SUPPLEMENT 4

Title: *Protocol for a multi-center randomized controlled trial of digital cognitive behavior therapy for insomnia compared with digital patient education about insomnia in individuals referred to secondary mental health services in Norway.*

Håvard Kallestad[1,2,3], Simen B. Saksvik[2], Øystein Vedaa[2,4], Knut Langsrud[2,3], Gunnar Morken[1,2,3], Stian Lydersen[2], Melanie R. Simpson[5], Signe K. Dørheim[6], Bjørn Holmøy[7], Sara G. Selvik[8], Kristen Hagen[9], Tore C. Stiles[10], Allison G. Harvey[11], Frances Thorndike[12], Lee Ritterband[13], Børge Sivertsen[2,4,14], Jan Scott[2,15].

[1]Department of Research and Development, St. Olavs University Hospital, Trondheim, Norway
[2]Department of Mental Health, Norwegian University of Science and Technology, Trondheim, Norway
[3]Department of Østmarka, St. Olavs University Hospital, Trondheim, Norway
[4]Department of Health Promotion, Norwegian Institute of Public Health, Bergen, Norway
[5]Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, Norway
[6]Department of Mental Health Care, Stavanger University Hospital, Stavanger, Norway
[7]Deparment of Mental Health Care, Akershus University Hospital, Follo, Norway
[8]Department of Mental Health Care, Namsos Hospital, Namsos, Norway
[9]Department of Mental Health Care, Molde Hospital, Molde, Norway
[10]Department of Psychology, Norwegian University of Science and Technology, Trondheim, Norway
[11]Department of Psychology, University of California, Berkeley, USA
[12]Pear Therapeutics, LLC, USA
[13]Department of Psychiatry and Neurobehavioral Sciences, University of Virginia, USA
[14]Department of Research and Innovation, Helse-Fonna HF, Haugesund, Norway
[15]Institute of Neuroscience, Newcastle University, Newcastle, England

Corresponding author:
Author 1 (Håvard Kallestad, havard.kallestad@ntnu.no) as shown in Scholar One

Håvard Kallestad
St. Olavs University Hospital
Department of Research and Development
PO Box 3250 Sluppen
7006 Trondheim
Norway

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DO YOU WANT TO PARTICIPATE IN THE RESEARCH PROJECT: 'DIGITAL SLEEP TREATMENT FOR INDIVIDUALS REFERED TO PUBLIC MENTAL HEALTH SERVICES'

WHAT IS THE PROJECT ABOUT?

You are invited to participate in a research project to try digital (internet-based) treatment for chronic sleep problems (insomnia).

Insomnia involves problems falling or staying asleep. Although insomnia is highly prevalent among persons with mental health disorders, it is very uncommon to receive non-pharmaceutical treatment for these problems. In this study we aim to establish an effective and accessible treatment for insomnia delivered through the internet. You will get access to the treatment via an internet page, accessible via a computer or a smart phone.

To be eligible for this study you must be over 18 years of age and be referred to treatment at a public mental health clinic ("distrikspsykiatrisk sykehus, DPS") in Norway.

This study is a collaboration project between NTNU, Folkehelseinstituttet, St. Olavs Hospital St. Olavs Hospital (Nidaros DPS, Tiller DPS, Orkdal DPS), Akershus universitetssykehus (Follo DPS, Groruddalen DPS, Nedre Romerike DPS, Øvre Romerike DPS), Helse Stavanger (Stavanger DPS, Sola DPS, Sandnes DPS), Helse Nord-Trøndelag (Namsos Sykehus, Levanger Sykehus, Stjørdal DPS), Helse Møre og Romsdal (Molde DPS, Kristiansund DPS, Ålesund DPS, Volda DPS), Helse Bergen (Kronstad DPS, Voss DPS), Vestre Viken (Bærum DPS), Oslo Universitetssykehus (Søndre Oslo DPS, Nydalen DPS), the University of Virginia and the University of California, Berkeley (USA). The project leader is psychologist Håvard Kallestad, PhD at St.Olavs Hospital

WHAT DOES THE STUDY INVOLVE?

The study period is 12 months and the sleep treatment lasts for 6-8 weeks. We will register information about you to investigate the effect of the sleep treatment.

We will ask you to complete questionnaires before the treatment as well as nine weeks, 6 months and 12 months after the treatment started (see time schedule in Chapter A). Registered personal information are contact information (name and address) and demographic information (sex, age and education). We will also ask about your general health, mental health, sleep habits and daily activity and habits. Your sleep pattern will be registered with a sleep diary which is a short form you can complete via the internet and takes about 2-3 minutes to complete.

To participate in this study you must first answer a short screening form via the internet. In this form it will be evaluated whether you have sleep problems and if you meet the criteria for participation. This form will start immediately after you have signed this consent form. If you are qualified for participation and consent to participate you will receive messages and get a phone call from the study administration prior to and after the treatment. The purpose of these contacts will be to give an oral presentation of what the study involves, to answer questions you may have regarding your participation in the study, to remind you to complete the questionnaires and to answer potential technical questions.

Before the treatment starts you will be randomized into one of two possible treatment groups. Both groups have previously been shown to have a good treatment effect on sleep problems in prior research:

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Group 1: In this group you will get access to a web page with relevant information about insomnia and good sleep habits.

Group 2: In this group you will get access to an internet-based treatment-program, designed to give individually adjusted instruction about how to improve your sleep. You will receive weekly assignments to complete. You must complete sleep diaries throughout the whole treatment period (6 weeks)

Participants who live in Trondheim will be contacted and asked to complete additional measurements of sleep and daytime activity with equipment fastened to the wrist (actigraphy). These participants will be specifically contacted about this.

POTENTIAL ADVANTAGES, DISADVANTAGES AND SERIOUS ADVERSE EVENTS

Your participation in this study will not have any consequences for your treatment options at the DPS. This study is an offer you receive in addition to the ordinary treatment at the DPS.

The advantage of participating in this study is that you may get a notably better sleep quality after treatment which may reduce your daytime sleepiness and improve your mood. Your participation may also improve the treatment options for insomnia in Norway, that you and others can receive in the future. A potential disadvantage with a participation in this study is that the program requires effort and time, and some may find this challenging. A part of the treatment may require that your time in bed is restricted for a short period which may result in a short period with a shorter sleep time and increased sleepiness.

VOLUNTARY PARTICIPATION

Participation in the study is voluntary. If you wish to participate, sign the declaration of consent at the bottom of the page. You can withdraw your consent to participate in the study at any time and without stating any particular reason. If you do not wish to participate in the study or wish to withdraw from the study this will not have any consequences for you or your future treatment options. If you withdraw your consent, we will stop the research on your health information. You can also demand to have your health information to be deleted or delivered to you within 30 days. The possibility to have data deleted or delivered does not apply if the data is anonymized. This possibility is also limited if the data is included in completed analyses.

If you wish to withdraw from the study or have any questions concerning the study, you may contact the project leader (see information on the bottom of the page).

WHAT WILL HAPPEN TO YOUR PERSONAL INFORMATION?

Any personal data concerning health that has been recorded about you will only be used as described in the purpose of the study, and will be stored until 31.12.2040. Potential extensions of the storing of the data will only apply after approval from the ethics committee and other relevant authorities. You have the right to access information that has been recorded about you and the right to stipulate that any error(s) in the information that is recorded is/are corrected. You also have the right to know which security measures have been/will be taken when your personal data concerning health is processed.

You have the right to submit a complaint on the processing of your personal health data concerning health to the Norwegian Data Inspectorate (Datatilsynet) and the Data Protection Official (Personvernombud) at the institution.

We will align data from the questionnaires with register data from the Norwegian Patient Registry, the Norwegian Prescription Database, Dødsårsaksregisteret, Kontroll og Utbetaling av Helserefusjon and Forløpsdatabsed (FD Trygd). This is done to obtain information not assessed in the questionnaires, for example diagnosis, reason for referral and the number of prior appointments in different clinics. It will be impossible to identify you in the result of this study when they are published. All information will be processed and used

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without your name or personal identification number, or any other information that is directly identifiable to you. A code links you and your personal data concerning health via an identifier list. Only the project leader Håvard Kallestad and the head of department at St.Olavs Hospital, Østmarka will have access to this list.

Information about you will be anonymized or deleted five years after the project has ended

SHARING OF PERSONAL DATA AND TRANSFER OF PERSONAL DATA ABROAD

By agreeing to participate in the study, you are also consenting to that your information acquired through questionnaires can be transferred to another country as a part of research collaboration and publication. This can be a country where the laws do not meet the requirements of the European Data Protection Law. The project manager will therefore ensure that your personal data concerning health is kept safe. The code that connects you and your personal data concerning health will not be released. All personal data will be processed in accordance with the European Data Protection Law (GDPR).

INSURANCE

As a participant in this study you are insured through the Norwegian patient injury compensation.

APPROVAL

The Regional Committee for Medical and Health Research Ethics has reviewed and approved the Research Project, REK Sør-Øst B 125068.

In accordance with the General Data Protection Regulation the controller St. Olavs Hospital and the project manager Håvard Kallestad is independently responsible to ensure that the processing of your personal data concerning health has a legal basis.

The processing of your personal data is based on your consent.

The processing of personal data is in accordance with the General Data Protection Regulation art. 6 e and art 9 number 2 j and the Norwegian “helseforskningsloven” § 9. Your consent ensures codetermination, openness, and predictability for you in this research project.

CONTACT INFORMATION

If you have any questions regarding the research project, you can get in touch with the project leader Håvard Kallestad, tlf 72823030, or the study coordinator, tlf 920 62 945, or send an email to post@sovnmestring.no.

St.Olavs Hospital is the controller for your personal data in this project, St. Olavs Hospital, Postboks 3250 Torgården, 7006 Trondheim.

You can also get in touch with the Institution’s Data Protection Officer (personvernombud) if you have any questions related to the use of your personal health data concerning health in the research project personvernombudet@stolav.no.

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Chapter A – Further explanation of what the study involves

SCHEDULE – WHAT HAPPENS AND WHEN DOES IT HAPPEN?

This is a schedule over your participation in the study including an explanation of what each time point of assessment involves and how much time it requires.

Weeks	0 weeks	1-8 weeks	9 weeks	6 months	1 year
Inclusion screener	X				
Questionnaires	X		X	X	X
Sleep diaries	X	X	X	X	X
Treatment		X			

The inclusion screener will take approximately 10 minutes to answer and will evaluate your sleep problems to ensure that the treatment in this program is suitable to you. If you are included in the study we will ask you to answer questionnaires about your work- and family situation, your sleep and health (maximum 30 minutes). You will also be asked to complete sleep diaries 10 days before the treatment, 10 days after treatment, 10 days 6 months after treatment and 10 days 1 year after treatment. If you are randomized to Group 2 you will also be asked to complete sleep diaries during the treatment (6 weeks).

Treatment: You will be randomized into one of two possible treatment groups:

- Group 1: You will get access to a web page with information about insomnia and good sleep habits. You will have access to this page in six weeks and may log in and read the content as many times as you wish in this period. There are no specific requirements beyond this.

- Group 2: You will get access to an interactive treatment program via the internet. This program is designed to give you individually adjusted instruction about how to improve your sleep. The treatment will last for 6 weeks. You will receive weekly assignments to complete and you will be asked to complete sleep diaries via the internet every day. This will require 1 – 2 hours of your time every week.

POTENTIAL ADVANTAGES, DISADVANTAGES AND ADVERSE EVENTS

The treatment being used in this study have been tested in several studies in Norway and other countries. The results have shown that those who use this treatment achieves a lasting improvement of their sleep and daytime functioning (less sleepiness and improved mood). An advantage of participating in the study is therefore that your sleep may be improved and that you may experience less sleepiness and improved mood in the daytime.

One part of the treatment involves completing assignments aimed to change your sleep habits. This requires effort and time as described above. Some may experience this as challenging.

If you are randomized to Group 2 you may be asked in the start of the treatment to reduce the time you spend in bed. This can result in less sleep and increased daytime sleepiness in the start of the treatment. This will be a transitory period and is an important step towards improving your sleep.

If you experience a worsening of your condition during the treatment you can contact the acute ambulatory team or the health professional at the DPS where you receive your health services. These will

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evaluate and ensure that you receive the necessary treatment. This follow-up and treatment are independent of the participation in this study, but we will receive information from the team if the follow-up suggest that the event is associated with your participation in the study.

OTHER CIRCUMSTANCES

If new information becomes available that might influence your willingness to participate in the study, we commit ourselves to inform you as soon as possible. We wish that you inform us if there are circumstances that may influence your qualification in the study. This may for example be if you start working night shifts. We also wish that you inform us if you for any reason want to end your participation in the study earlier than planned.

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I CONSENT TO PARTICIPATING IN THE RESEARCH PROJECT AND THAT MY PERSONAL DATA CONCERNING HEALTH AND BIOLOGICAL MATERIAL CAN BE USED AS DESCRIBED AS ABOVE

City/Town, date

Participant's Signature

Participant's Name (in BLOCK LETTERS)