More questions...

6. What happens at study follow-up visits?

Study visits include:

- Questions about your health and how you are feeling
- * Questions about drugs you are taking
- Questions about how you are doing in different areas of your life (for example, family/social, legal, employment areas)
- * Urine and breath samples for testing

The study follow-up visits will take about one hour each to finish.

7. What will I get for taking part in the study?

The therapies used in this study are designed to help you reach your recovery goals. Information from this study may help others in the future. Everyone will receive at least one prize for doing the intake, and up to \$75 for doing the follow-up interviews. Those assigned to the Motivational Incentives Therapy who also remain drug-free will be able to draw for more prizes.

8. Will I have any bad effects from taking part in the study?

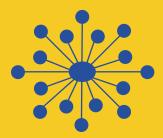
There are almost no known bad effects from the therapies in this study. You may be disappointed about not getting the therapy assignment that you wanted. But by signing the consent form, you are agreeing to take that risk. Also, much of the information collected during the study is private and there is a risk that others who are not involved in the study will see it. However, this is a very small risk because the research and clinic staff are well-trained in keeping the information confidential. Your name will not appear on any data or study reports that leave this clinic. For more information on the National Drug Abuse Treatment Clinical Trials Network, visit the NIDA website at *www.nida.nih.gov* or *www.drugabuse.gov*.

For information on other clinical trials, the National Institutes of Health (NIH) has created a website to help patients, family members, and the general public obtain information about government sponsored clinical trials. You may log on to *www.Clinicaltrials.gov* to learn about ongoing or new trials for all types of health related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The website is maintained and updated regularly by the National Library of Medicine.

National Institute on Drug Abuse Division of Treatment Research & Development Clinical Trials Network 6001 Executive Boulevard Room 4123, MSC 9551 Bethesda, Maryland 20892-9551 Telephone: (301) 443-6697 Fax: (301) 443-2317

National Drug Abuse Treatment

Clinical Trials Network



MOTIVATIONAL INCENTIVES

A study of new ways to help people remain abstinent

Should I join the Motivational Incentives Study? (Methadone Clinics)





Introduction

People who enter treatment for recovery from drug dependence may do better if they are rewarded for their abstinence. These rewards can be in many different forms, including kind and supportive words from therapists, family members, or other clients, or getting actual prizes. The National Drug Abuse Treatment Clinical Trials Network (CTN) is doing a study called *Motivational Incentives* to find out whether rewards in the form of prizes can help people stop drug use and maintain abstinence.

You are being asked to take part in this study. If you decide not to take part in the study, your treatment will not be affected in any way and you will not lose any of your treatment benefits.

Description of the Study

The study compares how well people do when they get a chance to get prizes for abstinence versus when they do not get the chance to get prizes. If you join the study, you will be assigned to either:

MOTIVATIONAL INCENTIVES

You will get all the treatment services that are usually offered at this clinic.

During the first *12 weeks* of treatment, you can *draw for prizes* whenever you give a urine sample that is negative for target drugs.

Prize draws depend on testing negative for:

stimulant drugs (cocaine, amphetamine, methamphetamine) and

* on blowing a negative breath alcohol reading

The longer you abstain and test negative for these drugs, the more prize chances you will be awarded.

You will also get *bonus prize draws* if your urine is negative for *opiates*.

STANDARD CARE THERAPY

You will get all the treatment services that are usually offered at this clinic, but you will not get the chance to draw for prizes for negative urine and breath samples.

If You Decide to Join

Before joining the study, an intake counselor or study coordinator will need to get your written permission. You will need to understand and sign an informed consent paper. You may ask as many questions as you want to help you decide whether or not to join.

If you decide to take part in the study, here is what you can expect:

- You will be assigned at random (for example, by the flip of a coin) to receive either Motivational Incentives with Standard Care or Standard Care therapy alone. In other words, you can't choose which therapy you will get. If you decide to join this study you must be willing to accept the therapy that you are assigned.
- 2. You will get a prize (worth about \$20) for completing the study intake procedure.
- 3. You will meet with a research assistant twice a week for 12 weeks to give a urine and breath sample. The urine sample will be tested for cocaine, amphetamine, methamphetamine, marijuana, and opiates. The breath sample will be tested for alcohol level.
- 4. You will need to return to the clinic 1, 3, and 6 months after starting the study for a follow-up interview and to give a urine and breath sample. You will be paid \$25 for each of these interviews, so you can earn up to \$75 for participating.
- 5. All of the information that you give us, including urine test results, will be kept confidential.

Questions about the study

These are the answers to some questions about the study that may help you decide if you would like to take part in the study.

1. How long will I be in the study?

Most of the study, including twice-weekly urine testing and prize drawings, happens in the first 3 months. There is one final follow-up at 6 months.

2. How many people will be taking part in the study?

About 400 people across the United States will take part in the study.

3. What will I have to do during the study?

You will not have to do much more than if you decide not to take part in the study.

- * Go to your counseling sessions as usual
- Fill out questionnaires and give urine and breath samples twice a week for 12 weeks
- * Arrange for make-up visits if you cannot come when scheduled.
- Return for study follow-up visits (even if you drop out of treatment)

4. If I am assigned to the Motivational Incentives group, what are the prizes I could win, and what are the chances of winning?

Some prizes are small items like sodas, candy bars and bus tokens. Other prizes are large items worth about \$20 like grocery vouchers, walkmans, radios and clothing. There is also a jumbo prize like a television or CD player that you could win.

The longer you stay drug-free, the more drawings you will have. The more drawings you have, the higher the chance that you will win prizes.

5. Can women who are pregnant or able to have children join the study?

Yes. There are no known side effects of these therapies on the health of pregnant women and unborn children.