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### ► To cite this version:

Marina Assadourian, Florian Bailly, Pierre Letellier, Antoine Potel, Bernard Duplan, et al.. Criteria for inclusion in programs of functional restoration for chronic low back pain: Pragmatic Study. *Annals of Physical and Rehabilitation Medicine*, 2020, 63 (3), pp.189-194. 10.1016/j.rehab.2019.06.019 . hal-02859969

**HAL Id: hal-02859969**

**<https://hal.umontpellier.fr/hal-02859969>**

Submitted on 8 Dec 2020

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# Criteria for inclusion in programs of functional restoration for chronic low back pain: Pragmatic Study

*CHARACTERISTICS ASSOCIATED TO INCLUSION IN FUNCTIONAL RESTORATION PROGRAMS: A CROSS-SECTIONAL STUDY OF 147 PATIENTS WITH CHRONIC LOW BACK PAIN.*

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**Word count:** 2488 words (abstract: 301 words), 41 references, 4 tables, 1 figure.

**Disclosures of interest:** None

## **Abstract**

**Introduction:** Chronic low back pain (cLBP) patients may benefit from multimodal functional restoration programs (FRPs). The aim of this study was to analyze patients' characteristics, when oriented or not towards such a program. As cLBP is a bio-psycho-social disorder medical and social parameters were analysed.

**Methods:** Observational cross-sectional study in six tertiary centers in France in 2017. Consecutive patients with cLBP visiting a rheumatologist or physical medicine and rehabilitation physician were included. Patients oriented or not towards a FRP were compared for demographic characteristics, duration of sick leave over the past year, self-reported physical activity >1h/week, pain, anxiety/depression (Hospital Anxiety and Depression Scale), disability (Oswestry Disease Index) and kinesiophobia (Tampa Kinesiophobia Scale). Univariate and multivariate logistic regression were performed.

**Results:** 147 patients were analysed: mean  $\pm$  standard deviation, age  $48.8 \pm 12.0$  years, mean cLBP duration  $9.1 \pm 9.4$  years, 88 (59.9%) women. Overall, 58 (39.5%) patients were oriented towards a FRP: these patients were younger (mean age  $46.3 \pm 11.2$  vs  $50.5 \pm 12.2$  years,  $p=0.036$ ), had longer sick leave (mean  $128.5 \pm 140.6$  vs  $67.6 \pm 107.6$  days/year,  $p=0.004$ ), less often self-reported physical activity ( $35.1\% \pm 48.1$  vs  $53.4\% \pm 50.2$ ,  $p=0.031$ ), and reported lower pain levels (mean  $6.1 \pm 2.0$  vs  $7.1 \pm 1.9$  on a 0-10 numeric scale,  $p=0.002$ ). There was no significant difference regarding functional disability, pain duration, kinesiophobia, psychological status. In multivariate analysis, lower pain (odds ratio, OR: 0.95, 95% CI [0.91;0.99] for an increase of 1 point), absence of physical activity (OR: 0.84, 95% CI [0.72;0.98]) and longer sick leave (OR: 1.03, 95 % CI [1.01;1.05] for 30 more days of sick leave) were independently associated with orientation towards a FRP.

**Conclusion:** Orientation towards FRPs was linked to pain, self-reported physical activity and sick leave. This confirms the biopsychosocial approach of FRPs for cLBP.

**Keywords:** *chronic low back pain; chronic pain; functional restoration program; physical activity; public health.*

## **Highlights**

- In patients with chronic low back pain (LBP), multimodal functional restoration programs (FRPs) have shown their effectiveness but are not always proposed.
- Longer sick leave, lower pain levels and low self-reported physical activity levels were linked to orientation towards a FRP.
- The lack of association of most of the medical variables with orientation towards a FRP support a biopsychosocial approach in LBP.

## Introduction

Chronic non-specific low back pain (cLBP) is a non-specific musculoskeletal symptom that has progressed for at least 3 months and that does not involve serious causes (malignancy, vertebral fracture, infection, or inflammatory disorders such as axial spondyloarthritis) [1]. It is an extremely common health problem with an estimated prevalence of more than 576 million in 2017 [2]. Years lived with disability caused by LBP have increased over the last decades, mainly because of population increase and ageing. LBP is now the leading cause of disability worldwide [1 ;2] and consequently leads to a major socioeconomic impact on society [1;3]. In Europe, cLBP is the most common cause of medically-certified sick leave and early retirement [4]: in Denmark and France, LBP accounts for 19-20% of all sick leave days and this increases in France for long-term sick leaves, to 30% of sick leaves of more than 6 months [5]. In 2008 in the USA, the total direct medical costs of cLBP were estimated at 8,386\$ per patient whereas in Germany, the annual direct costs were estimated at more than 7,000€ and work absenteeism accounted for 75% of the total costs per patient [6;7]. Its treatment and prevention therefore represent a major challenge for public health.

cLBP is associated with an avoidance and an apprehension behavior defining the term kinesiphobia, which leads to physical deconditioning, prolonged sick leaves and progressive social isolation [8]. Stress, anxiety and depression contribute to deconditioning, and are both consequences of and factors leading to pain chronicity [9]. Recent guidelines encourage a bio-psycho-social management of cLBP, addressing psychosocial factors and focusing on improvement in function and return to work [10]., Functional restoration programs (FRPs) are multidisciplinary programs run over several weeks, which include coordinated delivery of supervised exercise therapy, cognitive behavioral therapy, and medication [10-15]. Guidelines from Denmark, the USA and the UK recommend FRP for cLBP patients who have not responded to first line treatments, and who are substantially functionally disabled by pain [3;16 ;17]. However, currently it is unclear who should be and who is oriented towards an FRP, especially since FRPs are costly and time-consuming [18]. These programs may be more useful to some patients with specific clinical or social

characteristics. Knowledge of the characteristics of cLBP patients referred or not to these programs would be helpful to understand patient profiles in LBP.

The purpose of this study was to compare the characteristics of cLBP patients oriented or not towards a FRP.

## **Methods**

**Design:** French cross-sectional observational study, in six tertiary centers, in the context of routine care between July and November 2017. Ethical approval was obtained (Ethical committee Ouest V approval number: 18.08.21.46733.) and patients signed an informed consent.

**Patients:** Patients were included consecutively by their rheumatologist or physical medicine and rehabilitation physician, if they presented nonspecific LBP, according to the treating physician, evolving for at least 6 weeks, with or without leg pain; and if the main reason for consultation or hospitalization was LBP.

Non-inclusion criteria were: an age under 18 or over 66 years; surgery of the spine in the previous 3 months or scheduled surgery for low back pain in the next 2 weeks.

Patients were not analysed if there was no information on the treatment option (FRP or not); if patients had already performed a FRP and if they were not oriented towards a FRP and the physician put as reason, logistical reasons (e.g. distance from the FRP center).

**Data collection:** data were collected from the physician and from the patient through a self-questionnaire. Data collected from patients were: demographic characteristics (gender, age, education level, smoking status); occupational status (work status, sick leave status and its duration) and current self-reported aerobic physical activity. Physical activity was collected as number of sessions per week and their duration and was analysed as present if the patient reported exercising at least 30 minutes per session, at least twice a week (ie, at least 1 hour/week) which corresponds to a moderate level of physical activity [19]. Symptoms were collected from the patient regarding lumbar pain: duration, intensity (numeric rating scale, NRS: rated from 0=no pain, to 10/10=maximal pain), presence of leg pain, and functional disability

through the Oswestry disability index, specific for low back pain [20;21]. The 0-100 score was analysed as relevant disability for an Oswestry score > 40%, since this cutoff has been reported as reflecting severe disability. Psychological data were collected through the Tampa Scale for Kinesiophobia (TSK), with kinesiophobia defined as a score  $\geq 40/68$ , [22;23]; the Hospital Anxiety and Depression Scale (HAD), with anxiety/ depression defined as scores  $\geq 11/21$  [24]; and patient-reported psychological or psychiatric follow-up.

Physicians confirmed the diagnosis, informed about the presence of a discogenic lesion and gave information on previous treatment modalities including recent spinal surgery or not. The key outcome was the proposal to refer the patient towards a FRP or not. The physician also gave the reasons for not orienting towards a FRP through the following list: no medical indication, lack of patient motivation, patient profile not suitable for group sessions. The different therapeutic options offered by the physicians were also collected.

**Statistical analysis:** Univariate and multivariate logistic regression were performed on R, version 3.2.4. All variables with  $p < 0.20$  in univariate analysis were entered in the multivariate analysis, except for smoking, considered a potential confounding factor. There was no multicollinearity (defined as variance inflation factor  $> 5$ ). As no imputation of missing data was performed, 133 patients contributed to the multivariate analysis. A difference was considered significant for a  $p$ -value  $< 0.05$ .

## Results

Between July 2017 and November 2017, 174 consecutive patients were evaluated in 6 tertiary rheumatology or rehabilitation centers across France. Twenty-seven patients had to be excluded either because of incomplete data on the care option ( $n=8$ ), because they had already performed a FRP ( $n=15$ ) or because the program had not been proposed for logistical reasons ( $n= 4$ ) (Figure A).

Of the 147 patients analysed, mean age was 48.8 years  $\pm$  12.0 (standard deviation) and 59.9% were women. Mean duration of cLBP was 9.1 years  $\pm$  9.4 and mean

duration of sick leave was 3 months or 92.2 days  $\pm$  125.2 (Table A). Degenerative disc disease was present in 84 patients (57.1%  $\pm$  49.7).

Overall, 58 patients (39.5%) were referred to a FRP.

### Univariate analysis

Patients oriented towards an FRP (Table A), were significantly younger, reported a lower pain intensity and a longer sick leave. Low back pain was more often isolated in patients oriented towards a FRP: (33/58) 57.1%  $\pm$  49.9 of associated leg pain in the FRP group vs (65/89), 73.5%  $\pm$  44.3 ( $p= 0.042$ ). Patients oriented towards a FRP less often reported physical activity >1h/week and smoked less often (57.9 %  $\pm$  49.8 in the group FRP vs 75.9%  $\pm$  43.0,  $p= 0.023$ ). However, there were no significant differences regarding functional disability, kinesiophobia level, pain duration, anxiety and depression score. There was also no gender effect.

There was no significant difference between the two groups regarding previous management (Table B).

Table C represents the reasons for not referring to the FRP and the therapeutic options that physicians offered to these patients.

### Multivariate analysis

The multivariate logistic regression (performed without imputation, in 133 patients) included the following variables: age, gender, duration of sick leave, duration of low back pain, presence of leg pain or not, self-reported physical activity, pain level and functional disability.

Three characteristics were independently associated with orientation toward a FRP: a lower level of pain, low self-reported physical activity (less than 1h/week) and longer sick leave (Table D).



## Discussion

This observational study indicated that patients referred to a FRP had lower pain levels, reported less physical activity and had a longer sick leave. On the other hand, disability, kinesiophobia and the other medical characteristics assessed, were not found to be associated to proposing a FRP. Thus, orientation towards a FRP appeared more linked to socio-occupational than medical or psychological determinants. This confirms the biopsychosocial approach of FRPs for cLBP.

This study has strengths and weaknesses. Although the sample size is limited, strengths include consecutive inclusion of patients in several expert centers for FRP. Patients here may be considered representative; patient characteristics in the present study were in accordance with previous studies [11;12;25]. Our study population was slightly older than the others (the mean age of patients included in the FRP was 42 years old) and self-reported slightly more physical exercise (only 14.6% in Caby's study and 19.0% in Poulain's study) this is perhaps due to inclusion of consecutive patients rather than FRP patients only [12; 25]. A strength is the standardised assessment of factors potentially associated to inclusion in an FRP going from disease characteristics to psychological and social factors. The scores used to assess function, kinesiophobia and anxiety/depression are widely validated and have been used in LBP previously [15; 26, 27]. Even so, it is probable that in the present study, we did not collect all the elements to adequately reflect the decision-making process. Indeed, in the multivariate analysis, the ORs were small though significant which is a strong point in favour of the robustness of our conclusions but leaves space for unexplored factors. More specifically, it would have been interesting to collect more professional data such as stress at work. Working conditions, relations with colleagues, and occupational dissatisfaction are known to be risks factors of pain chronicity but are difficult to assess in quantitative studies [9, 28]. In the present study, physical activity was not assessed using a standardized questionnaire but rather simple questions. We also did not evaluate the strict threshold of 150 min of physical activity per week, as recommended by the World Health Organization (WHO) [29], but rather our binary assessment compared less than 60 minutes to an interval ranging from 60 min to 240 min per week. This choice was made because in patients with cLBP, physical activity is a major issue and reaching the WHO threshold

is difficult. The threshold used here of at least 1 hour/week corresponds to a moderate level of physical activity which might be useful for cLBP patients [19]. Furthermore, we did not collect anatomical findings in our patients. Here, only the presence or not of a degenerative disc disease was assessed. In cLBP patients, lesions are diverse going from total disjunction between imaging and symptoms, to severe degenerative disc disease [30; 31]. Of note, anatomical lesions have not been previously reported as factors explaining FRP efficacy [11; 12; 30-32].

A link was found between FRP proposal and lower pain levels. Although pain is linked to the disease, it is also linked to psycho-social elements in chronic conditions [33-35]. Thus, pain can be considered a mixed medical and psychosocial component of cLBP. Here, patients were oriented towards a FRP when they had less pain, though pain levels were still very high in those patients (mean level, 6.1). We can hypothesise that very painful patients were considered less adapted to perform a FRP, perhaps due to expected lower collaboration and active participation in the physical components of the programme. Patients with very high pain levels may be better candidates for medical pain management (improvement of analgesic treatments).

An association of FRP orientation with low levels of self-reported physical activity was found. The association with orientation towards a FRP is logical, as patients who already perform enough physical activity would not benefit substantially from FRPs, which include encouragement to move more. The cutoff used here to define self-reported physical activity was one hour per week, which is quite low. We believe patients who perform less than an hour per week of physical activity may be examples of the fear avoidance model: “the less I do, the more pain I feel and the less I do” [36]. Kinesiophobia is also often associated to less physical activity, however in the present study we did not analyse this relationship [36; 37].

Longer sick leave led to more orientation towards FRPs. There are several potential explanations to this finding. Firstly, the delay may have been due to the time needed to try different medications and physiotherapy in the context of standard" medical care. Secondly, given the small number of FRP centers, the waiting list is often long. And thirdly, perhaps physicians were reserving the costly and time-consuming

multimodal programs for patients with prolonged sick leave [18]. Patients with short sick leaves may have been oriented towards shorter outpatient programs, such as physiotherapy. However, FRPs have been developed to facilitate return to work and are more effective in patients with a shorter sick leave so that the present finding should raise discussions within specialists. Indeed, a study indicated that after 1 to 3 months of leave, return to work was observed in around 60% of patients whereas after 1 to 2 years of leave, this percentage was close to 0 [38].

The absence of correlation between some characteristics and orientation towards FRPs is of interest. No link was found for functional disability, in accordance with the literature [39; 40]. As tertiary centers we had a recruitment bias: patients with low functional impact were not screened. Kinesiophobia and psychological factors (here, anxiety and depression) contribute to the prolongation of lumbar pain and therefore to a progressive psychological and social deconditioning against which the FRP is useful [8;11-13; 15; 26; 41]. However here these elements were not found to be linked to FRP proposal, perhaps due to the recruitment bias previously mentioned. In this instance, this study speaks to the intangibility of the medical decision-making process in cLBP where many elements may play a role while being difficult to collect and quantify.

FRPs have varying methodologies. In most cases, they run for 3 to 6 weeks, all day long and involve several health care providers including but not limited to rheumatologists, nurses, dieticians, psychologists, physiotherapists, and/or sports coaches. Their content varies across centers; however, three components are common to all programs: physical, psycho-behavioural and socio-occupational [14]. The diversity of centres with FRPs involved in the present study reflects the diversity of such programs in practice and in this regard, increases the external validity of our findings. This study is truly a 'real-life' picture of current medical practices in France. Here, since orientation towards FRPs was linked to pain, self-reported physical activity and sick leave, it seems that orientation is more explained by socio-occupational factors than medical or psychological ones, within the limits of the data analysed in the present study. In any case, the present study confirms the biopsychosocial approach of FRPs for cLBP.

In conclusion, within the limits of the cross-sectional study, according to physicians, cLBP patients with controlled but still present pain, on longer sick leave and with a reduced physical activity were more oriented towards FRP than others. However, physicians' full evaluation and expertise, in term of benefits at the patient or societal level, take the lead in the choice of therapeutic management. Further studies would be of interest to explore the practical attitude of "medical decision-makers" when faced with cLBP patients.

### **Acknowledgments**

The referral centers were recruited via the spine section of the French Rheumatology Society.

**Funding source:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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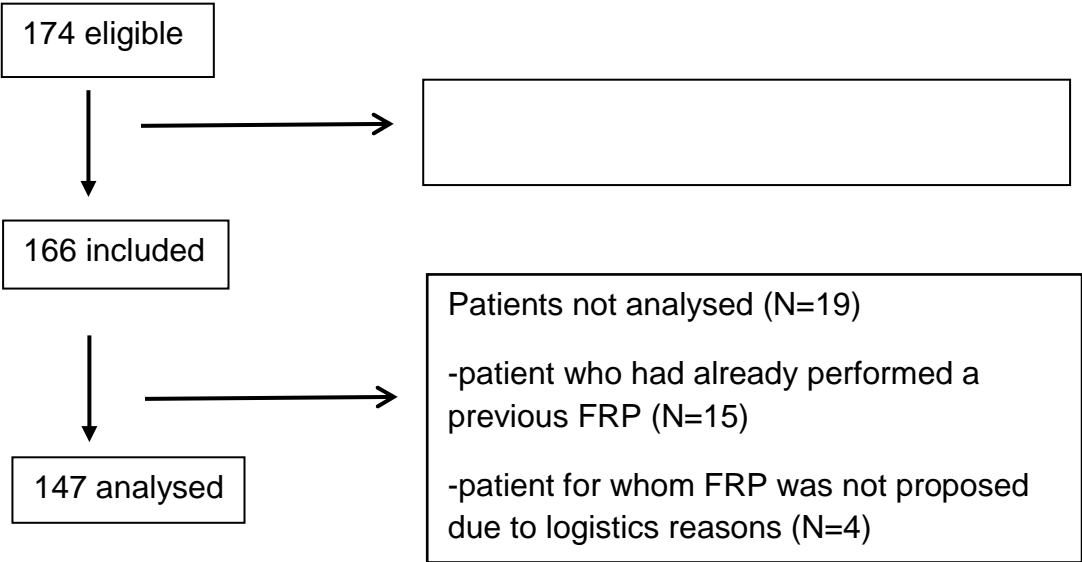
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**Figure A. Flow chart**



<b>Characteristics of patients</b>	<b>All patients (N=147)</b>	<b>Patients oriented to FRP (N=58)</b>	<b>Patients not oriented to FRP (N=89)</b>	<b>P value</b>
Women, % (SD)	59.9 (49.1)	51.7 (50.4)	65.2 (47.9)	0.105
Age (years SD)	48.8 (12.0)	46.3 (11.2)	50.5 (12.2)	0.036*
Education level ( $\geq$ end of high school), % (SD)	44.3 (49.9)	40.4 (49.5)	47.1 (50.2)	0.434
Current smoking, % (SD)	68.8 (46.5)	57.9 (49.8)	75.9 (43.0)	0.023*
High occupational category, % (SD)	67.8 (46.9)	74.1 (44.1)	63.6 (48.3)	0.051
Current sick leave, % (SD)	56.5 (49.8)	53.2 (50.4)	59.0 (49.6)	0.549
Duration of sick leave in the past year, days mean (SD)	92.2 (125.2)	128.5 (140.6)	67.6 (107.6)	0.004*
Duration of cLBP, years, mean (SD)	9.1 (9.4)	8.6 (9.0)	9.5 (9.7)	0.586
Pain NRS (0-10)	6.7 (2.0)	6.1 (2.0)	7.1 (1.9)	0.002*
Presence of leg pain, % (SD)	67.1 (47.1)	57.1 (49.9)	73.5 (44.3)	0.042*
Physical activity > 1h/week, % (SD)	46.2 (50.0)	35.1 (48.1)	53.4 (50.2)	0.031*
Oswestry disability index score /100 (SD)	42.0 (16.4)	38.9 (12.6)	43.9 (18.3)	0.072
Kinesiophobia (score $\geq$ 40/68), % (SD)	62.2 (48.7)	64.8 (48.2)	60.2 (49.3)	0.605
Depression (HAD $\geq$ 11/21), % (SD)	38.1 (48.7)	39.6 (49.3)	37.0 (48.6)	0.756

Anxiety (HAD $\geq$ 11/21), % (SD)	52.5 (50.1)	51.7 (50.4)	53.1 (50.2)	0.875
Psychological or psychiatric follow-up, % (SD)	7.7 (26.8)	13.0 (33.9)	4.5 (20.9)	0.069

**Table A. Patient characteristics according to proposal of FRP or not, for 147 patients with cLBP.**

cLBP: chronic Low back Pain; FRP: Functional Restoration Program; High occupational category designated managerial roles and intellectual professions; NRS: Numerical Rating Scale of pain ranging from 0 (no pain) to 10 (worst pain imaginable); Physical activity: patient-reported as >1h/week; Oswestry disability index in percentage (lower scores indicating less severe symptoms); TSK: Tampa Scale for kinesiophobia (kinesiophobia if  $\geq$  40/68); HAD: Hospital Anxiety and Depression scale present if  $\geq$  11/21).

**Table B. Previous cLBP management**

<b>Management</b>	<b>All patients (N=147)</b>	<b>Patients oriented to FRP (N=58)</b>	<b>Patients not oriented to FRP (N=89)</b>	<b>P value</b>
NSAID intake, % (SD)	30.6 (46.2)	27.6 (45.1)	32.6 (47.1)	0.528
Non-morphinic analgesics % (SD)	83.6 (37.2)	77.2 (42.3)	87.6 (33.1)	0.097
Opioids % (SD)	13.5 (34.3)	12.3 (33.1)	14.3 (35.2)	0.735
Physiotherapy % (SD)	44.8 (49.9)	52.6 (50.4)	39.8 (49.2)	0.130
Epidural corticosteroid injection % (SD)	14.7 (35.5)	15.5 (36.5)	14.1 (35.0)	0.818
Previous spine surgery % (SD)	16.8 (37.5)	19.2 (39.8)	15.1 (36.0)	0.543

NSAID: non steroidal anti inflammatory drug



**Table C. Reasons for non-orientation towards a FRP and other treatment options suggested by physicians for cLBP among 89 patients not oriented towards a FRP.**

<b>Reasons for non orientation</b>	<b>N (%)</b>
No medical indication	52 (58.4)
Lack of patient motivation	14 (15.7)
Patient profile not suitable for group sessions	1 (1.1)
Other	3 (3.4)
<b>Treatments options proposed</b>	
Surgery	3 (3.4)
Epidural corticosteroid injection	71 (79.8)
Referral to a pain management center	7 (7.9)
Psychological support	6 (6.7)
Non-pharmacological methods (sophrology, hypnosis, acupuncture...)	2 (2.2)

**Table D. Factors associated to orientation towards a FRP among 133 patients with cLBP: multivariate logistic regression**

<b>Characteristics</b>	<b>Odds Ratio</b>	<b>95% Confidence Interval</b>
Pain NRS (for 1 point)	0.95	[0.91; 0.99]
Duration of sick leave (for 30 days)	1.03	[1.01; 1.05]
Self-reported physical activity (yes)	0.84	[0.72; 0.98]

cLBP: chronic Low back Pain; FRP: Functional Restoration Program; NRS: Numerical Rating Scale.