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Original article

Home-based cycling program tailored to older people with lumbar spinal stenosis: Barriers and facilitators☆

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ABSTRACT

Background: Lumbar-flexion-based endurance training, namely cycling, could be effective in reducing pain and improving function and health-related quality of life in older people with chronic low back pain.
Objectives: To assess barriers and facilitators to home-based cycling in older patients with lumbar spinal stenosis (LSS).
Methods: We conducted a retrospective mixed-method study. Patients ≥ 50 years old followed up for LSS from November 2015 to June 2016 in a French tertiary care center were screened. The intervention consisted of a single supervised session followed by home-based sessions of cycling, with dose (number of sessions and duration, distance and power per session) self-determined by patient preference. The primary outcome was assessed by a qualitative approach using semi-structured interviews at baseline and 3 months and was the identification of barriers and facilitators to the intervention. Secondary outcomes were assessed by a quantitative approach and were adherence monitored by a USB stick connected to the bicycle, burden of treatment assessed by the Exercise Therapy Burden Questionnaire (ETBQ) and clinical efficacy assessed by change in lumbar pain, radicular pain, disability, spine-specific activity limitation and maximum walking distance at 3 months.
Results: Overall, 15 patients were included and data for 12 were analyzed at 3 months. At baseline, the mean age was 70.9 years (95% CI: 64.9–76.8) and 9/15 patients (60.0%) were women. Barriers to cycling were fear of pain and fatigue, a too large bicycle, burden of hospital follow-up and lack of time and motivation. Facilitators were clinical improvement, surveillance and ease-of-use of the bicycle. Adherence remained stable overtime. The burden of treatment was low [mean ETBQ score: 21.0 (95% confidence interval: 11.5–30.5)]. At 3 months, 7/12 patients (58.3%) self-reported clinical improvement, with reduced radicular pain and disability [mean absolute differences: −27.5 (−43.3 to −11.7), $P < 0.01$ and −17.5 (−32.1 to −2.9), $P = 0.01$, respectively].
Conclusions: For people with LSS, home-based cycling is a feasible intervention.

1. Introduction

Lumbar spinal stenosis (LSS) is the narrowing of the spinal canal caused by degenerative spinal processes [1]. It is a prevalent and disabling condition in older individuals. LSS results in radicular claudication when standing and walking, but symptoms regress in the sitting position [2]. Conservative therapy is the first-line option [1]. However, evidence of efficacy

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is heterogeneous and of limited quality, and no clear recommendations can be provided [3].

LSS-related symptoms worsen with lumbar extension, which may be explained by a shrinkage of the lumbar canal, and improve with lumbar flexion, attributable to an opening of the lumbar canal [4]. This observation has important implications for treatment. Lumbar-flexion-based exercise therapy is usually offered [5]. Lumbar-flexion-based endurance training, namely cycling, could be effective in reducing pain and improving function and health-related quality of life in older people with non-specific chronic low back pain [6]. In 54 patients with LSS, a 4-month cycling program was associated with reduced LSS-related symptoms [7]. Because it does not require lumbar extension, cycling could be a well-tolerated endurance training in people with LSS. Furthermore, cycling could improve symptoms related to ischemia of the caudal equina by enhancing perfusion and oxygen consumption [6–8].

However, even though patients' expectations about performing regular exercise therapy are usually favourable, barriers to adherence are numerous [6] and include patients' beliefs that cycling is boring and time-consuming [6]. Patient-centered barriers, facilitators and burden of treatment need to be assessed, to precisely design minimally disruptive and minimally burdensome home-based training programs for spinal disorders that are transposable to primary care [9–13]. We aimed to assess barriers and facilitators to a 3-month home-based cycling program with ergometric bicycles tailored to preferences of patients with LSS.

2. Methods

2.1. Design overview

We conducted a 3-month, monocentric, single-arm, retrospective, open pilot mixed-method study. A qualitative approach with two semi-structured interviews and a quantitative approach were carried out at inclusion and 3 months after inclusion, to determine barriers and facilitators to cycling and to assess efficacy outcomes, respectively. The qualitative study and the intervention are reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) statement [14] and the Template for Intervention Description and Replication (TIDieR) checklist and guide [15] (e-component 1), respectively. No changes to methods occurred after study commencement.

2.2. Setting and patients

All in- and outpatients followed up in the rehabilitation department of Cochin Hospital, Paris, France, from November 2015 to June 2016, for whom the diagnosis of LSS was recorded in the computerized medical database, were screened by phone by one investigator (CP) in chronological order from most recent to oldest. Recruitment started on August 29, 2016 and follow-up was completed on December 21, 2016. Inclusion criteria were: age $\geq$ 50 years; fulfillment of the International Society for the Study of Lumbar Spine clinical diagnostic criteria for LSS with the presence of at least 6 of the 7 following criteria [2]: "pain in the buttocks or legs while walking", "flex forward to relieve symptoms", "feel relief when using a shopping cart or bicycle", "motor or sensory disturbance while walking", "normal and symmetric foot pulses", "lower extremity weakness", and "low back pain"; and LSS detected qualitatively on MRI or CT scan. Exclusion criteria were: inability to speak or read French, impossibility or refusal to have an ergometric bicycle at home, ongoing lumbar-flexion-based endurance training, history of spinal surgery, cognitive impairment, neurological or vascular disorder involving the lower limbs, contraindication to cycling, and specific low back pain. Patients who were eligible were informed of the purpose of the study. Those who agreed to participate in the study had a face-to-face visit with the investigator. Inclusion and exclusion criteria were checked. Baseline characteristics collected were age, sex, body mass index, educational level, employment status, mean symptom duration, mean lumbar and radicular pain in the previous 48 h by use of a self-administered numeric rating scale (NRS; 0, absent, and 100, maximal), mean disability in the previous 48 h by use of a self-administered NRS (0, absent, and 100, maximal) [16,17], spine-specific activity limitation assessed with the Oswestry Disability Index (ODI; 0, absent, and 100, maximal) [18,19], self-reported current consumption of analgesics (yes/no) or non-steroidal anti-inflammatory drugs (yes/no), history and types of glucocorticoid spinal injections (yes/no), and physiotherapy (yes/no).

2.3. Intervention

The intervention was developed by a steering committee including 2 senior specialists in physical and rehabilitation medicine (SP, CN), 1 physiotherapist (AR) and 2 instructors specialized in physical training (AG, JL) with at least 5 years' clinical experience managing LSS, and 1 physical and rehabilitation medicine resident (CP). In the absence of clear and consistent evidence or recommendations, the steering committee specified the content and format of the intervention on the basis of clinical practice and experience. The intervention and its follow-up were designed to be minimally disruptive, minimally burdensome and easily transposable to daily life. With an understanding of the LSS-related symptom pathogenesis, the main content of the intervention was decided as a home-based lumbar-flexion-based endurance training program. Cycling by using an ergometric bicycle at home was considered the most appropriate lumbar-flexion-based intervention for the targeted population. The dose of cycling (number of sessions a week and duration, distance and power per session) was self-determined by patients' preferences, with the advice of a member of the steering committee and autonomously adjusted by the patient. The E3 ergometric bicycle model (Kettler France company, Schirmeck) was selected because it met the requirements specified by the steering committee: stability; adjustable seat height; small footprint; automatic and user-friendly monitoring of training sessions (distance, duration, speed, power) with a USB stick connected to the ergometric bicycle; internet connection not required; and delivery and installation of the ergometric bicycle at home. Overall, the intervention included a single supervised session followed by a 3-month home-based cycling program.

The supervised session was delivered individually at baseline at the investigating center by a member of the steering committee, within 10 days after the first semi-structured interview, and included oral instructions and demonstration on how to use the ergometric bicycle (15–20 min); after a 2-min warm-up at 25 W, setting up the aerobic intensity at 25 $\pm$ 10 W corresponding to the patient comfort zone while cycling (10 min); patient self-determination of individualized goals for the dose of cycling to perform depending on preferences, constraints (pain, fatigue, lack of motivation, etc.), context (holidays, travel, schedule, etc.) and abilities (performance) (15 min); and promotion of physical activity in general by use of a flyer (e-component 2) followed by a discussion with the therapist. Motivational take-home messages were about the specific benefits of lumbar-flexion-based endurance training for LSS, the meaning of a daily active lifestyle, and the adverse effects of prolonged rest (10 min). Participants were offered the possibility of having up to one refreshing supervised session a month on demand by contacting the investigator and were given a phone number to reach one of the investigators in case they had a question or a problem.

Home-based sessions included an initial phase of pedalling for 1 min at the minimum power of 25 W followed by incremental progression to the comfort zone self-determined by the patient during the supervised session. Data from the home-based sessions were automatically recorded on the USB stick connected to the bicycle. The USB stick was returned to the investigator at 3 months during a face-to-face visit. At the end of the study, patients could keep their ergometric bicycle or have it removed.

2.4. Outcomes

The primary outcome was the identification of barriers and facilitators to the intervention by a qualitative approach using semi-structured interviews conducted at baseline and 3 months and based on an inductive enquiry. We used investigator triangulation, whereby 3 independent investigators extracted themes and sub-themes from the dataset, but we did not use other types of triangulation such as method triangulation, theory triangulation, or data source triangulation [20]. The sole data source was individual in-depth interviews, because we found no literature sources that addressed a similar question and because the choice of the type of interview (i.e., focus groups or individual in-depth interview) depends on the resources available and the purpose of the interview. The purpose of our interviews was to collect patients' perspectives about an innovative intervention. Therefore, we felt that at this stage of the research, the individual in-depth interview was more suitable than focus groups. The individual in-depth interview is indeed considered one of the most powerful tools to explore a topic in depth. It collects rich information about personal experiences and perspectives. It allows for spontaneity, flexibility and individual response [20]. All interviews were conducted by the same investigator (CP), a physical and rehabilitation medicine resident, who received specific training in qualitative research before the study from a senior investigator (SP), who had a strong background in clinical epidemiology and qualitative research in musculoskeletal disorders [21–27]. All interviews were conducted during individual face-to-face visits organized in a room within the rehabilitation department of Cochin Hospital, Paris, France. These interviews followed a framework pre-specified by the junior (CP) and two senior investigators (SP, CN). They aimed to capture barriers and facilitators anticipated by the patient to a home-based cycling program and to encourage discourse and to comment on the patient's views about this type of program. A first version of the interview chart was elaborated by the junior investigator, then reviewed by the two senior investigators and modified accordingly. The final interview chart consisted of open-ended questions (e-component 3). If patients were unable to develop their answers spontaneously, the investigator could ask more specific questions selected from the pre-specified interview chart. The mean duration for each interview was 60 min, and each interview was audio-recorded. Each audio-recording was listened to 3 times: the first listening aimed at becoming familiar with the patient's answers and wording, the second extracting themes related to barriers and facilitators and the third transcribing examples.

The inclusion of patients in the study was consecutive, which was suitable for assessing the primary qualitative outcome. The number of patients was determined by convenience on the basis of the number of eligible patients among the total number of screened patients during the specified period of time. However, this convenience sample allowed for reaching data saturation defined as the point at which no new information or themes were observed for the data [28]. The dataset generated by the individual in-depth interviews was analyzed by three researchers (CP, CN, SP) by using the framework of thematic content analysis. Investigators manually and independently identified key themes from the data and established a categorizing system in accordance with the COREQ [14]. After consensus, barriers and facilitators were classified into 4 thematic subgroups: disease-related, patient-related, intervention-related and environment-related. This coding frame was used to systematically index the data and comprehensively and systematically analyse each audio-recording. We did not refine the individual interview guide during the study, and the literature did not influence the extracted themes because we found no previous qualitative studies on this topic.

Secondary outcomes were assessed by a quantitative approach and were adherence to the home-based cycling program assessed by automatic monitoring of distance, duration, speed and power during each cycling session on the USB stick connected to the bicycle, burden of treatment assessed by the Exercise Therapy Burden Questionnaire (ETBQ; 0, absent, and 100, maximal) [29], mean change from baseline in mean lumbar and radicular pain in the previous 48 h assessed by an 11-point NRS (0, absent, and 100, maximal), mean change from baseline in mean disability in the previous 48 h assessed by an 11-point NRS (0, absent, and 100, maximal) [16,17], mean change from baseline in mean spine-specific activity limitation assessed by the ODI (0, absent, and 100, maximal) [18,19] and mean change from baseline in mean maximum walking distance assessed by an adapted version of the self-paced walking test at 3 months [30]. All outcomes specified in the protocol and all outcomes assessed during the study are reported in the present manuscript.

2.5. Statistical analysis

Qualitative data are expressed as absolute and relative frequencies [n/N (%)] and quantitative data as mean [95% confidence intervals (CI)]. The normality of the distribution of the quantitative variables was assessed by the Shapiro–Wilk test. Normally-distributed quantitative variables were compared between inclusion and 3 months by paired *t*-test and non-normally distributed quantitative variables by Wilcoxon rank test. $P < 0.05$ was considered statistically significant.

2.6. Ethical consideration and role of the funding source

The work described was performed in accordance with the Declaration of Helsinki for experiments involving humans. The investigator gave oral and written information on the study, and informed written consent was obtained from all participants. Our study was retrospectively registered on the Clinical Trials website on October 30, 2017 (identifier NCT03325309) as a retrospective study. According to the Jardé Law of March 5, 2012 and its application decree (No. 2016-1537) of November 16, 2016, relating to research involving human persons in France, retrospective studies do not require formal approval by an institutional review board. The acquisition of ergometric bicycles was funded by the French National Institute of Health and Medical Research. The funding source was not involved in the study design, data collection or interpretation, statistical analysis, manuscript preparation, or the decision to submit the manuscript for publication.

3. Results

3.1. Patients

Overall, 20 patients met the inclusion criteria: 15 agreed to participate and 12 were included in the 3-month analysis. Three patients did not receive the intervention and their data could not be analyzed at 3 months: 2 did not succeed in riding the ergometric bicycle because of a short height and balance disorders,

Table 1
Demographics and clinical characteristics of patients with lumbar spinal stenosis ($n = 15$).

Age (years), mean (95% CI)	70.9 (64.9–76.8)
Women, *n* (%)	9 (60.0)
Body mass index (kg/m^2), mean (95% CI)	28.2 (26.3–30.0)
Education, *n* (%)	
≤ High school	7 (46.7)
> High school	8 (53.3)
Employment status, *n* (%)	
Employed	4 (26.7)
Retired	11 (73.3)
No. of patients with one or multiple stenosed lumbar level(s), *n* (%)	
1 level	8 (53.3)
2 levels	6 (40.0)
3 levels	1 (6.7)
Level of lumbar spinal stenosis, *n* (%)	
L1-L2	1 (6.7)
L2-L3	1 (6.7)
L3-L4	6 (40.0)
L4-L5	13 (86.7)
L5-S1	2 (13.3)
Symptom duration (years), mean (95% CI)	6.0 (3.9–8.1)
Lumbar pain (NRS, 0 to 100), mean (95% CI)	46.7 (35.9–57.5)
Radicular pain (NRS, 0 to 100), mean (95% CI)	58.7 (50.9–66.5)
Disability (NRS, 0 to 100), mean (95% CI)	68.7 (58.9–78.5)
Oswestry Disability Index (0 to 100), mean (95% CI)	36.3 (29.0–43.5)
Previous glucocorticoid spinal injections, *n* (%)	12 (80.0)
1 injection	3 (20.0)
2 injections	9 (60.0)
Type of glucocorticoid spinal injections, *n* (%)	
Facet joint	7 (46.7)
Epidural by caudal route	7 (46.7)
Epidural by interspinous route	6 (40)
Intrathecal	1 (6.7)
Current treatments, *n* (%)	
Analgesics	12 (80.0)
Non-steroidal anti-inflammatory drugs	4 (26.7)
Physiotherapy	8 (53.3)
Maximum walking distance (m), mean (95% CI)[a]	1183.6 (727.8–1639.5)
Walking speed (m/s), mean (95% CI)[a]	0.3 (0.2–0.4)

CI: confidence interval; NRS: numeric rating scale.
[a] $n = 13$.

respectively, and 1 found the bicycle too big and refused to install it (e-component 4). At baseline, the mean age was 70.9 years (95% CI: 64.9–76.8) and 9/15 patients (60.0%) were women. Mean symptom duration was 6.0 years (3.9–8.1), mean lumbar pain score 46.7 (35.9–57.5), mean radicular pain score 58.7 (50.9–66.5), mean disability score 68.7 (58.9–78.5), mean ODI score 36.3 (29.0–43.5) and mean maximum walking distance 1183.6 m (727.8–1639.5). Overall, 12/15 patients (80.0%) had glucocorticoid spinal injections, and 12/15 (80.0%) and 4/15 (26.7%) were taking non-steroidal anti-inflammatory drugs at baseline, respectively (Table 1). No patients requested refreshing supervised sessions.

3.2. Primary outcome

At baseline, the most frequent anticipated disease-related barriers were fear of pain [9/15 (60%)] (e.g., "i'm afraid of hurting myself") and fatigue [7/15 (46.7%)] (e.g., "after a training session, my muscles are weak. I'm breathless"). The most frequent anticipated intervention-related barriers were a too big bicycle (8/15, 53.3%) (e.g., "It's a monster") and the burden of hospital follow-up [11/15 (73.3%)] (e.g., "It's complicated to come to the hospital"). Finally, the most frequent anticipated patient-related barriers were lack of time [6/15, (40.0%)] (e.g., "I missed several sessions because I did not have time to ride the bicycle") and lack of motivation [3/15 (20.0%)] (e.g., "it's an obligation to ride a bicycle") (Table 2). Fear of pain and fatigue were less frequent at 3 months than at baseline and were reported by only 3/12 (25.0%) and 2/12 (16.7%) patients, respectively, as were lack of time and lack of motivation, reported by only 1/12 (8.3%) and 2/12 (16.7%) patients, respectively. The most frequent intervention-related barriers reported at 3 months were saddle discomfort [5/12 (41.7%)] (e.g., "the saddle is too inclined, too complicated to change"), difficulties in using the bicycle [3/12 (25.0%)] (e.g., "the bicycle is a bit complicated") and technical issues [3/12 (25.0)] (e.g., "the pedometer is not very sensitive").

At baseline, the most frequent anticipated disease-related facilitator was clinical improvement [10/15 (66.7%)] (e.g., "if I see that there are positive effects on pain, I will continue") and the most frequent anticipated intervention-related facilitator was surveillance [10/15 (66.7%)] (e.g., "we feel watched over") (Table 3). At 3 months, the most frequent reported disease-related facilitator remained clinical improvement [9/12 (75.0%)] (e.g., "it's been much better since I have started cycling"), and the most frequent intervention-related facilitators were comfort [3/12 (25.0%)] (e.g., "the bicycle is very comfortable, I have no pain during the sessions") and ease-of-use of the bicycle [3/12 (25.0%)] (e.g., "it's very easy to manage intensity"). To maintain adherence, 8/12 patients (66.7%) self-implemented motivational strategies such as concomitant entertaining activities (listening to music or radio, watching television or video, or making a phone call).

3.3. Secondary outcomes

Adherence was stable overtime, with total time and training distance of 275.5 min (95% CI: 199.9–351.0) and 113.2 km (73.2–153.2) in the first month and 271.6 min (169.5–373.7) and 109.1 km (62.8–155.3) in the third month, respectively (Table 4). At 3 months, the burden of treatment was low [mean ETBQ score: 21.0 (11.5–30.5)], and was mostly represented by fatigue [3.8 (2.0–5.7)], a reminder of the condition [3.7 (1.4–6.0)] and causing pain [3.0 (1.1–4.9)] (Table 5). Conversely, the cycling program was considered adapted to patients' physical activity objectives [0.6 (0.0–1.3)], not too difficult [1.0 (0.2–1.9)] and not too time-consuming [1.2 (0.0–2.4)]. At 3 months, 7/12 patients (58.3%) self-reported clinical improvement, with reduced radicular pain [mean absolute difference: −27.5 (−43.3 to −11.7), $P < 0.01$] and disability [mean absolute difference: −17.5 (−32.1 to −2.9), $P = 0.01$] (e-component 5). Other specified secondary clinical efficacy outcomes did not differ between baseline and 3 months (e-components 5 and 6). At 3 months, the number of patients reaching the patient acceptable symptom state (pain NRS ≤ 30/100) (12) was 7/12 (58.3%) for both mean lumbar and radicular pain as compared with 3/15 (20.0%) and 0/15 (0.0%) at baseline, respectively. At 3 months, 6/12 (50.0%) and 0/12 (0.0%) patients were receiving analgesics or non-steroidal anti-inflammatory drugs versus 12/15 (80.0%) and 4/15 (26.7%) at baseline.

3.4. Safety

No adverse events were reported during the 3-month follow-up.

4. Discussion

For patients with LSS, a home-based cycling program tailored to patients' preferences is feasible. At baseline, most frequent barriers to cycling were fear of pain and fatigue, a too big bicycle, the burden of hospital follow-up and lack of time and motivation. The home-based cycling program adherence was facilitated by clinical improvement, surveillance and comfort and ease-of-use of the bicycle. Adherence was stable over time, and patients self-implemented motivational strategies to maintain it. The burden of treatment was low. Preliminary efficacy results are promising:

Table 2
Barriers to home-based cycling program at baseline and 3 months.

Barriers	Inclusion	$n = 15$	At 3 months	$n = 12$	Examples
Disease-related	Pain, *n* (%)	9 (60.0)	Pain, *n* (%)	3 (25.0)	"I'm afraid of hurting myself" "At first I had pain in the lower back" "I had pain in the lower back before I got used to the bicycle"
	Fatigue, *n* (%)	7 (46.7)	Fatigue, *n* (%)	2 (16.7)	"After a training session, my muscles are weak, I'm breathless"
			No improvement, *n* (%)	1 (8.3)	"Cycling does not improve my condition"
Intervention-related	Burden of hospital follow-up, *n* (%)	11 (73.3)			"Coming only for cycling is not very interesting" "It's complicated to come to the hospital" "I do not see the value of meeting other patients" "Group sessions are useless for me" "It's a constraint on work schedule" "I live far from the hospital"
	Size and weight of the bicycle, *n* (%)	8 (53.3)	Size and weight of the bicycle, *n* (%)	1 (8.3)	"It's a monster" "We will make room to put it" "The bicycle is too heavy"
	Useless software program, *n* (%)	5 (33.3)	Useless software program, *n* (%)	12 (100)	"I don't know how to use the computer"
	Saddle not comfortable, *n* (%)	1 (6.7)	Saddle not comfortable, *n* (%)	5 (41.7)	"The saddle is too inclined, too complicated to change" "I put a towel under my butt" "I bought cycling shorts and it's much better"
			Difficulties with the material, *n* (%)	3 (25.0)	"The screen seems complicated" "The bicycle is a bit complicated"
			Technical issues, *n* (%)	3 (25.0)	"The pedometer is not very sensitive"
Patient-related	Lack of time, *n* (%)	6 (40.0)	Lack of time, *n* (%)	1 (8.3)	"I missed several sessions because I did not have time to ride the bicycle"
	Lack of motivation, *n* (%)	3 (20.0)	Lack of motivation, *n* (%)	2 (16.7)	"After a month of cycling I was fed up" "Getting into a routine" "It's an obligation to ride a bicycle" "My bad mood, my depressed state can prevent me from cycling"
			Shoulder pain, *n* (%)	1 (8.3)	"I have shoulder pain when I'm leaning forward"
			Genital herpes, *n* (%)	1 (8.3)	"It hurts to get on the saddle"

Table 3
Facilitators of home-based cycling program at baseline and 3 months.

Facilitators	Inclusion	$n = 15$	At 3 months	$n = 12$	Examples
Disease-related	Clinical improvement, *n* (%)	10 (66.7)			"If I see that there are positive effects on pain, I will continue" "The benefits of cycling" "That it brings me a profit"
			Clinical improvement, *n* (%)	9 (75.0)	"Great progress" "My legs are more muscular, I can climb stairs without problems" "My first motivation is the clinical and physical improvement that I can draw, especially analgesic" "It's been much better since I have started cycling"
			Physical improvement, *n* (%)	1 (8.3)	"I'm less breathless since I ride a bicycle"
			No pain when cycling, *n* (%)	2 (16.7)	"Do well" "When I ride my bicycle my pain disappears"
Intervention-related	Surveillance, *n* (%)	10 (66.7)	Surveillance, *n* (%)	2 (16.7)	"We feel surveilled"
	Accessibility, *n* (%)	3 (20.0)			"It's great you can do it when you want" "You can do physical activity at home"
			Comfort, *n* (%)	3 (25.0)	"The bicycle is very comfortable, I have no pain during the sessions"
			Ease-of-use, *n* (%)	3 (25.0)	"It's very easy to manage intensity"
	Playfulness, *n* (%)	2 (13.3)			"Give a goal"
			Adapted to small room, *n* (%)	1 (8.3)	"The bicycle doesn't take up too much space, I move it easily"
	Feedbacks, *n* (%)	4 (26.7)			"Lets see progress and get advice" "Accountable"
	Supervised session, *n* (%)	1 (6.7)			"It will allow me to move forward" "It can bring me a lot, when you're alone it's harder"
Patient-related	Reminder of physiotherapy, *n* (%)	2 (13.3)			"Good memory in physiotherapy"
			Sport activity, *n* (%)	2 (16.7)	"Thank to the bicycle I can do sport again, which I didn't do for a long time"
Environment-related	Music, *n* (%)	2 (13.3)	Music, *n* (%)	3 (25.0)	"I listen to a classical music program during my sessions"
			Television, *n* (%)	2 (16.7)	
			Phone, *n* (%)	1 (8.3)	
			Radio, *n* (%)	2 (16.7)	

Table 4
Adherence to home-based cycling program ($n = 12$).

Participation	In the 1st month	Between the 1st and 2nd months	Between the 2nd and 3rd months	Between inclusion and the 3rd month
Sessions (no.)	16.6 (12.4–20.8)	16.8 (11.8–21.8)	13.6 (9.2–18.1)	44.1 (33.9–60.3)
Sessions per week (no.)	4.2 (3.3–5.2)	3.7 (2.8–4.7)	3.4 (2.7–4.1)	3.8 (3.0–4.6)
Training duration (min)	275.5 (199.9–351.0)	298.6 (224.0–373.3)	271.6 (169.5–373.7)	846.5 (607.5–1085.5)
Training distance (km)	113.2 (73.2–153.2)	122.6 (83.9–161.3)	109.1 (62.8–155.3)	345.4 (224.9–465.9)
Session duration (min)	17.5 (12.7–22.3)	19.4 (13.8–24.9)	20.8 (13.5–28.2)	19.2 (13.4–25.0)
Session distance (km)	7.1 (4.9–9.3)	8.0 (5.3–10.6)	8.3 (4.9–11.8)	7.8 (5.1–10.5)
Session power (W)	49.7 (39.1–60.2)	53.0 (39.2–66.7)	53.6 (39.1–68.0)	56.1 (39.3–64.9)

Data are mean (95% CI).

Table 5
Burden of home-based cycling program ($n = 11$).

Exercise Therapy Burden Questionnaire (score range 0–10)	
The exercises cause me pain	3.0 (1.1–4.9)
The exercises cause me fatigue	3.8 (2.0–5.7)
I get bored when I exercise (too much repetition, not enough fun)	2.2 (0.5–3.9)
The exercises in my program are too difficult	1.0 (0.2–1.9)
I waste too much time exercising	1.2 (0.0–2.4)
Exercising reminds me of my condition	3.7 (1.4–6.0)
I lack support to exercise	1.8 (0.4–3.3)
I lack motivation to exercise	1.5 (0.4–2.7)
The exercises that I am asked to do are not adapted to my physical activity objectives	0.6 (0.0–1.3)
I feel that exercising is not efficient in my case	1.9 (0.5–3.3)
Total (0 to 100)	21.0 (11.5–30.5)

Data are mean (95% CI).

at 3 months, 7/12 patients (58.3%) self-reported clinical improvement, with a reduction in mean radicular pain and disability.

Fear of pain and fatigue were the most frequent anticipated barriers to the cycling program. Kinesiophobia is an important risk factor of poor clinical outcome in people with chronic low back pain. Therapeutic strategies in this subgroup of patients should include reassurance, positive reinforcement and motivational speech to help them cope with pain. Evaluating fears and beliefs about physical activity in patients with LSS could be useful for determining which patients would most likely benefit from supervised educational sessions in addition to the home-based cycling program.

Patients usually struggled in expressing their perspectives and expectations about barriers and facilitators to home-based cycling. Their answers were mostly short. Pain and fatigue were the most frequently anticipated barriers to task engagement. Characteristics of bicycles were also associated with unpleasant memories from previous supervised programs, and lack of time was associated with the fear of a routine. Clinical improvement was reported as the main facilitator to task engagement. In addition, regular medical follow-up and feedback, whatever their modalities, as well as surveillance were perceived as acceptable means to support motivation and task engagement.

Facilitators most frequently reported by patients were clinical improvement, surveillance and comfort and ease-of-use of the bicycle. In a French study assessing strategies designed to enhance adherence to home-based programs in 29 patients with non-specific chronic low back pain, the main facilitators were integrating exercise therapy into everyday life, creating a climate of trust between patients and healthcare professionals, taking into account patient history and preferences, offering a regular follow-up to help patients undertake exercise therapy and a switch from a "controlled" to "autonomous" motivation [31]. The cycling program we pilot-tested seemed to achieve most of these goals.

Adherence monitored by a USB stick connected to the bicycle was stable over time. Indeed, descriptive analysis did not show a numerical decrease over time in monthly training distance or duration. Maintaining or enhancing adherence to non-pharmacological interventions in health care and in clinical trials is an important challenge, and assessing adherence can be biased by self-reporting. In 2017, a self-administered questionnaire, the Exercise Adherence Rating Scale, designed to assess adherence to home-based exercise therapy in 234 patients with non-specific chronic low back pain, was published [32]. The questionnaire was able to measure adherence to home-based exercise therapy, with good psychometric properties. However, this study did not assess the relation between participation and self-adjustments to the program by the patients. Furthermore, even though the questionnaire provided qualitative information about adherence, it did not allow for quantitative assessment, contrary to digital tools, as in our study.

In some patients, surveillance may have supported task engagement (e.g., "we feel watched over"). However, experimental data in the field of psychology are inconsistent in this regard. Because it is perceived as an extrinsic attempt to control someone's activities, surveillance could conversely undermine intrinsic motivation [33]. Overall, clinical positive effects attributable to the intervention, reported by 9/12 patients (75.0%) at 3 months, may be the most powerful contributors to maintained adherence, rather than extrinsic measures to enhance adherence.

Mean radicular pain and disability were lower at 3 months than at baseline. Our results agree with those of two previous open-label studies including 29 and 54 patients with lumbar pain, respectively. These studies suggested that a cycling program could alleviate pain and improve quality of life at 3 months [6] and delay spinal surgery [7] but not improve maximum walking distance at 4 months [7]. To date, surgical and non-surgical treatments for patients with LSS have failed to quantitatively improve walking abilities [34]. The inability of our intervention to improve the ODI score is not surprising. The ODI is designed to assess low back pain rather than LSS-specific activity limitation and includes only one question related to walking. The Zurich Claudication Questionnaire designed to assess LSS-related activity limitation may be more sensitive and specific than the ODI in this condition [35].

Our study has limitations. We used investigator triangulation but not method or data source triangulation. Focus groups could usefully supplement individual interviews in a second step because participants can hear others' responses and complete their own comments [20]. Therefore, when the number of patients exposed to the intervention is sufficient, one may consider method and data source triangulation, for example, by means of focus groups of patients and therapists, to improve the validity of our first observations. Although the first observations are promising, our study was not designed to assess the clinical efficacy of cycling for patients with LSS. In the absence of a control group, we cannot conclude on the efficacy and safety of the intervention and its relative burden. However, the choice of a relevant control is difficult because of the absence of consensual guidelines for treating LSS. Efficacy outcomes were only secondary and were selected to preliminarily assess the effect of home-based cycling for patients with LSS before launching a larger randomized trial.

Whether these preliminary efficacy results are influenced by patients' perspectives was not assessed in a subgroup analysis because the sample size was too small to warrant methodological soundness. Finally, longer follow-up would also have been interesting for analyzing mid- and long-term adherence and burden of treatment.

5. Conclusion

Our pilot study demonstrates the feasibility of a home-based cycling program with ergometric bicycles tailored to patients' preferences in LSS. With the participation of patients in the design of the intervention, the present study allowed us to optimize and consolidate the content of the home-based cycling program and the measures to enhance adherence. This optimized version of the intervention will now be assessed in a randomized trial of 296 patients (*Programme Hospitalier de Recherche Clinique* 2016).

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Author contributions

Conception and design of the study. CP, AR, FR, SP, CN. Drafting of the original protocol. CP, AR, SP, CN. Acquisition of data. CP, AR, AG, JL, CN. Coordination of the study. CN. Design of the statistical analysis plan. CN. Obtaining of funding. SP. Drafting of the present manuscript. CP, CN. Final approval. CP, AR, AG, JL, FR, CN.

Disclosure of interest

The authors declare that they have no competing interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.rehab.2018.02.005.

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