



Cognitive behavioural group therapy to improve patients' strategies for coping with restless legs syndrome: a proof-of-concept trial

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ABSTRACT

Background: Restless legs syndrome (RLS) is a usually chronic disorder accompanied by clinically relevant psychosocial impairment. To date, no psychologically based approach is available to improve the coping strategies and quality of life of RLS sufferers.

Objective: To develop cognitive behavioural therapy tailored to this disorder (the RELEGS coping therapy programme) and present the results of this proof-of-concept study.

Methods: Twenty-five patients (five men, 20 women; 15 medicated, 10 unmedicated; mean (SD) age 56.1 (12.3) years) with subjective psychosocial impairment due to RLS participated in one of three consecutive therapy groups. The severity scales (IRLS and RLS-6) indicated moderate to severe RLS symptoms at baseline. Exclusion criteria were secondary RLS, foreseeable change of RLS medication during the study period, serious physical or psychiatric comorbidity, and severe cognitive deficits. Each group took part in eight group sessions (90 min each with a break).

Results: At the end of the treatment, both the RLS-related quality of life and the mental health status of the subjects had improved significantly (QoL-RLS scale: from 28.6 (12.8) to 23.4 (13.1); SCL-90-R: from 51.3 (37.0) to 45.9 (32.9)). The improvement remained at follow-up 3 months later. Subjective ratings of RLS severity had improved at the end of therapy and at follow-up. Psychometric scales not specific for RLS-related impairment remained unaffected by the treatment.

Conclusions: The study establishes the feasibility and high acceptance of the newly devised therapy programme. The application of RLS-oriented specific psychological strategies is a step toward an integrated treatment approach in RLS.

Restless legs syndrome (RLS), a common sensorimotor disorder,¹ usually has a chronic course with progression of symptom intensity in older people.² In clinical trials, dopaminergic substances showed good efficacy in the short-term treatment of RLS, although complete remission of symptoms does not occur in all patients,³ and long-term treatment with dopaminergic drugs may be complicated by loss of efficacy and augmentation.⁴ Symptom persistence has an effect on the general condition of patients, and recent studies have shown a high incidence of psychosocial impairment,⁵⁻⁷ a reduced quality of life,¹ and an increased prevalence of depressive and anxiety disorders associated with RLS.⁸

We developed a psychologically based group therapy approach tailored to the specific aspects of the disorder, with the aim of improving coping strategies and quality of life of patients with RLS (the RELEGS, Restless Legs Skills programme). The programme integrates cognitive behavioural elements and acceptance-based mindfulness approaches^{9,10} (for the conception of the study, see the addendum published online as supplementary material). The presented study is a proof-of-concept investigation to evaluate the feasibility, patient acceptance and efficacy of the group therapy.

PATIENTS AND METHODS

Approval for the study was granted by the local ethics committee. All patients gave their written informed consent before participating in the study.

Design

For this pilot study, we performed a pre-post comparison of outcome measures taken at baseline, at an intermediate mid-treatment assessment after 4 weeks, and at the final visit after conclusion of the group therapy as well as at follow-up. There was no control group. Evaluations of outcome parameters were performed by an independent rater who was not involved in any of the therapy procedures.

Patients

The group therapy was offered to a cohort of all patients with RLS seen during the study period at our Sleep Disorders Outpatient Unit. RLS diagnosis was based on accepted criteria.² For inclusion, patients must have reported in the clinical interview bothersome psychosocial impairment due to RLS. Both medicated and unmedicated patients were included in the study. Some of the medicated patients did not wish a further increase in dose. In other cases, a further increase in dose or a change of dopamine agonists or add-on therapies (eg, opiates) led to barely tolerable side effects. Exclusion criteria were secondary RLS (due to an underlying disorder known to trigger RLS, eg, renal failure, autoimmune disorders) serious physical comorbidity with possible deterioration of quality of life (eg, neurodegenerative disorders, active malignant tumours), serious psychiatric comorbidity (eg, severe depression with suicidality, post-traumatic stress disorder, substance dependency) and severe cognitive deficits. The screening procedure

consisted of a semi-structured interview to ascertain history of sleep disturbance, physical examinations, serum biochemistry and the Structured Clinical Interview for DSM-IV-TR.¹¹ Patients were untreated or could continue their current RLS medication if treatment response had been stable for 4 weeks before screening and no change of RLS medication during the study period was foreseeable.

Group setting

Three consecutive groups underwent a structured therapy programme. Each group session was chaired by two therapists, both trained in sleep medicine and psychotherapy. The therapists worked in the Sleep Disorders Outpatient Unit and were familiar with the clinical picture of RLS. After training of both therapists in the modules of the RELEGS programme, group sessions for each group took place on a weekly basis for a total of eight sessions of 90 min each (each session with a break).

Contents of the group therapy, questionnaires and psychometric scales

For a detailed description, see the addendum published online.

Statistical analysis

To test for treatment effects, statistical analysis of the within-subject changes used the Wilcoxon signed rank test. *p* Values (two-sided) <0.05 were considered indicative of non-random changes, and all test results were interpreted in an exploratory manner. The primary outcome measure was the change in the RLS-specific quality of life (QoL-RLS)¹² total score. The analyses were based on data from all participants; two patients without valid values at the follow-up assessment were excluded from analysis (one patient took additional RLS-specific medication during the follow-up period, and the other patient forgot to fill in the SF-36 questionnaire¹³ at follow-up). Unmedicated patients and patients receiving RLS-specific medication were

compared using the Mann–Whitney test. For this study, three coping therapy groups were planned with at least seven participants per group to evaluate stability of effects.

RESULTS

Participants

Data from 25 patients (five men, 20 women) in three groups were evaluated (nine, seven and nine participants in the groups, respectively). All patients completed the coping therapy programme. Most patients were middle-aged (mean (SD) 56.1 (12.3) years; range 35–76). In the Structured Clinical Interview for DSM-IV-TR, two patients were diagnosed as having a moderate recurrent depressive episode without suicidality, and two others had generalised anxiety disorder. The remaining patients had no psychiatric comorbidity. Ten patients were unmedicated, and 15 patients continued with their previous RLS-specific medication, which had not been changed during the study period (L-dopa, pramipexole, ropinirole, cabergoline and combinations of these). Unmedicated and medicated patients did not differ in statistical terms with regard to their age and their baseline scores (see the addendum, table 1A). The severity scales (IRLS, RLS-6) indicated moderate to severe RLS symptoms (table 1).

Psychosocial scales

Table 1 summarises the changes in the evaluated scales. There was a remarkable improvement at the end of the coping therapy course in RLS-specific aspects of quality of life (QoL-RLS, IRLS subscale “symptom impact”) and in mental health status (SCL-90-R). Sleep quality had improved at the end of the therapy (RLS-6 scale “sleep satisfaction”). Besides the global score of the SCL-90-R, the corresponding subscale “anxiety” had decreased significantly between baseline and the end of the course (from 6.0 (5.7) to 5.3 (4.7) points; *p* = 0.036). These effects remained stable until the follow-up visit. In addition, improvements were noted in the WBS-5 and the SF-36 mental component summary

Table 1 Psychometric assessments of the group therapy: quality of life and psychopathological measures

Scale	Baseline (BL)	After therapy (END)	<i>p</i> Value (BL vs END)	Follow-up (FU)	<i>p</i> Value (BL vs FU)
QoL-RLS ¹²	28.6 (12.8)	23.4 (13.1)	<0.001	21.2 (9.7)	0.001
SCL-90-R ¹⁴	51.3 (37.0)	45.9 (32.9)	0.031	43.7 (34.8)	0.001
WBS-5 ¹⁵	12.7 (4.6)	13.6 (4.3)	0.207	14.8 (4.2)	0.034
SF-36: mental component summary ¹³	46.0 (11.7)	47.4 (10.9)	0.445	49.8 (7.9)	0.026
SF-36: physical component summary ¹³	45.4 (9.3)	45.7 (10.4)	0.978	44.8 (9.6)	0.854
IRLS total score ¹⁶	25.9 (6.9)	19.1 (6.3)	<0.001	18.9 (7.0)	<0.001
IRLS subscale: impact of RLS on daily life ¹⁶	6.0 (2.3)	4.2 (1.9)	<0.001	4.0 (1.7)	<0.001
IRLS subscale: severity of RLS symptoms ¹⁶	15.1 (3.4)	11.1 (2.7)	<0.001	11.3 (4.4)	<0.001
RLS-6: severity at bedtime ¹⁷	5.2 (3.3)	3.1 (2.7)	0.008	3.0 (2.6)	0.004
RLS-6: severity during the night ¹⁷	4.4 (3.5)	3.4 (2.7)	0.096	3.7 (2.9)	0.339
RLS-6: severity during the day when at rest ¹⁷	2.7 (2.5)	1.7 (1.6)	0.010	1.8 (2.0)	0.077
RLS-6: satisfaction with sleep ¹⁷	6.4 (2.4)	4.5 (2.6)	0.009	5.0 (2.2)	0.035

Values are given as mean (SD). Results of the mid-treatment evaluation are reported in the text. BL, baseline evaluation; END, evaluation at the end; FU, evaluation 3 months after the end of therapy; QoL-RLS, Quality of life in RLS (0 = excellent, 54 = very bad. Note: item 8, asking for side effects of medication, was omitted); SCL-90-R, Symptom Check List-90 Revised Version (population-based reference value: 50 (10)); WBS-5, WHO-5 Well-Being Scale (0 = very bad, 25 = excellent; scores ≤ 13 indicative of depression); IRLS, International RLS Severity Scale (0 = no symptoms, 40 = very severe symptoms); IRLS impact subscale, sum score of the IRLS items 5, 9 and 10 (0 = no impairment, 12 = very much impaired); IRLS severity subscale, sum score of the IRLS items 1, 2, 4, 6, 7 and 8 (0 = no symptoms, 24 = very severe symptoms); RLS-6 scales, for each item: 0 = no symptoms, 10 = very severe symptoms.

score. At the mid-treatment evaluation, improvements in the IRLS global scale, the IRLS subscales and the RLS-6 (severity at bedtime) were already present (data not shown). The anxiety and the depression subscores of the Hospital Anxiety and Depression Scale¹⁸ and the total score of the Beck Depression Inventory¹⁹ did not change during the therapy. Unmedicated patients showed a tendency to benefit more than medicated patients, although there was no statistically significant difference between the groups.

RLS severity scales

Subjective ratings of RLS severity in the IRLS total score and the IRLS subscale “symptom severity” showed an overall improvement in RLS symptoms (see also table 1). The profiling of symptoms at different time periods during the day showed favourable changes in the RLS-6 scales “severity at bedtime” and “severity during the day when at rest”, but no changes in the scale “severity during the night”.

Global rating of patients

In the last session, patients were requested to rate different aspects of the coping therapy. The first part of this questionnaire comprised items about the global effect of the therapy. Patients rated the group therapy on a scale from 4 to 0 (“I agree fully” to “I do not agree”) as specific for RLS-related issues (3.9 (0.3)), of feeling better educated about RLS (3.8 (0.4)), and feeling better able to cope with RLS (3.2 (0.8)). In the second part, patients were asked to rank the most helpful elements of the therapy. Patients ranked as most helpful (in descending order) the mindfulness-based exercises (including breathing exercises), stress reduction strategies, diary-based analysis of factors aggravating RLS, and medical education.

DISCUSSION

We here present the evaluation of the first psychologically oriented approach to RLS management, the RELEGS therapy programme. The evaluations indicate disorder-specific effects on RLS-related quality of life and demonstrate the feasibility and high patient acceptance of the therapy programme.

An unexpected effect of the therapy was the significant improvement in RLS severity. The RLS-6 scales show that relief from symptoms occurred primarily when patients were awake but not during the night, indicating that the patients used the acquired coping strategies in their daily life. Furthermore, a change in the cognitive interpretation of RLS symptoms and its consequences during the course of therapy had possibly occurred—that is, a change in the subjectively perceived “bothersomeness” of the disorder.

We developed the group therapy both as a stand-alone treatment for unmedicated patients with RLS who do not need pharmacotherapy and as an adjunctive therapy for patients with partial remission of RLS symptoms under medication. We found no differences in the outcome measures between the two subgroups. The coping therapy therefore can be applied in both medicated and unmedicated patients. As our main concern was to evaluate the feasibility of the therapy programme, we did not have a control group and for this reason cannot exclude placebo effects. To confirm the efficacy of the coping therapy, randomised controlled studies (eg, using non-disorder-specific behavioural therapy and a standardised manual) are necessary and are currently being designed by our group.

A better understanding of the bio-psycho-social consequences of chronic diseases over the last few years has resulted in

recognition of the importance of patient self-management and health literacy.²⁰ Increasing evidence shows that adequate coping strategies—that is, adequate self-management—improves outcome and reduces overall managed-care costs in chronically ill patients.²¹ Current treatment trials in RLS still focus on drug therapy, and comprehensive psycho-biological management strategies have yet to be developed for this patient population. The therapy presented in this paper may be an important step in the development of an integrated treatment approach to RLS management.

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