Informed consent form for clinical research

Effectiveness of nonspecific methods of treatment and Zopiclone for chronic insomnia

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Investigational method:	Brief behavioral therapy program
Study Phase:	
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Funding Organization:	
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Approval:

PI Signature (Name and Title) *Date*

Information for Patient

Dear patient

You are invited to take part in the research in the study " Effectiveness of nonspecific methods of treatment and Zopiclone for chronic insomnia"

The research is conducted by the post-graduate student, neurologist Pchelina Polina under the direction of assistant professor of the Department of Nervous Diseases of the IPO of the I.M. Sechenov First Moscow State Medical University, Poluektov Mikhail Gurievich.

Please read this document carefully, it contains information about the study and possible risks. You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study. Or you may contact the investigator(s) at the phone numbers below.

Your signature certifies that you have decided to participate having read and understood the information presented. You will be given a copy of this consent form to keep.

You are invited to participate in this research, because your complaints meet the criteria for chronic insomnia, and you have not taken medications that have a sleeping pills during the last week

This research project will aim to determine the effectiveness of non-drug therapy in comparison with the hypnotic for the treatment of chronic insomnia.

Upon receipt of your informed consent for participation and inclusion in the study, your general and neurological status will be assessed and you will be asked to complete set of questionnaires to evaluate your psychological status, personal traits and extent of sleep disorders. Then you will be asked to have blood test for assessment of the sympathetic hyperactivation degree and 1 night in-lab polysomnography for evaluation of objective sleep time.

After the initial examination, you will be randomly assigned to one of two groups, in each of which you will receive treatment for chronic insomnia first by one method, then by another. The sequence of methods will be random.

The first method consists in a standard insomnia treatment with the hypnotic Zopiclone (Imovan) 7.5 mg taken 30 minutes before bedtime for 2 weeks.

The second approach of treatment is structured educational method for the treatment of chronic insomnia combining educational and behavioral methods: doctor will discuss healthy sleep, the causes of its disorders and the methods of nonpharmacological treatment prescribe your individual sleep-wake regimen and give you individual recommendations for improvement of your sleep. This method consists of 2 individual sessions lasting 1 hour, 1 time per week. After first session, you will be provided with reminder card containing basic information, flash players with relaxation audio recording facilitating falling asleep. It is expected that you will follow the doctor's recommendations on the regimen and hygiene of sleep, listen to the audio recording during the two-week treatment period.

After the first treatment course you will be asked to complete the complex of diagnostic procedures (questionnaires, blood sampling) - to evaluate the effectiveness of therapy (Week 2, Month 1).

After the first treatment course, a two-week break followed by complex of diagnostic procedures (questionnaires, blood sampling) are planned - to monitor the effectiveness of therapy dynamically (Week 6, Month 2).

After the two-week break you will get another treatment method for two weeks (if the first one was zopiclone then second one will be structured educational method vice versa) followed by complex of diagnostic procedures (questionnaires, blood sampling)

After the second treatment course, a two-week break followed by complex of diagnostic procedures (questionnaires, blood sampling) are planned - to monitor the effectiveness of therapy dynamically (Week 8, Month 2).

You will be asked to keep a diary of sleep 1 week before the start of the first course of treatment, and for the both treatment courses and break ups.

The duration of your participation in the study will be 8 weeks, 6 visits are expected, including two individual sessions with a doctor for 1 hour, one night polysomnography study, 5 questionnaires to assess the psychological status, the nature and extent of sleep disorders, and 5 Finger blood sampling for assessing the degree of sympathetic hyperactivation.

Possible benefits to you as a research participant involve a detailed study of your physical, neurological and psychological state to adjust individual therapy for you.

Possible discomforts associated with the research participation: the time spent on night polysomnography, filling out questionnaires and questionnaires, attending individual sessions with a doctor.

Possible risks associated with research participation is connected to blood sampling from the finger. The risk is minimal, since manipulation is done in aseptic conditions by trained personnel

No additional costs are foreseen for you.

Your participation in the study can be terminated when the doctor feel that it was not in your best interest to continue. The following is a list of possible reasons for study treatment discontinuation:

- Your withdrawal of consent (or assent)
- You have a condition exclusionary for study participation (acute disease, exacerbation of chronic disease, pregnancy etc.)
- You are not compliant with study procedures
- Adverse event

You will be immediately notified if additional information appears in the course of the study that may affect your consent to continue participating in the study.

Your name and other personal information will not be indicated in the reports and publications related to this study. You have the right to access information about your health.

Any information obtained during this study which could identify you will be kept strictly confidential in accordance with current legislative and regulatory acts of the Russian Federation. The information obtained in this study may be published in scientific journals or presented at scientific meetings but the data will be reported as aggregated data.

Participation in this study is voluntary. You can refuse to participate or withdraw at any time without harming your relationship with the researchers or the Clinic, or in any other way receive a penalty or worsening of your medical care quality to which you are otherwise entitled.

Contact telephones, for which you can get additional information:

Post graduate student - Pchelina Polina, mob.tel. +7 (903) 670 17 25;

Scientific supervisor - Poluektov Mikhail Guryevich, +7 (499) 248 75 25

Please contact the I.M. Sechenov First Moscow State Medical University Institutional Review Board at +7 (495) 622 97 06 to voice concerns about the research or if you have any questions about your rights as a research participant.

The research is conducted on the Department of Sleep Medicine, UKB № 3, A.Ya. Kozhevnikov Clinic of Nervous Diseases, I.M. Sechenov First Moscow State Medical University Ministry of Health of Russia,

legal and actual address: Moscow, ul. Rossolimo, 11, building 1;

Contact phones: 8-499-248-75-25

Thank you for your attention to this information.

Informed Consent Form

I _____
(Full name)

read the information on the research "Effectiveness of BBT-I and Zopiclone for Chronic Insomnia" and I agree to participate in it.

I had the opportunity to ask any questions about my participation in the research and to receive answers to them, and I had enough time to decide on voluntary participation in the research.

I understand that I can quit research at any time and if I do, it will not affect my subsequent treatment.

I give my consent to the storage and processing of my personal data in accordance with the current legislation of the Russian Federation.

I voluntarily agree that my research data should be used for scientific purposes and published with confidentiality.

I received a copy of "Information for Patients with a Form of Informed Consent".

_____
Initials of patient (in block letters)

_____
Patient signature, Date and time

_____
Initials of doctor-researcher (in block letters)

_____ _____
Signature of the doctor-researcher, Date and time