**). Patients then almost always say to me suspiciously, "Oh, that is going to make me sick when I drink, isn't it?" I comfort them with the truth. "No. That is another medicine that has nothing to do with this medicine. Most people that take naltrexone have no particular feeling at all." A minority of patients do have some transient, mild nausea. I sometimes avoid this by starting patients on a half dose the first two days.
5. **Smiles**. The patient often looks confused at this point and asks, "Let me get this straight doc (as if they must be missing something). All I have to do is to keep on drinking and take this pill before I drink?" Then I reply, "Yes, but you must wait one hour. That is very important. I had a woman who took it for 6 months without any benefit. It turned out she wasn't waiting that one hour. She confessed that she didn't think that was so important and that she was, in truth, taking her naltrexone with her first glass of wine. When she tightened up on waiting a full hour, she started to see steady, gradual, robust improvement in how much she drank. Four months later she went from drinking 2.5 liters of wine a day to an average of only 5 glasses of wine a week."

6. **Prescription**. Then I write a prescription for the pleased patient. "Naltrexone 50mg. Sig: one p.o. QD, as directed, one hour before alcohol beverages. Dispense #30 with 5 refills." Occasionally I receive a call from a zealous pharmacist telling me that it says on the package insert not to give naltrexone with alcohol. It is true that it does say that. I explain that that package insert was written about 20-30 years ago and that new information has come to light since then that says to use it with alcohol. In fact, one international expert advises that the treatment will not work unless the patient does drink WITH naltrexone. If the pharmacist is still not convinced I ask them to look up Vivitrol, a form of naltrexone. This once-a-month depot naltrexone injection clearly is to be given to alcoholics who are apt to be drinking alcohol. That convinces them. I explain to patients and to their family that taking naltrexone does not keep the patient from getting drunk when drinking too much alcohol. Until they begin to drink more moderately they must still take safeguards from injury to self and others by not driving the car, etc. I live in a very conservative and religious part of America. The non-Catholic, Protestant religions here are appalled if my patient tells them that the doctor said to keep on drinking. So, for peace, I sometimes say to my patient and to their Protestant, tea-totaler family, "Try to not drink." (expecting the patient will probably fail to abstain form alcohol.) "But if you do drink, at least take the naltrexone pill an hour before you do drink."
7. **Follow-up**. I usually see my patient back in a week with the family member because I want to clear up any misunderstandings early on. Then I see them next in a couple of weeks or a couple of months, depending on their understanding and compliance. Once the patient begins to drink substantially less alcohol, the family may no longer need to

come with the patient as they may have better things to do with their time. Eventually, it is like treating the patient for hypertension, with rare visits once or twice a year.

8. **Enhance desirable habits**. When the patient has made some headway such that they don't drink alcohol every day, with TSM, you can help the patient adopt desirable lifestyle behaviors. This is a great advantage. It is believed by one international expert, that on the non-drinking days, the alcoholic's endorphin receptor sensitivity is enhanced and if the patient, for example, *exercises* on those non-naltrexone days on an on-going basis, it is quite possible that the endorphin "kick" will aid a successful incorporation of a healthy *exercise* habit into their lifestyle, which otherwise might never have happened. This is one of the advantageous key elements of TSM that is not possible with the 30-day naltrexone injection or with traditional rehab methods of treatment.
9. **Forever**. TSM is forever. For as long as this patient drinks alcohol they must always take the naltrexone pill beforehand. I ask that patients always carry a pill with them on their person, in their work desk and in their car so they will not be non-compliant, just because they had no pill, and drink alcohol without naltrexone in their brain.
10. **Early relapse prevention**. We are all fallible human beings. Alcoholics that have been doing great on TSM may one day decide they don't need the pill any more. If they start drinking without naltrexone, in short order, they will be in trouble with binges of excessive alcohol. Relapses progress much faster than the improvement phase. I educate my patients when they are well to expect a relapse if they ever quit taking the pill and, when that should happen, to resume treatment immediately to recover. "Naltrexone + Alcohol = Cure"

I hope that sharing my approach to TSM will make you feel like giving this a try on your alcoholic patients. I had nobody in the medical field to give me encouragement and nobody to give me a stripped down protocol of how this is done. If just one of my physician colleagues adopts this as their treatment of first choice, then my volunteering to write this will not be in vain. You and I will have collaborated to save lives and keep families together. And that is what God wants us to do as physicians—to learn new and better ways to help make well those who here-to-fore were hopeless. There are no hopeless alcoholics, only doctors who have lost hope. Let us not lose hope. Let us never, never give up.

Stephen Cox MD

A Physician's Commonsense TSM (naltrexone extinction) Protocol

To Successfully Control Alcohol Dependency

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Diagnosis Confirm alcohol dependence.
Rule out contraindications by history, exam or lab of narcotic addiction, severe liver failure, pregnancy, and allergy. If you're suspicious, consider a naltrexone challenge test, narcotic drug screen, LFT's, pregnancy test. "Use more brain, less lab."
Family Involve family, if there is a family. Win them over to cooperate with plan.
Advantages. Encourage patient and family with the facts of how great TSM is. It's up to 40-78% effective. It is enormously less costly.
It's not Antebuse (disulfiram). "Naltrexone is not anything like Antebuse". Most patients have no bothering side effects.
Smiles. "So, doctor, all I have to do is take a pill an hour before I drink? No hospital? No de-tox? No meetings?" "I can do this, doctor!" (High Compliance)
Prescription *Rx naltrexone 50mg. Sig: take one pill q.d., one hour before drinking alcohol. Dispense #30 with 2 refills.* Suggest ½ doses the first two days.
Follow-up Visits. Every 10 days to 2 months, depending on the patient, at first. Eventually, once or twice a year for responding patients. It feels like you're treating uncomplicated mild hypertension.
Enhance desirable behaviors. After making solid progress and not drinking every day: On non-drinking days, have patient repetitively do a behavior that they'd like to acquire as a good personal habit. (TSM)
Does not poop out. This treatment continues to prevent relapse so long as it is used.
Early relapse prevention. Tell patient that if in the future they stop treatment they will relapse. They are to immediately come see you to start TSM again, just like if they stopped their blood pressure pill. For more*: The Cure for Alcoholism, Roy Eskapa, PhD, BenBella Books, second edition.*