



JÖNKÖPING UNIVERSITY  
*School of Health and Welfare*

## **Protocol**

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

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## BACKGROUND

RLS is a sensory-motor circadian rhythm disorder (1). The global prevalence in the adult population is estimated at 3% and increases with age (2). The etiology of RLS has been associated with dopaminergic dysfunction, iron deficiency, and genetic predisposition. The diagnosis can be secondary to other diseases or side effects of pharmacotherapy that may induce or exacerbate RLS symptoms (3) (Table 1).

**Table 1.** Diagnostic criteria for RLS (all must be met) according to the International Restless Legs Syndrome Study Group (IRLSSG).

1. An urge to move the legs, usually accompanied by uncomfortable sensations.
2. Symptoms begin or worsen during rest or inactivity.
3. Symptoms are relieved by movement.
4. Symptoms are worse in the evening or night.
5. Symptoms are not solely explained by another medical condition.

The discomfort is often described as crawling sensations, tingling, and pain, primarily in the legs, though it can also occur in the arms and other parts of the body (4). However, significant individual variations exist in how these symptoms are perceived. Symptoms appear during inactivity and are more pronounced in the evening and at night (5), leading to severe sleep disturbances (6). The resulting daytime sleepiness can affect cognition and social relationships, leading to a diminished QoL (7). In cases of severe symptoms, mood impacts such as depression and anxiety may manifest as suicidal ideation. Diagnosis is often made in primary care, where treatment is initiated. Both non-pharmacological (5,8,9) and pharmacological treatments (1) can alleviate symptoms but cannot provide a cure.

A limited number of studies have evaluated the effects of self-care activities such as regular physical exercise, stretching, acupuncture, acupressure, cognitive behavioral therapy (CBT), leg cooling, and various types of mental distraction before bedtime (5,8,9). If self-care activities are insufficient, individualized intermittent pharmacological treatment should be considered (1,10). Dopamine agonists, L-dopa, alpha-2-delta ligands, opioids, or iron are available depending on etiology and severity (1). For continuous medication, a dopamine agonist is often chosen. However, long-term treatment with dopamine agonists carries a risk of augmentation, a paradoxical worsening of RLS symptoms caused by the medication, requiring a dose reduction, discontinuation, or a switch to another medication (11). This can pose a significant barrier to the long-term management of moderate to severe RLS.

RLS shares significant similarities with other chronic conditions (e.g. chronic pain and tinnitus) where pharmacological treatment is either insufficiently effective or unsuitable for other reasons. In such cases, CBT serves as an alternative to improve symptom management and is delivered either face-to-face or via digital tools with equivalent outcomes. The treatment is based on self-observation and exposure, methods utilized in many successful CBT programs. Within this framework, how an individual relates to

their perceived symptoms and their capacity for behavioral change is essential. CBT for RLS can be considered an alternative when added to pharmacological treatment to facilitate the management of mild symptoms, or symptoms that medication does not fully alleviate. Currently, only one small RCT exists where face-to-face CBT targeted insomnia in patients with RLS; it showed positive effects, including reduced sleep problems and improved QoL three months post-treatment (12). However, studies on digital CBT-based self-care as a complement to standard RLS care are entirely lacking. Standard CBT principles can serve as a foundation for developing an RLS-specific intervention. Since disturbed sleep is often the primary reason patients seek care, a CBT-based self-care program need to, in addition to managing RLS symptoms, include modules for insomnia and sleep hygiene.

Digital CBT-based self-care has never been utilized for RLS. Current literature is dominated by a medical perspective focused on pharmacology (1). Despite RLS being a chronic condition with varying drug efficacy, large-scale controlled studies evaluating long-term structured self-care are lacking. This project addresses this gap by introducing the first-ever digital CBT-based treatment for RLS. By shifting focus from passive symptom relief to a proactive, theory-based model, the intervention aims to sustainably enhance patients' QoL, sleep, and psychological well-being. The program's functionality is ensured through the iterative integration of patient and staff experiences regarding treatment needs. Utilizing a co-creative design, the project accounts for e-health literacy (13) and specific barriers to engagement (15), thereby strengthening both feasibility and implementation potential. In the short term, this digital option is expected to increase care accessibility and patient engagement while promoting healthy self-care behaviors. In the long term, the intervention may reduce sleep disturbances and depressive symptoms, improve QoL, and lower healthcare costs for the large primary care population suffering from RLS.

## **AIM**

To evaluate patient recruitment and experiences of treatment content, but also feasibility and adherence to the digital CBT-based self-care treatment, focusing on the number of available patients who accept participation, complete the intervention, and its measurements. The potential effect of the intervention on patient-reported and clinical outcomes is also intended to be evaluated.

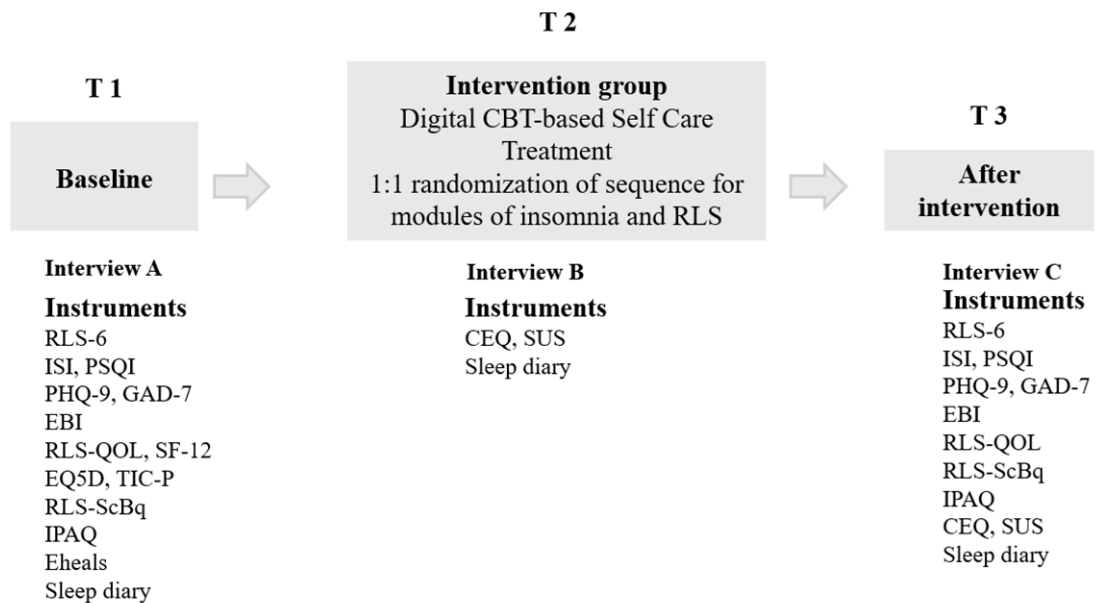
## **Research Questions**

1. How is the content of the digital CBT-based self-care treatment experienced and managed by the participants?
2. How do the planned recruitment pathways and outcome measures function in practice?
3. What are the differences between participants who accept versus decline participation (regarding gender and age), and how do those who drop out differ from those who complete the treatment (regarding gender, age, living situation, education level, and symptom burden)?
4. How are RLS symptoms, sleep, depressive symptoms, and life situation affected for patients with RLS when provided access to a digital CBT-based self-care treatment?

## METHODS

### Design

A quasi-experimental design is used, where a co-created digital CBT-based self-care treatment is tested in a pilot study (Figure 1).



**Figure 1.** Description of study design and instruments.

### Development and content of the digital co-created CBT-based self-care treatment

The program is based on the research group's experience in implementing digital CBT-based treatments, as well as co-creation with strategically selected stakeholders. Eight stakeholders from primary and specialist care across four healthcare regions (including two decision-makers/clinic managers and six healthcare professionals: physicians, psychologists, and nurses), along with six research partners, collaborated as equal partners in the program's design. Medical, psychosocial, and behavioural aspects were discussed, alongside pedagogical and technical considerations. Prototypes were developed and evaluated iteratively to create a user-friendly program. The group has assessed the subject matter, pedagogical structure, layout, and user interface.

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 BASS platform has been utilized in over 200 clinical digital intervention studies.

### **Sampling, data collection, outcome measures, and analysis**

A sample of 40 primary care patients with diagnosed RLS, recruited from Färjestaden Health Center (Region Kalmar), will participate.

*Inclusion criteria* for the study are a diagnosis of RLS (ICD-10: G258, ICD-11: 7A80, 7A87) and an age of 18 years or older. Exclusion criteria include diseases with short life expectancy (ICD-10: Z51.5, DV097, ZV400), psychiatric disorders making participation inappropriate (codes F20, F22, F23, or F31 registered twice in the last 2 years), and substance dependence (ICD-10: F10-F19 registered twice in the last 2 years).

Additionally, individuals are *excluded* if they have difficulty providing independent written informed consent, require a representative, such as an interpreter, third party, or caregiver, during clinical contact, or lack access to the internet, a computer, or a mobile phone. Participants will be recruited via a postal mail-out, where a study nurse is responsible for sending information to individuals identified through patient administrative systems. To access health data for research purposes, an application for data extraction have been approved by the Southeast Healthcare Region (SÖSR), which includes Region Kalmar County. Data have been released to the study nurse following approved confidentiality and harm assessments according to established procedures.

Data collection is described in Figure 1 and Table 2. Questionnaires are used to evaluate the content and feasibility of the intervention and the study protocol. Self-reported demographic, clinical, and treatment-related data, as well as questionnaires, are collected at baseline (T1), during the program (T2), and post-intervention (T3). Adherence to the treatment program is measured through logins and the completion of exercises.

Semi-structured interviews with 20–30 strategically selected patients with RLS are conducted before, during, and after the treatment (Figure 1). Qualitative methods, including content analysis (17), phenomenography (18) and critical incident technique (19), are used. Experiences and perceptions are gathered regarding the prerequisites for participation in a digital CBT-based self-care treatment (Interview A); the pedagogical structure, design, and factual content of information texts; and the feasibility and usability of exercises (Interview B). Experiences of factors that hinder or facilitate the usability of the digital CBT-based self-care treatment, and how these are managed, are also studied (Interview C).

Questionnaires regarding the treatment's usability will be answered by the participants via the digital platform (BASS) during the program.

**Table 2.** Instruments used in the pilot study.

Area	Instruments	References	Items
RLS-symptoms	Restless Legs Syndrome-6 Scale (RLS-6)	Kohnen et al 2016	6
Insomnia	Insomnia Severity Index (ISI)	Morin et al., 2011	7
Sleep	Pittsburgh Sleep Quality Index (PSQI)	Buysse et al., 1989	19
Depression	Patient Health Questionnaire-9 (PHQ-9)	Kroenke et al., 2001	9
Anxiety	General Anxiety Disorder-7 (GAD-7)	Spitzer et al., 2007	7
Wellness	Ethos Brief Index (EBI)	Knutsson et al., 2024	8
Quality of life	The Restless Legs Syndrome Quality of Life Instrument (RLS-QOL)	Abetz et al., 2005	18
	12-Item Short Form Survey (SF-12)	Ware & Sherbourne 1992	12
Self-care	RLS-Self-care Behaviour questionnaire (RLS-ScBq)	Odzakovic et al., 2024b	8
Coping	Pearlin Mastery Scale	Hellström et al., 2024	7
Physical activity	International Physical Activity Questionnaire (IPAQ)	Hagströmer et al., 2006	7
Usability	Credibility/Expectancy Questionnaire (CEQ)	Deville & Borkovec 2000	6
	System Usability Scale (SUS)	Deshmukh & Chalmeta 2024	10
Healthliteracy	EHeals	Nguyen et al 2016	8
Healtheconomy	EQ-5D	Devlin & Brooks 2017	5
	Treatment Inventory of Costs in Psychiatric Patients (TIC-P)	Timman et al., 2015	14

### Data collection

The questionnaires used are listed in Table 2, and their distribution across the three measurement points is described in Figure 1.

Participant adherence and usage are measured through logins and the completion of exercises within the digital platform. Adherence is evaluated based on the ratio between intended use and actual use. Usage is calculated as the number of times participants open the program per week, divided by the number of weeks (modules) in the program. The usability of the treatment programs is measured using questionnaires (CEQ and SUS) during and after both programs (Table 2).

Semi-structured interviews with 20–30 strategically selected patients with RLS will be conducted post-treatment (Figure 1). Qualitative methods, including content analysis (17), phenomenography (18), and critical incident technique (19), will be used. Data will be analysed regarding perceptions of the pedagogical structure, the design of the factual content in the texts, and the feasibility and usability of the exercises. Experiences of factors that hinder or facilitate the usability of the CBT-based self-care treatment, as well as how these factors are managed, will also be studied.

### Power

No previous studies have utilized a digital CBT-based self-care treatment for RLS. The pilot study size of 40 participants is considered to provide sufficient information

regarding feasibility, as well as quantitative data for a power calculation for a future RCT.

## **Analyses**

### Hypotheses related to PROMs and practical use

#### *Primary Hypothesis*

The digital CBT-based self-care treatment, delivered in a primary care setting, significantly reduces RLS symptoms and insomnia and improves RLS-related quality of life.

#### *Secondary Hypotheses*

The digital CBT-based treatment significantly improves sleep quality and quality of life and reduces depressive symptoms in patients with RLS.

### Statistical analyses of demographic data, PROMs, practical use, and healthcare utilization

Descriptive and analytical statistics for demographic, clinical, and survey data are analysed based on scale level, distribution, and research questions. Categorical variables are tested using Chi-squared, while continuous variables are analysed with independent t-tests or Mann-Whitney U tests. Changes in RLS symptoms (RLS-6), sleep (PSQI), and quality of life (RLS-QOL) from baseline to post-intervention will be analysed using paired samples t-tests or Wilcoxon signed-rank tests, depending on data distribution. Effect sizes (Cohen's d) will be calculated to assess the intervention's magnitude and inform future power calculations.

### Analysis of interview data

The analytical procedure follows established practices for the qualitative methods utilized (17, 18, 19). Transcribed interviews are reviewed by the group. Text segments describing perceptions, experiences, and management related to the specific aims are extracted. These are then organized into a category system where consensus and trustworthiness are established.

## **SIGNIFICANCE**

There is a lack of knowledge regarding the design and effects of digitally delivered self-care treatment as a complement to pharmacological treatment for RLS. A digital CBT-based self-care intervention that reduces RLS symptoms, improves sleep, decreases depressive symptoms, and enhances the overall life situation could be of significant value to a large group of patients with RLS.

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