Return to Work Randomized Controlled Trial: Counseling After Fatigue Treatment in HIV/AIDS

Consent form – 11/17/2017
ClinicalTrials.Gov ID: NCT 02140775

11.17.17
Questions about study:
Call Dr. J. Rabkin 646 774 8075

CONSENT FORM A

RETURN TO WORK STUDY: MODAFINIL AND COUNSELING

Purpose of Study
You have been asked to participate in a study of MODAFINIL (Provigil) for HIV+ men and women who wish to return to work but find that fatigue prevents them from doing so. The study has two parts. First, you will be treated for 4 weeks with modafinil , and, if your energy improves, medication will be continued for another 12 weeks. You will also have 8 counseling sessions (behavioral activation or supportive counseling) to help you succeed in finding work or training. Modafinil is approved by the Food and Drug Administration (FDA) for treatment of daytime sleepiness related to serious conditions called narcolepsy and obstructive sleep apnea, and for work-shift related sleep disorders. The aim of the study is to see whether counseling plus modafinil are helpful in overcoming fatigue and achieving vocational goals for adults with HIV/AIDS. The study is supported by the National Institute of Mental Health (NIMH).

Voluntary Participation
Participation in this research study is voluntary. If you decide not to participate, or if you decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate will not affect your treatment at New York State Psychiatric Institute. You will be notified of significant new findings that may relate to your willingness to Continue to participate in this project.

Alternative Treatments For Fatigue
Modafinil is available by prescription outside of the study, although it is not approved for treatment of fatigue. . Alternative treatments for fatigue include psychostimulants such as methylphenidate, dextroamphetamine, or steroids such as oxandrolone or testosterone (for men). Antidepressant treatment may also help with fatigue, which may be related to depression among other factors.

Alternative Programs Providing Assistance with Employment
New York City has 17 career centers that provide job placement services and career guidance. Community agencies such as Housing Works and GMHC also offer job promotion services.

Study Procedures
Before you begin, you will have had a comprehensive laboratory work-up which includes blood chemistries, thyroid tests, immune tests (T cell count), and hormone blood levels. You also will have had a physical examination (or you will get a letter from your health care provider saying you had one within the past 3 months). You will be asked to give permission for the study doctor to call your physician regarding your study participation if clinically indicated.

The clinical trial lasts 4 weeks. During this time, you will see the study psychiatrist weekly and take study medication every day. Please return any unused medication at the next study visit. During this time, you cannot start taking other medicines to increase energy. After 4 weeks, you and the doctor will decide together if your fatigue has been significantly reduced.

An additional 12 weeks of modafinil treatment is offered if you found it helpful and you participate in the counseling program. After that, you will be given a prescription, and thereafter your own doctor will be responsible for providing subsequent treatment.

At the first visit, you will meet with the study psychiatrist, review the nature of the study including risks and benefits, sign the consent form and start medication. You will be asked to return weekly for 4 weeks. After four weeks on modafinil, if you continue, visits will be scheduled every 2 weeks, or monthly. Study visits with the doctor will last about a half hour. You will take your medication by mouth once a day when you get up in the morning, unless otherwise instructed by your doctor. The starting dose is 100 mg/day, which may be increased slowly up to 200 mg/day in the absence of clinical effect and dose-limiting side effects.

After 2 weeks:
After 2 weeks of modafinil, you will meet with a study psychologist to identify specific work-related goals as well as other goals you seek to attain in the next 3 or 4 months. At this visit you will be assigned to one of the two forms of counseling, and at the Week 3 visit, meet with your counselor for the first counseling session. Initiation of counseling will be deferred if you have not responded to modafinil by Week 3. If you have not benefited from modafinil by Week 4, counseling will not be offered and your study participation will end.

Goal-Directed Counseling: Behavioral Activation Counseling ("BA") or Supportive Counseling ("SC")
There will be 8 counseling sessions, scheduled every other week from Week 4 on, to work on steps to accomplish your goals. Since we do not know which method is more helpful, we are comparing these two forms of counseling. BA is more focused on specific actions to promote each person's vocational goals. Supportive counseling focuses on emotional aspects of reaching such goals. You will be randomly assigned (as in the flip of a coin) to one or the other.

The counseling sessions will coincide with study visits for medication. The sessions each will be about an hour initially, but may be shorter over time depending on your needs regarding work or training. The counseling will include homework assignments between visits with the object of increasing goal-directed activities.

The sessions will be audiotaped, with no identifying information, to permit a clinical supervisor to monitor the counselor's work to be sure he or she is following the study guidelines. Audiotaping is a study requirement. If you do not agree to audiotaping, you cannot participate in the study.

One and three months after the final counseling session, you will be asked to return to see how you are doing, to repeat some of the questionnaires you filled out earlier, and evaluate goals. In the future, you may be contacted about participating in other studies, but you are under no obligation to do so.

When both medication visits and counseling occur in the same week, we will schedule them consecutively on the same day in our clinic unless you prefer a different schedule.

Study Measures and Tests
You will be asked to fill out brief rating scales at 4-week intervals during the study, in order to detect any changes that may occur in your energy level, mood, alertness, and goals.

At one or more of the regularly scheduled study visits, you will be asked for a urine sample for a toxicology (drug) screen.

Pulse and blood pressure will be measured at every study visit for the first 4 weeks, and then every 4 weeks thereafter.

Women of childbearing age: You should use barrier methods of protection, not hormonal patches or oral contraceptives during the study if you are sexually active, to avoid pregnancy. This is important because of the possibility that modafinil may reduce the effectiveness of oral contraceptives or patches.

If you are depressed before entering this study, please initial one of the following as appropriate:

" I have been told that I have depression which currently is not being treated. I have also been told that fatigue is one of the symptoms of depression, and that treatment for depression may help with my fatigue. However, at this time I do not wish to be treated with an antidepressant, and instead wish to participate in the modafinil study."
(Initials)_____

If you are already taking an antidepressant but are still depressed: "I have been told that I have symptoms of depression which are currently being treated with a dose of antidepressant that has not eliminated my symptoms. I understand that the study doctor can raise this dose for 2-4 weeks to see if this helps with my fatigue, before I enter the modafinil study. If I still have significant fatigue, then I can enter the modafinil study at that time. However, I do not want this option, but instead choose to participate in the modafinil study without this delay." (Initials)_____

Risks and Benefits
Risks. The most common side effect of modafinil is headache. Other side effects, reported by patients in our previous studies include increased irritability, and, uncommonly, dizziness, dry mouth, or anxiety. Although not observed in clinical trials, post-marketing cases of serious rash, including Stevens-Johnson Syndrome and other hypersensitivity reactions, have been reported among patients taking modafinil. In some cases this required hospitalization. While skin conditions or other hypersensitivity reactions connected to modafinil or armodafinil are extremely rare, we are bringing this information to your attention and request that you **immediately stop taking the study medication if you develop a rash of unknown origin, or swelling of the face, eyes, lips, tongue or larynx and/or difficulty breathing or swallowing. We ask that you call your doctor and also notify us if this occurs.**

The effects of modafinil on HIV viral load and the immune system are currently unknown. Also, drug interactions between modafinil and the antiviral medications or other HIV-related medications you may be taking are currently unknown; no data are available. One drug can sometimes increase or decrease the amount of the other drug in the blood, but the clinical significance of such changes, if any, are also currently unknown. We have treated about 300 HIV+ people with modafinil or armodafinil. For these patients, all of whom took either medication for at least 4 weeks and up to 26 weeks, on average there were no changes in CD4 cell counts or viral load over the period of observation.

There may be as yet unknown side effects from the combination of antidepressants and modafinil. However, to date we have treated over 100 study participants with modafinil or armodafinil who were also taking an antidepressant, and no adverse events were reported by them or observed by us. In 7 published studies where modafinil was used in combination with an antidepressant, there were similarly no reports of drug interactions. Nevertheless, it is a possibility.

Other risks include the possibility of elevated blood pressure (hypertension), and the possibility that your fatigue may worsen during the study. In addition, if you are depressed, your depressive symptoms also may worsen during the study. The risk of blood tests is the possibility of slight discomfort at the site of needle entry or a small bruise.

There also have been rare reports of worsened mental state in patients taking modafinil including psychosis (hallucinations, irrational thoughts), aggression, and thoughts of suicide. If you begin to feel worse mentally or emotionally, please let us know right away.

During counseling, you may become distressed or anxious about some of the topics that may come up. You can discontinue the conversation or the session if you wish to do so. Violation of confidentiality is another risk, although as we explain below, we take great precautions to protect your personal information.

Benefits. Participants may or may not benefit from study participation. In our clinical trials of modafinil and armodafinil, we found that most participants experienced reduced daytime sleepiness, and increases in energy, alertness and mood. However, only a minority of patients who said they wanted to return to work or school once their energy was restored were successful in doing so. We are conducting this study to see whether modafinil in combination with behavioral activation or supportive counseling is helpful to participants who seek these goals.. If counseling is not effective in promoting return to work, other programs meant to promote employment will be recommended. If modafinil is not helpful, alternative treatments for fatigue such as methylphenidate will be offered for up to 2 months as clinically indicated after the initial 4-week trial.

Benefits to other people: This study may help in identifying an effective strategy for HIV+ adults ho want to return to work. This would provide useful information for other people and their doctors in the future. Note on availability and cost of medication: Insurance programs may not provide coverage after the end of your study participation.

Confidentiality
All information including results of laboratory tests will be treated confidentially. To help us protect your privacy, this research is covered by a Certificate of Confidentiality issued by the National Institutes of Health. With this certificate, researchers cannot be forced to release any research data in which you are identified, even under a court order or subpoena, without your written consent. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to appropriate authorities.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold this information.

Records will be available to research staff, and Federal, State and Institutional regulatory personnel (who may review records as part of routine audits).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of results. You can search this web site at any time.

Your records will be labeled only with a pseudonym if you so request. All records will be kept in the investigators' offices and research records will be coded only by number.

Compensation
You will be paid $20 in cash for assessments at Weeks 4, 8, 12 and 16. For the follow-up visit one month after the last counseling session, you will be paid $40, and for the final follow-up you will be paid $50. In addition, at each visit you will be offered $6 (or whatever the fare is on public transportation at the time) to cover travel costs. Excluding carfare, the total compensation for all visits is $170.

In Case of Injury
Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

If you believe you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Judith Rabkin, at 646 774 8075 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by the New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute's capacity to provide. In addition, we will provide assistance in arranging follow-up care in such instances.
New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the courts by participating in this research.

Questions
Your study doctor is available to answer questions about the study at any time. He can be reached during the day at (646) 774-8082. Dr. Judith Rabkin, principal investigator, can be reached during the day at (646) 774 8075.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of human subjects in research studies.) You may call the IRB Administrative Director at (646) 774 7155 during regular office hours.

The study doctor can withdraw you from the study at any time without your consent for reasons such as improving your health, your failure to follow study requirements, worsening depression, or the occurrence of unusual or serious side effects. If you are depressed at the beginning of the study and your depression gets worse during the initial 4-week trial, you may ask to end the study and be treated for depression. If both the first and second urine toxicology screen test positive for substances you have not reported to the study doctor, you will be withdrawn from the study at that time.

You will be notified of significant new findings about modafinil that may relate to your willingness to participate.

Documentation of Consent
"I voluntarily agree to participate in the study described above.

NAME_____

SIGNATURE _____ DATE _____

I have discussed the proposed research with this patient including the risks, benefits, and alternatives (including non-participation). The participant has had the opportunity to ask questions, and in my opinion is capable of freely consenting to participate in this research.

NAME_____

SIGNATURE _____ DATE _____
Study Physician