

# Low Back Pain: Barriers and Effects of Exercise



# A Brief Review of Physical and Psychosocial Factors Involved in Chronic Low Back Pain

#### Abstract

There is a high incidence of low back pain (LBP) in developed countries. Researchers have investigated potential occupation setting(s) that increase the risk of LBP and have reported numerous job related adaptations to reduce the various identified risks. However, chronic LBP results in approximately 10% of all reported LBP cases which can result in frustrating prolonged disability and extensive financial costs to the healthcare system. In the absence/ successful treatment of medical and neurological pathology, biopsychosocial interventions may assist chronic LBP sufferers regain their personal and professional lifestyle. Following the biopsychological intervention model, recent research indicates that following 'normal' clinical practice guidelines for LBP and the feedback/recommendations made by healthcare practitioners (physicians' and therapists') plays a crucial role in chronic LBP patients treatment and recovery duration.

Keywords: Chronic low back pain; Disability; Management

#### Introduction

The lifetime prevalence of low back pain (LBP) is greater than 70-90% in industrialised countries [1,2]. Acute LBP is defined as, increased muscle tonus, and stiffness localised below the costal margin and above the inferior gluteal folds, sometimes accompanied by radiating pain, for up to six weeks; subacute LBP definition is used when the pain continues longer than six weeks, but does not exceed 12 weeks; post 12 weeks, the LBP is then classified as chronic LBP [1,2]. Acute LBP seems to be a common condition for which early intervention is required to prevent chronicity [3,4]. Most LBP episodes tend to improve within the first 60 days [5,6], however, 10% of patients experience prolonged pain and disability, and these cases account for 90% of workers' compensation costs related to LBP [7] as most of these chronic LBP cases cannot be predicted/diagnosed by anatomical or structural changes [8]. Work absence d mostly due to chronic LBP costs billions of dollars worldwide (estimated to be \$100 billion per annum in the USA alone) [9] due to decreased/lost productivity, treatment costs, employing and training a second staff member to fill the vacancy, and ongoing compensation payments [10,11].

#### Low Back Pain Cause(s) and Prevention Strategies

Many occupations require prolonged periods of lifting, standing, and turning. These activities have been associated with increased reports of musculoskeletal disorders, especially LBP, which result in acute and possibly long-term functional detrimental effects. This risk of LBP has prompted the use of mechanical lifts and other devices to assist workers. Hodder et al. [12] and Holmes et al. [13] suggested that posture analysis of the entire working shift with emphasis on all activities related to the respective workers should be examined. As an example, these researchers reported that long-term care health professionals performed patient lifts and transfers for less than 4% of the shift while patient care, unloaded standing and walking as well as miscellaneous tasks, accounted for 85% of the shift. Manual lifts and transfers occurred twice as often as mechanically assisted lifts but took only half the time. While performing manual lifts, the workers had a median trunk flexion angle of 9.2°, spent 25% of their time flexed beyond 30° and had peak flexion angles greater than 75° in many tasks. A study completed by Nelson-Wong et al. [14] at Regis University, Denver, CO and University of Waterloo, Waterloo, ON reported that 40% of the asymptomatic subjects developed LBP during a two-hour standing exposure. Also, while performing a unilateral stance for twohours, subjects experienced a decrease in vertebral joint rotation stiffness in lateral bending and increased centre of pressure excursion. As suggested by these researchers, it stands to reason there may be adverse effects to prolonged standing if followed by activities requiring precise balance or resistance of side loads [14]. However, the authors did not address possible a relationship between anthropometric (i.e. body weight, waist circumference, etc.) and functional capacity and the onset of LBP. As stated above, most physical impairments attributed to LBP are resolved within the first two months of injury [5,6,15]. Further, researchers have investigated various intervention strategies (anti-fatigue mats, shoe insoles, and more recently, sloped platforms) that seem to alleviate and/or decrease the risk of LBP [16-18]. Recent research has placed greater emphasis on the role of sloped platforms while performing manual lifts and published results suggest: A reduction in perceived low back pain when using sloped platforms is likely not the result of changes in morphology of the trunk musculature, but possibly related to altered kinematics caused by standing on these platforms [16], A 59.4% decrease in subjective LBP scores when using a sloped surface compared to level standing [17], Subjects preferred to stand further from the load as slope changed from downhill to uphill [18], A downhill slope led to increased torso lean [19], Lower back activity (erector spinae muscle group) was not affected by the sloped platform [18], and No significant movement differences were observed between men and women [18].

#### Potential Treatment Options for Chronic Low Back Pain

Various treatment modalities (non-pharmacology/psychologicalbased, manual therapy, and pharmacology-based) have been used to for chronic LBP sufferers. Recent Chocrane systematic reviews concentrating on psychological interventions reported the following:

- Problem solving therapy (PST) led to partial return to work (RTW) 17 days earlier compared to not no treatment or treatment by an occupational physician or general practitioner [20],
- Cognitive behavioural therapy (CBT) or PST does not expedite RTW full-time compared to receiving no treatment or treatment by an occupational physician or general practitioner [20],
- Only CBT has been adequately studied to allow tentative conclusions [21],
- CBT decreased somatic symptoms; however, small effect and considerable differences in effects were found between CBT effects [21], and
- Compared with enhance/structured (multidisciplinary) care, physiological therapies/CBT were not more effective [21],
- Chochrane and systematic reviews on the effectiveness of manual therapy found:
- No clinically related difference between spinal manipulative therapy (SMT) and other treatments to reduce LBP pain and improve patient function in patients with Chronic LBP [22],
- Based on a small number of available studies meeting the Cocharane review criteria, SMT was found to be no more effective in treating acute low-back pain compared to no intervention, sham SMT, or when combined to another treatment modality [23,24].

#### Biopsychosocial Factors and the Role of Healthcare Professionals (HCP) Associated with Chronic Back Pain

In the absence or successful treatment of a medical pathology and/or a neurological impairment, researchers have shifted their focus to biopsychosocial interventions in LBP rehabilitation to address concern(s) related to the 10% of patients who experience chronic LBP. The aim of this shift is to prepare chronic LBP sufferers to accept and manage their pain conditions [25] and is based on findings that indicate individuals with negative recovery expectations will remain absent from work two times greater than for those with more positive expectations [15,26-28]; positive patient recovery expectations were associated with a 37% faster suspension of time-loss benefits/return to work [26]. Further, Iles and colleagues [27] reported that recovery expectations measured within three weeks of the onset of low back pain are a strong predictor if that the pain will become chronic. Specifically, negative expectations about recovery were a significant strong predictor of future work absence despite variations in follow-up time and the use of different measurement instruments [15]. An individual's expected recovery time can be influenced by fear, pain, pain intensity, beliefs [28]. Previous experience [29] possible (although not supported by all researchers [30,31] low workplace support and low job satisfaction [32]; pain intensity was identified as a strong predictive factor for LBP chronicity (expected recovery time of more than three months) [29,33,34]. These experiences/influences can result in distress, a depressive mood and somatisation which lead to the progression to chronic LBP [35-37]. To assist patients overcome these beliefs, Udermann et al. [38], reported that educating patients may

have important efficacy results in decreasing LBP and reducing the frequency of, or even eliminating their recurrent LBP episodes. These authors found with patients experiencing 10.4 years of chronic LBP that after one-week of being presented with educational material, 51.6% of the chronic LBP sufferers reported noticeable improvements in their pain and related symptoms [38]. At nine-month follow-up, statistically significant and clinical relevant improvements were reported in pain levels, total number of episodes, and perceived benefits; at 18-months follow-up, these chronic LBP sufferers reported and presented with additional progress [38]. In addition, to assist health care professionals (HCP), researchers have developed 'prediction models' based on acute clinical LBP symptoms and psychosocial risk factors, to determine which patients may be at risk of unsuccessful return to work [39].

In the absence of medical pathology or neurological impairment, the 'normal' clinical practice guidelines (CPG) encourage physical activity, despite pain, recommend patients continue with normal daily activities, avoid bed rest and passive treatments, and return to work as soon as possible [40]. Nevertheless, published evidence suggests that HCPs do not always follows these guidelines [41-43] and personal beliefs and attitudes about LBP influence feedback to their patients, regardless of their knowledge of known CPG [44,45].

Past and recent research is also proposing that HCPs' attitudes and beliefs about back pain may influence the attitudes and beliefs that patients hold about their own LBP [15,46-52]. Further, Domenech et al. [53] and Darlow et al. [47] reported there was a strong correlation between both fear-avoidance and pain-impairment beliefs with the HCPs' work recommendations, which, strongly supports the hypothesis that beliefs and attitudes are potent modulators of clinical behaviour and may limit adherence to the CPG. These authors also confirmed previous suspicion that a strictly biomedical education/ orientation exacerbates maladaptive beliefs and consequently results in recommendations for work and activity levels that differ from those indicated by the evidence [47,48,53]. To assist HCPs, Rainville et al. [46], suggested clinicians enhance their understanding of fearavoidance beliefs and gain insight into the possible value of CPGs which will assist in decreasing fears and concerns of their patient suffering from LBP. Also, Evans et al. [51], reported that peerreviewed published education material seems to modify HCPs personal beliefs which led change in practice that followed CPG.

#### Conclusions

These factors associated with HCP influence may help explain the poor patient adherence to CPG guidelines/recommendations [54]. As such, for patients suffering from LBP, early biomedical diagnosis (elimination of medical pathology and/or neurological impairment) as well as early biopsychosocial interventions may assist patients receive adequate treatment and achieve rapid return to personal and professional wellbeing. Perhaps the key, as stated by Darlow et al. [47], HCPs must be sensitive about the association between their attitudes/ beliefs as their clinical management of their patients with LBP can have a direct influence on these patients.

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# Facilitators and barriers to physical activity in people with chronic low back pain: A qualitative study

# Abstract

# Background

For medical teams, one of the main objectives of rehabilitation for people with chronic low back pain is adherence to physical activity (PA).

# Objective

The objective of this study was to identify PA barriers and facilitators in this population.

# Methods

This qualitative study included 4 discussion groups and 16 semi-structured interviews conducted among people with non-specific chronic low back pain who were involved in a specific rehabilitation program or seen in primary care settings.

### Results

Three main themes were identified: physical factors, psychological factors and socio-environmental factors. The main barrier to PA practice is pain. Psychological barriers were associated with the difficulty in integrating PA in the person's daily life. Environmental barriers were dominated by lack of time. Facilitators identified associated the supervised nature of the physical activity (supervision by professionals) and group practice, which improved people's adherence.

# Conclusion

The results of this study will allow teams to target relevant educational objectives for these people and develop dedicated self-management programs.

#### Introduction

Physical activity is an integrant part of the care management of several chronic diseases (e.g. multiple sclerosis, cancer, coronary diseases, obesity) [1], and constitutes one of the objectives of multidisciplinary programs for non-specific chronic low back pain (CLBP) [2,3]. PA is described by the World Health Organization (WHO) as "any bodily movement produced by skeletal muscles that requires energy expenditure" [4]. This includes sports activities but also other daily activities such as housework or gardening.

The National Institute for Care and Excellence (NICE) and the European working group on CLBP integrated physical activity into their guidelines [5,6]. Physiotherapy management usually includes therapeutic education for patients on exercises they can perform alone at home in order to transition towards physical activities adapted to each patient's condition in order to decrease the functional impact of CLPB. PA's effectiveness in the care management of people with CLBP depends, among other things, on a person's adherence to the home exercise program and sustainable efforts on the long term, as well as resuming additional physical activities [7].

The rate of non-adherence to home exercise programs in this population reaches 50% and sometimes even more [8], yet these data are hard to quantify. In 1993, Sluijs and colleagues evaluated the adherence of patients to a physical activity program and highlighted certain main factors for non-adherence (barriers perceived by people with CLBP, disease-related level of disability, lack of PA positive effect) [9].

As a matter of fact, people with CLBP often have inaccurate beliefs regarding their condition and its treatment [10], which in turn influences their adherence to exercise programs [11], especially regularity in practicing a physical activity.

Qualitative studies have been published analyzing the satisfaction and experience with CLBP [12], type of exercise [13], or even factors influencing the adherence to exercise programs [8,11] in people with low back pain. However, these studies did not solely focus on people with CLBP, but also included persons with neck pain [8,11]. In 2014, a review of the literature on qualitative studies focusing on PA-related beliefs in people with non-specific CLBP highlighted several barriers and facilitators to PA practice in this population [14], but did not specifically explore barriers and facilitators to PA; therefore, there was a need to explore it in more details in this study.

The objective of our study was specifically identifying barriers and facilitators to PA practice in people with non-specific CLBP, both in primary and secondary care, in order to validate and enrich the array of barriers and facilitators previously identified in previous studies.

#### Materials and methods

#### Type of study

This is a cross-sectional qualitative study with two data collection methods, based on semistructured individual interviews and focus groups (semi-structured group interviews) conducted in Clermont-Ferrand, France from January 2012 to April 2014 (individual interviews were conducted from January to April 2012 and focus groups were conducted from February to April 2014).

The objective of the individual interviews was to identify barriers to physical activity in people with CLBP. Focus groups were conducted later to corroborate the barriers unveiled in the individual interviews and identify PA facilitators. The use of the focus group method enabled, via group interaction, to explore and better refine the opinion of each participant [15]. This type of qualitative study was chosen according to the principle of the grounded theory [16], to study and better understand how beliefs and thoughts in people with CLBP influence their behaviors towards PA, in order to formulate new hypotheses regarding predictive factors of regular physical activity in people with CLBP, and improve the care management in this population.

This study was conducted and reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) [17].

#### People with CLBP

**Recruitment.** For individual interviews, people with CLBP were recruited via three primary care physicians (independent from researchers). They had to identify in their daily practice people with CLBP who met the study's inclusion criteria (purposive sampling method). People with CLBP were then contacted by phone to schedule a face-to-face interview. Other people with CLBP were recruited at the Physical Medicine and Rehabilitation (PM&R) Department of the Clermont-Ferrand University Hospital, directly by the study investigator during the course of their care management in the service. People with CLBP were then contacted by phone to set up an interview.

For focus groups, recruitment took place within the Physical Medicine and Rehabilitation (PM&R) Department of Clermont-Ferrand, University Hospital, France via the functional spine rehabilitation program, also using the purposive sampling method.

Inclusion criteria for this study were: age > 18 with non-specific CLBP, as defined by pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain, persisting for at least 12 weeks and not attributable to a recognizable, known specific pathology (e.g. infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis), radicular syndrome or cauda equina syndrome) [6]. Exclusion criteria consisted in: presence of physical or mental impairment preventing the person's participation in a focus group/individual interview or filling-out written questionnaires, not speaking French and specific low back pain.

**Data collection on people with CLBP.** Nominative data were collected for each person with CLBP. They also filled out evaluation scales on low back pain: The Back Belief Questionnaire (BBQ; assessing patients' knowledge) [18], the Quebec Back Pain Disability Scale [19] (evaluating the impact of low back pain on daily life), Fear Avoidance Beliefs Questionnaire [20] (FABQ that evaluates fears and beliefs) and the Numeric Pain Rating Scale.

#### Interview guide

Two interview guides were developed in order to structure the individual interviews and focus groups. These guides were designed based on data from the literature, rehabilitation and occupational therapy experience and advice of low back pain experts (EC, AD). They included several main topics: low back pain, physical activity, barriers and facilitators (only for the focus group interview guide) to physical activity. These guides were not tested prior to the beginning of the study.

#### Study protocol

The purpose of individual interviews was to allow people with CLBP to speak freely about factors limiting their physical activity practice. Four interviews took place in a home setting, four others in a primary care setting, and the last nine interviews in a PM&R department setting (and in that latter case, the location of the interview was chosen by the person with CLBP). These interviews were conducted by a primary care (PC) resident. The person in charge of individual interviews had to lead the interview and encourage participants to express themselves freely.

Focus groups were organized in a room within the Clermont-Ferrand university hospital PM&R department. Each of the focus group started first with a review of the study objectives, and then people with CLBP were invited to share their experiences with low back pain and PA. A moderator and an observer were present in each focus group (PM&R resident (LB) and adapted physical activity trainer (CR) working within the PM&R department).

The interviewers (for both the focus groups and individual interviews) did not have a relationship with people with CLBP prior to recruitment and were not involved in their care management.

The role of the focus group moderator was to manage the group dynamics and goals. The focus group observer was responsible for the recording material and taking notes. Interview guides were used as the main thread for conducting individual and focus group interviews, recorded with a dictation recorder and transcribed in their entirety (verbatim). The study ended when data saturation was reached ("point at which no new information or themes were observed for the data" [21]).

The three persons (ER, LB and CR) who conducted the individual and focus group interviews received a specific training on qualitative research prior to the study.

**Data analysis.** Data were analyzed manually by coding them according to the data triangulation method: the first step consisted in reading the verbatim transcriptions of the different interviews/focus groups, and file each sentence/idea into different categories. The second step consisted in grouping the categories into themes. The third step was dedicated to assembling these themes to form more general concepts [22]. These themes and categories were inductively generated during the research, according to the grounded theory, method so they can name most accurately what the data were suggesting [16]. Data were analyzed progressively alongside the interviews and focus groups (i.e. data collection and analysis were performed simultaneously), with an adjustment of the themes and categories according to the data collected, according to the constant comparative analysis principle. The individual interview guide was refined during the study, in light of the first emerging results, and data stemming from the individual interviews helped design the focus group- interview guide. The literature research was conducted at the end of the study, in order for the data analysis to remain neutral and not influenced by themes existing in other studies.

Two persons [CR, LB] performed independently the data analysis and their conclusions were merged. When they disagreed on a result, the project manager [EC] made the final call.

#### Ethics considerations

Oral and written information on the study was given out to each people with CLBP. An informed and written consent form was collected for each participant not opposed to the study. People with CLBP were warned that they were free to accept or refuse to participate in the study and that it would in no way affect their quality of care. Data were anonymized by a third person who deleted the first and last names of participants and replaced them by a number.

Data were then stored on the server of the Clermont-Ferrand University Hospital, authorized to store healthcare-related data. The study received the approval from the Comité d'Ethique des Centres d'Investigation Clinique de l'inter-région Rhône-Alpes-Auvergne, centre de Grenoble, on March 22, 2012 (N° IRB 5044).

The study was reported on the Clinical Trials website on June 5, 2015, under the number NCT02466360.

#### **Results and analysis**

Twenty-nine people with CLBP participated in the study (Fig 1): 16 for the individual interviews and 13 for the focus groups (4 focus groups: 4 persons for focus group 1, then 3 persons for the other 3 focus groups). The mean duration of individual interviews was 20 minutes (7 15-minute interviews, 2 interviews that lasted about 20 min and 6 interviews that lasted longer than 20 min). The mean duration of the focus groups was 27 minutes (30 min, 22 min, 39 min and 18 min). Characteristics of the study population are summed up in Table 1.

Three main categories of barriers and facilitators to PA practice were identified: physical, psychological and environmental/professional. Sub categories were highlighted within each of these three main themes.

#### **Barriers**

**Physical barriers.** Pain: Pain appears to be the main barrier to physical activity. It was reported by most study participants. Pain intensity can sometimes be quite important: "any minimal physical activity, standing still in one spot, is torture" (line 1683); "when I am in pain, I do not do any physical activity" (line 499); "at times, just standing at the kitchen counter and peeling 3 vegetables is enough to trigger the pain, a pain so unberable I could cry" (line 1293). Pain does seem to impact not only physical activity but activities of daily living: "simple daily chores, washing dishes or shopping in general is torture in fact" (line 1680). Pain also has a psychological impact, bearing a negative influence on physical activity leading to a feeling of disability, social isolation, and loss of self-confidence: "after a while it affects our wellbeing. . .everything seems quite negative in fact" (line 1669); "if my back hurts, I don't do any activity that's for sure, I am not going to the garden and do some digging, that is out of the question! I have two children, if I am in pain and they want to play, my back hurts and I can't play with them. My back hurts I can't do it. It's not that I don't want to it is just that I cannot. I am unable to" (line 29).



#### Fig 1. Flow diagram.

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Table 1. Characteristics of the study	population
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Variables	Number of people with CLBP (n = 29)
Men / Women	19/10
20–30 years / 31–40 years / 41–55 years	3/10/16
Time since the onset of low back pain/year	
< 5 years / 6–10 years / >10 years	13/8/8
Occupational type	
Sedentary / physical / combination of both	7/19/3
Physical activity practice	
Yes/no	14 / 15
Physical FABQ (/24)	
< 14 / >14	9/20
Occupation FABQ (/42)	
< 34 / > 34	22/7
QUEBEC (/100)	
<40 / > 40	15/14
BBQ (/45)	
<23 / > 23	6/23
Numeric scale (/10)	12 A
<5/>>5	9/20
<23 / > 23 Numeric scale (/10) <5 / >5	6/23 9/20

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Comorbidities: For some people with CLBP, other back pain-related pathologies are responsible for the decrease in physical activity, especially osteoarthritis "*I am unable to do certain physical activities: running in particular. I have knee osteoarthritis as well, so I can't run*" (line 1043). Being overweight and having headaches also represent barriers for certain people with CLBP: «*What really helped before was running, now my weight gain really prevents me from enjoying it as I used to*" (line 451). The presence of other painful spots also affect PA practice: "*When I go walking, I realize that the pain is in my hips and in the sole of my feet.*" (line 465).

**Psychological barriers.** Lack of motivation and will to exercise: A large proportion of people with CLBP brought up their lack of motivation and will to exercise "*I don't have any desire to exercise. A lack of motivation, even apprehension*" (line 390); "there needs to be this spark to get motivated, and I just don't have it" (line 1335). This lack of motivation is sometimes pain-related: "motivation sometimes is...When one hurts the motivation goes down" (line 1791); or fatigue: "some days we are motivated, but other days the fatigue takes over..." (line 1883).

Kinesiophobia and anticipatory anxiety: Another consequence of pain is kinesiophobia, with or without anticipatory anxiety: "when I'm in pain, I don't do much, I stay on the couch! Rest! It's a fold-up couch! I move around a little but I am careful about the movements I make" (line 1420); "I need to be aware for any movement I make" (line 1581). People with CLBP interviewed brought up the fear of aggravating the pain: "The pain and sometimes even if it doesn't hurt right away, knowing we will be in pain later, in 2 hours or right after, and 3 hours later the pain will be intense" (line 2035); or they fear the pain will have an impact on their professional activity: "If I resume exercising and sports and then I hurt myself I will no longer be able to work." (line 2532).

False beliefs: Not all participants recognize PA as an integrant part of low-back pain treatment: *"Physicians who prescribe walking for low back pain: it's useless"* (line 1713). In that case PA is perceived as a factor aggravating the pain: *"Playing sports is probably not great for my*  back. We keep jumping around so I think it might not be so great and often after a game my back hurt, and I think that's what caused it" (line 1407). Loading was often brought up by people with CLBP as an aggravating factor for pain: "When I go grocery shopping, I can't carry heavy things, for example 6-packs of milk bottles are impossible to carry, I must take the bottles one by one" (line 1584); "Standing still, without moving much, walking, sports, exercising, physical things that make the pain worse. Carrying a load such as a computer, groceries." (line 94).

Lack of perceived benefits: It appears that several people with CLBP tried to resume an exercise routine, but this experience was fruitless, aggravating the pain or not bringing any improvement: "Sometimes I try to exercise and then I'm in pain, looking back had I known it would hurt I would probably not have done it" (line 2037), "my primary care physician recommended swimming, I did not know that breaststroke was not adapted to low back pain, since that is the only way I swam I was in pain and I gave up." (line 960). This sometimes leads to false beliefs with people with CLBP believing that PA can be harmful: "It can be harmful, I give you an example: I have a colleague with low back problems, similar to mine, and she loves to take step classes, but each time she exercises too much, she is in pain but continues. I think she should stop, it is quite dangerous for her" (line 378).

False interpretations: Some people with CLBP reported misunderstanding the terms used by the medical team: "*The term chronic low back pain, makes me think of recurrent back pain.* . . *it is frequently used by physicians, I have the feeling it is rather a "catch-all" term*" (line 90). Interviews showed that certain people with CLBP wrongly interpreted their additional examinations: "*I limited my activities, additional examinations for my acute back pain revealed a herniated disc, and spinal osteoarthritis* . . ." (line 24). Some people interpreted their pain as a sign of disease severity: "*I was really scared, I felt this close to being paraplegic, my back could not hold my weight, at 41 it was quite a shock.*" (line 246).

**Socio-environmental and occupational barriers.** Lack of time: This is one of the main socio-environmental barriers. Programming PA in a daily agenda requires scheduling efforts: "but it's impossible, these classes are at 6pm and I am often still at work, so I miss a class, really it was quite complicated and I did not go further" (line 410). People with CLBP who have long working hours bring up the difficulty in finding time to exercise: "Sometimes the days are just too short. When one starts at 6 am and finishes at 8pm it is ..." (line 1793); "I've been told that swimming would help, but I don't have any time. Time is the issue" (line 37).

Occupation: Working is often reported by people with CLBP. Some see it as a triggering or aggravating factor of their low back pain: "Yes I do think that working (well really there might be a genetic part) but work had to...Then at first we did not have all these technical aids, automated beds, Hoyer patient lifts, transfer stands, we did not have all this equipment so of course it affected our health. This is why most of my colleagues from this generation have problems." (line 417). Job dissatisfaction was also reported as a barrier to exercise, just like the workload: "What could prevent me from continuing my exercises would be to not to find another job, my goal is to find a job where I am happy to go to work in the morning, it must be your case I believe." (line 1287). Certain people with CLBP fear that their condition will have a negative impact on their work, mainly they are afraid of being laid off.

Some people with CLBP showed a lack of motivation to exercise after an intense workday, especially those with a physically demanding occupation: *"For me, my job is physically demand-ing, so in the evenings I don't really want to exercise*" (line 1698).

False recommendations from healthcare professionals: Some people with CLBP cited medical prescriptions and recommendations from healthcare professionals that went against promoting PA for low back pain: "In my case they stopped everything. The physiotherapist because the pain was too severe. They told me to stop exercising at home because it wasn't right either. . ." (line 2386); "they told me, do you want to finish in a wheelchair?" "Continue like this and you will end up in a wheelchair; then it will be over, you will no longer be able to run" (line 2491), "Yes I tried to see if I could run again but I was told not to" (line 78).

Family environment: People with CLBP are sometimes encouraged by their closed ones to rest, and they describe a rather paternalistic and protective attitude: "In fact my wife tells me to go easy etc., you are going to hurt your back. My wife tries to limit my activities" (line 558). Family members often have a patronizing approach: "Don't do this", "Don't chop wood or your back will hurt" (line 1861), "My girlfriend gets more worried. She is more inclined to help, if I don't feel good she tells me to wait and she will do it for her." (line 2160). In the long run this attitude can maintain people with CLBP in a vicious circle of physical inactivity.

Barriers less frequently reported: Other barriers to PA were less frequently reported: the monotonous nature of the exercises ("I would like to exercise but after a while you get really bored, it is no longer fun." (line 2509)), the environment, absence of prior sporting activity ("It really will be hard. Well if you never did any sports before. It is really hard to stick with it. I can see it every year, I try and then I give up, because. ..." (line 1894)), anxiety regarding the diagnosis' lack of precision ("And before that I was completely discouraged, in fact you don't know what you have, you are in pain but do not know why. Every night it is impossible to sleep, my wife can't sleep either, anxiety sets in" (line 1258)), lack of interest for physical exercise, poor weather, and unwillingness to exercise alone ("If I don't go walking it is because no one will come with me." (line 1385)).

#### Facilitators

**Physical facilitators.** Very few people with CLBP interviewed thought that a back support could improve their level of physical activity: "It relieves my pain especially when carrying heavy loads" (line 1925), "It bring more support really" (line 1926).

**Psychological facilitators.** The will to engage in physical activity: A great number of people with CLBP interviewed want to engage in PA, and some do in spite of the pain "even the permanent pain does not prevent me from doing things. At home I do a lot of DIY" (line 1681), "I would rather do something else, even walking for half-hour even if I will be in pain, rather than stay put and do nothing." (line 1721). This will to exercise also seems related to the positive image of PA: "When you see people who are well and do not exercise I feel. . ... It makes me sick" (line 2060).

The desire to recover their prior physical aptitude / level of physical activity: Still related to the impact of pain on their daily life activities, people with CLBP expressed their wish to resume activities they had to stop due to the low back pain: *"Being able to resume leisure activities I used to do, being able to do them again if possible"* (line 1964); and getting back to their previous health status: *"I just want to get back to what I had before. Nothing more"* (line 1876).

**Socio-environmental facilitators.** Supervision by healthcare professionals end teaching people with CLBP to perform self-exercises: Many people with CLBP shared their fear of executing the wrong exercise movements and were more willing to engage in exercise therapy if it were monitored by healthcare professionals, who would ensure that the exercises were done correctly: "*At home we might be doing the wrong movements, or gestures we should not do, that is why I think it is better to be supervised by healthcare professionals*"; (line 1837) "*Plus it is important to have a coach who motivates us, helps us exercise, and corrects our postures*" (line 1738), "*At the gym, you do cardio for 45 or 90 minutes, you go there and cycle. You get bored and continue.*" (line 1840).

PA follow-up: Regular monitoring of PA practice seems to be a great source of motivation: *"There is increased motivation behind. Thinking that after two months we will see progress. …it is a type of motivation"* (line 1888). Only one people with CLBP expressed an opinion

regarding follow-up practical modalities: "A follow-up. Even by post or a phone call. Even an email follow-up" (line 1850), "That way we can fix ourselves a goal and try to stick to it. It really depends on one's motivation really." (line 1853).

Group practice: The notion of group exercise was regularly reported: "It is always more motivating to be with someone, not necessarily a group, just a colleague, there is shared motivation. Because if you have to go alone you will find excuses for not going that night and pushing it back to the next day" (line 1829). Family PA practice was also reported a few times: "In the evening when she gets home not too late, we go for a walk" (line 1870).

Multimedia support: There seems to be a certain reticence in using multimedia supports, people with CLBP are often critical regarding the type of exercises offered on these supports: "Ok but only if there are good exercises. Because all the games right now on the Wii. ..." (line 1920). Participants with CLBP see it more as additional supervision: "I would say it is in addition to my routine, for example during busy weeks, I can do a half-hour of that thing. I can try to do it" (line 1922).

Daily life obligations: Participants with CLBP sometimes report feeling "obligated" to engage in PA when it is part of daily life: "Of course we do stuff me must do because one must earn a living, and then some like gardening because nobody else is going to do if for me" (line 1980),

The notion of pleasure: From the focus groups, it emerged that the nature of PA plays an important role, and when it is a pleasurable activity for the people with CLBP, it improves adherence: "It is really different to exercise to keep in shape like we do here for example when we are alone, compared to horse-riding, or playing sports, or walking around, for that I don't need anything. . . It is obvious" (line 2556); "If there were mushrooms all year long I would walk all the time (laughs)"; (line 2565).

**Others facilitators.** Other facilitators reported in group interviews and rarely brought up were: summer season (*"with the nice weather it is much easier*" (line 1822)), the will to feel better (*"If I felt better exercising I think I would stick to it*" (line 2513)), and explanations delivered by healthcare professionals on the benefits of PA for their low back pain (*"If they tell me that I need to do the same movements every morning for example during one hour because it will help my condition, I will do it and I will adapt"* (line 1947)).

The main results according to the two acquisition methods are summarized in Table 2.

#### Discussion

This study unveiled that there are multiple factors influencing PA practice in people with CLBP, varied, and often intertwined together. Furthermore, they differ from one person with CLBP to the next. Nevertheless, it seemed important to better refine these factors in order to detect them early on and adapt therapeutic strategies.

Our study unveiled three main categories of barriers and facilitators: physical, psychological and socio-environmental. The main physical barrier was pain. Regarding the main psychological barriers, we found that kinesiophobia and lack of motivation were at the forefront. The main socioenvironmental barrier was having a physically-demanding work. The will to practice a PA and supervision by a healthcare professional were the main facilitators to PA practice.

In our study, pain appeared to be a major barrier to participants' adherence to a PA program. However, the main effect of exercise therapy is not to alleviate pain but to bring functional improvement with decreased disability and incapacity. This unveiled also the lack of information delivered by healthcare professionals to people with CLBP regarding the expected benefits of this care management. This adds up to another barrier found in our study, which is

#### Table 2. Main barriers and facilitators.

	Individual interviews (n)	Focus group (n)
Low back pain	12	16
Feeling of disability	5	5
Psychological impact of the pain	5	9
Kinesiophobia / fear of pain	10	14
Lack of perceived benefits	4	6
Lack of motivation / physical occupation	9	12
False beliefs	6	3
Occupational PA: aggravating factor	12	1
Erroneous medical information	6	4
Lack of time	5	9
Immediate family	4	9
Will to engage in PA	De B	14
Desire to recover previous physical aptitude		4
Supervision/Self-exercise training	the starter of the second s	10
Follow-up		6
Group practice		7
Multimedia supports		4
Daily life obligations	F . 19	6
Notion of pleasure		4
Weather season		4
	Low back pain   Feeling of disability   Psychological impact of the pain   Kinesiophobia / fear of pain   Lack of perceived benefits   Lack of motivation / physical occupation   False beliefs   Occupational PA: aggravating factor   Erroneous medical information   Lack of time   Immediate family   Will to engage in PA   Desire to recover previous physical aptitude   Supervision/Self-exercise training   Follow-up   Group practice   Multimedia supports   Daily life obligations   Notion of pleasure   Weather season	Individual interviews (n)   Low back pain   Feeling of disability   Psychological impact of the pain   Supervision / physical occupation   Palse beliefs   Occupational PA: aggravating factor   Lack of time   Erroneous medical information   Lack of time   Supervision/Self-exercise training   Follow-up   Group practice   Multimedia supports   Daily life obligations   Notion of pleasure   Weather season

#### n = number of citations

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the absence of perceived improvement when exercising. Improving the information delivered to people with CLBP regarding the expected benefits of staying active associated or not to therapeutic self-management sessions could be a relevant pathway. It would be important to ensure that people with CLBP have correctly understood the set objective, i.e. not to have their pain disappear but rather to learn how to cope with it to promote functional improvements. Damsgard *et al* reported in their 2011 study that there were two main criteria influencing staying active in spite of chronic musculoskeletal pain: benefits of physical activity, possibility of resuming a social life thanks to PA [23].

However, the role of pain intensity in fear-avoidance of PA should not be neglected as mentionned by Bunzli et al in their 2015 study [24].

Our study highlighted that physical barriers and facilitators appear to be minor compared to psychological barriers, mainly fears (kinesiophobia and fear of pain) and false beliefs (related essentially to physical activity prescribed by healthcare professionals, reported to increase the pain according to a great number of people with CLBP interviewed).

This could partly be explained by the fact that participants in our study had a slightly higher VAS score and false belief score than other French studies on populations of people with CLBP, on the other hand the Functional Independence Measure (FIM) was comparable [25]. This meets the fear-avoidance model of people with chronic pain developing avoidance

strategies essentially based on positive punishment (PA leads to pain, which in turn progressively diminishes PA frequency until it stops completely) [10]. Since the care management of people with CLBP is based on the bio-psycho-social model [26], the principle of therapeutic self-management becomes highly relevant [27]. The therapeutic self-management supports, mainly written ones such as information booklets [27], deliver information to people with CLBP on their condition and its treatment. Some studies did already show, in acute low back pain, that adherence to PA was better when the verbal description of the exercises was associated with written guidelines [28]. Furthermore, graduated exposure to AP could be interested in these people with CLBP, even more so since they have a high score of false beliefs. Implementing individual or collective self-management sessions, appears like a good solution to improve compliance to physical activity in people with CLPB [27]. The efficacy of individual self-management in people with acute or subacute LBP seems to be effective. For people with CLBP, the effectiveness of individual education is still unclear [29]. The main challenge remains to implement self-management strategies in everyday's practice.

The influence of family members was brought up both as barriers and facilitators in our study. This underlines the great variability of the role played by family members. Friends and family appear as a potential source of increased adherence to PA, but only if they are educated on the subject. The implication of family members is even more important because the implementation of a regular exercise routine is often perceived as a great disruptor for the daily life organization, which is sometimes why patients give up their PA routine. Involving family members in the care management of people with CLBP, could alleviate certain barriers, especially lack of motivation.

The positive role of social support on PA adherence was already reported in the literature [30]. However, in 2009, Medina-Mirapeix *et al* showed that the influence of social interactions was more important than family support in regards to PA adherence in people with chronic pain [11]. Thus, this fact seems important to consider, especially since in 2013, *Bunzli et al* conceptualize the experience of "biographical suspension" in people with CLPB [31]. Family members could also have a negative impact in reinforcing sick behaviors [24].

It would be interesting to put an emphasis on the relevance of group exercise, which appeared in our study as a major facilitator.

Structured and supervised PA associated with people with CLBP education on self-exercises at home seems to be a source of motivation for several people with CLBP in our study as well as in the literature [32]. Hayden *et al* found in their study a better efficacy of the supervised exercises with an individualized program vs. simple exercises, associated with decreased pain scores and functional improvement [33]. Bronfort *et al* reported in 2011 increased satisfaction with supervised exercises, vs. home-based exercises [34]. The nature of the exercises taught to people with CLBP also seemed to influence their adherence, this is also confirmed in the literature [8]. The notion of pleasure in PA must also be accounted for. In light of these results, it seems relevant to initially propose an individual management, in order to offer a personalized exercise program for each person with CLBP.

The use of multimedia does not seem to appeal to most participants interviewed in our study. However, the emergence of new technologies such as virtual reality seem quite interesting for further exploration, to promote people with CLBP adherence to PA thanks to their recreational aspects. Results reported in the literature diverge. Miller *et al* concluded in their 2009 study that the use of video supports, such as DVDs was useful, mainly for the time period between two rehabilitation sessions [35]. Studies were conducted on "serious games" in people with chronic pain [36], but no game was specifically validated in people with non-specific CLBP [37].

The importance of follow-up by healthcare professionals is underlined in our study. Some people with CLBP explained that a follow-up helped them to set objectives. Coppack *et al* did not find any significant difference regarding adherence to an exercise routine between a group of people with CLBP who received set objectives to reach and another one who only had to do exercises supervised by a physiotherapist [38]. Liddle *et al* did highlight in their focus group that people with CLBP were in favor of a structured exercise program associated with personalized advice and follow-up [39]. According to the transtheoretical approach model developed by Proshaska [40], acquiring a positive behavior or changing a problematic behavior requires several steps, over a variable period of time. An appropriate follow-up by a healthcare professional would enable, in people with CLBP, to adapt the interventions to one's exact stage of behavioral change.

The attitude of healthcare professionals is also an important issue [8]. This study underlines the relevance of offering, on top of education, a specific training dedicated to healthcare professionals on self-care for CLBP and PA, in order to improve the quality of the information delivered to people with CLBP and limit the transmission of erroneous elements. The objective being for people with CLBP to acquire the bases for coping with their CLBP. Nevertheless, to reach this level of autonomy, it seems that people with CLBP need comprehensive information on their condition and advice on adapted PA [41], in order to understand the efficacy mechanisms of the treatments proposed and increase their compliance [42]. In 2010, Crowe *et al* showed that patients developed coping mechanisms, based on their own experience and advice from healthcare professionals [43]. Darlow B *et al* reported in a systematic review of the literature that attitudes and beliefs of people with CLBP were closely related to the attitude and beliefs of their consulting physician [44].

Our results match those of the literature review proposed by Slade *et al.* [14]. People with CLBP show individual preferences regarding the type of exercise, and the playful nature of the latter would seem to increase PA compliance. The importance of the physician-patient relationship and subsequent communication was also highlighted in their article as a factor improving the impact of therapeutic education on the people with CLBP. PA facilitators identified in their study and ours were similar (exercise supervision, follow-up, individually-tailored exercise programs). This is also the case for barriers (lack of time, kinesiophobia). However, in our study no financial barrier was identified. The review of the literature published by Jordan *et al* also noted an improved exercise compliance when the program was supervised or tailored to individual needs, and when patients were taught self-management techniques [45].

#### Limitations

Our study bears a certain number of biases. The main one being the absence of results' generalization, the sample of people with CLBP in our study was not designed to be representative of the general population. The focus group method can also be a bias in itself, comparatively to the individual interview method, if the group interaction is less than satisfactory. It is also important to note that most people with CLBP recruited were involved in a functional spine rehabilitation program and thus presented with a higher functional disability level. Furthermore, these people with CLBP followed in a PM&R department tended to be better informed on their condition and the relevance of PA compared to the general population, which might have influenced the results. In the table listing the characteristics of participants recruited we can also note that men were predominant in our study.

#### Implications

Our study unveiled the main barriers and facilitators to PA in people with CLBP. All these results converge towards defining a personalized approach for treating people with CLBP via self-management. This will help identify barriers and facilitators that vary from one person with CLBP to the next, and consequently adapt the care management to each individual person in order to promote the best PA compliance by reinforcing facilitators and correcting barriers. Encouraging the autonomy of people with CLBP with personalized self-exercise programs at home could also allow a reduction of costs related to this condition. This study could be a pre-liminary step for a wider-scale study to evaluate the efficacy of therapeutic education sessions on the compliance to PA of people with CLBP.

#### Conclusion

Barriers and facilitators to PA practice in people with CLBP identified in this qualitative study could lead to new care management strategies, through self-care programs and supervised physical sessions that could lead to decrease barriers to PA and reinforce facilitators. It seems essential to assess barriers and facilitators, which are specific for each person with CLBP, at early stages in order to implement an individualized rehabilitation program.



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# Low back pain in healthy postmenopausal women and the effect of physical activity: A secondary analysis in a randomized trial

# Abstract

Epidemiological studies on the prevalence of musculoskeletal pain have consistently shown that this is a relevant health problem, with non-specific low back pain (LBP) being the most commonly reported in adult females. Conflicting data on the association between LBP symptoms and physical activity (PA) have been reported. Here, we investigated the prevalence of LBP and the effect of a 24-month non-specific PA intervention on changes in LBP prevalence in a series of Italian healthy postmenopausal women. We performed a secondary analysis in the frame of the DAMA trial, a factorial randomized intervention trial aimed to evaluate the ability of a 24-month intervention, based on moderate-intensity PA, and/or dietary modification, in reducing mammographic breast density in healthy postmenopausal women. The PA intervention included at least 1 hour/day of moderate PA and a more strenuous weekly activity, collective walks and theoretical group sessions. A self-administered pain questionnaire was administered at baseline and at the end of the intervention. The questionnaire was specifically structured to investigate the occurrence of musculoskeletal pain, the body localization, intensity and duration of the pain. Two hundred and ten women (102 randomized to PA intervention, 108 not receiving the PA intervention) filled out the questionnaires. At baseline LBP was present in 32.9% of the participants. Among women randomized to the PA intervention, LBP prevalence at follow up (21.6%) was lower than at baseline (33.3%) (p = 0.02), while in women who did not receive the PA intervention the LBP prevalence at baseline and follow up were 32.4% and 25.9%, respectively (p = 0.30). Overall, there was no significant between-group effect of PA intervention on LBP. Further studies are needed to understand the role of non-specific PA intervention, aimed to improve overall fitness, on LBP prevalence.

#### Introduction

Epidemiological studies have reported a high prevalence of musculoskeletal pain in the adult general population, particularly in women [1, 2]. Among spinal musculoskeletal disorders, low back pain (LBP) is an extremely common problem that most people, mainly females, experience at some point during their life [3]. In particular, an increasing prevalence of LBP with a peak in the sixth decade has been reported [4]. LBP is a major health problem throughout the world causing considerable physical and psychological impairments, absence from work and high socioeconomic costs [4, 5].

LBP is usually defined as pain localized below the margin of the last ribs (costal margin) and above the inferior gluteal line, with or without lower limb pain. LBP is typically classified as "specific" or "non-specific" [6, 7]. Non-specific LBP is characterized by the absence of structural anatomical changes [7] and seems to affect more than 85% of individuals [5, 7]. The etiology of LBP is multi-factorial and not fully understood. Previous studies have identified several risk factors for LBP including age, female gender, educational status, obesity, smoking, sleep deprivation, prolonged driving, computer usage and lack of exercise. In particular, it has been suggested that physical deconditioning may play an important role in the etiology of chronic LBP. Subjects practising strenuous physical activities and subjects with sedentary lifestyle are both at increased risk for the development of chronic LBP [8]. Psychosocial factors, such as stress and depression, may also play a role in this scenario [4].

There are several treatments for LBP (e.g., medications, physical intervention), but their efficacy is not fully proven [7]. Physical activity (PA) has been suggested as an effective treatment for patients with sub-acute or chronic non-specific LBP [9], though which types of specific exercises may be most beneficial is still unclear. To prevent chronic pain, it is very important that the treatment focuses on promotion of PA despite the pain. Therefore, in the acute phase educational and PA promoting measures should be the primary treatment options [5]. However, future strategies should focus on possible interventions aimed at preventing new episodes of LBP with greater impact both on the health status and the reduction of socio-economic costs.

In this context, the objective of our study was to investigate, in a series of Italian healthy postmenopausal women, the prevalence of LBP, and the effect of a 24-month PA intervention on possible changes in LBP prevalence.

#### Materials and methods

#### Study participants

The present study represents a secondary analysis of the DAMA trial [10] and includes the 210 participants, out of the 234 overall women enrolled in the DAMA trial, who also answered a questionnaire on non-specific musculoskeletal pain both at baseline and after 24-month intervention. Due to logistic and organizational reasons the remaining 24 participants did not complete the baseline and/or follow up questionnaires on non-specific musculoskeletal pain and were excluded from the current analyses.

The DAMA (Diet, physical Activity and MAmmography) trial (ISRCTN28492718) is a factorial randomised trial aimed to evaluate the ability of a 24-month intervention, based on moderate-intensity PA, and/or dietary modification, in reducing mammographic breast density (MBD) in healthy postmenopausal women. The DAMA trial was approved by the Ethics Committee of the Local Health Authority in Florence (Italy). Informed consent form was signed by all study participants.

Methods and design of the DAMA trial have been previously described in detail [10]. Briefly a total of 234 Italian healthy postmenopausal women, aged 50-69 years, not using Hormone Replacement Therapy, non-smoking and with high MBD, a well-known risk factor for breast cancer (>50% as assessed in the frame of the local screening programme), were recruited to participate at the trial. At baseline and at the end of the DAMA intervention, all participants filled out a food frequency questionnaire (FFQ) to assess dietary habits and a lifestyle questionnaire to assess lifestyle behaviours including occupational, household and recreational PA [11]. Anthropometric parameters, such as height and weight, were also measured using standard protocols and used to calculate body mass index (BMI, kg/m<sup>2</sup>). After the baseline visit women were randomly assigned to one of the following four study arms: 1) "dietary intervention" in which women received a series of specific practical and educational activities on healthy dietary habits; 2) "PA intervention" in which women received a series of specific practical and educational activities on healthy PA habits; 3) "dietary and PA intervention" in which women received exactly the same activities proposed in arm 1 and 2; and 4) in which women received only general advices on both dietary and PA healthy habits. This factorial design allows to evaluate separately the effect of dietary or PA intervention comparing the groups receiving the same treatment (in this analysis the PA intervention) with the groups not receiving the specific treatment.

#### Physical activity intervention

According to the DAMA trial protocol, the participants included in the present study and randomized to the arms receiving the PA intervention (study arms 2 and 3; 108 women), hereafter referred to as "the PA intervention group", were required to daily increase moderate recreational activities up to 1 hour/day (corresponding to about 3-5.9 metabolic equivalent (MET)hours/day), in combination with more strenuous weekly activity (6-10 MET-hours/week) and to participate in theoretical group sessions. The exercise program was planned by an exercise specialist and was applied gradually according to the baseline level of activity of each subject. Suggested moderate activities were, for example, walking, biking and slow dancing. Women were also provided with some equipment (an elastic band, dumbbells, a gym mat) and a specific booklet to exercise at home. In addition, women were requested to attend weekly 1-hour exercise sessions led by exercise specialists in an appropriate fitness facility for the whole study period (total 97 sessions). The primary aim of these exercise sessions was to increase aerobic capacity, physical strength, postural control, coordination and mobility of the limbs and trunk. The PA intervention protocol also included participation in 6 collective walks and 6 theoretical group sessions (approximately 25 women/session) in which evidences about PA health benefits were presented and discussed and women were instructed on how to gradually increase daily levels of PA, breathe properly during exercise, improve and keep good posture. Moreover, women were requested to keep 5 periodical weekly written PA diaries in order to monitor the achievement and maintenance of the intervention aims.

Women randomized to the arms not receiving the PA intervention (study arms 1 and 4; 102 women), hereafter referred to as "the control group", received, at baseline, only a leaflet with general advices on healthy PA patterns and were invited to participate in a single specific conference on the general beneficial effects of PA.

#### Pain questionnaire

A specific self-administered questionnaire on non-specific musculoskeletal pain was filled, at baseline and at the end of the 24 months intervention, by participants. The pain questionnaire

included questions elaborated through translation and adaptation from previously validated instruments used in the literature [12–14].

Specifically, women were asked if they had recently experienced pain in any body areas and when the last episode occurred (response option were: last 48 hours, last 1–2 weeks, last 3–4 weeks, more than 3 months ago). The specific localization of the pain was then requested (neck, shoulders, elbows, hip, knee, leg, cervical spine, thoracic spine, lumbar spine, sacral spine). One or more pain localizations could be specified by each participant. Information on pain localization was then combined to represent the following anatomical sites: upper back (i.e. neck and cervical spine), lower limb (i.e. knee and leg), mid back (i.e. thoracic spine), low back (i.e. lumbar spine and sacral spine) and spine (i.e. neck, cervical spine, thoracic spine, lumbar spine and sacral spine).

Study participants were also requested to indicate the pain intensity of the most recent episode in each body localization according to a numeric rating scale (NRS) [15]. The NRS for pain is an unidimensional measure of pain intensity ranging from 0 (no pain) to 10 (pain as bad as you can imagine/worst pain imaginable). Pain intensity, assessed by NRS scale, was categorized into three levels: score 1-3 = mild, score 4-6 = moderate, and score  $\geq 7 =$  severe pain [16].

To assess the pain duration of the most recent episode, the following question was asked: "*How long have you had your current pain problem*?". The response options were: 0 days; 1–2 days; 3–7 days; 8–14 days; 15–30 days; 1 month; 2 months; 3–6 months; 6–12 months; over 1 year.

In addition, the subjects were asked to report the pain frequency during the last 12 months: 0 time; 1 time, 2 times, 3 times, 4 times; over 4 times.

#### Statistical analysis

The current analysis represents a secondary analysis focused on postmenopausal women participating into the DAMA trial who completed the pain questionnaire at baseline and at follow up. The primary outcome of the present study was the prevalence of LBP.

Assuming an expected prevalence of LBP of 40% at baseline [3, 17] and a LBP prevalence of 20% in the PA intervention group after the 24-month intervention and with a sample size of 210 study participants (108 women in the PA intervention group and 102 women in the control group), the statistical power for our analyses was 81%. Distribution of the main baseline characteristics was investigated overall and according to PA intervention. For continuous variables means (standard deviations), medians (10° - 90° percentiles) and *p values* from mean comparison test between groups (PA intervention Yes/No) were calculated. For categorical variables frequency number, relative percentages and *p values* from Fisher exact test were calculated. Prevalence and body localization of pain at baseline were also investigated. Specific analyses were carried out for LBP prevalence at baseline and follow up. Among women reporting LBP at baseline, pain intensity and duration were evaluated.

The proportion of women reporting LBP presence before and after the 24-month intervention was investigated according to PA intervention and following the intention to treat principle. The McNemar test for matched pairs was performed in order to evaluate the differences in LBP presence at baseline and follow-up within groups. The difference in LBP prevalence at follow up according to PA intervention was evaluated and a test of proportion was performed. A crude and a multivariate logistic model (adjusted for age at enrolment, body weight, educational level, total PA level and LBP presence/absence at baseline) were also run in order to evaluate the real effect of the PA intervention on LBP prevalence.

#### Results

Overall, 210 healthy postmenopausal women, aged 50–69 years, were involved in this study. Baseline characteristics of the participants are detailed in <u>Table 1</u>. The PA intervention group included 102 women and the control group included 108 women. No significant differences between the two groups at baseline were observed for age, BMI, educational level, leisure-time PA and occupational activities (Table 1).

At baseline, 56 women (26.6%) had no pain while 154 (73.3%) reported pain referred to one or more different parts of the body. The main localization of pain was the spine (55.2%), mostly in the low back area (32.9%), followed by lower limb (21.9%), shoulder (21.4%), hip (9.0%) and elbow (5.7%) (Table 2). In particular, the prevalence of LBP (32.9%) was higher than that of upper and mid back pain (30.5% and 6.7%, respectively) (Fig 1).

As regard the 69 women reporting LBP at baseline, 78.3% (54 out of 69) referred a pain duration lower than 3 months (acute pain). LBP was defined as severe in 24 (34.8%), moderate in 28 (40.6%) and mild in 17 (24.6%) women. Moreover, 44.4% of women reporting LBP with duration lower than 3 months referred five pain episodes or more in the last year.

No differences in LBP prevalence emerged at baseline between the PA intervention group (33.3%) and the control group (32.4%, p = 0.89).

Table 3 shows the overall prevalence of self-reported LBP at baseline and after the 24-month intervention by group. In the PA intervention group LBP prevalence at follow up (21.6%) was lower than at baseline (33.3%) (McNemar test p = 0.02). Within this group 18 women (17.6%) reporting LBP at baseline did not refer LBP at follow up, while 6 (5.9%) without LBP at baseline reported LBP at follow up. In the control group the reported LBP prevalence at baseline and follow up were 32.4% and 25.9%, respectively (McNemar test p = 0.30). Within this group 20 (18.5%) out of the women reporting LBP at baseline did not refer LBP at baseline did not prefer LBP at baseline did not refer LBP at baseline did not refer LBP at baseline did not prefer LBP at baseline did not pref

When we compared the prevalence of reported LBP at follow up between the PA intervention group and the control group (21.6% and 25.9%, respectively), the difference (-4.3%; 95% CI -15.8%, 7.2%) did not reach the statistical significance (p = 0.46). In a multivariate analysis, a non significant inverse association between PA intervention and LBP presence at follow up emerged both in a crude model (OR 0.79; 95% CI 0.42–1.49) and in an adjusted model taking into account a series of confounders including the presence of LBP at baseline (OR 0.72; 95% CI 0.36–1.45).

#### Discussion

In the present study, non-specific spinal pain showed a high prevalence in a large Italian series of healthy postmenopausal women, and LBP was more frequent than mid or upper back pain.

In particular, here we evaluated the effect of a 24-month non-specific PA intervention on LBP prevalence specifically in postmenopausal women, aged 50–69 years. Our McNemar test results revealed a significant lower prevalence of LBP at follow up than at baseline among women randomized to a PA intervention program combining supervised and non-supervised exercise sessions and theoretical education sessions. However, the enthusiasm that might be generated by this positive finding should be tempered by the observation that there was no significant between-group effect on LBP prevalence when comparing the PA intervention and control groups.

LBP prevalence in the general population has been investigated in numerous previous studies [4, 6, 7, 18]. LBP is very common, but its prevalence estimates vary possibly owing to differences in diagnostic criteria, LBP definitions and the population characteristics [19–21]. Otherwise there are few reports that described the association between LBP and PA [17].

Table 1. Baseline characteristics of the study participants overall and	d according to physical activity (PA) intervention.
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Baseline	Total	PA inter	p value *		
	(N = 210)	Yes (N = 102)	No (N = 108)	•	
Mean (SD)					
Median (10°-90° percentiles)					
Age (years)	59.0 (5.1) 58.3 (52.4–66.4)	59.3 (4.7) 59.0 (53.4–65.6)	58.7 (5.4) 57.5 (51.9–66.9)	0.37	
Body mass index (kg/m²)	24.3 (3.4) 23.8 (20.3–28.8)	24.5(3.5) 23.7 (20.7–28.8)	24.2 (3.3) 23.8 (20.1–28.6)	0.56	
Non occupational physical activity (h/week)	26.8 (14.3) 24.2 (11.8–46.5)	26.7 (15.3) 22.4 (11.7–52.0)	26.9 (13.3) 26.0 (11.9–45.2)	0.90	
- Recreational physical activity (h/week)	6.4 (4.5) 5.5 (1.5–12.4)	6.1 (4.2) 5.0 (1.2–12.0)	6.7 (4.7) 6.0 (1.5–13.0)	0.31	
- Household physical activity (h/week)	20.4 (13.2) 14.6 (5.2–40.1)	20.6 (14.2) 14.1 (6.3–40.7)	20.2 (12.2) 15.4 (4.4–38.5)	0.83	
N (%)		Ċ			
Occupational physical activity					
- Sedentary	74 (35.2)	35 (34.3)	39 (36.1)		
- Standing	29 (13.8)	13 (12.7)	16 (14.8)		
- Manual	15 (7.1)	7 (6.9)	8 (7.4)		
- Heavy manual	2 (0.9)	1 (1.0)	1 (0.9)		
- No paid work	90 (42.9)	46 (45.1)	44 (40.7)	0.96	
Level of education			~		
- None/primary school	59 (28.1)	25 (24.5)	34 (31.5)		
- High school	90 (42.9)	44 (43.1)	46 (42.6)		
- University	61 (29.0)	33 (32.3)	28 (25.9)	0.45	

\* P values from mean comparison test for continuous variables and from Fisher exact test for categorical variables.

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Table 2. Prevalence and body localization of pain reported by study women at baseline, overall and according to physical activity (PA) intervention.

Baseline	Total	PA inte	p value *		
	N (%)	Yes N(%)	No <i>N (%)</i>	-	
Pain presence	(N = 210)	(N = 102)	(N = 108)		
Yes	154 (73.3)	74 (72.5)	80 (74.1)		
No	56 (26.6)	28 (27.5)	28 (25.9)	0.80	
Body localization <sup>a</sup>					
Spine	116 (55.2)	58 (56.9)	58 (53.7)	0.65	
- Upper back	64 (30.5)	34 (33.3)	30 (27.8)	0.38	
- Mid back	14 (6.7)	6 (5.9)	8 (7.4)	0.66	
- Low back	69 (32.9)	34 (33.3)	35 (32.4)	0.89	
Shoulder	45 (21.4)	21 (20.6)	24 (22.2)	0.77	
Elbow	12 (5.7)	2 (2.0)	10 (9.3)	0.02	
Hip	19 (9.0)	7 (6.9)	12 (11.1)	0.28	
Lower limb	46 (21.9)	23 (22.5)	23 (21.3)	0.83	

\* P values from Chi squared test

<sup>a</sup> One or more pain localizations could be reported by each participant.

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Fig 1. Baseline prevalence (percentage) of different types of back pain in the 210 study women.

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Moreover, previous studies often included relatively shorter follow-up periods with great heterogeneity in gender and ages of participants [6] and the "dose" of PA was not well defined [22]. Therefore, lack of uniform definitions of both PA and LBP makes outcomes difficult to compare [22]. However, the most recent evidence suggests that exercise alone or in combination with education is effective in the prevention of LBP [23].

In this context, our present study has a specific focus on the prevalence of LBP in healthy postmenopausal women (aged 50–69 years) as well as the possible changes in LBP prevalence

Table 3. Distribution, N (%), of low back pain presence (yes/no) at baseline and follow-up in the 210 study women according to physical activity (PA) intervention.

		PA intervention					
		Yes (N = 102)			No (108)		
		Follow-up					
		No pain	Yes pain	Total	No pain	Yes pain	Total
	No pain	62 (60.8)	6 (5.9)	68 (66.7)	60 (55.6)	13 (12.0)	73 (67.6)
Baseline	Yes pain	18 (17.6)	16 (15.7)	34 (33.3)	20 (18.5)	15 (13.9)	35 (32.4)
	Total	80 (78.4)	22 (21.6)	102	80 (74.0)	28 (25.9)	108
	McNemar Test <sup>a</sup>	p = 0.02 p = 0.30					

<sup>a</sup> P values from McNemar Test for paired data evaluating the differences in pain presence at baseline and follow-up within PA intervention group and control group.

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following a well-defined 24-month PA program, though non-specific for LBP. According to our data, the baseline prevalence of LBP was 32.8%. Our data are consistent with those described in previous studies [17, 24, 25]. In particular, in the MONICA study, LBP prevalence was 41% in a population consisting of 5798 subjects aged 25-79 years. Furthermore, LBP prevalence was higher among women (44.1%) than men and highest in the group aged 55-64 years [17]. Moreover, in that study women with LBP were more often smokers compared with women without LBP suggesting that smoking should be considered among the risk factors of LBP [17]. Of note, non-smoking habit was one of the eligibility criteria for women enrolled in the DAMA trial. Although the prevalence of LBP has been investigated in numerous studies [17], the present report is to our knowledge the first presenting data on non-specific LBP in a sample of Italian healthy post-menopausal women aged 50-69 years. Moreover, there are very few studies that described the association between LBP and levels of PA in adult [17, 26]. At variance with previous reports [17, 22], here we carefully described the methodology of a well planned PA intervention. In particular, in our protocol women were required to daily increase moderate recreational activities up to 1 hour/day, in combination with more strenuous weekly activity.

It is known that the non-specific LBP affects multiple aspects of an individual's life including physical function with limitation of multiple activities, psychological well-being and the ability to work in the general adult population, and particularly among females [27–37]. In addition, fear of LBP recurrence may further limit activities [38]. As a consequence, LBP continues to be one of the most challenging issues in primary care [30].

In the light of the above, the identification of new effective and economic LBP prevention strategies with long-term impact appears of major importance [39]. Among non-pharmaco-logical intervention, PA is widely recognized as an important health-related lifestyle factor with the potential of increasing the quality of life. The psychosocial and biological health bene-fits of PA are well established, and there is clear scientific evidence that regular and moderate PA can reduce the risk of morbidity of various diseases [40]. Of note, PA is also prescribed in rehabilitation programmes for LBP treatment [31, 41]. PA maintains or improves fitness helping to control the pain and decreasing the risk of acute pain in chronic LBP [41]. Current international guidelines advocate increasing PA as a management strategy for chronic LBP [42]. In particular, individually designed exercise programs delivered in a supervised format seem the most effective strategy [43]. PA may include either aerobic exercise or muscle strengthening and stretching exercises specific for the treatment area, even if currently there is limited evidence regarding the most effective type of exercise [38]. Patient recommendations

for the treatment of acute LBP consist instead in the advice to stay active for maintaining fitness and flexibility [32]. Indeed, regular exercise seems the only effective strategy in prevention of LBP [6].

We can speculate that our non-specific PA intervention, primarily aimed to increase aerobic capacity, physical strength of all major muscle groups, postural control, coordination and mobility of the limbs and trunk, could improve functional ability maintaining and/or ameliorating the fitness level with consequent reduction in the prevalence of LBP at follow up. These aspects are crucial because acute LBP is often caused by trunk muscle weakness resulting from insufficient exercise, obesity, and improper posture [44]. Interestingly, the present PA intervention included not only practical but also educational activities aimed to either increase the overall fitness or reduce a sedentary behaviour possibly affecting the LBP prevalence. In this context, previous observations [37, 43] highlighted the importance of maintaining an active lifestyle through a well-defined and regular PA along with changing of sedentary lifestylerelated unhealthy behaviours to prevent non-specific LBP onset. However, our analyses revealed that there was no significant effect on LBP prevalence when comparing the PA intervention and control groups. Overall, these findings should be interpreted in the context of the limitations of our study. Indeed, the present data could be limited by the relatively small sample size investigated and a study design based on self-report assessments. In addition, it should be considered that this is a secondary analysis of the DAMA trial which was primarily designed to evaluate different outcomes. Therefore, the type of PA intervention was not specifically designed for LBP, but rather planned to improve the overall woman fitness. It is also possible that different results could be found when employing different exercise training modalities or studying other subject populations.

Despite the aforementioned limitations, this study has also some strengths worth mentioning. First, our study design provided a 24-month follow up time on healthy women from a randomized controlled clinical trial with a relatively high adherence rate. The reason for this might be because our PA intervention included also supervised training sessions which are important for adherence to study protocol. In particular, the employment of exercise professionals with knowledge of biomechanics and focusing on each subject's needs are important to avoid PA interruption [7]. In addition, in our trial there were no adverse events related to the exercise intervention. Of note, this longitudinal study afforded an opportunity to investigate a randomly recruited female population, which was not selected on the basis of a previous history of LBP. Our findings also highlight the importance of the exercise maintenance as primary prevention against non-specific LBP development, thus supporting the need of health education through PA. Another strength of this study is that our PA protocol follows the current PA recommendations [45]. The present findings might therefore contribute to promote adherence to PA and provide a guide for educators and clinicians in LBP management. Finally, our data might even help in the design of further clinical trials in the same interventional area.

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