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Development and pilot testing of a digital cognitive behavioral therapy (CBT)-based self-care treatment for patients with restless legs syndrome

Submission date
28/05/2026

Recruitment status
Recruiting

Registration date
28/05/2026

Overall study status
Ongoing

Last Edited
28/05/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Restless Legs Syndrome (RLS) is a long-term condition that causes uncomfortable "crawling" sensations or pain in the legs, usually in the evening. This often leads to severe sleep problems, daytime tiredness, and a lower quality of life. In serious cases, it can also lead to feelings of depression or anxiety. Currently, RLS is managed with lifestyle changes or medication. However, common medications can sometimes cause a problem where symptoms actually get worse over time. Because of this, there is a great need for new, drug-free ways to help patients. Cognitive Behavioral Therapy (CBT) is a type of treatment that helps people manage long-term health issues by changing how they handle their symptoms and daily habits. While CBT is known to help with other conditions like chronic pain, there is almost no research on using it for RLS through digital tools. We have developed and will in the current study test a digital CBT-based self-care program that patients can use on their phone or computer. The program includes specific steps to help with RLS symptoms, sleep habits, and insomnia. Our goal is to provide a new, easy-to-use tool that helps patients manage their condition and feel better in their daily lives.

Aim:
To evaluate participant recruitment and experiences of the treatment content, as well as the feasibility of and adherence to the digital CBT-based self-care intervention, focusing on the number of eligible patients who accept participation and complete both the intervention and its assessments. Furthermore, the potential effect of the intervention on patient-reported and clinical outcomes will be evaluated.

Who can participate?
The study is open to adults aged 18 years or older who have a confirmed diagnosis of RLS.

Potential participants will be excluded if they have a serious illness that significantly limits their life expectancy or if they have certain severe mental health conditions that would make participation unsuitable. Additionally, individuals with a history of drug or alcohol dependence

within the last two years are not eligible to take part. The study also excludes those who are unable to independently understand or sign the consent form, as well as anyone who requires a third party, such as an interpreter or caregiver, during medical appointments. Finally, because the treatment is digital, those without access to the internet, a computer, or a smartphone cannot participate.

What does the study involve?
This study uses a pilot test design to evaluate a digital CBT-based self-care program that has been developed together with patients. The CBT treatment is delivered through a secure online platform called BASS, created by Karolinska Institutet in Sweden. Participants with RLS will follow an eight-week program consisting of one module per week. These modules use text, pictures, and practical exercises to help manage both sleep problems (insomnia) and specific RLS symptoms. The content includes easy-to-understand information about the condition, advice on medications, and techniques for managing stress and learning to live with the symptoms. To make the program relatable and practical, each week includes "stories" based on real-life experiences of people living with RLS. These stories have been checked by patients to ensure they are helpful and relevant to daily life. Participants in the study will complete questionnaires before, during, and after the treatment. These surveys cover areas such as RLS symptoms, sleep, and quality of life, as well as the participants' experiences using the treatment program. We will also conduct interviews with patients on three separate occasions (before, during, and after the treatment). All work regarding participant recruitment, delivery of the treatment, and data collection will take place during 2026–2027.

What are the possible benefits and risks of participating?
The study offers a new CBT-based self-care program providing potential benefits with minimal risk. As the treatment is digital and educational, and complements the individual's current pharmacological treatment, there are no clear and foreseeable physical risks or side effects. While reflecting on symptoms during interviews may be emotionally challenging, we ensure a supportive environment. The participant’s privacy is protected using a highly secure, established platform (BASS) and strict confidentiality laws. Participation is entirely voluntary, and the person can withdraw at any time. Overall, the benefit of developing an accessible way to manage RLS symptoms far outweighs the minor, short-term psychological risks of participation.

Where is the study run from?
School of Health and Welfare, Jönköping University, Jönköping, Sweden.

When is the study starting and how long is it expected to run for?
Study Start Date: June 2026. Primary Completion Date: September 2027

Who is funding the study?
School of Health and Welfare, Jönköping University, Gjuterigatan 5, Jönköping, Sweden. Grants have been received from The Kamprad Family Foundation (Grant/Award number: 20223144) and Medical Research Council of Southeast Sweden (FORSS) (Grant/Award Number: FORSS Grant FORSS-969214).

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Additional identifiers

Study information

Scientific Title
Development and pilot testing of a digital CBT-based self-care treatment for patients with restless legs syndrome

Acronym
JU Sleep Well

Study objectives
To evaluate participant recruitment and experiences of the treatment content, as well as the feasibility of and adherence to the digital cognitive behavioral therapy (CBT)-based self-care

intervention, with a focus on the number of eligible patients who accept participation and complete both the intervention and its assessments. Furthermore, the potential effect of the intervention on patient-reported and clinical outcomes will be evaluated.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/12/2025, Swedish Ethical Review Authority (Swedish Ethical Review Authority, Box 2110, Uppsala, 75002, Sweden; +46-10-4750800; registrator@etikprovning.se), ref: 2025-07467-01

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Restless legs syndrome

Interventions
The digital CBT-based treatment is delivered via BASS, a well-established platform from Karolinska Institutet, and consists of two parts: one focusing on insomnia and the other on RLS symptoms. The content includes RLS-specific psychoeducation, descriptions of lived experiences, information on pharmacological treatments related to RLS symptoms, stress management and acceptance, and RLS-specific self-care advice. The program aims to support patients in managing distressing thoughts and feelings that can cause sleep disturbances or exacerbate depressive symptoms, anxiety, and worry. It further aims to help patients find ways to relate to their current situation to achieve symptom reduction, improved sleep quality, and better overall well-being. The intervention comprises eight modules (four for RLS and four for insomnia), with each module having a specific focus. Participants are assigned one module per week.

The Insomnia part:
The intervention includes four weekly modules based on established internet-delivered CBT for insomnia, tailored in this study for RLS-specific needs. The content includes psychoeducation,

sleep diaries, stimulus control, and sleep restriction, as well as deactivation methods and cognitive interventions. Each module integrates “cases” validated by research partners to ensure clinical relevance and high user acceptance. The adaptation of the traditional insomnia protocol is based on data from preparatory studies and iterative consensus discussions between researchers, clinicians, and patients. A central hypothesis is that this part of the digital CBT-based treatment provides particularly high clinical utility for patients with moderate RLS symptoms, where secondary insomnia constitutes a significant portion of the total disease burden.

The RLS part:
The intervention also comprises four weekly modules dedicated to managing specific RLS symptoms. Its development is based on expertise in RLS care as well as CBT for tinnitus, a condition which, like RLS, is characterized by involuntary sensory experiences and distress. By transferring strategies for habituation and acceptance to an RLS context, an innovative support system for patients is created that has never been tested before. Here too, content and exercises have been designed iteratively with research partners to address RLS-specific symptomatology. Each module integrates validated “cases” that strengthen clinical relevance and patient identification. The methodology rests on the same theoretical foundation as the insomnia component but is calibrated for patients with moderate to severe RLS symptoms. A central hypothesis is that this part, in conjunction with medication, is crucial for reducing the disease burden and improving QoL for the most severely affected patients.

Intervention Type
Behavioural

Primary outcome(s)
1. RLS symptoms measured using Restless legs syndrome-6 scale at Three time points; before treatment, during treatment and after treatment

Key secondary outcome(s)
1. Sleep measured using Pittsburgh Sleep Quality Index (PSQI) at Three time points; before treatment, during treatment and after treatment

2. Quality of life measured using The Restless Legs Syndrome Quality of Life Instrument (RLS-QOL) at Three time points; before treatment, during treatment and after treatment

Completion date
20/09/2027

Eligibility

Key inclusion criteria
1. Restless legs syndrome diagnosis (ICD-10: G258, ICD-11: 7A80, 7A87)
2. Min Age: 18 years. Max Age: No limit.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
123 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Disease with short survival (ICD-10: Z51.5, DV097, ZV400)
2. Psychiatric disorder making participation inappropriate (codes F20, F22, F23, or F31 registered twice in the last 2 years)
3. Substance dependence (ICD-10: F10-F19 registered twice in the last 2 years)
4. Inability to provide independent written informed consent
5. Requirement for a representative (e.g., interpreter, third party, or caregiver during clinical contact)
6. Lack of access to the internet, a computer, or a mobile phone

Date of first enrolment
03/06/2026

Date of final enrolment
20/02/2027

Locations

Countries of recruitment
Sweden

Study participating centre
Färjestaden Healthcare Center
Färjestadens hälsocentral, Safirvägen 2
Färjestaden
Sweden
386 34

Sponsor information

Organisation
Jönköping University

ROR
https://ror.org/03t54am93

Funder(s)

Funder type

Funder Name
The Kamprad Family Foundation (Grant/Award number: 20223144)

Funder Name
Medical Research Council of Southeast Sweden (FORSS) (Grant/Award Number: FORSS Grant FORSS-969214)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Consent form		28/05/2026	No	No
Participant information sheet			28/05/2026	No	Yes
Protocol file			28/05/2026	No	No