



JÖNKÖPING UNIVERSITY

Information and invitation to participate in an ongoing research study examining the effects of internet-based self-care using cognitive behavioral therapy (CBT) for individuals with restless legs syndrome

A research study is currently underway at Jönköping University examining the effects of a digital self-care program using cognitive behavioral therapy (CBT) for individuals with restless legs syndrome (RLS). The attached documents provide further information about the study and an invitation to participate.

Contact details for the project leads:

Anders Broström, Professor

Email: anders.brostrom@ju.se

Telephone: +46-72-228 44 09

Elzana Odzakovic, Assistant Professor

Email: elzana.odzakovic@ju.se

Telephone: +46-73-796 68 61



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Why are you receiving this letter?

Restless Legs Syndrome (RLS) is a condition characterized by an irresistible urge to move the legs and/or arms, often accompanied by uncomfortable sensations. This letter is addressed to individuals with RLS and contains information about a research study on the condition, as well as an invitation to consider participating. The study aims to examine experiences of taking part in an internet-based self-care treatment for RLS, and how the treatment affects RLS symptoms, sleep problems, depressive symptoms, and life situation. The treatment is based on cognitive behavioral therapy (CBT).

The study is conducted at Färjestaden Health Center, Region Kalmar County, and includes adults who have been diagnosed with RLS according to their medical records. The Head of Operations at Färjestaden Health Center has been informed about the study and has approved the researchers' access to the relevant diagnostic registry. The research principal for the project is Jönköping University. The research principal is the organization responsible for the project. The study has been approved by the Swedish Ethical Review Authority, and the reference number for the review is 2025-07467-01. This letter was written by the researchers conducting the study and has also been reviewed and approved by the Head of Operations at Färjestaden Health Center. If you choose to participate in the study and return the pre-paid envelope, you will be contacted by the research group for further information.

What is the purpose of the study?

The purpose is to evaluate how a CBT-based self-care treatment delivered via the internet affects RLS symptoms, sleep problems, depressive symptoms, and the overall life situation. The study will also utilize interviews to examine how participants experience the content and structure of the treatment.

How does the study work?

If you choose to participate, you will first be interviewed over the phone by a nurse involved in the study. You will be asked to verbally answer a number of questions about your health to determine if you meet the requirements for participation. The requirements are that you must have a diagnosed RLS, be at least 18 years old, be able to read and understand Swedish, and have an electronic ID (such as Bank-ID). You must not suffer from any other serious health condition or ailment that affects your ability to participate in the study. If you wish to participate and meet the eligibility criteria, you will be granted access to the treatment program.

The study tests an eight-week self-care treatment that is added to your regular treatment for RLS. The treatment is based on cognitive behavioral therapy (CBT). This self-care program, which you can access via either your computer or smartphone, aims to evaluate how CBT-based self-care affects your RLS symptoms when added to your current RLS care. CBT is a form of treatment based on learning strategies to manage various difficulties or symptoms through various exercises and by exploring your own thought patterns and the emotions they trigger. Half of the program (4 weeks) focuses on thoughts, feelings, and the management of sleep problems, while the other half (4 weeks) covers the same areas for RLS symptoms. The content provides you with information about sleep, RLS as a condition, and how RLS can be experienced and managed by individuals. We estimate that it takes about one hour per week to read through the material. Self-care advice regarding sleep and RLS, as well as exercises related to stress management and acceptance, are included. The exercises can benefit from being repeated, and the time this takes depends on how often you use them.

While you are participating in the program, you will receive questionnaires via the treatment platform on three occasions (before, during, and after the program). The questionnaires cover RLS symptoms, sleep, health, emotional well-being, and your views on the content and implementation of the program. You will receive these questionnaires once before the treatment starts, once during the program, and once immediately after you have finished. The questionnaires are sent to you automatically via the treatment platform, and you answer them within the program using your computer or phone. Completing the questionnaires is estimated to take approximately 15–20 minutes each time. The medication you receive for RLS is based on what you and your doctor have decided and is not affected by whether you participate in the study or not. If you would like to participate in the digital cognitive behavioral therapy-based self-care treatment, please indicate this on the form on the last page of this information. Send the form in the pre-paid envelope to the project lead, Anders Broström.

If you consent to participate in the internet-based CBT self-care treatment, you are also invited to take part in telephone interviews on three occasions (once before, once during, and once after the program). If you choose not to consent to the interviews, you will not be contacted for them. You can participate in the internet-based CBT self-care treatment without

being interviewed. You may also decline further participation in the interviews at any time, even after completing one or two of them.

The interviews are conducted by a nurse involved in the study and will be recorded and transcribed. The interview questions concern your experience of living with RLS (interview before), your thoughts on the content of the self-care treatment (interview during), and how you feel the treatment has affected your situation (interview immediately after). It is difficult to say exactly how long an interview will take, as it depends on how much you choose to share. Typically, these types of interviews take 30–60 minutes. Those who choose to be interviewed decide the time for the interview. Only the interviewer will know your identity; other members of the research group will only have access to the transcribed interview, with no information that can be linked to you personally. If you are willing to be interviewed, please indicate this on the form on the last page of this information. Please also provide your contact details (phone number). Send the form in the pre-paid envelope to the project lead, Anders Broström.

Are there any possible consequences or risks of participating in the project?

Your participation will not affect your medication or any other treatments. Internet-based cognitive behavioral therapy is an established and widely used treatment for sleep problems, but it has not yet been tested for patients with RLS. The treatment may initially be perceived as strenuous, as you are encouraged to sleep less, which is a standard part of the therapy. This may lead to increased daytime sleepiness for a period of time. We recognize that this, as well as answering questionnaires (both individually and repeatedly) and participating in interviews, can be demanding; however, you can always choose not to answer questions you do not feel comfortable with. The questionnaires used in the study have been previously tested and used in other research. If you find the interview situation difficult, you can terminate the interview without providing a reason. If you have participated in one interview, you may decline participation in further interviews without providing a reason. No specific benefits can be promised to you personally. In the long term, the knowledge gained through this study can hopefully be used to improve care for future patients receiving the same treatment.

For you as an individual, there are no obvious or direct benefits to participating in the study. The hope is that the results will improve the treatment of patients with RLS in the future and strengthen patients' ability to manage their symptoms through self-care. Participation does not involve any changes to medications, blood tests, or other examinations. The questions in the surveys and interviews concern your health and symptoms, which are details that can be perceived as sensitive or personal. Participation is entirely voluntary, and even if you choose to participate, you may refrain from answering any questions you find sensitive or do not wish to answer. You may decline further participation in additional interviews after completing one or two, without providing a reason and without affecting the quality of your

regular care. If you have any questions, do not hesitate to contact project lead Anders Broström (anders.brostrom@ju.se or 072 – 228 44 09).

What will happen to your data?

The collected information (data) consists of your responses to the questionnaires and the recorded and transcribed interviews. The researchers will not have access to your medical records. Your answers will be handled so that unauthorized persons cannot access them. In addition to the surveys and interviews, the researchers wish to collect information regarding your age, gender, medical history, marital status, education level, and facts about your RLS diagnosis (such as current treatment). You will provide this information yourself through your responses within the treatment program. This information is collected to see if factors other than the program affect your RLS symptoms and sleep. All forms of personal data are "pseudonymized," which means a code is assigned to each person to ensure that the answers provided cannot be linked directly to you. Results published from the study are presented at the group level and will not contain any information that can be traced back to you as an individual.

All collected information will be stored on a server at Jönköping University, where only researchers involved in the study have access to the content. According to law, the storage period for archiving is 10 years, after which all information will be deleted. Jönköping University is responsible for your personal data. According to the EU General Data Protection Regulation (GDPR), you have the right to access the data processed about you in the study free of charge and, if necessary, have any errors corrected. You can also request that your data be deleted and that the processing of your personal data be restricted. However, the right to deletion and restriction of processing does not apply when the data is necessary for the ongoing research. If you wish to access your data, please contact the principal investigator: Anders Broström, anders.brostrom@ju.se or 072 – 228 44 09. The Data Protection Officer at Jönköping University is Oscar Westergren, who can be reached at oskar.westergren@ju.se or dso@ju.se. If you are dissatisfied with how your personal data is handled, you have the right to lodge a complaint with the Swedish Authority for Privacy Protection (IMY), which is the supervisory authority.

How will you receive information about the results of the study?

If you wish to access your own data (individual data) and/or the study results, you can contact the project leads (see below). Results from the study as a whole will be published in scientific journals in English, as well as in popular science descriptions in Swedish in appropriate magazines. If you wish to read these articles, you can order them through a library. Upon request, the project group can provide you with the information the library needs to order the articles for you.

Insurance and compensation

No insurance has been taken out for the study participants, as the study is not assessed to involve any insurable risks. As a participant, you will not receive any payment or other compensation, and no financial costs are expected to arise for you should you choose to participate.

Participation is voluntary

Your participation is voluntary, and you may choose to withdraw at any time. If you choose not to participate or wish to withdraw, you do not need to provide a reason, and it will not affect your future care or treatment. If you wish to withdraw your participation, please contact the principal investigator (see below). If you choose to withdraw after completing part of the study, you may choose whether your collected data should be destroyed or if you agree to its continued use in the research.

Contact details for the project leaders:

Anders Broström, Professor

Elzana Odzakovic, Assistant Professor

Email: anders.brostrom@ju.se

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