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Feature Article

Pilot testing a stretching regimen for prevention of night time nocturnal leg cramps

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ABSTRACT

Nocturnal leg cramps (NLC) are painful, involuntary muscle contractions that affect the quality of sleep. The aim of this study was to examine the feasibility and effectiveness of a stretching regimen in frail older adults aged over 75 years with NLC. The experimental group ($n = 15$) received an intervention, which they were instructed to perform three daily exercises to stretch the calves and hamstrings. After six weeks, frequency and pain intensity of NLC were both significantly decreased in the experimental group compared to the control group. A paired samples t -test reveals a statistically significant decrease in cramp frequency ($t = 2.2$, $df 28$, $P = 0.04$) and cramp intensity ($t = 2.7$, $df 28$, $P = 0.01$). Therefore, a six-week stretching regimen is likely to reduce the frequency and pain intensity of NLC in frail older adults aged over 75 years.

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Introduction

Nocturnal leg cramps (NLC) in the calf, hamstrings, or foot are characterized as intensely painful, involuntary muscle contractions lasting from mere seconds to a maximum of 10 min, which affect the quality of sleep and may result in distress.^{1,2} In most cases, persistent pain continues afterwards. Although the diagnostic criteria are highly distinctive, NLC is often confused with restless legs syndrome (RLS).¹ In contrast, RLS is characterized by uncomfortable sensations in the legs, feet, or arms with an urge to move the limbs so as to partially or totally relieve the unpleasant sensation. RLS generally occurs during rest in the evening or at night.³ NLC is often associated with chronic diseases such as chronic liver and renal failure, vascular diseases, varicose veins, dehydration, and magnesium or calcium deficiency.⁴ The incidence and prevalence of NLC increases with age, and older females are more affected than older males.^{5,6}

Although based on conflicting evidence and associated with multiple adverse effects, quinine is the most common pharmacological treatment option.⁷ In contrast to this, non-pharmacological interventions such as a pre-sleep stretching technique have proven to be effective in reducing the frequency and intensity of the

cramps in a vital sample of older adults with a mean age of 70 years.⁸ This pre-sleep stretching regimen is easy to perform just before sleep with no recognized side effects. Although a gold standard is lacking, frailty can be defined as a clinical syndrome involving physical and cognitive functioning associated with ageing and is combined with disability and chronic diseases.⁹

Because NLC increases with age and is associated with several comorbidities and side effects of medication use, it is not clear whether the stretching protocol can be implemented in frail older adults aged over 75 years.¹⁰ It is shown that the population of frail older adults is less physically active and accompanied by a decline in mobility, which results in an increase in shortened muscle length.¹¹ Consequently, frail older adults may be more at risk of developing NLC.¹² The stretching of muscles in frail older adults increases the range of motion and functional mobility, resulting in improved gait and preventing the loss of knee extensor performance.^{13,14}

The purpose of this study was to examine the impact of a stretching protocol on the incidence of leg cramps among older adults. The aim of this study was to examine the feasibility and effectiveness of an adjusted pre-sleep stretching regimen derived using a sample of frail older community-dwelling adults aged over 75 years. Specifically, it was hypothesized that participants exposed to the pre-sleep stretching regimen would have fewer night time cramps and less pain when compared to those in no treatment control group.

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Materials and methods

Study design

A CONSORT statement for the recommendation in reporting of prospective randomized controlled trials was approved by the medical ethics committee of the Hanze University of Applied Sciences and is registered at the registry of clinical trials under the number [NCT01421628](#). This six-week pilot study comprised of two groups in a randomized controlled trial with pre- and posttreatment measures. Participants were sampled consecutively and had signed their informed consent before randomly allocated to the experimental group (daily stretches before sleep) or control group (no stretching). This was performed by a computer-generated assignment schedule, whereby an independent researcher, not present at the research site, blindly allocated participants to each group. Both groups were treated identically excluding the stretching protocol. Results were analyzed using an intention-to-treat analysis.

Participants

The study was conducted in three physiotherapy clinics in the northern part of the Netherlands. Home-care nurses and physiotherapists consecutively recruited older adults to participate in the study after eligibility was verified. Eligible participants were community-dwelling adults aged over 75 years using home care.

Inclusion criteria for participating in the study were: aged over 75 years and classified as “frail” according to the subdomains “Daily Activities”, such as shopping, walking outdoors, dressing and undressing, and going to the toilet (sum score > 1), of the Groningen Frailty Indicator (GFI),¹⁵ and, at least once a week, NLC marked by involuntary intense pain during a period of at least mere seconds, with a maximum of 10 min, located in the calf, foot, or hamstrings, and accompanied by persistent subsequent pain, sleep disruption, and distress.¹ In addition, participants had to be capable of standing upright without help and able to perform the stretch protocol.

Exclusion criteria were: age <75 years, not classified as “frail,” prevalence of NLC less than once a week, the inability to perform the stretch protocol, and the use of hydroquinine.

After eligibility was verified, an informed consent agreement was read aloud, handed out, and then signed by the participant.

Sample size

A total of 58 frail older adults were approached for recruitment, 10 of whom did not meet the inclusion criteria. Forty-eight participants were eligible and signed the informed consent agreement, one of whom later withdrew due to a lack of motivation. Therefore, 47 were enrolled in the study and randomized into the experimental group ($n = 23$) or control group ($n = 24$). Nine participants were lost in follow-up (19%). The number of frail older adults enrolled in this pilot study meet the assumptions for the sample size of pilot studies.^{15,16} The flowchart of participants throughout the trial and the reasons for exclusion are presented in [Fig. 1](#). Baseline characteristics are presented in [Table 1](#).

Intervention

A focus group of experienced geriatric physiotherapists suggested a stretch time of a maximum of 20 s per stretch exercise. Feland et al. suggest that a stretch time of at least 60 s is most beneficial for the range of motion best and mobility.^{17,18} Three stretch exercises of 20 s each, lasting a total stretch time of 60 s had to be performed each day before sleep for six weeks. Participants were instructed to remain calm and to continue breathing during the 20-second stretch

exercises. The pre-sleep stretching regimen in this study was adjusted: The hamstring stretch performance is changed from a standing to a sitting position.

At baseline participants enrolled in the study were informed by a physiotherapist about the aims of the study. Participants performed the stretch protocol after being instructed by a physiotherapist. A research assistant checked whether the subjects were able to perform the stretch exercises correctly. Participants were advised to stop stretching in the case of illness. If necessary, the stretch technique was corrected. In addition, participants were instructed on how to keep a daily record of the frequency and intensity of pain, and the stretch procedures were demonstrated. After three weeks, the research assistant examined the quality and safety of the implementation of the stretch exercises.

The control group was not instructed to perform the stretch protocol. The participants in the experimental and control group were asked to continue their usual daily physical activity.

Measurements

Diary

The participants kept a diary in week 1 and week 6 that was based on recall on the number of cramps and the pain that was related to cramping at night and not to other causes. If there had been no cramping it was also noted.

Groningen frailty indicator (GFI)

To recruit participants who met the inclusion criterion of “frailty” in both community-dwelling and institutionalized older adults at baseline, the GFI, consisting of 15 self-report items, was used. Psychometric studies examining the overall internal consistency of the GFI show moderate internal consistency (Cronbach's α values ranging $\alpha = 0.68$ to $\alpha = 0.73$).^{19–21} The GFI yielded statistically significant scores with correlations for the convergent validity (range 0.45–0.61) and discriminant validity (range 0.08–0.50).²²

Outcome measures

Frequency of NLC per day over a one-week period was assessed in the week prior to starting the six-week stretching program (week 0) and again in the final week of the stretching program (week 6). A difference in the average number of nocturnal leg cramps of one cramp per night is identified as clinically relevant.

Pain was measured using the eleven-item Numerical Pain Rating Scale (NPRS) with 0 representing no pain and 10 representing the worst pain the participant could imagine. The daily diary was used to record all information over the same one-week period before and at the end of the six-week period. Adverse events had to be recorded in the diary. Test-retest reliability is $r = 0.96$, and construct validity correlations range from $r = 0.86$ – 0.95 .²³

Statistical analyses

For each outcome, the difference between the experimental and control groups in the change from baseline to post-intervention was calculated as a mean difference. Results were expressed as means, $\pm$ standard deviations with 95% confidence intervals (CI). To quantify the difference between the two groups and assess the clinical relevance, the effect sizes (Cohen's d) were calculated.^{24,25} The difference between the experimental and control groups, in terms of the change from baseline to post-intervention, was calculated by using a t -test. Statistical significance was set at $P < 0.05$.

All analyses were performed using SPSS Statistical package version 25.0 (IBM SPSS Statistics, IBM Corporation, Armonk, NY).

Fig. 1. Flowchart of participation throughout the study.

Results

All participants ($n = 29$) were able to perform the stretches and checked in the diaries that all participants did the exercises daily, so the likelihood of performing the stretching regimen was feasible. This was evaluated after three and after six weeks of stretching by the research assistant. In addition, in both groups, no adverse events were reported. The most common location of NLC is the foot. In Table 1 demographic data obtained from the participants.

Table 1
Characteristics of the study sample.

	Exp. ($n = 15$)	Con ($n = 14$)	Total ($n = 29$)
Age (years), mean (SD)	85.3 (± 3.7)	84.4 (± 3.8)	84.9 (± 3.8)
Gender, n females (%)	15 (52)	14 (48)	29 (100)
Location (n)			
Hamstrings	2	3	2
Calf	5	2	7
Foot	6	8	16
Whole leg	2	1	4
Groningen Frailty Indicator (sd)	1.6 (1.1)	1.6 (1.0)	1.6 (1.0)
Frail n (%)	13 (88)	13 (93)	25 (86)

Exp: experimental, Con: control. Groningen Frailty Indicator includes; shopping; walking outside; dressing and undressing; toileting.

In Table 2, data for both outcomes are presented. At baseline, in the intervention group, a frequency of 3.5 cramps per night was recorded and this decreased to 2.5 cramps per night, therefore NLC decreased on average by 1.0 (95% CI 0.3–1.5) cramps per night. At baseline, in the intervention group, intensity of pain decreased from 6.1 at baseline to 5.2 after six weeks, therefore, pain decreased on average by 0.9 (95% CI 0.4–1.3) on the NPRS scale. In both groups, intensity of pain also showed slight improvement. A paired samples t -test reveals a statistically significant decrease in cramp frequency ($t = 2.2$, $df 28$, $P = 0.04$) and cramp intensity ($t = 2.7$, $df 28$, $P = 0.01$).

In both outcome measures, frequency and pain intensity of NLC, a statistically significant difference ($P < 0.05$) between pre- and post-assessment were found. For assessing clinical relevance, effect sizes for frequency $d = 0.29$ and cramp intensity $d = 0.61$ were calculated.

Discussion

The results of our study indicate that the adjusted six-week pre-sleep stretch regimen is a feasible and safe exercise protocol to perform in frail older adults with NLC with a mean age of 85 years. In this pilot study, the adjusted pre-sleep stretch regimen may significantly reduce the frequency and intensity of pain, and no side effects were found in contrast to most pharmacological treatment options.

Table 2

Mean (sd) of groups, mean (sd) difference within groups and mean (95% CI) difference between groups for both outcomes.

Outcome	Groups				Difference between groups Week 6 minus week – 1 Exp minus Con	t-test		
	Week – 1		Week 6			t	df	P
	Exp	Con	Exp	Con				
Frequency NLC (cramps/night, mean (sd))	3.5 (± 1.4)	2.7 (± 1.5)	2.5 (± 1.4)	2.8 (± 1.4)	–0.9 (–0.3 to –1.5)	2.2	28	0.04
NLC intensity (0 to 10), mean (sd)	6.1 (±0.8)	6.0 (±1.1)	5.2 (±1.1)	5.8 (± 0.9)	–0.7 (–0.4 to –1.3)	2.7	28	0.01

Significant at the <0.05 level (two-tailed test).

This reduction in the frequency of NLC in a sample of frail older adults is in line with the reduction in the frequency of NLC in a sample of more vital older adults aged 70 years.⁸ In contrast with this study, the male-female distribution is more balanced in the experimental and control group. It is remarkable that the prevalence of NLC in the foot is the most common location of NLC in this sample of frail older adults. The intensity of pain also showed a significant reduction, although less impressive compared to the frequency of NLC. This result fits well with the conclusion of a recent cross-sectional study designed to identify more treatment options for this highly prevalent nonspecific disorder.²⁶

In a recent review, a pre-sleep stretching program combined with quinine use in NLC was proven to be ineffective, and a Cochrane review concluded that magnesium is unlikely to provide prophylaxis in older adults with NLC.⁴ Due to conflicting evidence, the modest benefit and the additional risks of using quinine as a widely used treatment option increase the doubt about providing this drug.⁷ We suggest that this stretching protocol is a useful alternative, especially in frail older adults. Therefore, a pre-sleep stretching regimen in frail older adults constitutes a relevant non-pharmacological alternative for pharmacological treatments, without side effects. Furthermore, we assume that collaboration between (home-care) nurses and physiotherapists will be promoted in this non-pharmacological treatment for NLC. Moreover, stretching in older adults also helps with flexibility due to the increase in range of motion.¹⁰

A number of methodological characteristics of this study are relevant to the interpretation of the study results. The standardized pre-sleep stretching regimen was adapted to the sample of frail older adults with NLC in this study.¹ In addition, the duration of the stretch exercises was based on the suggestion of a focus group of experienced geriatric physiotherapists. In contrast with earlier studies, we used seven substantiated diagnostic criteria to classify patients with NLC.

Limitations of this study come from its small sample size: The effect of the intervention may be overestimated. Although all diaries were kept daily in week 1 and week 6 and were fully completed in the morning by all participants, information on frequency of cramps and pain intensity during the last night is a concern and may have been distorted by recall bias. This may have affected the outcome.

In future research, it would be important to control for the number of comorbidities that these frail older participants have and replicate this study methodology in a larger sample size. However, due to the increasing prevalence of frail older adults with NLC, the clinical relevance of this six-week stretching regimen is obvious and can be applied were found to be feasible and safe.

Conclusion

In community-dwelling frail older adults with a mean age of 85 years, the adjusted pre-sleep stretching regimen of six weeks can be performed safely. In the management of nocturnal leg cramps, this intervention is feasible, has no side effects, and is effective for frequency and intensity of pain.

Declaration of Competing Interest

The authors declare that they have no competing interests.

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Ethical approval and consent to participate

The Ethics Committee(s) of Hanze University approved this study. All participants gave written informed consent before data collection began.

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Consent for publication

Not applicable.

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