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# Immediate effect of hamstring stretching in patients with chronic low back pain

Lech Dobija

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UNIVERSITÉ CLERMONT AUVERGNE

ECOLE DOCTORALE DES SCIENCES DE LA VIE ET DE LA SANTE, AGRONOMIE, ENVIRONNEMENT

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# EFFET IMMEDIAT DE L'ETIREMENT DES MUSCLES ISCHIO-JAMBIERS CHEZ LES PATIENTS PRESENTANT UNE LOMBALGIE CHRONIQUE

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THESE

En vue de l'obtention du grade de

DOCTEUR DE L'UNIVERSITE CLERMONT AUVERGNE

Spécialité : Ingénierie de la santé

Thèse présenté le 22 décembre 2023 par :

**Lech DOBIJA**

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Co-directeur de thèse



CLERMONT AUVERGNE UNIVERSITY

ECOLE DOCTORALE DES SCIENCES DE LA VIE ET DE LA SANTE, AGRONOMIE, ENVIRONNEMENT

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# IMMEDIATE EFFECT OF HAMSTRING STRETCHING IN PATIENTS WITH CHRONIC LOW BACK PAIN

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DOCTORAL THESIS

In order to obtain the degree of PhD at CLERMONT AUVERGNE UNIVERSITY

Specialty: Health Engineering

Thesis presented on December 22, 2023 by:

**Lech DOBIJA**

In front of a jury composed of:

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Mme. Pr Agnès ROBY-BRAMI, Sorbonne Université Paris	Examiner
M. Pr Emmanuel COUDEYRE, Université Clermont Auvergne	Supervisor of the thesis
M. Pr Arnaud DUPEYRON, Université Montpellier	Co-supervisor of the thesis

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## List of Abbreviations

AKE	Active Knee Extension
ASLR	Active Straight Leg Raise
AUC	Area Under the Curve
BMI	Body Mass Index
CHU	Centre Hospitalier Universitaire
CI	Confidence Interval
CLBP	Chronic Low Back Pain
CNS	Central Nervous System
CONSORT	Consolidated Standards of Reporting Trials
CSD	Clinically Significant Difference
CSI	Central Sensitization Inventory
EP	Etirement passif
EPA	Etirement passif et actif
ES	Effect size
FABQ	Fear-Avoidance Beliefs Questionnaire
FTF	Fingertip-to-Floor
HADS	Hospital Anxiety and Depression Scale
HM	Hamstrings muscles
IASP	International Association for the Study of Pain
ICC	Intraclass Correlation Coefficient
IMC	Indice de Masse Corporelle
IVD	Intervertebral Disc
LBP	Low Back Pain

LOA	Limits of Agreement
MCID	Minimal Clinically Important Difference
MDC	Minimal Detectable Change
MID	Minimal Important Difference
MIJ	Muscle Ischio-Jambier
ODI	Oswestry Disability Index
PAS	Passive and active stretching
PASS	Patient Acceptable Symptom State
PBU	Pressure bio-feedback unit
PKE	Passive Knee Extension
PS	Passive stretching
RCI	Reliable Change Index
ROC	Receiver Operating Characteristic
ROM	Range of motion
SEM	Standard Error of Measurement
SLR	Straight Leg Raise
SPIRIT	Standard Protocol Items: Recommendations for Intervention Trials
SRT	Sit-and-Reach test

## ABSTRACT

Progress in healthcare management increased life expectancy globally but disabling consequences of diseases remain the major problem. Despite the progress that has been made in healthcare management, chronic low back pain (CLBP) remains the leading cause of disability. The deficit in hamstring muscles (HM) flexibility, combined with a deficit in neuromuscular control, contributes to disability in CLBP. In this work, we first describe the context that links pain mechanisms, the biopsychosocial model, and biomechanics, with a specific focus on HM flexibility deficits. Then, we estimate the measurement properties of the Active Knee Extension (AKE) and Straight Leg Raise (SLR) measures taken with a new digital inclinometer in CLBP patients. Intrarater reproducibility was found to be acceptable, with a Minimal Detectable Change of 9-11° for AKE and 7-10° for SLR. Following that, we conducted the EFIM1 study to evaluate the immediate effect of passive hamstring (HM) stretching on flexibility and to analyze the impact of psychosocial factors on change following HM stretching in 90 CLBP patients. Hamstrings flexibility improved significantly after stretching; AKE mean difference was 4° (95%CI, 2.4 to 5.1;  $p < 0.001$ ); SLR mean difference was 7° (95%CI, 5.5 to 8.6,  $p < 0.001$ ), Fingertips-to-Floor mean difference was 2 cm (95%CI, 1.7 to 3.0,  $p < 0.001$ ). No correlation was found between improvement in any of the HM flexibility measurements and Fear-Avoidance Belief Questionnaire (FABQ) or Hospital Anxiety and Depression Scale (HADS) scores ( $p > 0.05$ ). Additional group-based analysis showed that the Positive Responders and Non-Responders groups were similar in demographic and clinical characteristics, except for lower Body Mass Index (BMI) values within the Positive Responders group. Passive HM stretching induced an immediate, statistically significant improvement in HM flexibility in people with CLBP. However, only the change in SLR amplitude is likely to be of clinical importance. Psychosocial factors were not related to observed improvements in flexibility. This suggests that the neuromuscular system needs active stimulation to generate active movement in the newly acquired passive range of motion (ROM). Therefore, in response to this conclusion we present a new study protocol, EFIM2. From the patient's perspective, the ultimate goal is to achieve an important improvement in active, pain-free ROM. However, passive stretching did not yield satisfactory improvements in active flexibility. This is why we propose a combination of passive and active stretching exercises, with the expectation that it facilitates improvements in both passive and active ROM. To test our hypothesis that combining active and passive stretching is more effective than passive stretching alone in improving active flexibility, we present a randomized controlled study, EFIM2.



## RESUME EN FRANÇAIS (vérsion courte)

Malgré les progrès réalisés par le système de santé, la lombalgie chronique reste la principale cause d'invalidité. Le déficit d'extensibilité des muscles ischio-jambiers (MIJ), combiné à un déficit de contrôle neuromusculaire, contribue à l'invalidité dans la lombalgie chronique. Dans ce travail, nous décrivons d'abord les mécanismes de la douleur, le modèle biopsychosocial et la biomécanique, en se concentrant sur les déficits d'extensibilité des MIJ. Ensuite, nous estimons les propriétés métrologiques des mesures de l'extension active du genou, *Active Knee Extension* (AKE), et de la levée de jambe tendue, *Straight Leg Raise* (SLR) obtenues à l'aide d'un nouvel inclinomètre électronique chez les patients souffrant d'une lombalgie chronique. Cette analyse a été effectuée sur les 90 patients inclus dans l'étude EFIM1. La reproductibilité intra-évaluateur pour AKE et SLR s'est révélée excellente, avec un coefficient de corrélation intraclasse, *Intraclass Correlation Coefficient* (ICC) supérieur à 0,9. Les valeurs de différence minimale détectable, *Minimal Detectable Change* ( $MDC_{95}$ ) ont été de 9 à 11° pour AKE et de 7 à 10° pour SLR. Des corrélations modérées à fortes, ont également été trouvées entre AKE, SLR et la distance doigt-sol, *Fingertip-to-Floor* (FTF), ce qui confirme la validité de construit de nos mesures. L'étape suivante concernait l'évaluation de l'effet immédiat de l'étirement passif des MIJ, ainsi que l'analyse de l'impact des facteurs psychosociaux sur le changement résultant de l'étirement (étude EFIM1). Les mesures répétées de l'extensibilité des MIJ (AKE, SLR, FTF) ont été effectuées sur 90 patients atteints de lombalgie chronique avant et immédiatement après l'intervention. Celle-ci consistait en une minute d'étirement passif des MIJ réalisée de manière bilatérale par un kinésithérapeute. Les facteurs psychosociaux ont été évalués avant l'intervention grâce aux questionnaires *Fear-Avoidance Belief Questionnaire* (FABQ) et *Hospital Anxiety and Depression Scale* (HADS). L'extensibilité des MIJ s'est améliorée de manière significative après l'étirement; la différence moyenne de l'AKE était de 4° (IC à 95 % : 2,4 à 5,1° ;  $p < 0,001$ ), la différence moyenne de la SLR était de 7° (IC à 95 % : 5,5 à 8,6°,  $p < 0,001$ ), la différence moyenne de FTF était de 2 cm (IC à 95 % : 1,7 à 3,0cm,  $p < 0,001$ ). Aucune corrélation n'a été trouvée entre l'amélioration d'extensibilité des MIJ et les scores des questionnaires FABQ ou HADS ( $p > 0,05$ ). L'étirement passif des MIJ a entraîné une amélioration immédiate et statistiquement significative de l'extensibilité des MIJ chez les personnes atteintes de lombalgie chronique. Cependant, seul le changement d'amplitude passive de la SLR semble avoir une importance clinique. Cela suggère que le système neuromusculaire nécessite une stimulation active pour générer un mouvement actif dans l'amplitude de mouvement passive nouvellement acquise. Par conséquent, nous présentons un nouveau protocole d'étude randomisée contrôlée, EFIM2 pour vérifier si la combinaison d'étirements actifs et passifs est plus efficace que l'étirement passif seul pour améliorer la flexibilité active chez les patients souffrant d'une lombalgie chronique.

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## Résumé en français (version longue)

Les progrès dans la gestion des soins de santé ont permis d'augmenter l'espérance de vie au niveau mondial, mais les conséquences handicapantes des maladies demeurent le principal problème. Malgré les progrès réalisés par le système de santé, la lombalgie chronique reste la principale cause d'invalidité. Le déficit d'extensibilité des muscles ischio-jambiers (MIJ), combiné à un déficit de contrôle neuromusculaire, contribue à l'invalidité dans la lombalgie chronique. Dans ce travail, nous décrivons d'abord le contexte qui relie les mécanismes de la douleur, le modèle biopsychosocial et la biomécanique, en se concentrant sur les déficits d'extensibilité des MIJ. La distinction entre la douleur et la nociception, les types de douleur, ainsi que les mécanismes nociceptifs et neuropathiques principaux relatifs à la lombalgie chronique sont discutés. L'intégration du problème dans le modèle biopsychosocial est également présentée. Afin de compléter le contexte, les aspects biomécaniques de la stabilité fonctionnelle de la région lombo-pelvienne, y compris le rôle des muscles profonds et des chaînes musculaires, sont présentés. Un focus sur l'anatomie et la fonction des MIJ dans la chaîne musculaire postérieure est présenté et mis en relation avec la problématique de la lombalgie chronique. La problématique du déficit d'extensibilité des MIJ chez les personnes souffrant d'une lombalgie chronique est également abordée. La littérature propose différentes interventions d'étirement pour améliorer ce déficit. Les méthodes d'étirement des MIJ et l'intérêt clinique d'étudier l'effet immédiat de l'étirement musculaire sont ensuite discutés.

Avant d'étudier l'intervention visant à améliorer l'extensibilité des MIJ, nous nous concentrons sur les techniques de mesure de celle-ci. Les concepts des propriétés métrologiques sont d'abord expliqués, incluant la reproductibilité relative et absolue, l'analyse intra- et inter-évaluateur, la validité, la sensibilité au changement et la différence minimale cliniquement pertinente, *Minimal Clinically Important Difference* (MCID). Une synthèse des techniques existantes visant l'évaluation de l'extensibilité des MIJ est présentée, en prenant en compte leurs propriétés métrologiques. Nous proposons ensuite l'utilisation d'un nouvel inclinomètre électronique pour évaluer l'extensibilité des MIJ grâce à la mesure de l'extension active du genou, *Active Knee Extension* (AKE), et de la levée de jambe tendue, *Straight Leg Raise* (SLR). Ensuite, nous estimons les propriétés métrologiques des mesures

d'AKE et de SLR obtenues à l'aide d'un nouvel inclinomètre électronique chez les patients souffrant d'une lombalgie chronique. Cette analyse a été effectuée sur les 90 patients inclus dans l'étude EFIM1. La reproductibilité intra-évaluateur pour AKE et SLR s'est révélée excellente, avec un coefficient de corrélation intraclasse, *Intraclass Correlation Coefficient* (ICC) supérieur à 0,9. Les valeurs de différence minimale détectable, *Minimal Detectable Change* (MDC<sub>95</sub>) ont été de 9 à 11° pour AKE et de 7 à 10° pour SLR. Des corrélations modérées à fortes, ont également été trouvées entre AKE, SLR et la distance doigt-sol, *Fingertip-to-Floor* (FTF), ce qui confirme la validité de construit de nos mesures. Une fois l'analyse des propriétés métrologiques effectuée, nous avons mené l'analyse principale de l'étude EFIM1, comprenant l'évaluation de l'effet immédiat de l'étirement passif des MIJ sur l'extensibilité, ainsi que l'analyse de l'impact des facteurs psychosociaux sur le changement résultant de l'étirement. Cette étude multicentrique a été menée conjointement au CHU de Clermont-Ferrand et au CHU de Nîmes, avec l'inclusion de 90 patients atteints de lombalgie chronique. Les mesures répétées de l'extensibilité des MIJ (AKE, SLR, FTF) ont été effectuées par un évaluateur indépendant de l'intervention avant et immédiatement après celle-ci. L'intervention consistait en une minute d'étirement passif des MIJ réalisée de manière bilatérale par un kinésithérapeute. Les facteurs psychosociaux ont été évalués avant l'intervention grâce aux questionnaires *Fear-Avoidance Belief Questionnaire* (FABQ) et *Hospital Anxiety and Depression Scale* (HADS). L'extensibilité des MIJ s'est améliorée de manière significative après l'étirement ; la différence moyenne de l'AKE était de 4° (IC à 95 % : 2,4 à 5,1° ;  $p < 0,001$  ; taille d'effet côté droit = 0.24, côté gauche = 0.23) ; la différence moyenne de la SLR était de 7° (IC à 95 % : 5,5 à 8,6°,  $p < 0,001$  ; taille d'effet côté droit = 0.44, côté gauche = 0.42), la différence moyenne de FTF était de 2 cm (IC à 95 % : 1,7 à 3,0cm,  $p < 0,001$  ; taille d'effet = 0.20). Aucune corrélation n'a été trouvée entre l'amélioration d'extensibilité des MIJ et les scores des questionnaires FABQ ou HADS ( $p > 0,05$ ). Les résultats montrent que l'étirement passif des MIJ a entraîné une amélioration immédiate et statistiquement significative de l'extensibilité des MIJ chez les personnes atteintes de lombalgie chronique. Cependant, seul le changement d'amplitude de la SLR est susceptible d'avoir une importance clinique. La mesure SLR est réalisée de manière passive, sans la commande motrice du mouvement par le patient, tandis que lors des mesures AKE et FTF, le patient effectue lui-même le mouvement. Le système neuromusculaire du patient est impliqué dans la réalisation des

mesures AKE et FTF. Cela suggère que le système neuromusculaire a besoin d'une stimulation active pour générer un mouvement actif dans l'amplitude de mouvement passive nouvellement acquise. Contrairement à notre hypothèse, les facteurs psychosociaux n'ont pas eu d'impact sur le gain d'extensibilité des MIJ. Néanmoins, seuls les questionnaires FABQ et HADS ont été utilisés pour évaluer les facteurs psychosociaux. Des méthodes plus directes de reconnaissance des émotions humaines, utilisant par exemple l'électroencéphalographie ou la variabilité de la fréquence cardiaque, pourraient fournir des résultats différents. Cela pourrait être examiné au cours de futures études.

Nous avons remarqué une variabilité considérable dans la distribution des changements observés après l'étirement. Certains patients ont montré des améliorations substantielles, tandis que d'autres ont présenté des améliorations minimales, voire aucune amélioration. Du point de vue clinique, comprendre les raisons des réponses différentes à l'étirement passif des MIJ chez les patients atteints de lombalgie chronique est essentiel. Afin de fournir une description plus complète des patients ayant montré une amélioration cliniquement importante de l'extensibilité et de ceux qui ne l'ont pas présentée, nous avons réalisé une analyse supplémentaire en divisant les participants de l'étude EFIM1 en deux groupes distincts. Nous avons établi un seuil d'amélioration de 7° de l'angle de SLR pour le membre inférieur moins flexible au départ, servant de critère pour différencier les groupes des « Répondeurs » et des « Non-répondeurs ». Les caractéristiques des groupes correspondants ont ensuite été comparées afin d'identifier d'éventuelles différences statistiquement significatives entre eux. Cette analyse supplémentaire a montré que les groupes des « Répondeurs » et des « Non-répondeurs » étaient similaires en termes de caractéristiques démographiques et cliniques, à l'exception de valeurs plus basses de l'indice de masse corporelle (IMC) dans le groupe des « Répondeurs », ( $25.2 \pm 5.5$  versus  $28.1 \pm 5.7$ ;  $p=0.007$ ). Ainsi, l'étirement passif des MIJ a été moins efficace chez les patients en surpoids ou obèse.

En conclusion, l'étude EFIM1 nous a permis d'évaluer l'effet immédiat de l'étirement passif des MIJ sur leur extensibilité. Nous avons pu observer que l'amélioration de l'extensibilité est statistiquement significative tant pour les mesures actives que passives. Cependant, il semble que seule l'amélioration de l'extensibilité passive soit cliniquement importante. Les facteurs psychosociaux n'ont pas influencé les résultats de l'étirement, mais il est à noter que le surpoids et l'obésité semble entraver l'amélioration de l'extensibilité des MIJ chez les patients souffrants d'une lombalgie chronique.

Par conséquent, en réponse à cette conclusion, nous présentons un nouveau protocole d'étude, EFIM2. Du point de vue du patient souffrant d'une lombalgie chronique, l'objectif ultime est d'atteindre une amélioration significative de l'extensibilité, autrement dit une souplesse active et sans douleur. Cependant, l'étirement passif n'a pas donné d'améliorations satisfaisantes de la souplesse active. C'est pourquoi nous proposons une combinaison d'exercices d'étirement passif et actif, avec l'attente d'améliorations à la fois pour la souplesse passive et active. Pour tester notre hypothèse selon laquelle la combinaison de l'étirement actif et passif est plus efficace que l'étirement passif seul pour améliorer la souplesse active. Le protocole EFIM 2 est une étude contrôlée, randomisée et multicentrique. L'objectif principal est de comparer l'effet immédiat d'une nouvelle combinaison d'exercices d'étirement passif et actif avec l'étirement passif des MIJ seul sur la souplesse active. Le critère d'évaluation principal sera la valeur moyenne de deux mesures de l'AKE prises du côté le moins souple, avant et immédiatement après l'intervention. Les objectifs secondaires comprennent la réalisation d'une comparaison similaire pour la flexibilité passive (SLR), la mesure FTF, la raideur des MIJ et l'inclinaison pelvienne, ainsi que l'estimation de la différence minimale cliniquement pertinente pour les mesures de l'extensibilité des MIJ. Un inclinomètre électronique sera utilisé pour mesurer l'angle de SLR, ainsi que l'angle de l'inclinaison pelvienne lors du mouvement FTF. La distance FTF sera mesurée avec un mètre ruban. De plus, un dynamomètre sera utilisé lors du SLR pour mesurer la raideur des MIJ. Quarante-deux patients souffrant d'une lombalgie chronique seront répartis de manière aléatoire dans le groupe d'étirement passif et actif (EPA) ou d'étirement passif seul (EP) et recevront les interventions respectives. L'intervention aura la même durée dans les deux groupes, soit 15 minutes. Les patients dans le groupe EPA recevront d'abord une minute d'étirement passif des MIJ réalisé par le kinésithérapeute de manière bilatérale, puis effectueront trois exercices visant à solliciter les muscles de manière globale, en mettant l'accent sur les antagonistes des MIJ, les muscles profonds du tronc et le travail excentrique des MIJ. Les patients du groupe EP recevront seulement trois répétitions de l'étirement passif, d'une durée d'une minute chacune, réalisées de manière bilatérale par le kinésithérapeute. Les mesures avant et immédiatement après l'intervention seront réalisées par un kinésithérapeute indépendant et en aveugle quant à la répartition des patients. À la fin de l'intervention, une question portant sur la perception d'un

gain de souplesse sera posée au patient, et cette réponse servira à estimer la différence minimale cliniquement pertinente.

Ce protocole d'étude constitue la première opportunité d'évaluer si la combinaison d'étirements passifs et actifs des MIJ est plus efficace que les étirements passifs seuls pour obtenir une amélioration immédiate et cliniquement pertinente de la flexibilité active chez les patients souffrant d'une lombalgie chronique. Les résultats fourniront des informations précieuses et économiques en temps pour le développement de programmes de rééducation plus complets, tant pour la clinique que pour la recherche. La conception d'un essai contrôlé randomisé avec une taille d'échantillon adéquate nous permettra de parvenir à des conclusions solides. De plus, estimer la différence minimale cliniquement pertinente pour les mesures de l'extensibilité des MIJ améliorera l'interprétation des changements obtenus dans la présente étude et, de manière plus générale, dans la pratique clinique.

En résumé, l'ensemble du travail réalisé à l'occasion de cette thèse a permis d'appréhender le rôle des MIJ et la problématique du déficit d'extensibilité des MIJ chez les personnes souffrant d'une lombalgie chronique. Les propriétés métrologiques des mesures de l'extensibilité des MIJ ont été estimées spécifiquement dans cette population. Ensuite, l'étude EFIM1 a permis d'observer une amélioration statistiquement significative de la souplesse passive et active, cependant, seule la souplesse passive semble s'améliorer de manière cliniquement pertinente. Les facteurs psychosociaux n'ont pas influencé le gain de souplesse, mais le surpoids et l'obésité étaient plus fréquents chez les « Non-répondeurs » aux étirements. Afin d'obtenir une amélioration cliniquement pertinente de la souplesse active, nous proposons une nouvelle intervention basée sur la combinaison de l'étirement passif et actif. Son efficacité sera évaluée dans l'étude randomisée contrôlée, EFIM2. De plus, celle-ci permettra d'estimer la différence minimale cliniquement pertinente qui permettra d'ajuster l'interprétation des résultats.



## INTRODUCTION

This work focuses on flexibility of the hamstring muscles (HM) in patients with Chronic Low Back Pain (CLBP), specifically on examining the immediate effects of passive HM stretching on flexibility and its relationship with psychosocial factors. Chapter 1 provides an explanation of the context of the research problem by connecting current knowledge about CLBP mechanisms with the biomechanics of the lumbopelvic region and HM. Chapter 2 presents the first phase of the study, which aimed to determine the measurement properties of HM flexibility assessments used for further evaluation of the stretching effect. Chapter 3 constitutes the next phase of the work and focuses on evaluating the immediate effect of passive HM stretching and the impact of related psychosocial factors in CLBP patients. This chapter presents the main part of the work and is presented in an article format. In Chapter 4, supplementary group-based analysis is presented in a Letter to the Editor format. Finally, Chapter 5 features the last phase of the presented work, where a study protocol is developed in response to the conclusions drawn from the preceding research. This protocol is also presented in an article format.

## CHAPTER 1: LINKING THE CONTEXT OF CHRONIC LOW BACK PAIN AND HAMSTRING MUSCLES FUNCTION

### PAIN MECHANISMS

#### Chronic Low Back Pain

Progress in healthcare management increased life expectancy globally but disabling consequences of diseases remain the major problem. The latest evaluation of years lived with disability revealed leading contribution of Low Back Pain (LBP) in the global burden of diseases.(Chen et al., 2022; GBD 2016 Disease and Injury Incidence and Prevalence

Collaborators, 2017) This condition is commonly defined by pain, stiffness or muscle tension located between the margin of the lower rib and the buttock creases with or without radiating pain in the lower limb.(Chen et al., 2022) The prevalence of LBP range between 1.4 and 20% and it was estimated that between 50 and 80% of adults experience LBP at some point in their life.(Fatoye et al., 2019) In 20% of peoples aged between 20 and 59 years the symptoms persist over three months and then are considered as CLBP.(Meucci et al., 2015) Although, prevalence of CLBP vary between countries regarding heterogeneity of studies criteria (ex. CLBP definition, population's age and sex) the impact of this condition is important on socio-economic level in addition to individual sufferance. In France LBP represent 20% of workplace accidents and cost of €1 billion per year taking into account direct and indirect costs.(“Les lombalgies liées au travail | L'Assurance Maladie,” 2017) Factors like pain intensity, higher body weight, carrying heavy loads at work, difficult working positions, depression and general anxiety were identified as predictive for pain chronicity.(Nieminen et al., 2021) Others factors like fear avoidance beliefs and negative expectation about recovery are associated with prolonged sick leave.(Hallegraeff et al., 2012; Trinderup et al., 2018) Yet, some physical factors are also predictive for development of LBP, namely restriction in lateral flexion, hamstrings flexibility deficit and limited lumbar lordosis.(Sadler et al., 2017)

To introduce reasoning and more largely the context and complexity of the problematic of this work, below I present the neurophysiological basis of pain, nociceptive drivers of LBP, non-nociceptive drivers of LBP with the focus on psycho-social factors and bio-psycho-social model, the biomechanical aspects of the lumbopelvic functional stability, the role of HM in lumbopelvic stability, HM flexibility deficit with explicative mechanisms proposed in the literatures.

## Pain definition

Defining pain presents a challenge, given its personal and subjective nature while its definition is further influenced by advancements in comprehending the underlying neurophysiological mechanisms. Therefore, pain definition is regularly updated by the International Association for the Study of Pain (IASP).(Cohen et al., 2018) The latest IASP update define pain as “*an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.*”(Raja et al., 2020) Additional notes complete this definition:

- *“Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors.*
- *Pain and nociception are different phenomena. Pain cannot be inferred solely from activity in sensory neurons.*
- *Through their life experiences, individuals learn the concept of pain.*
- *A person’s report of an experience as pain should be respected.*
- *Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being.*
- *Verbal description is only one of several behaviors to express pain; inability to communicate does not negate the possibility that a human or a non-human animal experiences pain.* “(Raja et al., 2020)

We could conclude that the experience of pain is a complex process which implicate the person’s interpretation of the actual situation. Further, external evaluation of pain should not be reduced to identification of the damaged tissue. Person’s apprehension of threat and psychosocial aspects should also be considered.(O’Sullivan et al., 2018)

## Nociception

The neural processes of encoding and processing noxious stimuli are called nociception. (Loeser and Treede, 2008) This definition refers to signals arriving at the central nervous system from nociceptors, receptors specialized in detection of noxious stimulus. The later are the signals related to extremes temperature, high pressures and presence of the chemical substances related to inflammation and potentially causing tissue damage. Which is important here is that pain sensation is not necessarily implied. Nociceptors are classified by the velocity of transmission and the diameter of their related neuron fibres. Broadly, group III, type A $\delta$  fibres correspond to medium diameter (2-5 $\mu$ m) myelinated afferent fibres with conductive velocity of 5-30m/s and are implicated in acute, well-localized pain sensation. Type C, group IV unmyelinated afferent fibres with average diameter below 2 $\mu$ m and maximal conductive velocity 2m/s are related to slow, poorly localized pain sensation. (Dubin and Patapoutian, 2010; Nikolenko et al., 2022) Nociception serves to protect tissues from damage, however in some body tissues like articular cartilage, lung parenchyma, brain, visceral pleura nociceptors have not been found. (Chang et al., 2023) On the other hand, numerous nociceptors are present in different tissues of lower back region and thus are targeted in clinical practice to explain and treat nociceptive pain.

## Types of pain

Nociceptive pain describe pain occurring with normally functioning somatosensory nervous system and appear due to the activation of nociceptors. It's arises from actual or threatened damage to non-neural tissue and is designed to contrast with neuropathic pain. (Kratz et al., 2021)

Neuropathic pain in turn, is caused by a lesion or diseases of either central or peripheral somatosensory nervous system. (Scholz et al., 2019) This strict binary classification, however

has been completed by term “nociplastic pain”, corresponding to pain arising from altered nociception despite no clear evidence of actual or threatened tissue damage causing the activation of peripheral nociceptors or evidence for disease or lesion of the somatosensory system causing the pain. This type of pain is related to alternation in pain processing at the central nervous system and is referred also to “central sensitization”.(Kratz et al., 2021; Sanzarello et al., 2016) Furthermore, the concept of coexisting nociceptive and neuropathic symptoms of pain has been proposed and is referred as “mixed pain”.(Freynhagen et al., 2019) On the other hand, the distinction between mechanical and inflammatory pain have a relevant clinical implication in the diagnosis and treatment of LBP. (Grinnell-Merrick et al., 2020; Viswanathan et al., 2020) Finally, the terms specific and non-specific LBP are used to describe the pain with clearly identifiable cause (ex. Spondyloarthritis, vertebral fractures and tumours) and no clearly identifiable cause, respectively.(Balagué et al., 2012)

### Nociceptive drivers of Low Back Pain

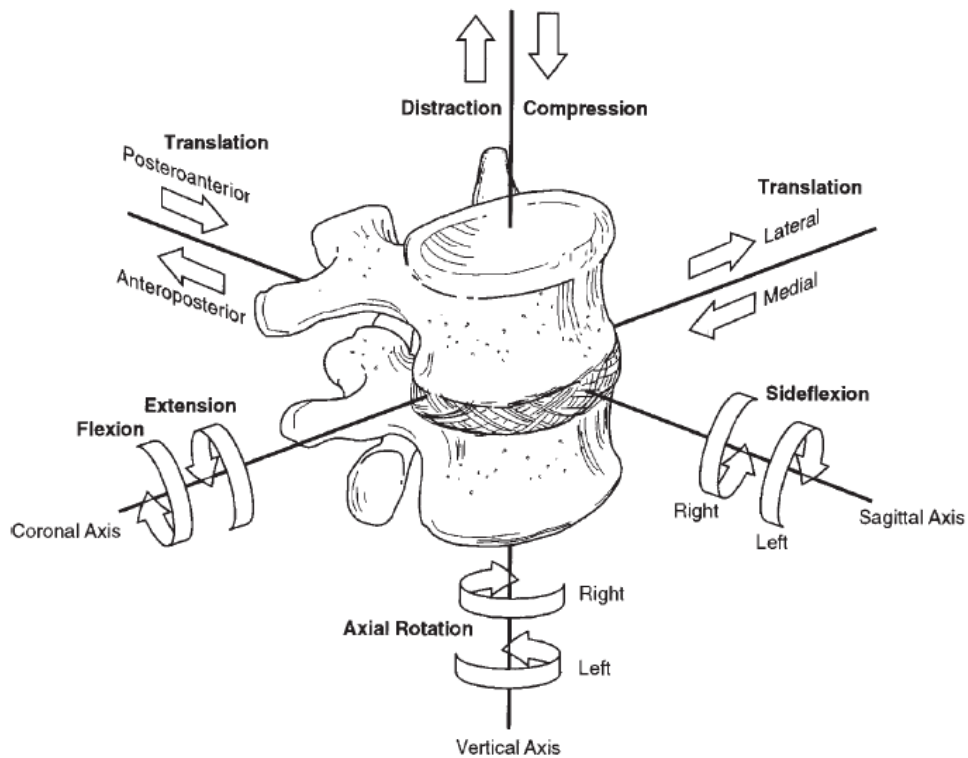
Numerous tissues of the lumbopelvic region receive innervation from the central nervous system including A $\delta$  and type C fibres (nociceptive nerves fibres). Thus, each tissue containing nociceptors could be potentially considered to produce nociceptive input in patients complaining of LBP. However, it is not intention of this work to explore fully all possible nociceptive inputs and the related pathology of LBP. Only main nociceptive LBP paradigms considered in clinical practice are presented below.

### Lumbar disc pathologies

Intervertebral disc (IVD) connect two adjacent vertebral bodies allowing movements in six degrees of freedom, three rotations (flexion/extension, right and left inclinations and right and

left rotations) and three translations (anteroposterior, mediolateral, distraction/compression). (Fardon et al., 2014; Landon and Bolton, 2001) It is composed of highly hydrated gelatinous material called nucleus pulposus encircled by 10 to 12 lamellas of annulus fibrosus. Both structures contain fibres of collagen while nucleus pulposus contain mostly proteoglycans matrix with high hydrophilic properties. Such structure permits to redistribute applied loads in the equal manner within IVD, to transmit the loads to adjacent segments, and to realise movements within specified range of motion. (Landon and Bolton, 2001), (Figure 1). It was reported that in normal IVD only three outer lamellae of annulus fibrosus receive somatosensory innervation from lumbar sinuvertebral nerves, branches of the lumbar ventral rami and the grey rami communicants containing A $\delta$  and type C fibres, however in degenerative IVD nerves fibres could proliferate deeper, even up to the inner third of degenerative disc. (Bogduk, 1991; Edgar, 2007)

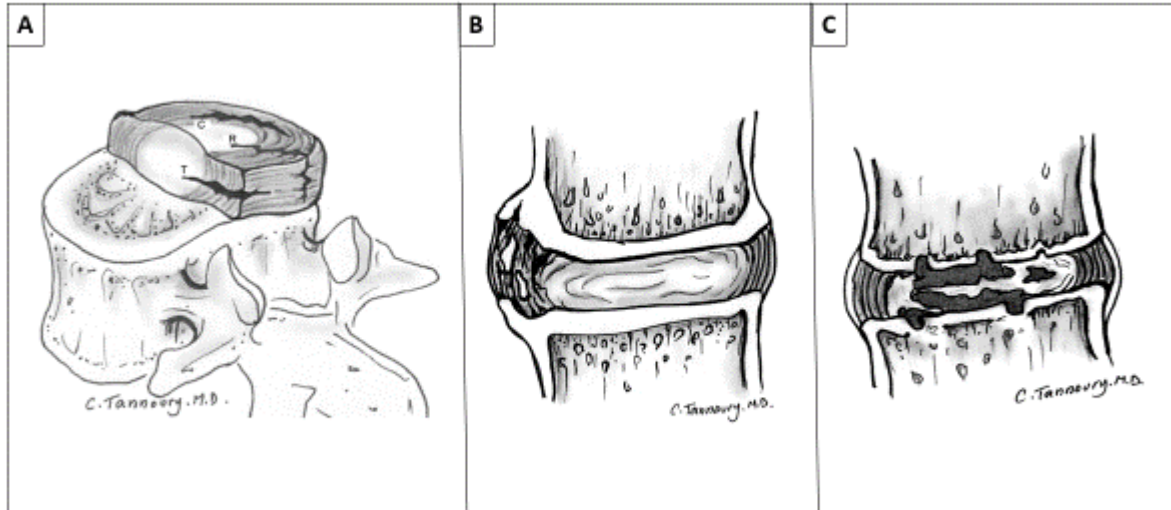
The lumbar disc nomenclature presented below are based on the consensus of the North American Spine Society, the American Society of Spine Radiology and The American Society of Neuroradiology.(Fardon et al., 2014)



**Figure 1. Lumbar spinal segment with all possible movements and corresponding axes.**(Lee Diane, 2011)

### Degenerative lumbar disc changes

Degenerative changes is a category that include annular fissures, degeneration and herniation. Firstly, annular fissures are separations between the annular fibres or between annular fibres and their attachments to the vertebral bone. (Figure 2.)



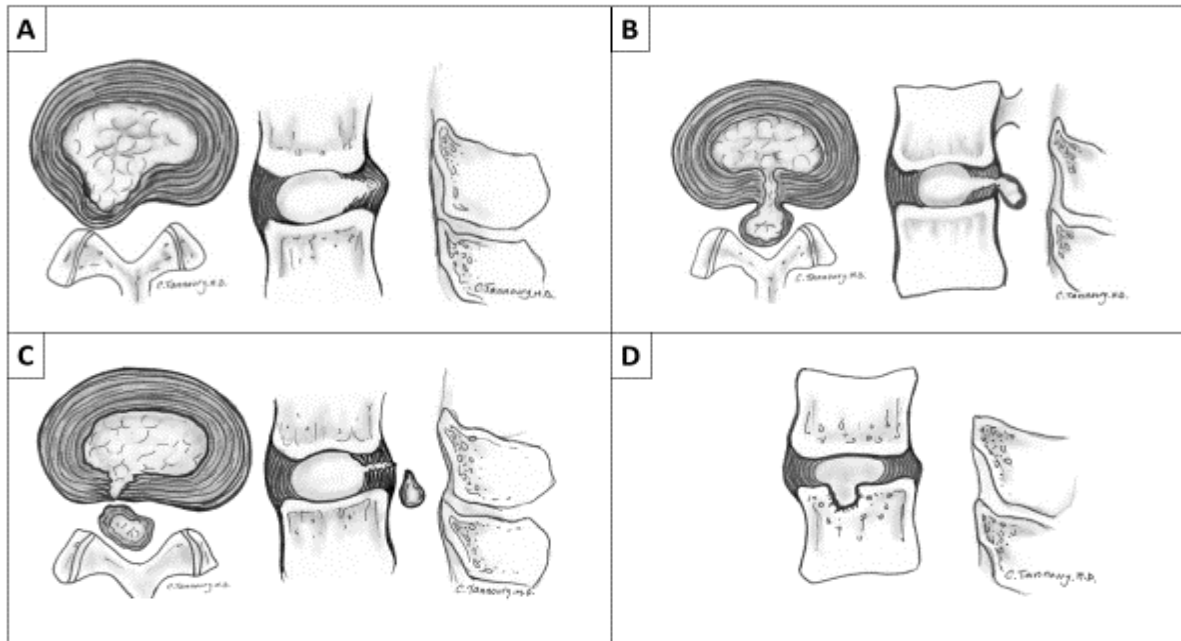
**Figure 2. Degeneration changes: (A) fissures of the annulus fibrosus., (B) apophyseal osteophytes, (C) space narrowing with severe fissuring and end plate cartilage erosion.**

(Fardon et al., 2014)

Degeneration of IVD refers to at least one of the following changes: desiccation, fibrosis, narrowing of the disc space, diffuse bulging of the annulus beyond the disc space, fissuring, mucinous degeneration of the annulus, intradiscal gas, osteophytes of the vertebral apophyses, defects, inflammatory changes, and sclerosis of the end plates.(Fardon et al., 2014)

Disc herniation refers to displacement of disc material beyond the limits of the IVD space. Disc material can be nucleus, cartilage, fragmented apophyseal bone, annular tissue, or any combination thereof. (Fardon et al., 2014) Further, protrusion occurs when herniation disc material extending beyond less than 25% of the disc space and extrusion refers to the greatest measure of the displaced disc material. (Figure 3.)





**Figure 3. Herniated disc: protrusion (A), extrusion (B), sequestration (C) and intravertebral herniation (Schmorl node) (D).** (Fardon et al., 2014)

Disc herniation is frequently used by clinicians to associate biomechanical factors in the development of LBP. (Steffens et al., 2014) Bending, twisting regular heavy loads lifting and bad posture are considered to constrain and to affect the IVD, thus increase the risk of LBP onset. (Cejudo et al., 2021b; Ramond-Roquin et al., 2015; Steffens et al., 2014; Ye et al., 2017) Yet, the impact of some of these biomechanical factors in LBP (ex. lumbar flexion during lifting) is not really clear. (Saraceni et al., 2020)

#### Disc inflammation or infection

This category refers to infection, infection-like inflammatory discitis, and inflammatory response to spondyloarthropathy including ankylosing spondylitis, reactive arthritis and psoriatic arthritis. (Fardon et al., 2014) Also in this category are the inflammatory changes of the end plate and bone marrow of vertebral body called Modic type I. The latter is usually

associated with degenerative changes of IVD.(Viswanathan et al., 2020) In addition, Modic type 1 is one of the degenerative changes that present worse pain manifestation and has been identified to increase risk of no improvement in pain and function, and failure to return to work in 1-year follow-up. (Jensen et al., 2014)

#### Other lumbar disc pathologies

Other changes in IVD integrity are neoplasia which refers to primary or metastatic morphologic changes caused by malignancy, miscellaneous paradiscal masses of uncertain origin and morphologic variant of unknown significance. (Fardon et al., 2014)

#### Lumbar facet joints pathology

Degenerative changes of the lumbar facet joints referred to osteoarthritis are also considered as nociceptive driver of LBP. (Faber, 2019) The degenerative process is multi-factorial but closely related with IVD degeneration.(Varlotta et al., 2011a) However, changes like facet articular cartilage degeneration, subchondral bone sclerosis and osteophytes are difficult to reliably assess with magnetic resonance imaging. (Little et al., 2020) Other particularity of lumbar facet joints pathologies is the fact that it could produce “pseudoradicular” referred pain located in the lower limb. (Varlotta et al., 2011b) In the referred pain the underlying mechanism is explained by convergence of afferent pathways, the inputs from two different tissues arrive at the same spinal neuron thus, the origin of the nociceptive input could be confounded resulting in pain sensation in the distal region.(Arendt-Nielsen and Svensson, 2001) In such convergence-projection model, there is no neural tissues injury or disease.(Baron et al., 2016)

### Sacroiliac joint dysfunction

The sacroiliac joint disposes very limited ROM and is innervated by posterior branches of L5-S1 spinal nerves.(Steinke et al., 2022) Its functional stability is considered to be curtail in providing functional stability of the lumbopelvic region.(Lee Diane, 2011) Disorders in the sacroiliac joint related to functional instability and degenerative changes could be a generator of nociceptive input causing LBP or referred “pseudoradicular” symptoms in lower limb. (Völker et al., 2022) Particular case in sacroiliac joint dysfunction occurs in postpartum women when influence of hormones on sacroiliac ligaments provokes functional instability and the pelvic girdle pain.(Wang et al., 2021)

### Myofascial dysfunction

The lumbar muscles and their corresponding fascia are also taken into account in nociceptive LBP. (Chen et al., 2021; Wilke et al., 2017) One of the muscular mechanism of acute LBP is strain or contraction of the quadratus lumborum or the paraspinal muscles and is known as lumbago.(Casiano et al., 2023) The deep trunk muscles weakness or motor control impairments can provoke increased activity of others paraspinal muscles in the compensatory mechanism to protect against uncontrolled movements.(van Dieën et al., 2019) This in turn can lead to *trigger point* onset and related myofascial pain. The *trigger point* is defined as hyperirritable nodule in a taut band of skeletal muscle which is palpable and tender during physical examination. (Shah et al., 2015) Such zone of contraction knots in muscle fibres is supposed to produce referred pain with specific topography.(Simons and Travell, 1983) Both, trigger point with myofascial pain and lumbago are the mechanism that could coexist with degenerative changes, disk herniation, or other pathologies.(Casiano et al., 2023; Shah et al., 2015)

## Spondylolysis and Isthmic Spondylolisthesis

Spondylolysis is a bony defect or fracture of the pars interarticularis which results from repeated excessive loading of the lumbar spine in extension and rotation. It could appear in relation to degenerative changes, dysplasia, traumatism or other bones pathologies (ex. infection, neoplasia, or systemic disease).(Tenny and Gillis, 2023) The situation when the bilateral lesion cause the translation of a vertebra relative to the adjacent one is described by the term isthmic spondylolisthesis.(Mohile et al., 2022) The magnitude of this translation provide a relevant clinical information and is classified into five grades regarding percentage of the slip: grade I 0 to 25%, grade II 25 to 50% grade III 50-75%, grade IV 75 to 100% and grade V greater than 100%.(Tenny and Gillis, 2023) Degenerative spondylolisthesis is related to insufficient neuromuscular stabilization of the lumbar spine since the improvement in pain and function was obtained by using the specific stabilizing exercise. (O’Sullivan et al., 1997) Yet, spondylolysis and isthmic spondylolisthesis commonly occurs in young athletes and seems to be related to sport activities that require hyperextension of the lumbar spine like gymnastics, wrestling or diving.(Mohile et al., 2022) However, Aoki et al. have recently reported high prevalence of spondylolisthesis also in older adults.(Aoki et al., 2020) Nevertheless, it seems obvious that such bony lesion imply nociceptive input in somatosensory nervous system. However, the presence of spondylolisthesis hasn’t been associated with current or future LBP severity.(Kasch et al., 2022) On the other hand, in some cases isthmic spondylolisthesis associated with IVD lesions could lead to foraminal stenosis and nerve root compression causing neurological symptoms like radicular pain, sensibility or motor deficits.(Mohile et al., 2022)

## Neuropathic drivers of Low Back Pain

The CLBP can involve neuropathic pain components which may sometimes be under-recognized in clinical practice.(Baron et al., 2016) The presence of neuropathic pain components in CLBP can be as high as 56%.(Gudala et al., 2017) However, such estimations are limited by lack of gold standard for the diagnosis of neuropathic pain components. One of the most common neuropathic pain mechanism in which peripheral nervous system is involved is lumbar radicular pain. (Fairag et al., 2022; Govind, 2004)

## Lumbar radicular pain

The irritation of sensory root or dorsal root ganglion of a spinal nerve which causes ectopic nerve impulses is responsible to produce lumbar radicular pain. (Govind, 2004) More commonly used term in such situation is ‘sciatica’. From the anatomic point of view sciatica refers to pain in the distribution of the sciatic nerve due to pathology of the nerve itself and radicular pain point out the problem at the nerve root or spinal nerve level.(Bogduk, 1991; Govind, 2004) Nevertheless, it is now adopted in the scientific literature that sciatica refers to sciatic nerve roots (L4-S3) involvement.(Fairag et al., 2022) In the case of sciatica the pain arise from lower back and irradiate downward to posterior or posterolateral side of the leg. When upper lumbar nerve roots (L2-L3) are affected the pain irradiate downward to groin and anterior side of the thigh, the term used to describe such pain is ‘cruralgia’. The estimations of prevalence of sciatica are widely variable, ranging from 1.6% to 43% and cruralgia is considered to be less frequent but literature lacks the precise estimations of its prevalence.(Mostofi et al., 2018) Still, the mechanism of this type of pain isn’t clear regarding the lack of concordance between magnetic resonance imaging (MRI) and patient’s symptoms.(Kasch et al., 2022) Conventionally, disc herniation, spinal stenosis, synovial cysts,

infection, vascular abnormalities or neoplasia could produce mechanical compression or inflammation of the nerve root responsible to pain descending in the corresponding nerve root territory.(Govind, 2004) It was recognized that the simple compressive mechanism is insufficient to explain radicular pain as in patients whose symptoms of sciatica had resolved still showed herniated IVD on magnetic resonance imaging.(Hu and Liu, 2015; Komori et al., 1996) Indeed, in the case of disc herniation the nucleus pulposus demonstrated inflammatogenic and leukotactic properties in contact with the nerve root.(McCarron et al., 1987) Another proposed mechanism is neurodynamics deficits.(Shacklock, 2005) In normally functioning nervous system while the extremities or spine moves small sliding movements occur also in the spinal cord, nerve roots and peripheral nerves in relation to surrounding tissues.(Harrison et al., 1999) Also, the spinal cord and nerves have a physiological tolerance (in some extent) to stretch thanks to its elastic properties.(Harrison et al., 1999) In the irritated nerve root, oedema, ischemia and fibrosis can hamper neurodynamics properties leading to further damage resulting in pain and decreased function.(Plaza-Manzano et al., 2020) Some patients in addition to radicular pain present sensory and motor deficits in the territory innervated by the affected nerve root. Such clinical symptoms are describe by the term ‘radiculopathy’ and in such a case surgical intervention is frequently needed especially when sacral nerve roots are involved causing cauda equine syndrome.(Quaile, 2019)

### Deep gluteal syndrome

The particular situation when pain arise from the buttock and radiates downward sciatic nerve territory is when deep gluteal muscles entrapment sciatic nerve. Conventionally, the term ‘piriformis syndrome’ has been used to describe such pathology. (Cass, 2015) However, successive studies showed that other structures like obturator internus or gemelli muscle can be also involved, thus the term ‘deep gluteal syndrome’ has now been proposed.(Kizaki et al.,

2020) As the sciatic nerve is affected in deep gluteal syndrome it can be considered as one of the neuropathic pain driver.

#### Lumbar spinal stenosis

Radicular pain can also occur as a consequence of lumbar spinal stenosis. This can occur as anatomic malformation or when degenerative changes, spondylolisthesis, trauma or neoplasia cause narrowing of the spinal canal or intervertebral foramen and cause neural compression. (Lai et al., 2020; Zaina et al., 2016) Degenerative lumbar stenosis is considered as a primary cause of LBP and sciatica in older adults. (Hennemann and de Abreu, 2021) Symptoms are commonly intermittent, exacerbated by spinal extension, prolonged standing or walking and are diminished by rest, flexed or seated position. Reduction in walking capacity called 'neurogenic claudication' is characteristic to lumbar spinal stenosis, this consist of neuropathic pain and neurological symptoms in lower limbs limiting walking.(Zaina et al., 2016)

#### Local neuropathic pain

Local neuropathic pain is present when damage affects nerves supplying the structures of the lumbar spine namely dorsal ramus and meningeal branch of spinal nerve.(Baron et al., 2016) Degeneration of the IVD, lumbar facet joints, or spinal ligaments can affect the neural endings of the aforementioned parts of the spinal nerve, potentially provoking neuropathic pain localized in the lumbar spine. Seemingly, both nociceptive and neuropathic components coexist in such condition and should be considered in CLBP management.(Morlion, 2011)

## Central sensitization

In CLBP patients neuropathic pain components could also be related to the mechanism of central sensitization. (Sanzarelo et al., 2016) This mechanism affects processing of pain perception at the central nervous system (CNS). Underlying structural, functional and chemical changes in CNS make it more sensitive to stimuli.(Volcheck et al., 2023) Patients presenting central sensitization report diffuse, migrating and incongruent pain, chronic fatigue and sensory hyper-responsiveness. Clinical examination become inconclusive and identification of such condition is important. However, direct evaluation of structural, functional and chemical changes in CNS is inaccessible in clinical settings, so identifying the presence of central sensitization is based on indirect evaluation. For this purpose, the Central Sensitization Inventory (CSI) questionnaires was developed by an interdisciplinary team of experts to investigate the symptoms related to central sensitization like for example, sleep perturbations, fatigue, sensibility to bright light and smells or general pain in the body.(Mayer et al., 2012) Identifying central sensitization could allow for the avoidance of unnecessary and ineffective diagnostic and treatment strategies. Further, an adequate medication and treatments targeting psychosocial factors could be more beneficial.(O'Sullivan et al., 2018; Xu et al., 2016)

## Biopsychosocial model

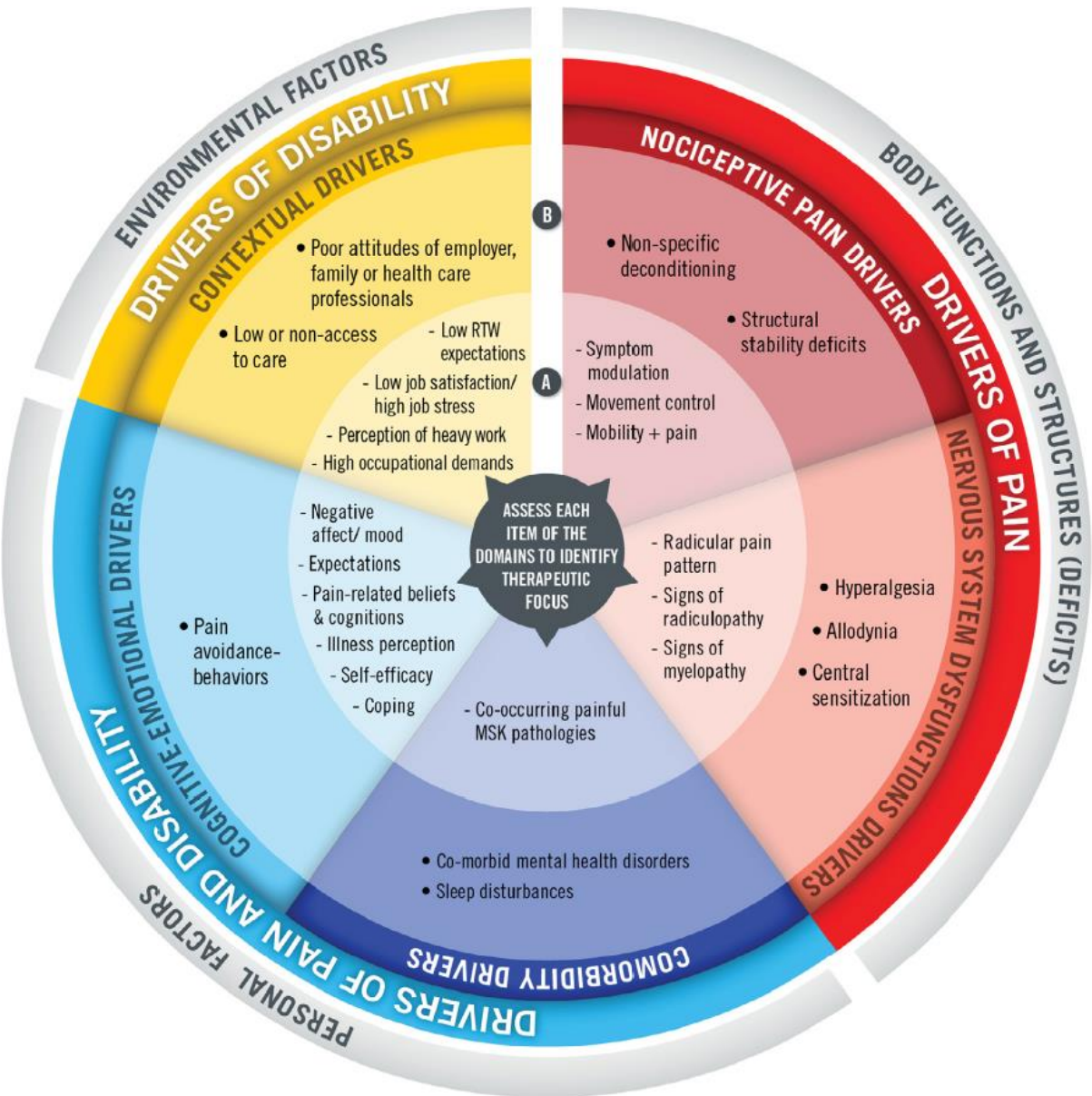
Regarding the complexity of CLBP, the failure of approaches targeting only structural explanation of pain (biomedical model) and the complexity of pain integration mechanisms the need of a new healthcare model was postulated. The biopsychosocial model was first proposed in 1977 by Engel.(Engel, 1977) In this approach biomedical aspects were completed by the integration of psychological, social and behavioural dimensions. These aspects were further developed by proposing five domains which could drive the LBP pain. (Figure 4) Namely,



contextual drivers, nociceptive pain drivers, nervous system dysfunction, comorbidity and cognitive-emotional drivers.(Tousignant-Laflamme et al., 2017) The proposed domains include the factors like for example, pain avoidance-behaviours, attitudes of employer, family or healthcare professionals, job satisfaction, negative affect, expectations and pain related beliefs. Evidences from a systematic review show the prognostic impact of fear-avoidance beliefs on CLBP development.(Wertli et al., 2014) Other psychosocial factors like, carrying heavy loads at work, difficult working positions, anxiety and depression increase the risk of CLBP.(Nieminen et al., 2021; Oliveira et al., 2019) Also, the status of claims for lumbar spine work-related injury (accepted or not by insurance agency) impact the pain severity and functional impairments.(Melloh et al., 2015) The above studies support the pertinence of biopsychosocial model. The interventions targeting some of the psychosocial factors are now integrated into international guidelines for CLBP management.(Bailly et al., 2021; George et al., 2021) Different patient education intervention has been proposed to change fear-avoidance beliefs and patient's pain-related behaviour including cognitive behaviour therapy,(O'Sullivan et al., 2018) education about pain neurophysiology,(Volcheck et al., 2023) written self-management information such as a booklet,(Dupeyron et al., 2011), self-management education using smartphone applications,(Dobija et al., 2022), individual or in group patient education with the messages reassuring on benefices of physical activity, to stay active, to avoid worry, to deal with self-management of stress and anxiety.(Engers et al., 2008) However, patient education alone have a little effect on pain and function.(Furlong et al., 2022) This is in the line with the biopsychosocial model that recommend to couple psychosocial intervention with physical and biomedical intervention like exercises, physical therapy, manual therapy, and if needed, medications or multidisciplinary management.(Bailly et al., 2021) Evidence shows that multidisciplinary biopsychosocial rehabilitation for CLBP is more effective on pain , function and work ability than usual care or physical intervention alone.(Kamper et al., 2014) However,

authors of the above cited systematic review suggest that only those patients with significant psychosocial impact should be referred to multidisciplinary intervention.(Kamper et al., 2014)

Regarding favourable cost-effectiveness analysis of multidisciplinary management, it could be discussed whereas such strategy should be expanded to wider range of patient characteristics.(Salathé et al., 2018)



**Figure 4. Biopsychosocial factors integrated in “Pain and disability driver management model”.**(Tousignant-Laflamme et al., 2017)

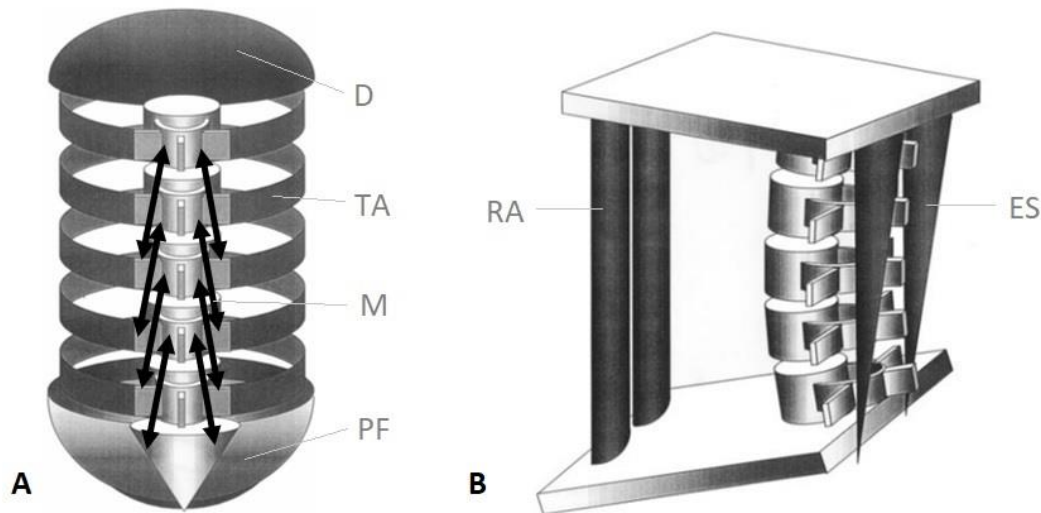
## FUNCTIONAL BIOMECHANICS RELATED TO CHRONIC LOW BACK PAIN

Forward bending activities increase the loading of the lumbar spine, and cumulative work-related lumbar loading increase the risk of LBP development.(Coenen et al., 2013) On the other hand, the lumbar spine is well-constructed, and its stability is reinforced by surrounding ligaments, tendons, and muscles. This is the case at both local and global anatomical levels. In addition, complex neuromuscular control mechanisms optimize spinal loading.(Hodges and Richardson, 1999; Richardson et al., 2004) Impairment function of the above structures and altered neuromuscular control can trigger nociceptive or neuropathic LBP drivers. Therefore, a thorough understanding of lumbopelvic region functioning is a major issue in the management of CLBP. In the following section, lumbopelvic functional stability will be described at both the local level (involving core muscles) and the global level (involving muscle chains, with a focus on hamstring muscles).

### Lumbopelvic functional stability

Early analysis of lumbopelvic functional stability has been described by Panjabi, who proposed that three subsystems contribute to maintaining appropriate vertebral alignment, thus preventing uncontrolled excessive movements when forces act on the spine.(Panjabi, 1992a, 1992b) The passive subsystem includes the vertebrae, disc, and ligaments; the active subsystem includes muscles and tendons, and the control subsystem includes the nerves and central nervous system. All three subsystems act together to provide functional stability. In Panjabi's concept when dysfunction affect one of the subsystem compensatory mechanisms are necessary to maintain function, yet when dysfunction persist, it can lead to LBP onset.(Panjabi, 1992a) In the light of this reasoning the lumbar functional instability has been proposed as a one of the potential mechanism generating nociception in LBP.(Demoulin et al., 2007) Uncontrolled,

excessive movements at individual segment could damage either a disc or a ligament, and can be involved in CLBP.(Fujiwara et al., 2000) The term “functional instability” has been proposed in contrast to so-called “clinical instability”. The first one refers to dysfunction of motor control (neural control subsystem) or poor muscles function (active subsystem) in absence of excessive detectable movements. The clinical instability refers to instability documented by excessive translation or rotation in dynamic radiographs, proving that passive subsystem is also affected.(Alyazedi et al., 2015) Even if detecting functional instability in clinical practice is problematic, the exercises targeting to restore spinal stability are widely addressed in the management of CLBP and show positive effect.(Denteneer et al., 2017; O’Sullivan et al., 1997; Owen et al., 2020) The crucial role in maintaining functional lumbopelvic stability is attributed to “core muscles”, namely lumbar multifidus, transversus abdominis, pelvic floor muscles, and diaphragm.(Hodges, 1999) (Figure 7) The core muscles contribute to improve functional stability through two mechanisms: increasing segmental stiffness via muscle contraction and raising intra-abdominal pressure during synergistic contractions.(Cholewicki et al., 1999; Hodges et al., 2005; Hodges and Richardson, 1996) Other superficial trunk muscles, such as rectus abdominis, external oblique, internal oblique, and erector spinae, also contribute to functional stability but primarily play a role in the overall orientation or posture of the lumbar spine. However, on their own, these muscles cannot control movements at the individual segmental level.(Hodges, 1999)



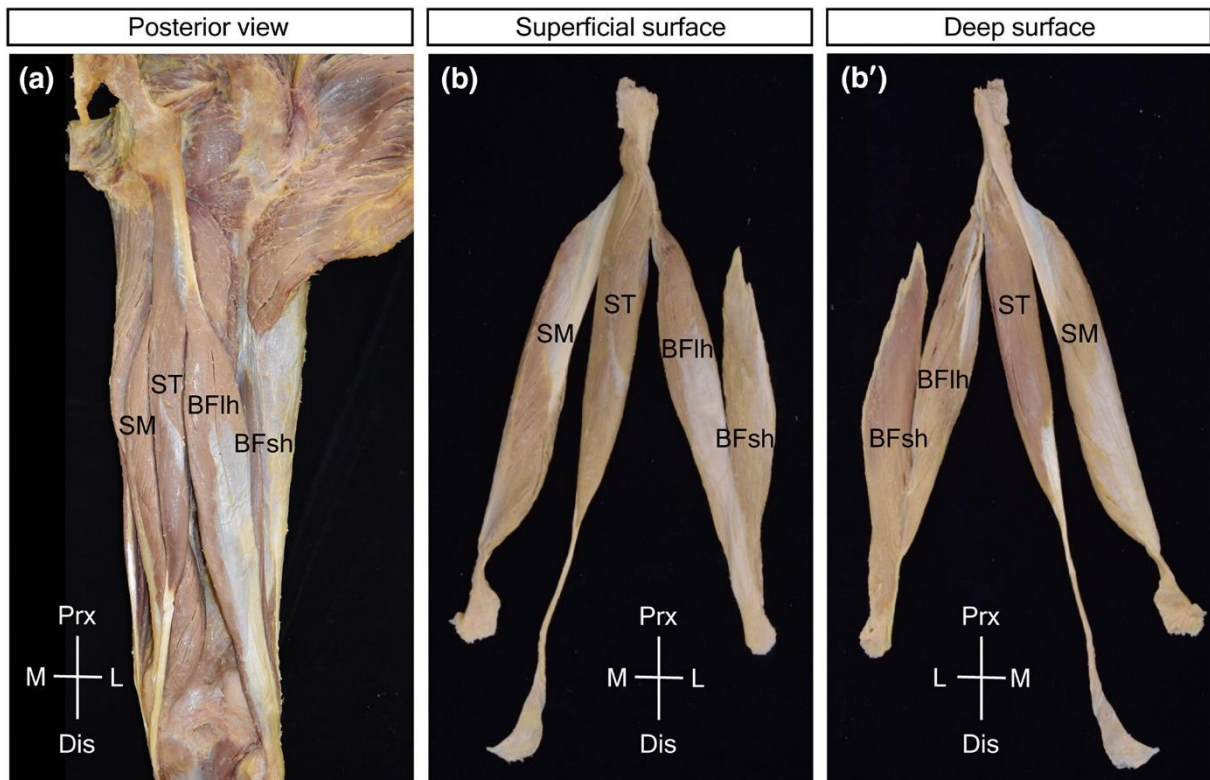
**Figure 7. Models presenting (A) core muscles and (B) superficial trunk muscles. D, diaphragm; TA, transversus abdominis; M, multifidus; PF, pelvic floor muscles; RA, rectus abdominis; ES, erector spinae. (Hodges, 1999)**

The studies also report a close relationship between the functional stability of the lumbar spine and the adjacent sacroiliac joints, particularly concerning load transmission between the lower limbs and the spine. (Lee Diane, 2011; van Wingerden et al., 1993a) The action of core muscles also enhances the stability of the sacrum between the two iliac bones, directly impacting the L5-S1 segment and indirectly influencing other lumbar segments. (Lee Diane, 2011; Nagamoto et al., 2015; Richardson et al., 2002; van Wingerden et al., 1993a) The sacroiliac joints are stabilized by both muscles compression forces, “force closure” and by the configuration of the interfacing joint surfaces, “form closure”. (Vleeming and Schuenke, 2019) It is important here to emphasize the role of neural control subsystem which is responsible for sensorimotor control of the all above mentioned muscles. (Panjabi, 1992a) Complex mechanisms, including feed-forward and feed-back reactions, integration, interpretation processes, and responses to somatosensory inputs, have been analysed using various experimental models in numerous studies. (Hodges et al., 2007; Hodges and Richardson, 1999, 1997; Maaswinkel et al., 2016; Norrie et al., 2021) These investigations collectively enhance our comprehension of

neuromuscular control and the broader functioning of the lumbopelvic region. Furthermore, other studies reported the influence of LBP on neuromuscular control,(Abboud et al., 2018; Gnat et al., 2021; Hodges and Richardson, 1996; Leinonen et al., 2007, 2003; Skotte et al., 2004; van Dieën et al., 2019) and provide a scientific foundation for the development of physical therapy strategies aimed to improve neuromuscular control.(Hlaing et al., 2021; Kim and Yim, 2020; Richardson et al., 2004; Saragiotto et al., 2016)

### Anatomy and Biomechanics of hamstring muscles

A basic anatomy and function of the hamstring muscles are introduced before describing their role in lumbopelvic stability. Consequently, hamstring muscles are a group of three muscles located on the back of the thigh, running from the pelvis to the knee joint. They play a crucial role in the movement and stability of the lower limb. The three muscles that make up the hamstrings are biceps femoris, semitendinosus and semimembranosus. (Figure 5)



**Figure 5. Hamstring muscle group in situ and in isolated specimens. (a) In situ posterior view of the hamstrings in the posterior thigh. (b, b') Isolated specimens of the whole hamstrings in the superficial surface (b) and deep surface (b'). BFlh, biceps femoris long head; BFsh, biceps femoris short head; SM, semimembranosus; ST, semitendinosus.**

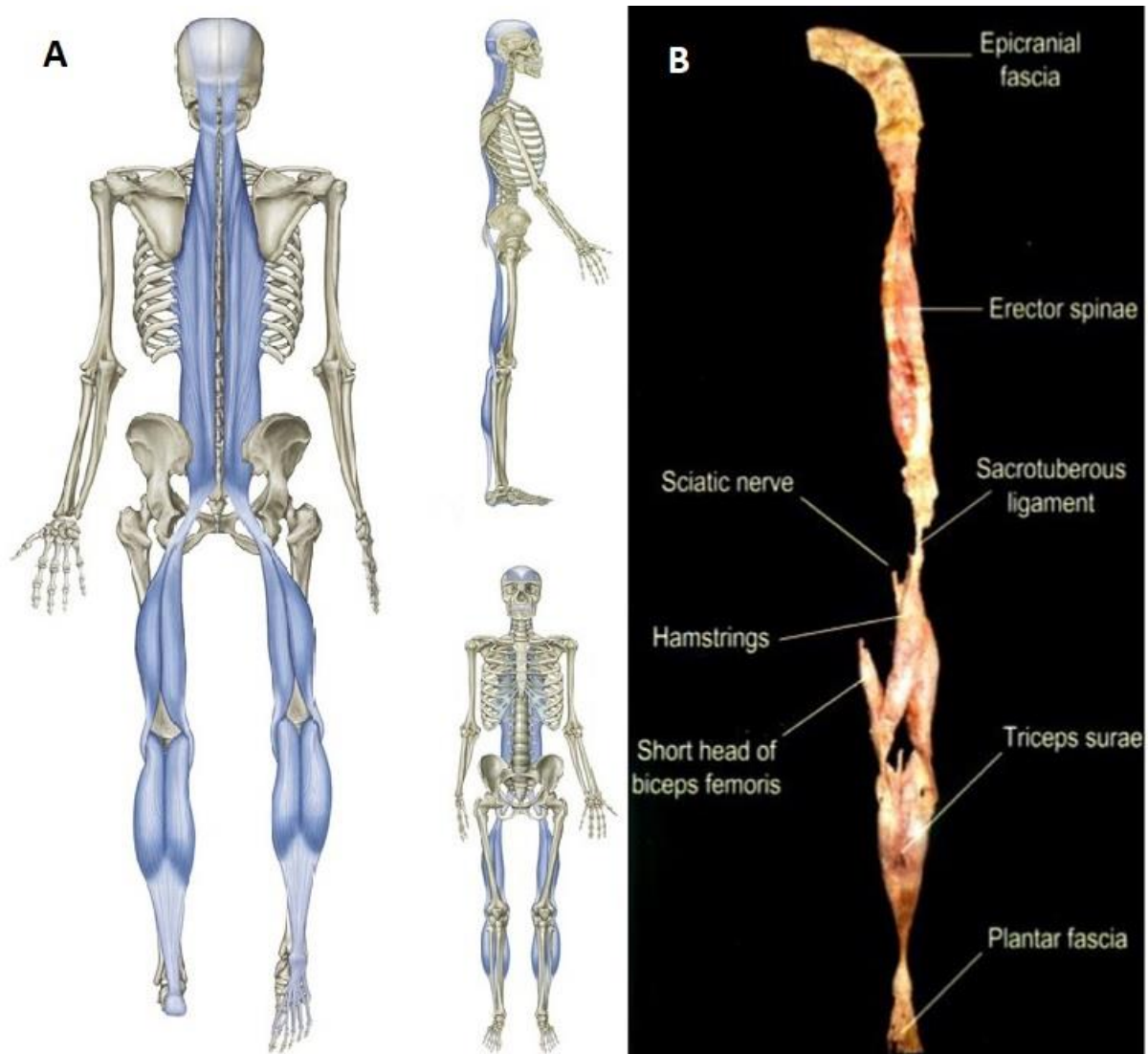
(Takeda et al., 2023)

The biceps femoris is the most lateral of the three muscles and has two parts - the long head and the short head. The long head originates from the ischial tuberosity, a bony prominence in the pelvis, while the short head originates from the back of the femur. Both parts of the biceps femoris merge and attach to the head of the fibula.

The semitendinosus is the middle muscle of the hamstring group. It arises from the ischial tuberosity and runs down the back of the thigh to its insertion point at the upper part of the tibia.

The semimembranosus is the most medial muscle of the hamstrings. Like the semitendinosus, it originates from the ischial tuberosity. However, it attaches to the posterior surface of the medial condyle of the tibia and also has a membranous expansion on its upper part. (Takeda et al., 2023) Anatomical studies have revealed structural connection between biceps femoris, sacrotuberous ligament and erector spinae muscle. (Myers, 2011; van Wingerden et al., 1993a; Vleeming et al., 2012) The superficial fibres of the biceps femoris muscle's proximal tendon encompass the ischial tuberosity and directly integrate with the sacrotuberous ligament. This connective tissue pathway called by Myers "Superficial Back Line" continues further into the deep thoracolumbar fascia and the erector spinae muscle. (Figure 6) (Lee Diane, 2011; Myers, 2011) This structural connection was also earlier described by Vleeming et al. and called "Longitudinal Sling". (Figure 8C)





**Figure 6. Superficial Back Line: A, graphic presentation; B, dissection specimen.**

(Myers, 2011)

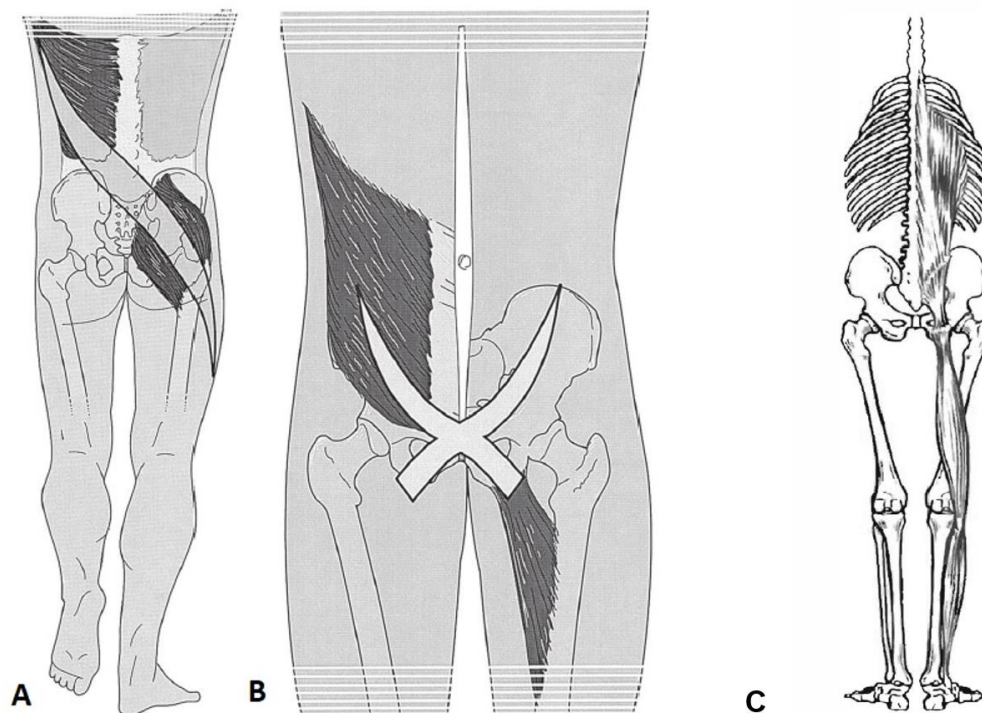
Conventionally, the primary function (concentric contraction) of the HM is hip extension and knee flexion, as the HM pass over the hip and knee joints posterior to their axes of movement in the sagittal plane.(Standing, 2020) Secondary, in the knee flexed position concentric contraction of biceps femoris externally rotates knee while concentric semitendinosus and semimembranosus contraction internally rotate knee joint.(Kapandji, 2010) From the functional point of view HM are essential for actions like standing up from a seated position, bending the knee while walking, running and climbing stairs.(Besier et al., 2009; Orakifar et al., 2019; Yali

et al., 2015) During forward bending HM allows to control anterior pelvic tilt, this involves eccentric contraction and elongation of the HM.(Zawadka et al., 2018) Flexibility of the HM is one of the determinants in many professional or housework activities demanding forward bending.(Jandre Reis and Macedo, 2015) However, forward bending in CLBP patients is frequently pain provoking and leads to compensatory kinetic and kinematic patterns.(Massé-Alarie et al., 2016) Patients frequently report fear regarding the tasks which demand forward bending and particularly bending and load lifting.(Tissot et al., 2023) Loading forces at the lumbar spine are greater during forward bending in CLBP patients compared to healthy controls.(Shum et al., 2010) Moreover, patients with greater ROM deficits measured by Straight Leg Raise (SLR) test demonstrated even greater loading forces at the lumbar spine.(Shum et al., 2010)

### Hamstring muscles and lumbopelvic stability

Regarding anatomical studies which describe structural and functional connections between different muscles, ligaments and fascia (Lee Diane, 2011; Myers, 2011; van Wingerden et al., 1993b) the lumbopelvic stability models have been completed by the influence of the global muscle connections called also muscle chains.(De Ridder et al., 2013) Several muscle chains were described and their contribution to lumbopelvic stability was postulated.(Lee Diane, 2011; van Wingerden et al., 1993b; Vleeming and Schuenke, 2019) (Figure 8.) Simultaneous coordinated contraction of the muscles in the described chains results in augmentation of compression forces acting on the joint surfaces in the lumbopelvic region, (force closure). This, in turn, leads to better joint stability.(Vleeming and Schuenke, 2019) Hamstring muscles have a role in lumbopelvic functional stability as they act in the posterior longitudinal muscle chain. Hu et al. have reported that during Active Straight Leg Raise (ASLR) in supine lying contralateral HM activity equalize the forces exerted by hip flexors on the pelvis, thus enhanced

lumbopelvic stability by preventing excessive rotatory movements of the iliac bones. (Hu et al., 2012) Yet, the core muscles are also involved in the force closure mechanism in ASLR movement.(Crasto et al., 2020; Liebenson et al., 2009) Therefore, the ASLR procedure is now used to evaluate lumbopelvic functional stability.(Crasto et al., 2020; Linek et al., 2015; Paris-Alemany et al., 2018) Different compensation mechanisms were reported during ASLR in LBP patients, namely core muscles activity impairments and excessive lumbopelvic rotatory movement.(Bruno et al., 2014; Crasto et al., 2020; Plaza-Manzano et al., 2022)



**Figure 8. Muscle chains contributing to lumbopelvic functional stability: (A) Posterior Oblique Sling (latisimus dorsi – thoracolumbar fascia – contralateral gluteus major); (B) Anterior Oblique Sling (external oblique – controlateral internal oblique – hip adductors); (C) Longitudinal Sling (erector spinae – thoracolumbar fascia – sacrotuberous ligament – biceps femoris – fibularis muscles). (Lee Diane, 2011)**

It is important to note, that influence of force closure mechanism exerted by HM via the posterior muscle chain is more pronounced in forward bending than in erect posture.(van Wingerden et al., 1993b) This could be explained by an increase in the moment of force exerted on the lumbar spine in the flexed position, as well as an increase tension of the HM, sacrotuberous ligament, and erector spinae muscle. (Zawadka et al., 2018) When a muscle is at rest and not actively contracting, it still possesses a certain degree of stiffness that opposes elongation or stretch. This stiffness is mainly due to the structural composition of the muscle namely, arrangement of the connective tissue, contractile and non-contractile proteins of the sarcomere cytoskeleton, and the elastic propriety of the tendon and fascia.(Gajdosik, 2001) In the HM passive muscle stiffness increase during hip flexion and knee extension according to measurements realized with the ultrasound shear wave elastography (Miyamoto et al., 2020) or with a dynamometer measuring passive muscle torque during passive SLR movement.(Marshall et al., 2009) Thus, the force closure mechanism in forward bending can be also influenced by the passive HM muscle stiffness.(Kuszewski et al., 2018)

### Hamstring muscles and Low Back Pain

Regarding anatomy and biomechanics of the HM presented earlier, it seems logical that CLBP can affect hamstring function. Several studies have focused on hamstring function in individuals with CLBP. Some of them reported HM strength deficits, (Madić et al., 2020; Marshall et al., 2010) others evaluated HM flexibility or stiffness.(Arab and Nourbakhsh, 2014; Halbertsma et al., 2001; Hori et al., 2021; Hultman et al., 1992; Kellis et al., 2015; Marshall et al., 2009; Nourbakhsh and Arab, 2002; Sadler et al., 2017) The clinical characteristics of patients suffering from CLBP can vary significantly among individuals, and the presence of HM flexibility deficits hasn't been reported in all samples of CLBP patients. Some authors have found deficits in HM flexibility,(Arab and Nourbakhsh, 2014; Fasuyi et al., 2017; Halbertsma

et al., 2001; Hultman et al., 1992; Kellis et al., 2015; Marshall et al., 2009; Nourbakhsh and Arab, 2002) and others have reported no difference comparing to healthy persons or no association with CLBP.(Allam et al., 2022; Koley and Likhi, 2011; Stutchfield and Coleman, 2006) The recent systematic review with meta-analysis reveals that, regarding methodological issues, it is impossible to conclude whether persons with LBP have deficits in HM flexibility and stiffness.(Hori et al., 2021) On the other hand, in the study we have conducted and which is presented in an article format afterward, we have screened 211 patients with CLBP and have found only 26 (12%) patients with good HM flexibility (FTF<5cm or AKE>85degrees). The differences between the study's results regarding HM flexibility could be a consequence of population characteristics; articles reporting no HM deficits have studied young athletes with LBP,(Stutchfield and Coleman, 2006) or female students with LBP.(Allam et al., 2022) Some authors suggest that deficit in HM flexibility results from poor core muscle function.(Ahn et al., 2020; Hungerford et al., 2003; Kim and Yim, 2020; Kuszewski et al., 2018; van Wingerden et al., 2008) Indeed, passive HM stiffness may play a role in sacroiliac joint force closure mechanism by transferring compression forces via the sacro-tuberous ligament.(van Wingerden et al., 1993b; Vleeming and Schuenke, 2019) Therefore, HM tightness could be a sub-optimal compensatory mechanism for a poor core muscles function that further negatively impact lumbopelvic region.(Jandre Reis and Macedo, 2015; Sadler et al., 2017; van Wingerden et al., 2008) The deficit in HM flexibility and reduced lumbar lordosis was also reported in systematic review with meta-analysis as a predictive factor for development of LBP.(Sadler et al., 2017) Similar results concerning the predictive value of HM flexibility have been found in the recent study; this was the case independently of gender.(Cejudo et al., 2021a) Furthermore, the improvement in forward bending range of motion during the first month after low back pain onset has shown valid prognostic value for functional recovery at one year.(Ekedahl et al., 2012) Yet, screening of the HM flexibility can predict also lower limb injury.(Knapik et al.,

2001; Mizutani et al., 2023; van der Worp et al., 2011) However, results showing no impact of HM flexibility on risk of lower limb injury have been also reported.(Dallinga et al., 2012; O'Connor et al., 2019)

The HM flexibility is a factor that is frequently targeted in the prevention and treatment programs for CLBP. (Ahn et al., 2020; Kim and Yim, 2020; Mizoguchi et al., 2022; Moon et al., 2017; Shamsi et al., 2022) It is frequently linked with core muscle exercises and others strengthening exercises. Ahn et al. have compared core muscle activation during active HM stretching to conventional active stretching. Although HM flexibility improved in both groups, the experimental group exhibited better lumbopelvic stability.(Ahn et al., 2020) Other example is stretching intervention of the hip muscles and core stability exercises which both improve pain and function but HM stretching provide better flexibility improvement.(Kim and Yim, 2020) One study has compared passive HM stretching versus HM strengthening in LBP patients and has showed similar effect in both groups.(Shamsi et al., 2020) Interestingly, the improvement in HM flexibility has been also shown following core muscle training. (Kuszewski et al., 2018)

### Immediate effect of hamstring muscles stretching

To improve HM flexibility, stretching interventions are commonly conducted over multiple sessions.(Ahn et al., 2020; Medeiros et al., 2016; Mizoguchi et al., 2022; Shamsi et al., 2020) Although, in some clinical situations an immediate effect could gave a pertinent information. It can guide subsequent treatment choices and help to establish a functional diagnosis. For example, if forward bending ROM does not improve after HM stretching, other structures (ex, the piriformis muscle, sciatic nerve or lumbar spine) could be considered as the drivers of the limitation, and could be evaluated, treated and re-evaluated to refine the diagnosis. In contrast,

if ROM improves immediately, the same technique could be repeated in the following sessions to obtain a cumulative effect. However, if no improvement occurs with repeated interventions, and no red flags are present,(Evjenth and Hambers, 1988; Krauss et al., 2006) psychosocial or behavioral factors may be involved in the limitation.(Tousignant-Laflamme et al., 2017)

The immediate effect of HM stretching has been reported in the literature, but this has mainly been studied in healthy individuals. Nishikawa et al. found an immediate improvement in AKE angle of 15.8 degrees after passive HM stretching (Nishikawa et al., 2015) Similarly, Aye et al. reported immediate improvement of 5-6cm in FTF distance following HM stretching in healthy individuals.(Aye et al., 2017) Puentedura et al. reported an immediate improvement of approximately 9 degrees in AKE following both Hold-Relax and static stretching sessions in healthy subjects.(Puentedura et al., 2011) In individuals with CLBP, fear-avoidance beliefs and the perception that movement is a threat can limit the capacity to relax muscles during stretching, potentially reducing stretching efficacy.(Moseley and Vlaeyen, 2015; O'Sullivan et al., 2018) Similarly, symptoms of anxiety or depression could reduce the stretching effect.(Lewis et al., 2012) Yet, in people with non-specific LBP, the SRT test results improved immediately after passive HM stretching and procedures using Graston soft tissue mobilisation.(Moon et al., 2017) However, the interpretation of these results is limited due to the small sample size and measurement technique used.

## CHAPTER 2: DETERMINING MEASUREMENT PROPERTIES FOR HAMSTRING MUSCLES FLEXIBILITY ASSESSMENTS

This chapter will focus on methods of assessing HM flexibility. However, the introduction of general concepts concerning measurement properties will precede the description of existing HM flexibility measurement techniques. A synthesis of the studies estimating the measurement properties of HM flexibility assessments provides a background for our estimation conducted on CLBP patients. This chapter does not correspond to an article submission but will follow the IMRaD structure as it constitutes the first phase of the conducted EFIM1 study.

### INTRODUCTION

Each form of evaluation need to possess acceptable measurement properties to be useful in clinical or research settings.(Hegedus et al., 2015) Regardless of whether it is a questionnaire, a functional test, or a clinical measurement, it needs to be assessed for reproducibility, validity, and responsiveness before its results can be interpreted and used in research or clinical reasoning.(Davidson and Keating, 2014) The estimation of measurement properties requires conducting studies with a specific study design. The first phase of the present work is focused on estimation of reproducibility and validity of the HM flexibility measurements. This estimation was necessary because a new measurement tool (EasyAngle® digital inclinometer) was used for AKE and SLR measurements in CLBP population. Furthermore, the interpretation of the immediate effect of HM stretching could be more accurate, thanks to the preliminary estimation of measurement properties. The concepts of reproducibility, validity and responsiveness is introduced below.



## Reproducibility

Reproducibility refers to the extent to which repeated measurements yield consistent or similar results.(de Vet et al., 2006) Repeated measurements may vary due to biological variations among individuals, as even stable characteristics can exhibit slight day-to-day differences. Others sources of variation may arise from the measurement instrument itself or the conditions in which the measurements are conducted. In the literature there are some variations regarding the terminology however, two complementary types of reproducibility are reported: reliability or relative reproducibility and absolute reproducibility, called also agreement.(de Vet et al., 2006) The first is usually expressed by Intraclass Correlation Coefficient (ICC) for continuous variables or by Cohen's kappa coefficient for categorical variables.(Mandrekar, 2011) Reliability relates the measurement error to the variability between the individuals being evaluated. Thus, it could be influenced by inter-individual differences among the sample. On the contrary, agreement refers to the measurement error, and assesses exactly how close the scores for repeated measurements are.(de Vet et al., 2006) Agreement is expressed in the unit of a specific measurement or in percentage. There are several statistical methods permeating estimate agreement, specifically Standard Error of Measurement (SEM), Minimal Detectable Change (MDC),(Haley and Fragala-Pinkham, 2006) also called Smallest Detectable Difference (SDD) and Bland and Altman Limits of Agreement (LOA).(Giavarina, 2015) The SEM represent the amount of variability or fluctuation that can be expected in an individual's measure due to random error or inconsistency in measurement, whereas MDC can be interpreted as the minimal amount of change that is not likely to be due to chance variation in measurement. The MDC is expressed with 90% or 95% Confidence Interval (CI) which refers to degree of certitude.(Haley and Fragala-Pinkham, 2006) The formulas of the ICC, SEM and MDC are presented in Figure 13. The 95% LOA is calculated as mean difference  $\pm 1.96$  SD of the

difference and can be also represented graphically by Bland and Altman plots. (Giavarina, 2015) The LOA can be interpreted in a manner akin to MDC, however LOA method do not use the ICC value in calculation, thus is considered to be not influenced by inter-individual's variability.(Giavarina, 2015) It is important to note that excellent reliability is not always accompanied by excellent agreement. Globally, it could be assumed that reliability refers more to the capacity to distinguish differences among a group of individuals, whereas agreement permits the discrimination between true changes and measurement errors. Therefore, agreement is of greater interest in clinical settings.(de Vet et al., 2006; Haley and Fragala-Pinkham, 2006)

$$ICC = \frac{\textit{variability between study objects}}{\textit{variability between study objects} + \textit{measurement error}}$$

$$SEM = SD \sqrt{(1 - ICC)}$$

$$MDC_{95} = SEM \times 1.96 \times \sqrt{2}$$

**Figure 13. The simplified formulas for calculation of Intraclass Correlation Coefficient (ICC), Standard Error of Measurement (SEM) and Minimal Detectable Change (MDC). SD, Standard Deviation. (de Vet et al., 2006)**

Both agreement and reliability can be evaluated in intra-rater or test-retest analysis and inter-rater analysis. It is also important to note that population characteristics can influence the estimated measurement properties. Thus, even if good reproducibility for a specific measure has been demonstrated in healthy individuals, its reassessment is necessary before the measure can be used in a specific patient population.

## Validity

The validity of a measure refers to its ability to accurately assess the specific construct, ensuring that the measure truly measures what it intends to. The validity needs always be described relative to the standard against which it has been studied. The evidence for validity of a measure is gathered through multiple studies and cannot be established definitively by a single investigation. Validation of a measure should be also conducted within the specific population of interest. There are several types of validity and new methods of validity analysis continue to emerge.(Davidson and Keating, 2014) Criterion validity is defined by the extent to which a measure correlates with the one achieved by a 'gold standard' measure. If there is no 'gold standard' measure available for a specific construct, construct validity can be estimated by examining the correlation between other measures intended to assess the same construct.(Hegedus et al., 2015) To evaluate validity the most frequently used correlation coefficients are the Spearman Rank-order correlation coefficient for ordinal or not normally distributed variables and the Pearson product–moment correlation coefficient for continuous normally distributed variables.(Mukaka, 2012) On the other hand, predictive validity is estimated in longitudinal cohort studies and serves to determine if a specific measure has predictive value for a defined outcome.(Davidson and Keating, 2014) For example, if HM flexibility measure can predict a lower limb injury. The method for estimating predictive validity is based on the Receiver Operating Characteristic (ROC) curve, which relates the true-positive rate (sensitivity) and the false-positive rate (1-specificity). The Area Under the Curve (AUC) is often reported, along with the corresponding cut-off value that best predicts the outcome.(Davidson and Keating, 2014)

## Responsiveness

Responsiveness, also known as longitudinal validity, refers to the capacity of a measure to detect change over time. In other words, it determines the amount of change that can be detected by a specific measure within a given period, assuming that the measured construct really changes during this time. The responsiveness is commonly estimated by effect size (ES) for paired difference. (King and Dobson, 2000) When a measure has been taken two times, and we assume that a difference occurred in this interval, a comparison of means (t-test or ANOVA) could be conducted to detect the statistical significance of the difference. Additionally, Cohen's effect size (ES) will express the responsiveness of a measure, quantifying the magnitude of the difference between the means in terms of standard deviation units. (Davidson and Keating, 2014; King and Dobson, 2000) The values of Cohen's ES are commonly interpreted as 0.2 for small, 0.5 for medium, and  $\geq 0.8$  for large effects. (Sullivan and Feinn, 2012)

## Minimal Clinically Important Difference

The demand for estimating clinically significant or remarkable changes in specific measures is growing in clinical research and practice. Several methods have been proposed to provide such values and different terminology has been reported regarding this idea. Specifically, Minimal Clinically Important Difference (MCID), Minimal Important Difference (MID), Clinically Significant Difference (CSD), Reliable Change Index (RCI), and the MDC discussed above have all been reported to describe clinically significant or remarkable changes. (Haley and Fragala-Pinkham, 2006) The concept should be used with caution, considering its relativity to the method employed for its estimation. In the anchor-based methods patients or family member rate the perceived improvement or change. The MCID is then determined as the difference on the clinical outcome measure that corresponds to a meaningful change in the anchor. (Revicki

et al., 2006) In the Delphi method an expert consensus approach is used where a panel of experts is asked to rate the level of clinical importance for different change values. Through multiple rounds of anonymous feedback and discussion, a consensus is reached on the MCID value.(Revicki et al., 2006) On the other hand, distribution-based methods are based on the statistical properties of the data distribution and correspond to MDC concept.(Haley and Fragala-Pinkham, 2006) An interesting compromise is the use of distribution-based anchor methods, which leverage the anchor data to determine the optimal distribution-based estimate of the MCID.(Haley and Fragala-Pinkham, 2006; Revicki et al., 2006) Other proposed methods include the Patient Acceptable Symptom State (PASS) approach, which determines the MCID as the change needed to transition patients from an unacceptable to an acceptable state, and ROC curve analysis, which identifies the optimal threshold using sensitivity and specificity to detect patients who have experienced a meaningful change.(Myles et al., 2017) Access to estimated values of MCID for a particular measure can certainly improve clinicians' and researchers' reasoning. However, it is essential to acknowledge the limitations regarding the method or anchor used, the validity and reproducibility of the patient statements, and the discussion about the limited generalizability of MCID.(Haley and Fragala-Pinkham, 2006) Furthermore, many of the currently used measures or tests in healthcare management were not studied for the estimation of MCID. Instead, patient-reported outcomes, such as questionnaires, are given priority.(Davidson and Keating, 2014; Goh et al., 2022) Therefore, the interpretation of certain measurements used in clinical practice is based on the best available data.

### Hamstring muscles flexibility

Flexibility of the HM refers to ability of muscles to lengthen allowing combined hip flexion and knee extension. Several methods have been proposed to measure HM flexibility including passive measurements like SLR and Passive Knee Extension (PKE) (Gnat et al., 2010; Marshall

et al., 2009; Medeiros et al., 2016; Neto et al., 2015) and active measurements like AKE, FTF and SRT.(Jandre Reis and Macedo, 2015; Medeiros et al., 2016; Moon et al., 2017; Neto et al., 2015; Nishikawa et al., 2015) In clinical practice lengthening of the muscle cannot be measured directly, instead the ROM of the joint(s) that the muscle act on is measured to estimate muscle flexibility. In the passive methods evaluated person is asked to relax all muscles allowing the movement to occur without any muscle contraction. Instead, the forces necessary for the movement are applied either by the evaluator or by the use of a machine.(Gnat et al., 2010; Marshall et al., 2009) In this case the forces applied to realize the movement could impact recorded end of ROM, greater force could result in greater ROM.(Marshall et al., 2009) This parameter can be controlled by using a dynamometer allowing standardisation of the applied torque.(Gnat et al., 2010; Iwata et al., 2019; Marshall et al., 2009) Another issue is the decision to stop the movement; namely, is it the first sensation of stretch, the intense stretch sensation, the onset of pain, or the maximal tolerable sensation. While all of these endpoints represent individual's stretch tolerance, they could result in different ROM.

On the other hand, Killeis et al. have proposed a direct measure of HM elongation using ultrasound measurement in CLBP patients, however they have found low correlation with SLR angle.(Kellis et al., 2015) This finding indicate that besides HM elongation measured via ultrasonography others factors determine the SLR angle. Similarly, evaluation of the relationships between the SLR angle and HM stiffness measured by ultrasound shear wave elastography revealed that factors other than HM stiffness strongly influenced SLR measurement. (Miyamoto et al., 2018)

In clinical practice, the passive SLR is commonly employed to assess HM flexibility due to its simplicity, requiring only a universal goniometer or an inclinometer and an examination couch to conduct the measurement.(Ekedahl et al., 2012; Miyamoto et al., 2018; Neto et al., 2015) (Figure 9) However, when performing the SLR manoeuvre, the nerve roots supplying the sciatic

nerve and the sciatic nerve itself also undergo stretching.(Gilbert et al., 2007) This leads to slight nerve root displacement, and can trigger blood flow and electrophysiological impairments in the presence of lumbar disc herniation.(Takamori et al., 2011) Thus, the SLR manoeuvre is also a test used for diagnosing of disc herniation and nerve root compression despite some limitations concerning its diagnostic accuracy.(Ekedahl et al., 2018; Majlesi et al., 2008; Rabin et al., 2007) For this purpose the results of the SLR test are analysed as a binary variable, positive or negative. Reduced ROM and shooting pain radiating down the posterior thigh and the lower leg along the distribution of the sciatic nerve is considered as positive test.(Majlesi et al., 2008) On the contrary, for the HM flexibility measurement the SLR result is presented as a continuous variable expressed in degrees.(Neto et al., 2015)



**Figure 9. Straight Leg Raise measurement.**

Another method to evaluate HM flexibility is to measure knee extension angle while maintaining hip in 90 degrees flexed position. Both, the passive or active ROM can be measured using the PKE or AKE method, respectively. (Gnat et al., 2010; Neto et al., 2015) When taking

measure with these methods, 90 degrees hip flexion need to be controlled by supplementary device. (Figure 10) It was also postulated that in passive methods force applied by examiner can influence the recorded angle and thus decrease reproducibility of the measure, especially in interrater settings.(Norris and Matthews, 2005) For this reason Norris and Mathews recommend to use AKE rather than PKE or SLR methods.(Norris and Matthews, 2005) Another interesting aspect is that the movement of the lumbar spine during all three measures mentioned above can have an impact on the measured angle.(Herrington, 2013; Norris and Matthews, 2005) Recently, to solve this problem, Ahn et al. have proposed using a pressure biofeedback unit to maintain the anterior pelvic tilt position during the AKE test and stretching procedure.(Ahn et al., 2020)



**Figure 10. Active Knee Extension measurement.**

Flexibility of the HM is also evaluated in clinical settings by global functional movements like in Fingertip-to-Floor (Figure 11) or Sit-and-Reach measurement. (Figure 12) The intrinsic joint



alignment in the end position is similar in both tests. Specifically, there are maximal flexion of the thoracolumbar spine, an anterior pelvic tilt, hip flexion with full knees extension, and upper limbs are reaching towards the toes. Thus, the result represents a sum of the component movements or flexibility of the posterior muscle chain rather than pure HM flexibility. The result is defined by a distance measured between fingertips and floor or an equivalent measure is taken with a special device.(Barlow et al., 2004) (Figure 12)

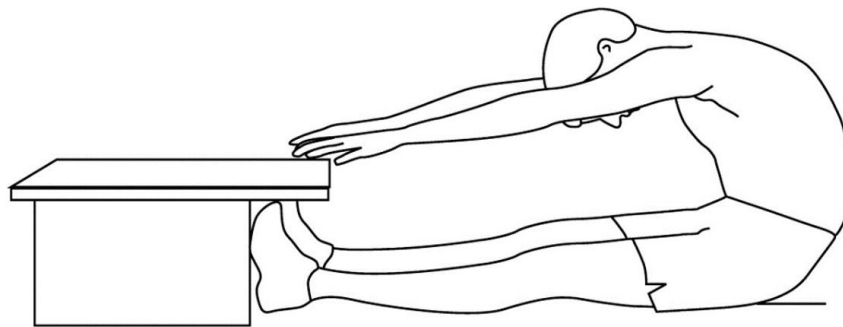


**Figure 11. Fingertip-to-Floor distance measurement.**

Differences between the two measurement methods could arise due to variations in body position in space. Standing position in FTF method could be more challenging for the neuromuscular system since balance in the standing position needs to be coordinated with bending forward.(Massé-Alarie et al., 2016) On the other hand, in SRT, the sitting position could be less challenging for balance control due to a larger base of support. However, in CLBP patients with an important flexibility deficit, the sitting position with knees extended could be

impossible to achieve. Other potential difference is spinal loading which could be different in two position, but literature is controversial regarding such difference.(Li et al., 2022)

Nevertheless, all of the above mentioned measurements methods have their limits. Generally, active methods will challenge the neuromuscular system (muscle activation, balance control) at the same time as flexibility. Therefore, in CLBP patients, neuromuscular control impairments could impact the measure.(Abboud et al., 2018; Hodges and Richardson, 1996; Leinonen et al., 2007; Massé-Alarie et al., 2016; Meier et al., 2019; van Wingerden et al., 2008)



**Figure 12. Sit-and-Reach test.** (Barlow et al., 2004)

#### Measurement properties of Hamstring muscles flexibility assessment

A synthesis of the available estimations for the measurement properties of HM flexibility measurements is presented in Table 1. Literature provides information regarding the reliability, agreement, and validity of flexibility measurements using a universal goniometer or a bubble analogue inclinometer for HM flexibility. However, a digital inclinometer could potentially offer improved reproducibility due to more precise inertial motion capture technology. Additionally, digital inclinometers allow for simplified result recording. Compared to the universal goniometer, the digital inclinometer requires fewer anatomical markers for

measurements. In the present study we use a new Easy Angle® digital inclinometer for AKE and SLR angle measures in CLBP patients. This device allows for inertial measurement to assess the range of motion in all three orthogonal planes. The precision of the sensor integrated into this device is 1°, and it is designed for user-friendly one-handed operation. The objective of this part of the present work is to estimating measurement properties in this particular setting. This will enable an appropriate interpretation of the effects of further HM stretching interventions.

**Table 1. Measurement properties estimated in the literature for HM flexibility assessment.**

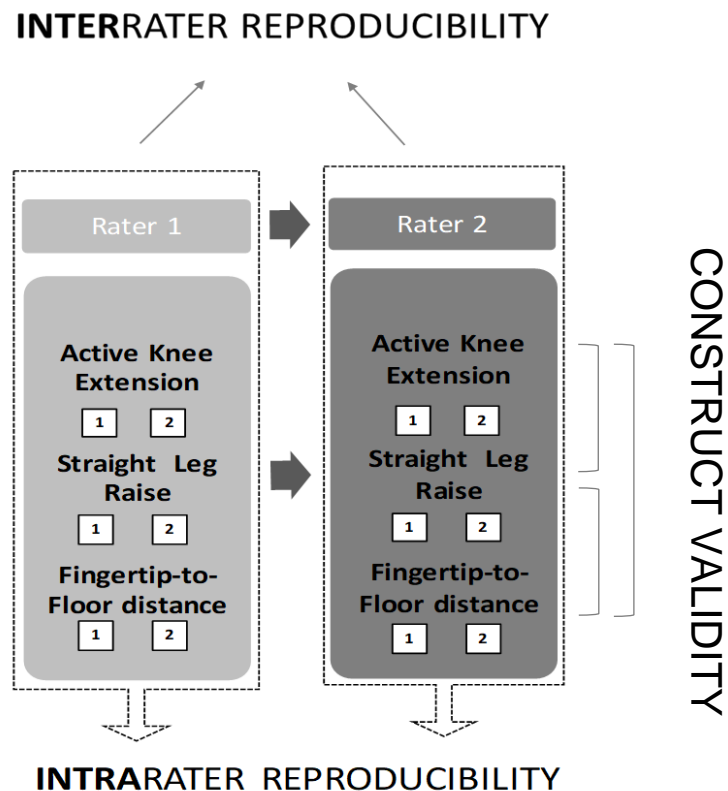
	Reliability	Agreement	Validity	Responsiveness	Measurement tool	Study sample	Reference
Active Knee Extension	ICC: 0.87-0.94 †	MDC <sub>95</sub> : 7-8° †	AKE vs SLR r = 0.71 DS r = 0.67 NDS	-	Universal goniometer	Healthy adults	(Neto et al., 2015)
	ICC: 0.882 †	MDC <sub>95</sub> : 12° †	-	-	Bubble inclinometer	Healthy adults	(Olivencia et al., 2020)
	ICC: 0.886 ‡	MDC <sub>95</sub> : 12° ‡	-	-	Universal goniometer	Healthy adults	(Hamid et al., 2013)
	ICC: 0.78-0.92 †	MDC <sub>95</sub> : 10° ‡	-	-	Universal goniometer	Healthy adults	(Hamid et al., 2013)
	ICC: 0.81-0.87 ‡						
Passive Knee Extension	ICC: 0.92-0.95 †	-	AKE vs SLR r = 0.63 AKE vs SR r = 0.57	-	Universal goniometer	Healthy adults	(Davis et al., 2008)
	ICC: 0.96-0.99 †	SEM: 1-2° †	-	-	Universal goniometer, Electro-goniometer	CLBP patients	(Shamsi et al., 2019)
	ICC: 0.88-0.97 †	MDC <sub>95</sub> : 7-10° †	-	-	Bubble inclinometer	Healthy adults	(Gnat et al., 2010)
Passive Knee Extension	ICC: 0.88-0.97 ‡	MDC <sub>95</sub> : 6-10° ‡	-	-	Bubble inclinometer	Healthy adults	(Gnat et al., 2010)
	ICC: 0.77 ‡	MDC <sub>95</sub> : 21° ‡	-	-	-	Peoples with hamstring injury	(Reurink et al., 2013)
Straight Leg Raise	ICC: 0.93-0.97 †	MDC <sub>95</sub> : 6-7° †	AKE vs SLR r = 0.71 DS r = 0.67 NDS SLR vs AKE	-	Universal goniometer	Healthy adults	(Neto et al., 2015)
	ICC: 0.92-0.95 †	-	r = 0.63 SLR vs SR r = 0.65	-	Universal goniometer	Healthy adults	(Davis et al., 2008)

	-	MDC <sub>95</sub> : 5.7° †	SLR vs 1-month change in disability r = 0.13	1-month change ES = 0.5	Universal goniometer	Acute/ subacute LBP	(Ekedahl et al., 2012)
	r = 0.81 right † r = 0.79 left †	-	-	-	Cybox electronic inclinometer	-	(Hunt et al., 2001)
	ICC: 0.95-0.98 †	MDC <sub>95</sub> : 1.5-3.4° †	Hand-held inclinometer vs digital goniometer r: 0.88-0.93 mean difference: 9-10°	-	Hand-held inclinometer, digital inclinometer, digital goniometer	Healthy adults	(Boyd, 2012)
	-	MDC <sub>95</sub> : 4.5cm	FTF vs 1-month change in disability r = 0.63	1-month change ES = 1.0	Measuring tape	Acute/ subacute LBP	(Ekedahl et al., 2012)
Fingertip-to- Floor	ICC: 0.98 † ICC: 0.95 ‡	-	-	-	Measuring tape	LBP patients	(Gauvin et al., 1990)
	ICC: 0.99 † ICC: 0.99 ‡	95%LOA = 2.8cm	FTF vs dynamic radiographs r = -0.96	Change after 5 weeks of rehabilitation ES = 0.87	Measuring tape	CLBP patients	(Perret et al., 2001)
	ICC: 0.92-0.95 †	-	SR vs AKE r = 0.57 SR vs SLR r = 0.65	-	Measuring tape	Healthy adults	(Davis et al., 2008)
Sit-and Reach	-	-	SR vs submaximal trunk flexion r = 0.71	-	Measuring tape	Healthy adults	(Crotti et al., 2018)

†, intrareter; ‡, interrater; ICC, Intraclass Correlation Coefficient; MDC, Minimal Detectable Change; SEM, Standard Error of Measurement; LOA, Limit of Agreement; AKE, Active Knee Extension; SLR, Straight Leg Raise; FTF, Fingertip-to-Floor; SR, Sit-and-Reach; ES, Effect Size; LBP, Low Back Pain; CLBP, Chronic Low Back Pain; DS, dominant side; NDS, non-dominant side.

## METHODS

To assess the reproducibility and validity of AKE and SLR, we employed the study design used as a part of the EFIM1 study, which is presented afterward in an article format. (Figure 14) First, Rater 1 performed the AKE, SLR and FTF twice each. Then, Rater 2 also performed them twice each. Both raters were blinded to the other's measurement. The order of the measurements (AKE, SLR, and FTF) was randomized. Participants were asked to walk for about 30 seconds when the rater changed. The whole study procedure was performed on the intervention session just before stretching. The raters were physical therapists or medical doctors who all had experience in CLBP treatment and were trained in the measurement procedures and the study protocol. The measurements procedures are detailed in the article presented in the next section.



**Figure 14. Study design schema for reproducibility analysis.** (A part of EFIM1 study design)

## Statistical analysis

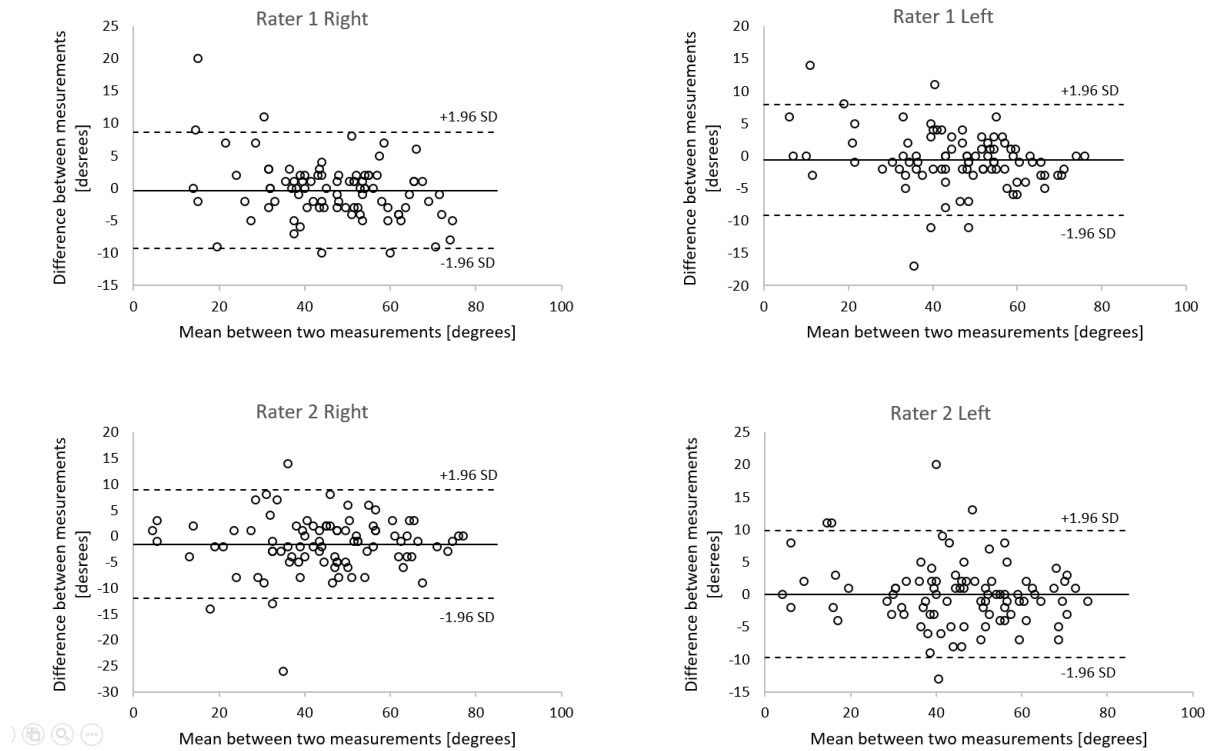
The Intraclass Correlation Coefficient (ICC) was calculated to evaluate intra- and interrater reliability. Two-way random effects, absolute agreement, multiple raters/measurements model [ICC<sub>(2,k)</sub>] was used for intrarater analysis and one-way random effects, absolute agreement, multiple raters/measurements model was used for interrater analysis [ICC<sub>(1,k)</sub>]. The ICC values between 0.75 and 0.9, and superior or equal to 0.9 were considered as good and excellent reliability, respectively. (Koo and Li, 2016) Additionally, Bland and Altman plots were utilized along with the (MDC) calculated at a 95% confidence interval. For construct validity, Pearson's correlation coefficients were computed between AKE, SLR, and FTF measurements. Statistical analysis was performed using version 15 Stata software, (StataCorp, College Station, TX, US).

## RESULTS

Ninety patients with CLBP were included in analysis of intrarater reproducibility and construct validity, 89 patients were analysed for interrater reproducibility. Missing data concerns one patient who received measurements only by one rater due to an organisational error in the beginning of the study.

### Active Knee Extension

Intrarater reproducibility was excellent for AKE, with an ICC 95% CI of 0.917 to 0.975 and an agreement estimated by MDC<sub>95</sub> ranging between 8.6 to and 10.8 degrees. (Table 2) Similar results were obtained using Bland and Altman plots method indicating a 95% LOA of about 10 degrees. (Figure 15) Interrater reliability was moderate to good, with an ICC 95% CI of 0.719 to 0.899. However, the values of MDC<sub>95</sub> for interrater setting reach as high as 19 degrees.

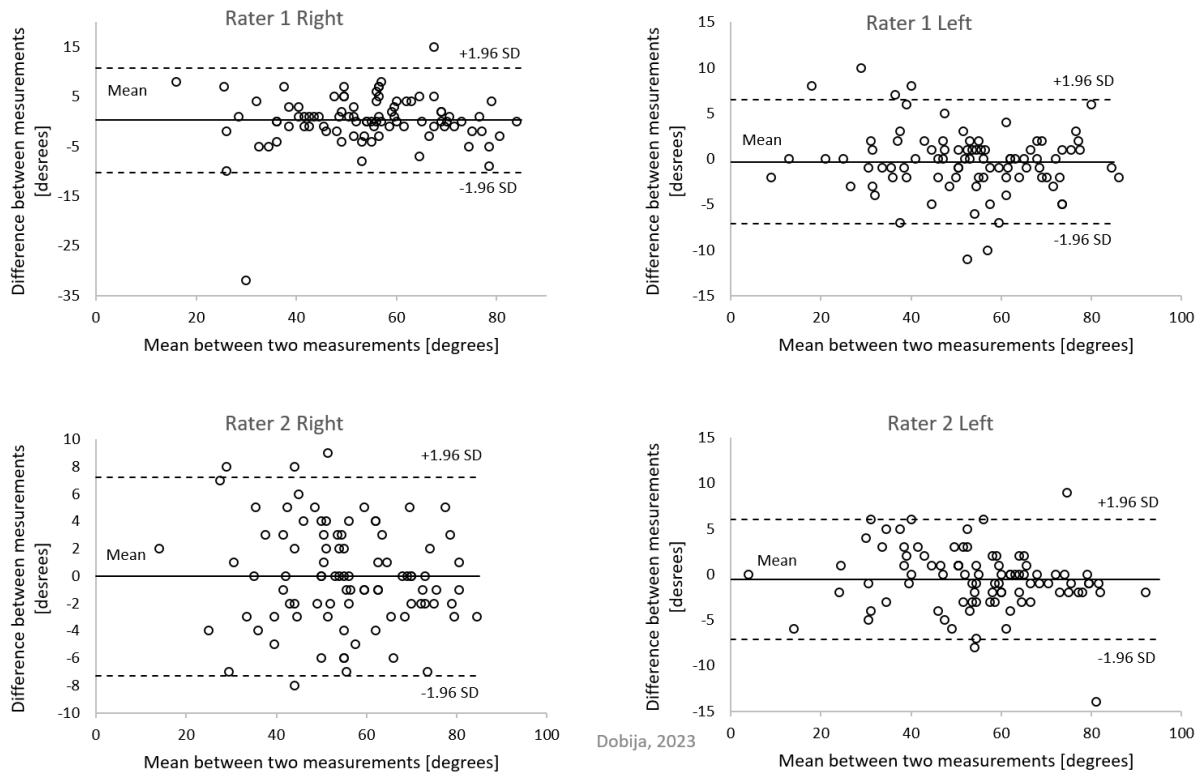


**Figure 15. Intrarater agreement of Active Knee Extension estimated with Bland and Altman plots.**

### Straight Leg Raise

Intrarater reliability for SLR was excellent, with an ICC 95% CI of 0.908 to 0.987 and an  $MDC_{95}$  between 6.8 and 10.4 degrees. (Table 2) Further Bland and Altman plots demonstrate that, in most cases, the 95%LOA were approximately 7 degrees, except for measurements conducted by Rater 1 on the right lower limb. In this particular case, a single extreme difference between measurements resulted in a 95% LOA as high as approximately 10 degrees. (Figure 16) The interrater ICC 95% CI was 0.775 to 0.907, indicating good reliability but the values of  $MDC_{95}$  for interrater setting reach as high as 18 degrees.





**Figure 16. Intrarater agreement of Straight Leg Raise estimated with Bland and Altman plots.**

**Table 2. Intrarater reproducibility of Active Knee Extension and Straight Leg Raise measurements in CLBP patients (n=90)**

	Active Knee Extension				Straight Leg Raise			
	Right		Left		Right		Left	
	Rater 1	Rater 2	Rater 1	Rater 2	Rater 1	Rater 2	Rater 1	Rater 2
<i>ICC</i>	0.951	0.941	0.959	0.954	0.935	0.968	0.978	0.978
<i>(95% CI)</i>	(0.932 0.970)	(0.917 0.965)	(0.943 0.975)	(0.936 0.973)	(0.908 0.961)	(0.955 0.981)	(0.969 0.987)	(0.969 0.987)
<i>SEM [deg]</i>	3.22	3.91	3.11	3.53	3.75	2.62	2.45	2.42
<i>MDC<sub>95</sub> [deg]</i>	8.94	10.85	8.62	9.78	10.40	7.27	6.78	6.70

CLBP, Chronic Low Back Pain; *ICC*, Intraclass Correlation Coefficient; *CI*, Confidence Interval; *SEM*, Standard Error of Measurement; *MDC*, Minimal Detectable Change.

**Table 3. Interrater reproducibility of Active Knee Extension and Straight Leg Raise measurements in CLBP patients (n=89)**

	Active Knee Extension		Straight Leg Raise	
	Right	Left	Right	Left
<i>ICC</i>	0.795	0.837	0.849	0.838
<i>(95% CI)</i>	(0.719 0.871)	(0.775 0.899)	(0.790 0.907)	(0.775 0.900)
<i>SEM [deg]</i>	6.88	6.36	5.64	6.58
<i>MDC<sub>95</sub> [deg]</i>	19.06	17.62	15.64	18.25

*ICC*, intraclass correlation coefficient; *CI*, confidence interval; *SEM*, standard error of measurement; *MDC*, minimal detectable change.

**Table 4. Construct validity of Active Knee Extension and Straight Leg Raise measurements estimated with Pearson correlation coefficient in CLBP patients (n=90)**

		Active Knee Extension		Straight Leg Raise	
		Right	Left	Right	Left
<b>Active Knee Extension</b>					
	Right	-			
	Left	0.756*	-		
<b>Straight Leg Raise</b>					
	Right	0.711*	0.503*	-	
	Left	0.529*	0.618*	0.799*	-
<b>Fingertip-to-Floor</b>		-0.414*	-0.452*	-0.571*	-0.548*

\* $p < 0.05$

### Construct validity

Moderate to strong significant correlations were found between AKE, SLR and FTF measurements confirming construct validity of the analysed HM flexibility measurements. (Table 4)

### Responsiveness

Responsiveness of the HM flexibility measurements (AKE, SLR, and FTF) is expressed in terms of Cohen's Effect Size of change following HM stretching. To avoid redundancy, these values are presented and discussed in the article below.

## DISCUSSION

Using the EasyAngle® digital inclinometer for measuring AKE and SLR angles in CLBP patients demonstrates excellent intrarater reliability. Differences exceeding 9-11 degrees for AKE and 7-10 degrees for SLR can be considered as real changes with 95% confidence. Construct validity was confirmed for both AKE and SLR measure. The responsiveness is better for SLR measurements compared to AKE and FTF. Our results are similar to those reported in previous studies. (Table 1) However, in our study, we conducted repeated measures on CLBP patients, whereas in the previous study, estimations were conducted on healthy individuals (Davis et al., 2008; Gnat et al., 2010; Hamid et al., 2013; Neto et al., 2015; Olivencia et al., 2020) or using different devices.(Ekedahl et al., 2012; Shamsi et al., 2019) Therefore, generalizing the available results to our specific setting may lead to inaccuracies. The reproducibility of AKE and SLR measures taken with EasyAngle® digital inclinometer in CLBP patients was not better than those reported using a universal goniometer.(Ekedahl et al., 2012; Shamsi et al., 2019) The variability in the repeated measures appears to be influenced by factors other than the measurement tool. Nevertheless, our study allows us to assess the

reproducibility and concurrent validity of AKE and SLR measurements specific to our study setting and the characteristics of our population. Both intrarater reproducibility and concurrent validity are acceptable for conducting further evaluations of the effect of HM stretching. However, a limitation of our validity analysis is that it only assessed relationships between AKE, SLR, and FTF measurements. Establishing correlations between our measurements and direct HM elongation measures, such as ultrasound or shear wave elastography, would provide greater value. This would allow to evaluate to what extent AKE and SLR angles are determined by HM flexibility in CLBP patients. We also acknowledge that, in the present analysis, the anchor-based MICD was not evaluated. Instead, we calculated the  $MDC_{95}$  and 95% LOA, which are distribution-based methods for determining a relevant change in repeated measures. (Haley and Fragala-Pinkham, 2006) Estimating the anchor-based MICD would require a different study design, and this should be considered in future studies to account for patients' perceived changes.

## Conclusion

The intrarater reproducibility and concurrent validity of the AKE and SLR measurements taken with EasyAngle® digital inclinometer in CLBP patients are acceptable to conduct further evaluation of the effect of HM stretching.

## CHAPTER 3: IMMEDIATE EFFECT OF PASSIVE HAMSTRING STRETCHING ON FLEXIBILITY AND RELATIONSHIP WITH PSYCHOSOCIAL FACTORS IN PEOPLE WITH CHRONIC LOW BACK PAIN. EFIM1 STUDY

Once we have determined the measurement properties of the AKE and SLR measurements taken with a new EasyAngle® digital inclinometer in CLBP patients, we could then conduct the analysis of the immediate effect of passive HM stretching. Such effect on flexibility could be now interpreted in a more accurate way. Furthermore, integrating the analysis of the relationship between patients' psychosocial factors and the effects of HM stretching aligns with the contemporary biopsychosocial model approach. The EFIM1 study comprises the core components of the conducted work, including study conceptualization, preliminary feasibility testing, regulatory procedures, study team training, patients recruitment, study procedure realisation, data collection and analysis, and, lastly, article redaction and publication. Below, the report of the EFIM1 study is presented in an article format published in the Heliyon journal.

Dobija, L., Pereira, B., Cohen-Aknine, G., Roren, A., Dupeyron, A., Coudeyre, E., 2023. Immediate effect of passive hamstring stretching on flexibility and relationship with psychosocial factors in people with chronic low back pain. *Heliyon* 9, e19753. <https://doi.org/10.1016/j.heliyon.2023.e19753>

In response to rapporteur's comments we explain the choice of stretching technique by a compromise of feasibility and a potential of effectiveness. The passive HM stretching is the simplest way to obtain gain in HM flexibility.(Bandy et al., 1998; Lempke et al., 2018; Umegaki et al., 2015) Other techniques demonstrate similar improvements in flexibility or are more complex to standardize within our bi-centric study settings.(Ahn et al., 2020; Aye et al., 2017; Lempke et al., 2018; Moon et al., 2017) In our study, the duration of static stretching was set at 1 minute to target the viscoelastic properties of the HM and to influence stretch tolerance.(Halbertsma et al., 2001; von Duvillard et al., 2021) Previous studies have demonstrated that this

duration is sufficient to achieve improvements in flexibility among healthy subjects. (Aye et al., 2017; Bandy et al., 1997; Nishikawa et al., 2015) We chose to stretch HM by starting with hip flexion and then adding maximal, pain-free knee extension. This technique is conventionally used in manual therapy and has an advantage in improving HM stiffness, potentially resulting in less stretching of the sciatic nerve compared to the technique of initially extending the knee during hip flexion.(Evjenth and Hambers, 1988; Miyamoto et al., 2017)





## Immediate effect of passive hamstring stretching on flexibility and relationship with psychosocial factors in people with chronic low back pain

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Active knee extension  
Straight leg raise

### ABSTRACT

**Background:** Hamstring muscle tightness contributes to disability in people with chronic low back pain (CLBP). HM stretching improves flexibility in healthy individuals, but the immediate effect of stretching is unknown in people with CLBP. Moreover, the stretching effect could be influenced by psychosocial factors.

**Objectives:** To evaluate the immediate effect of passive HM stretching on flexibility in people with CLBP and the relationships between psychosocial factors and change in hamstring flexibility.

**Design:** Non-randomized, pilot trial.

**Method:** One minute of passive stretching was performed in 90 people with CLBP. Change in Active Knee Extension and Straight Leg Raise angles (digital inclinometer), and Fingertips-to-Floor distance (measuring tape) were measured before and immediately after stretching. Correlations between change in flexibility and baseline Fear-Avoidance Beliefs Questionnaire (FABQ) and Hospital Anxiety and Depression Scale (HADS) scores were analyzed.

**Results:** Hamstring flexibility improved significantly after stretching; Active Knee Extension mean difference was 4° (95% CI, 2.4 to 5.1;  $p < 0.001$ , right ES = 0.24, left ES = 0.23); Straight Leg Raise mean difference was 7° (95% CI, 5.5 to 8.6,  $p < 0.001$ , right ES = 0.44, left ES = 0.42), Fingertips-to-Floor mean difference was 2 cm (95% CI, 1.7 to 3.0,  $p < 0.001$ , ES = 0.20). No correlation was found between improvement in any of the hamstring flexibility measurements and FABQ or HADS scores ( $p > 0.05$ ).

**Conclusions:** Passive hamstring stretching induced an immediate, statistically significant improvement in hamstring flexibility, but only the change in Straight Leg Raise amplitude was clinically important. Psychosocial factors were not related to improvements in flexibility after hamstring stretching.

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Providing optimal treatment for people with chronic low back pain (CLBP) is a major challenge for physical therapists and healthcare professionals. Despite the progress that has been made in physical therapy [1–3], CLBP remains the leading cause of disability [4]. The bio-psycho-social framework addresses the complexity of CLBP by targeting factors that more broadly contribute to the problem [5,6]. Furthermore, the consideration of psychosocial aspects within biomechanical treatment concepts could improve the management of CLBP.

One biomechanical factor that impacts functional capacity is limitation in range of motion (ROM). For example, forward bending during housework or professional activities could be limited by hamstring muscle (HM) tightness. Forward bending involves anterior pelvic tilt and elongation of the HM [7]. However, HM tightness can limit anterior pelvic tilt [8,9] and could contribute to disability in people with CLBP. Improvement in forward bending ROM during the first month after low back pain onset is a valid predictor of functional recovery at one year [10]. Furthermore, the posterior longitudinal muscles connect the HM to the erector spinae muscle via the sacrotuberal ligament and produce compression forces that enhance lumbopelvic stability [11–13]. It has been suggested that reduced HM flexibility could result from poor core muscle function [14,15]. Therefore, HM tightness could be a sub-optimal compensatory mechanism for a lack of core stability that further increases the risk of development of CLBP [16].

Repeated HM stretching sessions improve HM flexibility [17]. Moreover, in healthy people, the result is immediate [18,19]. When combined with core stability exercises, repeated HM stretching improves physical function and decreases pain in people with CLBP [20]. In people with CLBP, pain and fear of pain, fear of movement, and anxiety may impact on the effect of HM stretching. To our knowledge, only one study has evaluated the immediate effect of HM stretching in people with CLBP, showing a positive effect, however only the sit-and-reach test was evaluated, and the sample was small [21].

The immediate effect of a manual therapy intervention provides important information to the physical therapist. It can guide subsequent treatment choices and help to establish a functional diagnosis. For example, if forward bending ROM does not improve after HM stretching, other structures (eg, the piriformis muscle, sciatic nerve or lumbar spine) could be considered as the drivers of the limitation, and could be evaluated, treated and reevaluated to refine the diagnosis. In contrast, if ROM improves immediately, the same technique could be repeated in the following sessions to obtain a cumulative effect. However, if no improvement occurs with repeated interventions, and no red flags are present [1,22], psychosocial or behavioral factors may be involved in the limitation. In people with CLBP, fear-avoidance beliefs and the person’s perception that movement is a threat can limit the capacity to relax muscles during stretching, which could limit stretching efficacy [5,23]. Similarly, symptoms of anxiety or depression could reduce the stretching effect [24]. Identifying a relationship between psychosocial factors and the effect of HM stretching could help clinicians to determine the need to address psychosocial factors before performing a stretching intervention. However, no study has evaluated this relationship.

The primary aim of our study was to evaluate the immediate effect of passive HM stretching on HM flexibility in people with CLBP. The secondary aim was to analyze the relationship between psychosocial factors and change in HM flexibility after stretching. We hypothesized that HM flexibility would improve after one session of passive HM stretching, but that improvements would be smaller in people with higher levels of fear-avoidance beliefs, anxiety or depression reported at baseline.

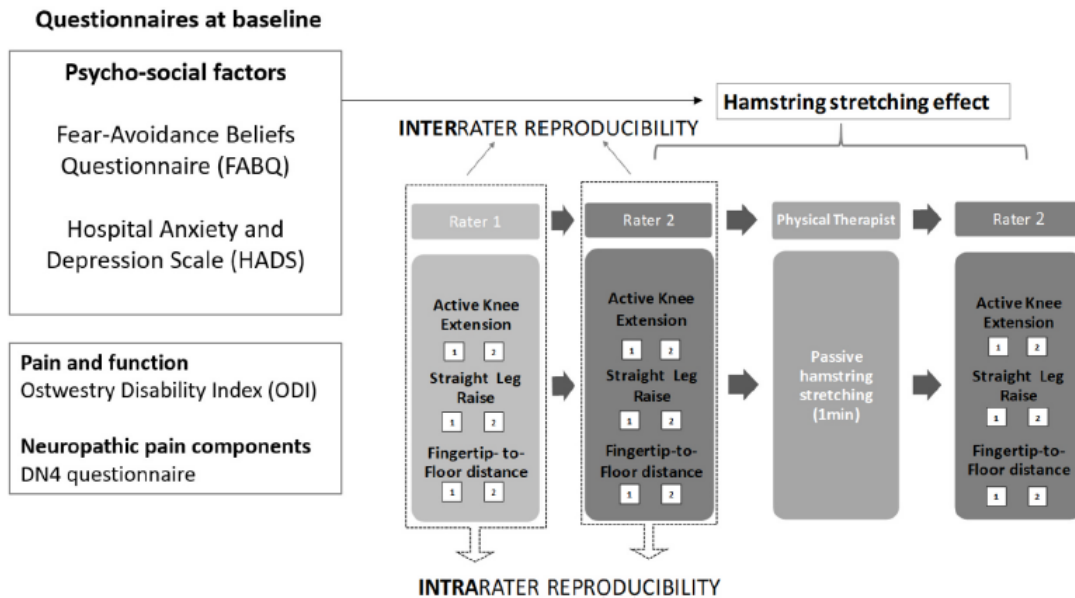


Fig. 1. Schema of the study design.

## 1. Methods

### 1.1. Study design

This multicenter, non-randomized, pilot clinical trial was approved by our local ethics committee (Comité de Protection des Personnes – Ouest 1, Identifier: 2020T2-01\_RIPH2 HPS\_2019-A03000-57). Informed consent was obtained from all participants, including consent for the publication of photographs of them. The study is reported according to the CONSORT guidelines, adapted for our study design (Fig. 1). The study was registered on the [ClinicalTrials.gov](https://www.clinicaltrials.gov) database (Identifier: NCT04551326). The study schedule is shown in Fig. 1.

### 1.2. Participants

People with CLBP according to the definition in current clinical guidelines [25] and corresponding to the MG30.02 International Classification of Diseases code were recruited from referrals to the physical and rehabilitation medicine departments of two French University Hospitals. Informed consent was obtained from all participants. The inclusion criteria were age between 18 and 60 years, low back pain for more than three months with or without associated pain in the buttock or thigh, reduced HM flexibility (Finger-tip-to-Floor [FTF] distance more than 5 cm and Active Knee Extension [AKE] less than 80°). People were not included if they had neurologic, cardiac, respiratory or oncological disease, a history of significant surgery (ex. hip or knee arthroplasty, arthrodesis of more than two vertebral segments), discopathy Modic 1, or radicular pain, were pregnant or breastfeeding women, had restricted mental/legal autonomy or were not covered by the social security system.

### 1.3. Evaluation procedure

All participants were allocated to the same study procedure. Three HM flexibility measurements were performed by two raters: AKE, Straight Leg Raise (SLR) and FTF (Fig. 1). We used the EasyAngle® digital inclinometer for AKE and SLR measurements. Because this is a novel method for these measurements, we performed a preliminary evaluation of the intra- and interrater reliability and construct validity of the AKE and SLR angle measurements in 90 people with CLBP [26]. First, Rater 1 performed the AKE, SLR and FTF twice each. Then, Rater 2 also performed them twice each. Both raters were blinded to the other's measurement. One minute of passive HM stretching was then applied bilaterally by a different physical therapist (see below). After HM stretching, Rater 2 repeated AKE, SLR and FTF measurements twice each. The order of the measurements (AKE, SLR, and FTF) was randomized. Participants were asked to walk for about 30 s when the rater changed and between the stretching and the measurements. The whole study procedure was performed on the same day and the intervention session lasted between 30 and 45 min for each participant. The raters were physical therapists or medical doctors who all had experience in CLBP treatment and were trained in the measurement procedures and the study protocol. The measurements procedures are presented in Fig. 2.



Fig. 2. Measurement procedure: (A1, A2) Active Knee Extension angle, (B) Straight Leg Raise angle, (C) Fingertip-to-Floor distance.

### 1.3.1. Active Knee Extension

AKE was measured with the participant lying in supine on the examination table. The EasyAngle® digital inclinometer was first calibrated to zero degrees on the surface of the examination table. Then, the participant was instructed to place their thigh vertically. The 90-degree angle was verified with the inclinometer placed on the distal anterior surface of the participant's thigh. In addition, the participant was asked to keep their thigh against a plastic stick placed against the anterior surface of their thigh to ensure that it remained vertical during the measurement. The contralateral limb rested in extension and was stabilized by the rater's hand if necessary. The participant was asked to extend the tested knee as much as possible. The rater placed the inclinometer on the tibial crest, directly below the tibial tuberosity to record the maximal knee extension angle (Fig. 2, A1, A2).

AKE angle is frequently used to evaluate HM flexibility. It has acceptable reliability and agreement in healthy individuals using a universal goniometer [27]. Our reliability assessment in the 90 participants with CLBP found excellent intrarater reliability, with an intraclass correlation coefficient (ICC) 95% CI of 0.917–0.975 and an agreement estimated by Minimal Detectable Change (MDC<sub>95</sub>) between 8.6 and 10.8°. Interrater reliability was moderate to good, with an ICC 95% CI of 0.719–0.899 [26].

### 1.3.2. Straight Leg Raise

For the SLR measurement, the participant also lay supine on the examination table and the EasyAngle® digital inclinometer was first calibrated to zero degrees on the surface of the table. The rater then explained the measurement procedure to the participant. The participant was asked to stay relaxed while the rater slowly raised their extended limb. The contralateral limb rested in extension and was stabilized by the rater's hand if necessary. The participant was asked to say "stop" at the moment of the first stretch sensation or pain onset and rater stopped the movement and recorded the angle. Like for the AKE measurement, the inclinometer was placed on the tibial crest, directly below the tibial tuberosity (Fig. 2, B).

The SLR is a passive HM flexibility measurement that is frequently performed with a universal goniometer or an analogue inclinometer. It has acceptable reliability and agreement [10,27]. Our reliability assessment in 90 people with CLBP found excellent intrarater reliability, with an ICC 95% CI of 0.908–0.987 and an MDC<sub>95</sub> between 6.8 and 10.4°. The interrater ICC 95% CI was 0.775–0.907, indicating good reliability [26].

Fingertip-to-Floor distance.

The conventional procedure was used for the FTF measurement [28]. Participants stood with their feet together and bent forward with the knees extended, they were asked to reach as far as possible to the floor with their fingertips. The fingertip to floor distance was then measured by the rater using a standard measurement tape (Fig. 2, C).

This measurement is widely used to measure HM and spinal extensor muscle flexibility in people with CLBP, and it has good measurement properties [10,28].

Participants completed the following questionnaires before performing the HM flexibility measurements: Oswestry Disability Index (ODI) [29], Fear Avoidance Belief Questionnaire (FABQ) [30], and Hospital Anxiety and Depression Scale (HADS) [31]. The maximum score for the ODI is 100 points, indicating complete disability. Maximum score for the FABQ physical activity subscore is 24 points and for the work subscore is 42 points. For the HADS, the maximum anxiety subscore is 21 and the maximum depression subscore is 21.

### 1.3.3. Pain

Before and immediately after the intervention, participants were asked to rate the intensity of their low back pain on a Visual Analog Scale (VAS). Additionally, the presence of neuropathic pain was evaluated at baseline using the DN4 questionnaire [32]. A score of 4 points or more indicates a neuropathic component of the CLBP [33].

## 2. Intervention

### 2.1. Passive hamstring muscle stretching

Passive HM stretching was performed by a physical therapist experienced in the treatment of CLBP and trained in the study protocol. A simple, passive procedure was used to facilitate standardization and enhance repeatability. The procedure was based on stretching in manual therapy standards [22]. First, the physical therapist explained the procedure to the participant and reassured them that the stretching could be stopped if it was too hard to tolerate. With the participant lying supine, the stretched limb was placed in maximal, pain free hip flexion with the knee flexed, then the physical therapist slowly and gradually extended the knee to the maximal pain free position. In this position, participants felt an intense stretching sensation in the back of the thigh. If the position caused pain in the lower back, the hip flexion was reduced to the maximal, pain free ROM. A stopwatch was used to ensure the final position was held for 1 min for each limb.

## 3. Outcomes

The primary outcome was AKE angle. The mean value of the two measurements taken by Rater 2 before HM stretching were compared to the mean value of the two measurements taken by Rater 2 after the HM stretching. The secondary outcomes, SLR and FTF were compared in the same manner. The ODI, FABQ and HADS scores were collected at baseline and correlations with the change in AKE angle, SLR angle and FTF distance after HM stretching were analyzed.

### 3.1. Statistical analysis

For the primary outcome (change in AKE angle), a sample size calculation found that 90 participants were required to achieve effect-sizes above 0.2 with a two-sided type I error of 5%, statistical power above 80% and within-subject correlation of 0.8. This sample size was also appropriate to evaluate the secondary outcomes with satisfactory statistical power: (i) the correlations between psychosocial factors and change in HM flexibility and (ii) intra- and inter-rater reproducibility using ICCs.

Continuous data are presented as mean  $\pm$  standard deviation. The normality of the distribution was assessed using the Shapiro-Wilk test. The paired Student t-test or Wilcoxon test was used to analyze change in pain intensity and change in flexibility measurements (AKE, SLR and FTF). The equality of variances was analyzed using Pitman's test. The relationships between continuous variables (ie, between change in AKE, SLR and FTF; and FABQ and HADS scores) were analyzed with Pearson or Spearman's correlation coefficients, as appropriate. All statistical analyses were performed using version 15 Stata software, (StataCorp, College Station, TX, US). The tests were two-sided with a type I error set at 5%. Cohen's d was calculated to determine the effect sizes, which were

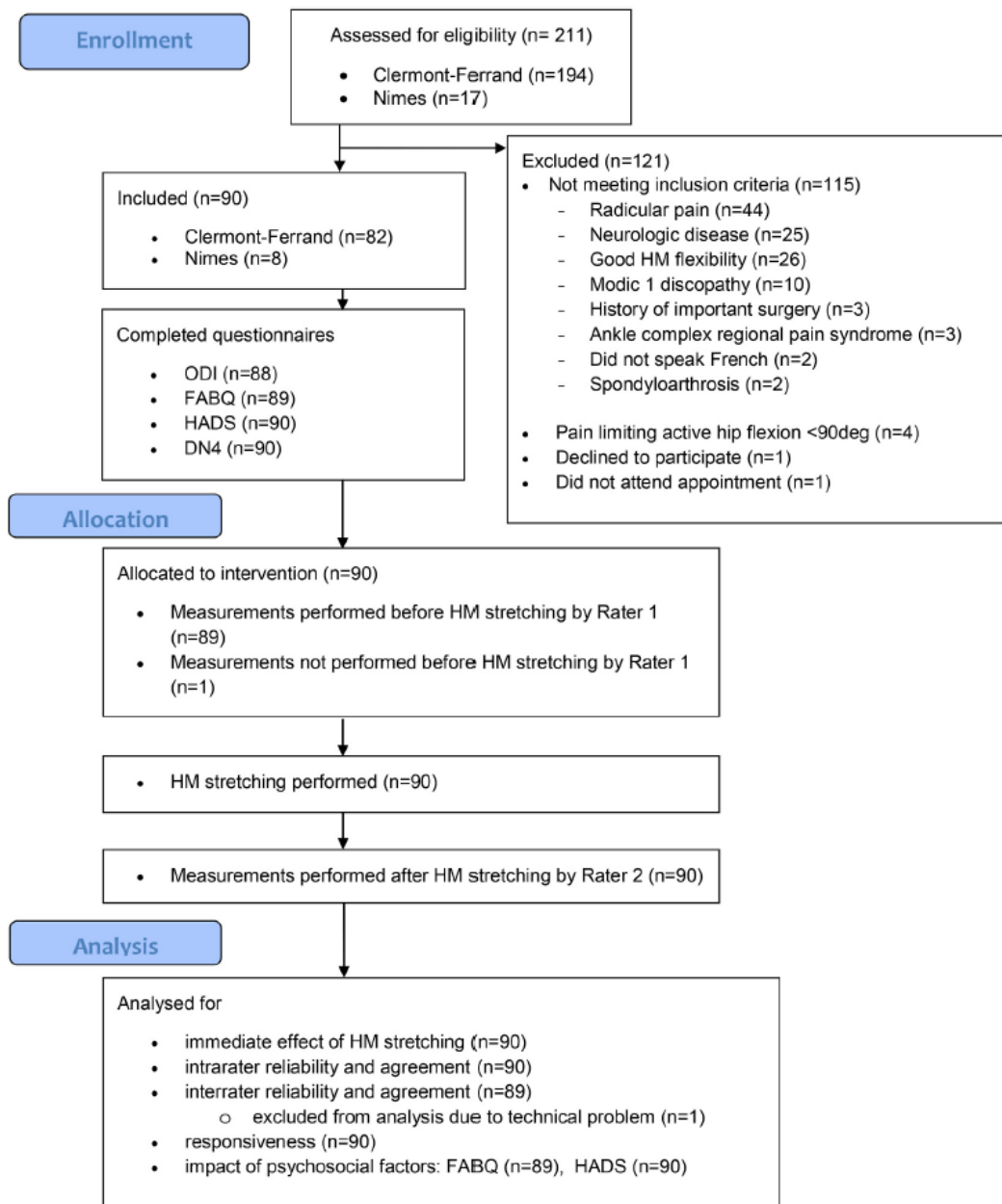


Fig. 3. Flow diagram.

interpreted as small (ES: 0.2), medium (ES: 0.5) and large (ES: 0.8, “grossly perceptible and therefore large”).

#### 4. Results

Participants were recruited from July 3rd 2020 to May 5th 2022. The overall study duration was 22 months. Ninety people with CLBP were included. Eight physical therapists participated either as raters or therapists for the application of the HM stretching. Their clinical experience in the management of CLBP ranged from 2 to 16 years. Five physical medicine and rehabilitation doctors participated in the recruitment procedure (including diagnosing the CLBP) and as raters; their experience in the management of CLBP ranged from 2 to 5 years. No serious adverse events occurred during the study. The recruitment process is presented in a flow diagram (Fig. 3), and participant characteristics are shown in Table 1. The number of participants included in the primary objective analysis was 90 (100%). For the secondary analysis, missing data were the consequence of non-response to the ODI (n = 2) and FABQ (n = 1).

Of the 211 people with CLBP screened, 26 (12%) had good HM flexibility, indicating a high prevalence of HM tightness among those in our physical medicine and rehabilitation departments. Mean ODI score was  $33.7 \pm 12.7$ , indicating moderate disability. Pain increased slightly after the intervention (mean VAS before  $38 \pm 2$  versus mean VAS after  $42 \pm 2$ ,  $p = 0.026$ , ES = 0.17). The scores of the FABQ and HADS are shown in Table 1.

All three HM flexibility measurements improved significantly after stretching. Mean improvement in AKE angle was  $4^\circ$ , 95% CI 2.4 to 5.1 (right AKE  $44.7 \pm 1.7$  vs  $48.4 \pm 1.6$ ,  $p < 0.001$ , ES = 0.24; left AKE  $45.3 \pm 1.7$  vs  $49.0 \pm 1.6$ ,  $p < 0.001$ , ES = 0.23) (Fig. 4, A), in SLR angle was  $7^\circ$ , 95% CI 5.5 to 8.6 (right SLR  $55.2 \pm 1.5$  vs  $62.0 \pm 1.7$ ,  $p < 0.001$ , ES = 0.44; left SLR  $54.9 \pm 16.3$  vs  $62.0 \pm 17.4$ ,  $p < 0.001$ , ES = 0.42) (Fig. 4, B), and in FTF distance was 2 cm, 95% CI 1.7 to 3.0 (FTF  $23.2 \pm 1.3$  vs  $20.9 \pm 1.3$ ,  $p < 0.001$ , ES = 0.20) (Fig. 4, C).

No significant correlations were found between change in any of the HM flexibility measurements and the FABQ or HADS scores ( $p > 0.05$ ).

#### 5. Discussion

This is the first study to determine the immediate effect of HM stretching on AKE and SLR, measured with a new digital inclinometer, and FTF in people with CLBP. All three outcomes improved significantly after 1 min of passive HM stretching, although the effect size was small. Contrary to our hypothesis, there was no relationship between the HM flexibility outcomes and psychosocial factors as measured by FABQ and HADS.

Our study confirms that HM stretching immediately improves HM flexibility. Nishikawa et al. found an immediate improvement in AKE angle of  $15.8^\circ$  after passive HM stretching, which is much greater than in our study [19]. However, their study was conducted in healthy individuals; in our study, CLBP and associated psychosocial factors could have limited the improvement in HM flexibility

**Table 1**  
Sample characteristics.

Age [years]	44.4 ± 9.1
Men/women [n (%)]	52/38 (58/42)
Height [m]	171.2 ± 7.9
Mass [kg]	79.8 ± 18.3
BMI [kg/m <sup>2</sup> ]	27.2 ± 5.7
Education level [n (%)]:	45 (50)
Less than baccalaureate	32 (36)
Baccalaureate level	13 (14)
Higher education studies	
Type of work [n (%)]:	22 (24)
Sedentary	48 (53)
Physical	20 (23)
Mixed	
Active smoking [n (%)]:	37 (41)
Yes	53 (59)
No	
Workplace accident [n (%)]:	17 (19)
Yes	73 (81)
No	
Time since pain onset [months]	81.0 ± 91.2
ODI	33.7 ± 12.7
FABQ PA	14.0 ± 5.9
FABQ W	27.1 ± 11.4
HAD A	9.3 ± 3.9
HAD D	8.1 ± 3.3
DN4	4.4 ± 6.3

BMI, Body Mass Index; ODI, Oswestry Disability Index; FABQ, Fear-Avoidance Beliefs Questionnaire; PA, physical activity; W, work; HAD, Hospital Anxiety and Depression scale; A, anxiety; D, depression; DN4, neuropathic pain questionnaire.

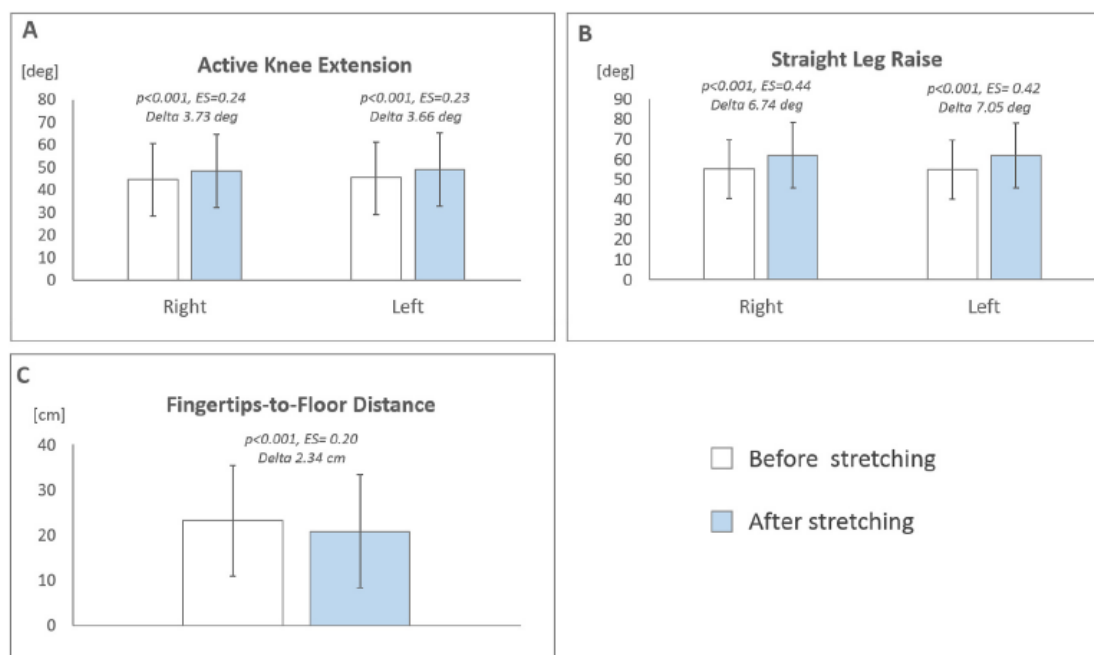


Fig. 4. Immediate effect of hamstring muscle stretching on Active Knee Extension angle (A), Straight Leg Raise angle (B) and Fingertip-to-Floor distance (C) in 90 people with chronic low back pain.

following stretching either by inhibiting motor control mechanisms, decreasing stretch tolerance [34–37] or by fear and anxiety symptoms. Similarly, a greater immediate effect of HM stretching on FTF distance was found in healthy individuals than in our study (mean difference 5–6 cm) [18]. In people with non-specific LBP, the sit and reach test results improved immediately after HM stretching procedures [21]. This is in line with our results; however, the small sample size and different measurement technique limits the interpretation of their results. Interpretation of the results according to the minimal clinically important difference is necessary to define their clinical relevance, however no such values have been determined for the AKE, SLR or FTF. We estimated the MDC with 95% confidence bounds for the AKE and SLR [26]. The agreement for the FTF was previously determined [28]. According to these values, the changes in AKE angle and FTF distance may have resulted from measurement error. However, the effect size for the change in SLR angle was nearly twice that of AKE and FTF, and was at the limit of the  $MDC_{95}$  thus, the change is more likely to be of clinical importance. The SLR measurement was passive which may explain why it improved more after passive stretching than the active AKE and FTF measurements in which activation of the neuromuscular system is needed [38]. This suggests that the neuromuscular system needs active stimulation to generate active movement in the newly acquired passive ROM. This hypothesis is supported by the existence of both local and global neuromuscular control impairments, which are largely documented in CLBP [34–36].

We had hypothesized that protective behavior due to fear of pain, kinesiophobia or motivational aspects would limit changes in flexibility in some individuals. Evidence in the literature suggests that fear-avoidance beliefs are a prognostic factor for poor outcomes in people with LBP [39]. Furthermore, it has been reported that anxiety and depression limit the efficacy of a multidisciplinary intervention in people with CLBP [40]. However, in our study, the improvement in HM flexibility was not related to FABQ or HADS scores. This suggests that either psychosocial factors do not impact the immediate effect of HM stretching, or other approaches are required to evaluate these aspects. More direct human emotion recognition methods, using for example electroencephalography, galvanic skin response or heart rate variability, could yield different results [41]. This could be considered in further studies. This is the first study to evaluate a relationship between the presence of psychosocial factors and the immediate effect of HM stretching; no relationship was found.

### 5.1. Study limitations

This study has several limitations. First, to facilitate the feasibility of the study, we did not include a control group. However, the repeated measurements before and after HM stretching and the large sample size strengthen our results. Second, the measurement techniques do not directly measure change in HM flexibility, as ultrasound measurement would [42]. This and other measurements (eg, HM stiffness, HM electromyography or elastography) could be considered in further studies to better understand the effect of HM stretching. Also, only the FABQ and HADS were used to explore the impact of psychosocial factors. Other questionnaires or more direct measures of fear and stress could reveal different results thus could be used in future studies. Furthermore, in our study only immediate effect of HM stretching was evaluated, the impact of psychosocial factors could be different on cumulative effect of multiples stretching sessions.

## 6. Conclusion

Passive HM stretching immediately improved HM flexibility in people with CLBP. The AKE angle, SLR angle and FTF distance improved significantly; however only the change in passive SLR angle was clinically important, the changes in the active tests were not. In contrast with our hypothesis, psychosocial factors were not related to the magnitude of improvement in flexibility after HM stretching. Other methods of psychosocial evaluation could be considered in future studies. We recommend using passive HM stretching in addition to other interventions to obtain clinically important improvements in both passive and active movements.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2023.e19753>.

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## CHAPTER 4: GROUP-BASED ANALYSIS

The complementary group-based analysis is presented below in a Letter to Editor article format and is submitted to the journal. Such a posteriori analysis was conducted, as significant variability among participants was observed in the changes in flexibility following stretching. Describing patients who have shown clinically significant improvement and those who have not could provide relevant information.

**Comparison of clinical characteristics between Responders and Non-responders to hamstring stretching in individuals with chronic low back pain**

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Dear Editor,

In a previous article, we presented the results of a study on the immediate effect of passive hamstring muscles (HM) stretching on flexibility in 90 people with chronic low back pain (CLBP). (Dobija et al., 2023) This study was approved by a local ethics committee (Comité de Protection des Personnes – Ouest 1, Identifier: 2020T2-01\_RIPH2 HPS\_2019-A03000-57) and informed consent was obtained from all participants. The improvement in HM flexibility was statistically significant, with the Straight Leg Raise (SLR) angle showing a mean improvement of 7° (95% CI 5.5 to 8.6°,  $p < 0.001$ , ES: 0.42-0.44), Active Knee Extension angle showing a mean improvement of 4° (95% CI 2.4 to 5.1°,  $p < 0.001$ , ES: 0.23-0.24) and Fingertip-to-Floor distance showing a mean improvement of 2cm, (95% CI 1.7 to 3.0cm,  $p < 0.001$ , ES=0.20). Furthermore, there was considerable variability in the changes after stretching; substantial improvements occurred in some individuals, whereas others exhibited minimal or no change. From a clinical perspective, understanding the reasons behind the different responses to passive HM stretching in people with CLBP is very important. To provide a more comprehensive description of those who experienced a relevant improvement in flexibility and those who did not, we divided the participants into two distinct groups. Based on the mean improvement and on Minimal Detectable Change estimated previously, (Dobija et al., 2023) we fixed a threshold of 7° to indicate an improvement in passive SLR angle and differentiate between 'Responders' and 'Non-responders'. We then compared the clinical characteristics of these groups using a Fisher's exact test or Chi-squared test. (Table 1)

After 1 minute of passive stretching, the improvement in SLR angle was equal to or exceeded 7° in 28 participants (31%) (Responders); the change was less than 7° (Non-responders) in 62 participants (70%). We found no statistically significant differences in any of the characteristics analysed between the Responders and the Non-responders except for body mass index (BMI), which was greater in the Non-responder group. (Table 1)

**Table 1. Comparison of clinical characteristics between Responders and Non-responders.**

	Responders	Non-responders	<i>p value</i>
Number and percentage of participants	28 31%	62 70%	
Age [years]	45.6 ± 8.9	43.8 ± 9.2	0.372
Men	16 (30%)	37 (70%)	0.822
Women	12 (32%)	25 (68%)	
BMI [kg/m <sup>2</sup> ]	25.2 ± 5.5	28.1 ± 5.7	0.007*
Education level:			
No diploma	0 (0%)	1 (100%)	0.152
Less than baccalaureate	13 (30%)	30 (70%)	
Baccalaureate level	8 (25%)	24 (75%)	
Higher education studies	7 (58%)	5 (42%)	
Type of work:			
Sedentary	9 (43%)	12 (57%)	0.214
Physical	11 (23%)	36 (76%)	
Mixed	7 (37%)	12 (63%)	
Living environment:			
Urban	19 (31%)	43 (69%)	0.887
Rural	9 (32%)	19 (68%)	
Active smoking			
Yes	10 (27%)	27 (73%)	0.644
No	18 (34%)	35 (66%)	
Workplace accident			
Yes	2 (12%)	15 (88%)	0.056
No	26 (36%)	47 (64%)	
Time since pain onset [months]	73.9 ± 97.5	84.1 ± 88.9	0.295
Pain before stretching			
VAS [0-100]	36.8 ± 21.8	38.2 ± 22.5	0.877
Pain after stretching			
VAS [0-100]	40.5 ± 21.6	42.7 ± 23.8	0.835
Pain change			

VAS [0-100]	3.7 ± 12.6	4.0 ± 18.1	0.605
ODI	34.4 ± 14.2	34.4 ± 12.0	0.785
FABQ Physical Activity	14.6 ± 5.4	14.2 ± 6.3	0.949
FABQ Work	25.0 ± 11.3	28.5 ± 10.6	0.193
HADS Anxiety	10.1 ± 3.8	10.1 ± 3.5	0.953
HADS Depression	7.9 ± 3.1	8.1 ± 3.3	0.728

Data are n (%) or mean ± SD. BMI, Body Mass Index; VAS, Visual Analogue Scale; ODI, Oswestry Disability Index; FABQ, Fear-Avoidance Beliefs Questionnaire; HADS, Hospital Anxiety and Depression Scale; \*  $p < 0.05$ ; 'Responders' were defined as those with an improvement of  $\geq 7^\circ$  in Straight Leg Raise angle after stretching and 'Non-responders' as a change  $< 7^\circ$ .

We performed this supplementary analysis to identify clinical differences between Responders and Non-Responders to passive HM stretching, however only BMI differed between groups; it was significantly smaller in Responders. The reason for the effect of BMI on stretch efficacy is not obvious.

Anxiety has been shown to be more frequent in people with obesity or overweightness than in the general population. (Amiri and Behnezhad, 2019) Anxiety could potentially reduce the capacity to relax muscles during stretching and thus reduce stretching efficacy. In addition, higher levels of fear of movement have been reported among people with CLBP and obesity compared to those without obesity (Vincent et al., 2011). However, we found no correlation between Hospital Anxiety and Depression Scale (HADS) and Fear-Avoidance Belief Questionnaire (FABQ) scores and improvement in flexibility, suggesting that other factors may play a role in the BMI and stretching effect relationship. On the other hand, the application of stretching force on the HM by the therapist requires greater effort in individuals with obesity or overweight due to the increased mass of the lower limb. This, in turn, may influence the effectiveness of the stretching. Despite a marginal difference ( $p=0.056$ ), the results showed that of the 90 participants, 17 had experienced a workplace accident, and the majority of these individuals ( $n=15$ , 88%) were in the Non-Responder group. Workplace-related factors are known to impact the recovery of patients with CLBP; therefore, a workplace accident could indeed influence the stretching effect. (Ia et al., 2017)

The interpretation of this supplementary analysis is limited by the fact that adequate statistical power was not reached; a much larger sample size would be required to draw a robust conclusion for such a

group-based analysis. The hypothesis of the initial study was that psychosocial factors would impact stretching efficacy,(Dobija et al., 2023) but the overall and group-based analyses revealed no relationship between these factors. The question of why HM flexibility improves after HM stretching in some individuals can therefore not simply be explained by psychosocial characteristics evaluated by the FABQ and HADS questionnaires. Other clinical factors like state of lumbar degenerative changes, flexibility of other muscles (ex. piriformis, erector spinae, hip adductors), and neurodynamics issues need to be considered. In the presence of pain, muscles in the posterior chain may contract simultaneously during stretching (Weisman et al., 2014), which may prevent effective stretching of the HM. Furthermore, the SLR does not only stretch the HM; therefore, its amplitude may be limited by other anatomical structures. One study found that increases in HM flexibility measure could be achieved through myofascial release techniques applied to the posterior muscle chain but not specifically the HM. (Fauris et al., 2021) Therefore, it is important to thoroughly examine the individual to find the cause or causes of the reduced SLR angle. None of the participants presented radicular pain. Therefore, it is unlikely that the stretching effect was limited by radicular pain. However, some participants had degenerative changes within the intervertebral disc or a history of radicular pain that might have influenced neurodynamics, even in the absence of evident radicular symptoms. These conditions could potentially impact the effectiveness of stretching. (Shacklock, 2005) Future studies should take the above factors into account in order to explain why some CLBP patients improve HM flexibility while others do not.

In conclusion, the only clinical factor found to relate to a positive response to HM stretching was a low BMI.

**Declarations of interest:** none.

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## CHAPTER 5: COMPARISON OF THE IMMEDIATE EFFECT OF PASSIVE VERSUS PASSIVE-ACTIVE HAMSTRING MUSCLES STRETCHING ON FLEXIBILITY IN PATIENTS WITH CHRONIC LOW BACK PAIN. A PROTOCOL OF A RANDOMIZED CONTROLLED STUDY. EFIM2

The final chapter of this work presents a study protocol developed in response to the conclusions drawn from the EFIM1 study. From the patient's perspective, the ultimate goal is to achieve an improvement in active, pain-free ROM. However, passive stretching did not yield satisfactory improvements in active flexibility. This is why we propose a combination of passive and active stretching exercises, with the expectation that it facilitates improvements in both passive and active ROM. To test our hypothesis that combining active and passive stretching is more effective than passive stretching alone in improving active flexibility, we will conduct a randomized controlled study outlined below. The study protocol is presented in an article format and will be submitted to PLOS One journal.

**Comparison of the immediate effect of passive versus passive-active hamstring muscles stretching on flexibility in patients with chronic low back pain. A protocol of a randomized, controlled trial. EFIM2**

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## **Abstract**

Individuals with chronic low back pain (CLBP) are affected by deficits in hamstring flexibility and lumbopelvic neuromuscular control. While passive hamstring stretching immediately improves passive hamstring flexibility, no clinically important difference in active range of motion has been observed.

The primary objective of the present randomized controlled study protocol is to compare the immediate effects of a novel combination of passive and active stretching (PAS) exercises with passive hamstring stretching (PS) alone on active flexibility.

The secondary objectives include conducting a similar comparison for passive flexibility, hamstring stiffness, and pelvic tilt, as well as estimating the Minimal Clinically Important Difference (MCID) for hamstring flexibility measures. Ninety CLBP patients will be randomized into PAS or PS group and will receive respective interventions. Primary outcome will be the mean value of two measurements of Active Knee Extension taken before and immediately after the intervention. Secondary outcomes, Fingertip-to-Floor distance, Straight Leg Raise, hamstring stiffness and pelvic tilt will be recorded and compared in the same manner. A group-by-time comparison will be conducted for primary and secondary outcomes. An anchor question about perceived by participants change in flexibility following intervention will serve to estimate MCID.

This study protocol is the first opportunity to assess whether combining passive and active hamstring stretching is better than passive stretching alone for achieving an immediate and clinically important improvement in active flexibility among CLBP patients. The results will provide valuable and time-efficient insights for the development of more comprehensive rehabilitation programs in both clinical and research settings.

## Introduction

Neuromuscular control and flexibility deficits in people suffering from Chronic Low Back Pain (CLBP) are critical physical factors contributing to pain and disability.(Arab and Nourbakhsh, 2014; Halbertsma et al., 2001; Hodges and Richardson, 1996; Hori et al., 2021; Kääriäinen et al., 2013; van Dieën et al., 2019) Core muscles together with global muscle chains are responsible for functional stability of the lumbopelvic region.(De Ridder et al., 2013; Hodges, 1999; Hodges and Richardson, 1997; Lee Diane, 2011; van Wingerden et al., 1993a) People with CLBP exhibit altered neuromuscular control at both local and global levels, including delayed activation of core muscles (Crasto et al., 2020; Hodges and Richardson, 1996; Hungerford et al., 2003; Leinonen et al., 2003; van Dieën et al., 2019) as well as changes in neuromuscular control in the lower (Hungerford et al., 2003; Suter and Lindsay, 2001) and upper limbs (Kääriäinen et al., 2013; Leinonen et al., 2007), postural control alternations (Knox et al., 2018; Tsao et al., 2008; Yang et al., 2023), and impairments in the central nervous system.(Meier et al., 2019; Schabrun et al., 2017; Tsao et al., 2008) To cope with these alternations and perform necessary functional activities, CLBP patients develop compensatory mechanisms. One of the frequent compensatory mechanism is hamstrings muscle tightness.(Arab and Nourbakhsh, 2014; Fasuyi et al., 2017; Halbertsma et al., 2001) The hamstrings, which are part of the posterior muscle chain, enhance lumbopelvic stability by exerting compression forces on the sacroiliac joints.(van Wingerden et al., 1993a; Vleeming and Schuenke, 2019) This occurs through muscle contraction and passive muscle stiffness, the latter is more pronounced at the end of the range of motion (ROM).(van Wingerden et al., 2008) When controlling adequate muscle contraction is compromised, increasing passive muscle stiffness may help provide the necessary stability for performing functional activities.(Kuszewski et al., 2018; Massoud Arab et al., 2011; van Wingerden et al., 2008) However, employing such a compensatory strategy can generate an excessive load on the

lumbar spine and increase the risk of lower back and lower limb problems.(Cejudo et al., 2021a; Jandre Reis and Macedo, 2015; Sadler et al., 2017)

Passive hamstrings stretching conducted over multiple sessions improve flexibility,(Medeiros et al., 2016; Mizoguchi et al., 2022; Shamsi et al., 2022) and the effect can be seen also on a single session.(Aye et al., 2017; Moon et al., 2017; Nishikawa et al., 2015) Our previous study showed immediate improvement of hamstring flexibility following a single session of passive stretching in CLBP patients.(Dobija et al., 2023) The effect was statistically significant on both active (Active Knee Extension [AKE], Fingertip-to-Floor [FTF]) and passive measures (Straight Leg Raise [SLR]) ( $p < 0.001$ ). However, only the change in passive SLR angle could be considered clinically relevant (mean improvement of  $7^\circ$ , 95%CI 5.5 to  $8.6^\circ$ , ES: 0.42 to 0.44).(Dobija et al., 2023) It appears that the neuromuscular system requires additional stimulation in order to effectively translate improvements in passive ROM into active movement within the newly acquired ROM. Quadriceps, hip flexors and abdominal muscles activation is necessary in the assessment of AKE. However, in patients with CLBP the inhibition of quadriceps and the alteration of neuromuscular control in trunk muscles can hinder performance in the AKE.(Suter and Lindsay, 2001; van Dieën et al., 2019) Similarly, in the assessment of FTF distance, altered neuromuscular control of posture, trunk, and lower limbs appears to prevent the achievement of a full ROM.(Kim and Yoo, 2013; van Dieën et al., 2019) On the other hand, active stretching intervention are proposed to integrate stimulation of neuromuscular activation including: active movement in the full ROM (Bandy et al., 1998; Nishikawa et al., 2015), hold-relax or contract-relax techniques,(Lempke et al., 2018) a combination of passive and active stretching (Alshammari et al., 2019) and a simultaneous core muscles activation while performing active stretching movements.(Ahn et al., 2020) Nevertheless, in healthy individuals active movement in the full ROM revealed less effective than passive stretching.(Bandy et al., 1998; Nishikawa et al., 2015) Hold-relax or contract-relax

techniques which use the principle of post-isometric relaxation, show similar effectiveness on flexibility compared to passive stretching.(Lempke et al., 2018) Using a combination of passive and active stretching showed better flexibility improvement than passives techniques alone in healthy subjects.(Alshammari et al., 2019) Further, using core muscles activation while performing active stretching movements in healthy subjects results in similar effect on classic AKE angle but superior effect is achieved when AKE angle is measured with lumbar position controlled by pressure bio-feedback unit.(Ahn et al., 2020) The latter stretching method seems promising for CLBP patients because it targets core neuromuscular control and hamstrings flexibility which are both altered in this population. Likewise, core muscle training alone has been also shown to enhance hamstring flexibility in healthy subjects.(Kuszewski et al., 2018) Another intervention for improving hamstring flexibility could involve an eccentric strengthening program. Although, it has demonstrated effectiveness in increasing passive flexibility, it appears to have no impact on active flexibility in healthy subjects.(Delvaux et al., 2020)

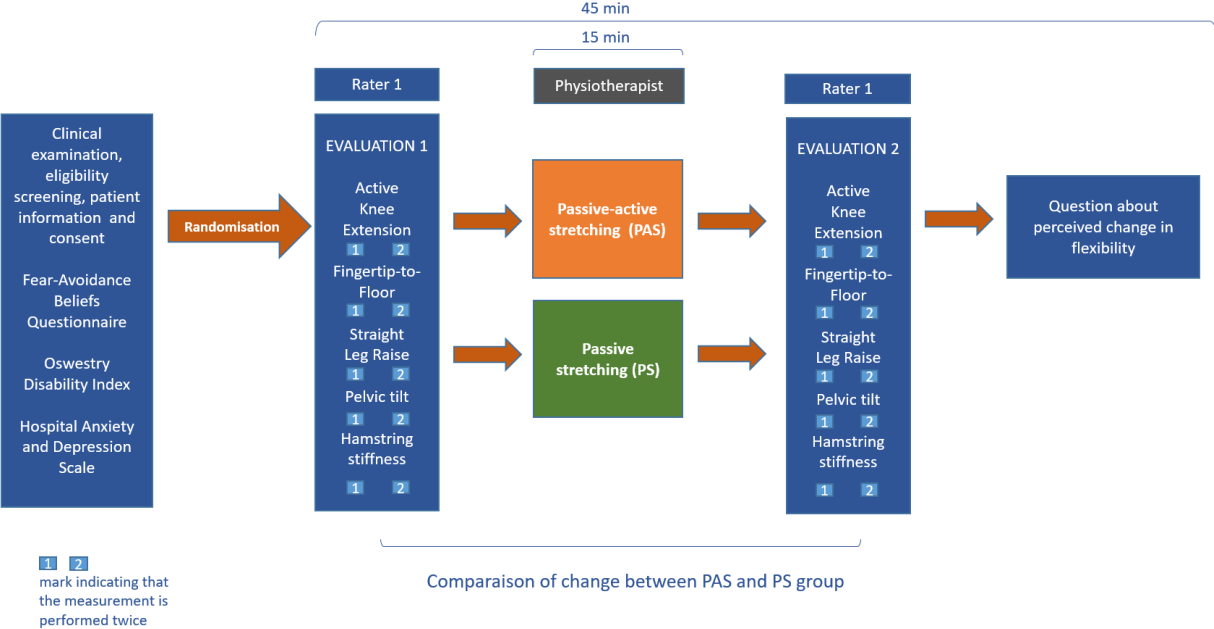
The final objective of a stretching intervention is to help patients improve their pain-free ROM in functional movements that were initially restricted. Therefore, achieving gains solely in passive ROM does not align with the patient's needs. The question of the present study is which type of stretching intervention could provide a clinically important and time-efficient improvement in active ROM in CLBP patients.

The main objective of the present study is to compare the immediate effect of passive hamstring stretching versus a novel combination of passive and active stretching exercises on active flexibility (AKE). The secondary objectives are to conduct the same comparison on hamstring flexibility measured by FTF and SLR, hamstring stiffness and pelvic tilt; also to estimate minimal clinically important difference (MCID) for the hamstring flexibility measures (AKE, SLR, and FTF).

# Methods

## Study design

We will conduct a randomized, single-blind, parallel group, two-arm superiority clinical trial, using a 1:1 allocation rate and a follow-up realized immediately after intervention. Two arms of the study will be composed of passive stretching (PS) group and combined passive-active stretching group (PAS). The duration of the intervention (15min) will be the same in both groups. All outcomes will be evaluated before and immediately after the intervention, thus patients will complete their participation in the study in one day. The schema of the study design is presented in Fig. 1. The study protocol is written in accordance with the Standard Protocol Items: Recommendations for Intervention Trials. (SPIRIT) statement.(Chan et al., 2013) The results will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.(Butcher et al., 2022)



**Fig. 1 Schema of study design**

## Study settings

Participants will be recruited from referrals to the physical and rehabilitation medicine department and rheumatology department, of a French university hospital and a nearby private physiotherapy clinic. The study will be conducted at the both above mentioned healthcare facilities. We will additionally recruit participants through announcements on social media and via the email list of our university hospital's employees.

## **Sample size calculation**

The estimation of the required number of subjects is based on a comparison between randomization groups regarding the gain in AKE angle. The hypotheses were established using data from our initial study EFIM1 (ClinicalTrials.gov identifier: NCT04551326), which has recently been published.(Dobija et al., 2023) Additionally, in order to detect a minimum difference in the gain for AKE angle of approximately 25% with a standard deviation of 35%, it is necessary to include 42 patients per group for a bilateral Type I error rate of 5% and a power of 90%. Ultimately, it is proposed to include 90 patients, with 45 in each randomization group.

## **Participants**

Ninety individuals suffering from CLBP, and presenting hamstrings flexibility deficit ( $AKE < 80^\circ$ ,  $FTF > 5\text{cm}$ ,  $SLR < 80^\circ$ ) will participate in the study. Sixty participants will participate in the study at the physical and rehabilitation medicine department of our university hospital and 30 participants will participate in the study at a nearby private clinic. A complete eligibility criteria are specified in Table 1. A physiotherapist with 20 years of clinical experience in managing CLBP patients will assess eligibility. If there are any doubts, a physical medicine and rehabilitation physician will evaluate the suitability of the inclusion, potentially using additional imaging if necessary.



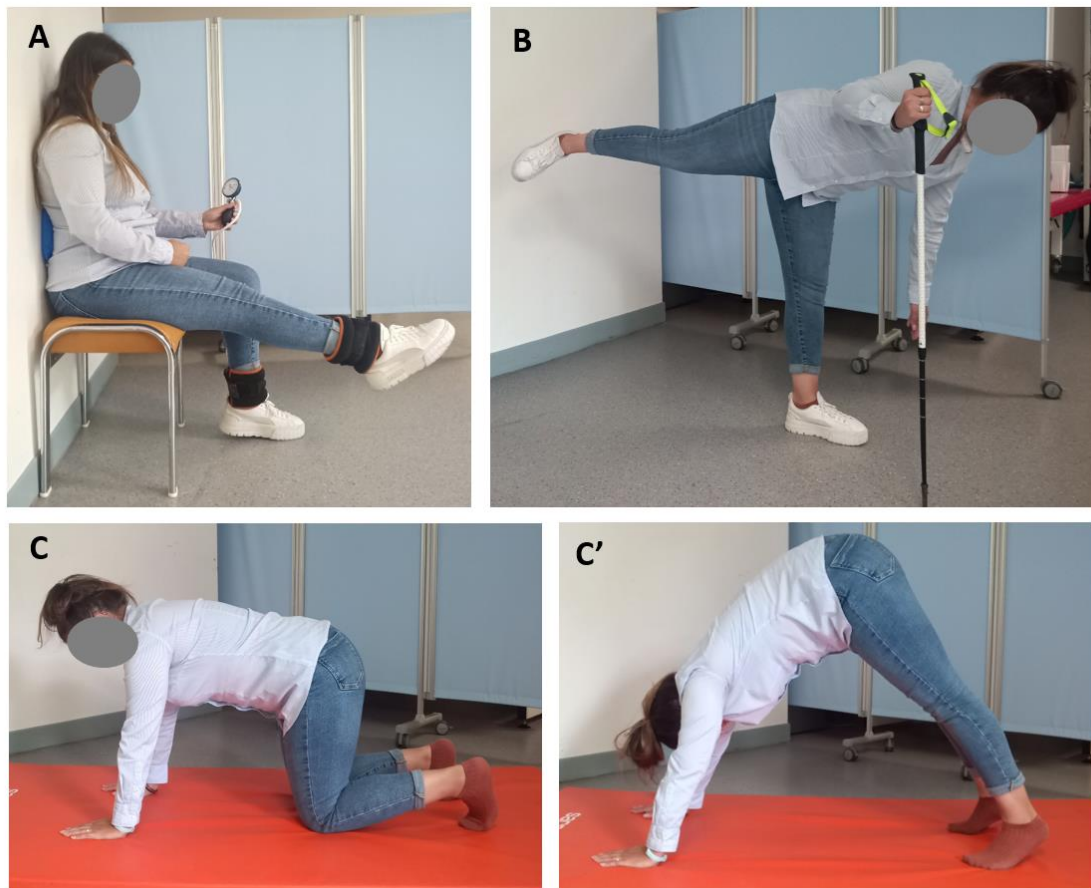
**Table 1. Eligibility criteria for participants**

<b>Inclusion criteria</b>	<ul style="list-style-type: none"><li>• Age 18 to 65 years</li><li>• Hamstring flexibility deficit (AKE&lt;80°, FTF&gt;5cm, SLR&lt;80°)</li><li>• Low back pain duration &gt;3 month</li><li>• Health insurance coverage</li></ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"><li>• Radicular pain (sciatica)</li><li>• Neurologic, cardiac, respiratory or oncological disease</li><li>• History of significant surgery (ex. hip or knee arthroplasty, arthrodesis of more than two vertebral segments)</li><li>• People under guardianship, curatorship or protection of the court</li><li>• Fibromyalgia, Complex Regional Pain Syndrome</li><li>• Pregnancy and breast feeding</li></ul>

## **Interventions**

The intervention in experimental group called, passive-active stretching (PAS) group will consist of two phases. The first phase of the intervention consist of bilateral passive hamstring stretching and was detailed in the previous study.(Dobija et al., 2023) Briefly, a physiotherapist will slowly extend participant’s knee joint with a hip joint positioned in the maximal pain free flexion. The physiotherapist will stop extending the knee when the participants achieve maximal tolerable, pain free ROM with the intense stretch sensation in the back of the thigh. This end position will be kept for one minute (time measured by a stopwatch). The participants than will be asked to breathe normally and to relax all muscles. After this the participant will be asked to walk for about 30 seconds. Next, three exercises targeting the activation of muscles that promote hamstring elongation will be performed, with a 30-second transition rest time

between each exercise. (Fig. 2) First exercise will be realized in sitting position with the back against the wall; STABILIZER® pressure bio-feedback unit (PBU) will be placed between patient's back and the wall at the lumbar spine. Patients will activate their core muscle than will maximally extend their knee while maintaining the initial position of the lumbar spine thanks to core muscle contraction and maintaining the pressure of 40 mmHg on PBU. Participants will wear one kilogram ankle weights during this exercise to stimulate muscle activation. The maximal knee extension position will be kept for 5 seconds. Ten repetitions for each lower limb will be realized. (Fig. 2A)



**Fig. 2 Active stretching exercises: A - knee extension with resistance and a pressure bio-feedback unit, B - one-leg deadlift; C, C' - bear-squat exercise.**

The one-leg deadlift will be performed with the support of a stick or wall bars to assist participants in maintaining their balance. While standing on one leg, participants will bend their trunk forward and lift their non-standing lower limb as high as possible, keeping their trunk and the elevated lower limb in straight line alignment. This exercise target the coordinated activation of lower limb and trunk muscles, along with a full-range eccentric contraction of the hamstring muscles in the standing limb. Ten repetitions with a five-second rest in the final position will be performed bilaterally. (Fig. 2B)

The bear-squat exercise begins in the all-fours position, participants lift and fully extend their knees, shifting their weight onto their toes and hands. Additionally, participants move their pelvis backward while keeping their knees extended to increase hamstring elongation. After holding this end position for five seconds, participants return to the starting position. Ten repetitions will be performed. (Fig. 2C, C')

In the control group, participants will receive one minute of passive hamstring stretching applied three times for each lower limb, with a 30-second rest time between stretches. This ensures that the intervention time is consistent in both groups, totalling approximately 15 minutes. The day before participants take part in the study, all exercises will be demonstrated to them, with special attention given to core muscle activation using the drawing-in manoeuvre and the utilization of the PBU. The intervention in both groups will be administered by a physiotherapist experienced in managing CLBP and trained in the study protocol. All exercises will be adapted to the participants' maximum range of motion and their comfort level, ensuring pain is either absent or within a tolerable range.

## **Assignment of interventions**

After obtaining informed written consent from participants, they will be randomized into either the PAS or PS group with a 1:1 ratio. The randomization sequence will be generated by a using of the REDCap™ software, independently overseen by a statistician. Randomization will be

conducted by random-sized blocks using minimization method, stratified by center, sex and BMI (<25, 25-30, >30). The procedure of randomization will be realized in the coordinating office which remain separate from participant enrollment and assessments. Access to the randomization list and allocation concealment will be limited solely to the independent statistician.

## **Primary outcome**

All measurements will be realized by raters who are physiotherapists trained in the study protocol and experienced in managing CLBP. The raters will not be involved in the intervention and will be blinded to the participants' group allocation. The primary outcome will be Active Knee Extension angle evaluated at baseline and immediately after intervention. The mean value of the two measurements taken before intervention will be compared with the mean value of two measurements taken immediately after intervention. The change in AKE values of the less flexible lower limb will be used to compare the effect between PS and PAS group. The measurement procedure for AKE was described in the previous study and demonstrated excellent interrater reliability (ICC: 0.917–0.975) with an MDC<sub>95</sub> range of 8.6 to 10.8° in CLBP patients.(Dobija et al., 2023) The raters will be physiotherapists experienced in managing CLBP and trained in the study protocol. A rater will measure the AKE angle using the EasyAngle® digital inclinometer twice before and twice immediately after the intervention. Participants will maintain 90° hip flexion by keeping their thigh against a plastic stick placed on the anterior surface of the thigh during the measurement. (Fig. 3A)



**Fig. 3 Hamstring flexibility and stiffness measurements: A – Active Knee Extension angle, B – Straight Leg Raise angle and hamstring stiffness, C – Fingertip-to-Floor, D – pelvic tilt**

## Secondary outcomes

At the same time-points, we will record and compare the SLR angle and hamstring stiffness during SLR, FTF distance and pelvic tilt angle.

The SLR angle measurement procedure will closely follow that described in the previous study, which showed excellent intrarater reliability (ICC: 0.908–0.987) with MDC<sub>95</sub> values ranging from 6.8 to 10.4°. (Dobija et al., 2023) The rater will raise the participant's lower limb until the first sensation of stretch or pain is felt. The angle will then be recorded using the EasyAngle® digital inclinometer, which will be attached with a Velcro strap to the lateral part of the lower limb at the level of the tibial tuberosity. The EasyForce® digital dynamometer will allow to measure hamstrings stiffness. To raise the leg, a pulling force will be applied perpendicularly to the length axis of the leg at the ankle joint. The pulling force consists of the weight of the limb and the stiffness of the hamstring muscles. Hamstring muscle stiffness will be calculated with the gravity correction and using the SLR angle, limb length, and the pulling force. (Halbertsma et al., 2001) Participants will be asked to relax their muscles during measure in order to record the component of passive hamstring muscles stiffness. This measurement will be taken twice before the intervention, at the end of the SLR range. The stiffness measurement

will also be taken twice after the intervention at the SLR angle measured before the intervention. (Fig. 3B)

The FTF measurement will be conducted in the standard manner by measuring the distance between the fingertips and the floor using a measuring tape at the end of the forward bending range, with knees fully extended. (Fig. 3C) The MDC<sub>95</sub> estimated earlier in CLBP patients was 4.5cm.(Ekedahl et al., 2012) Additionally, pelvic tilt will be measured by placing the EasyAngle® digital inclinometer at the sacrum at the end of forward bending range. (Fig. 3D) This measure was previously used in a study that demonstrated excellent intrarater reliability (ICC: 0.97-0.99).(Kuszewski et al., 2018) As for the other measures, we will compare the mean values of two FTF and pelvic tilt measurements taken before the intervention with two measurements taken immediately after the intervention.

To estimate the MCID for hamstring flexibility measurements, participants will be asked after each post-intervention measurement whether they feel any difference in flexibility, and their responses ('yes' or 'no') will be recorded. Additionally, participants' characteristics recorded at baseline will include: age, sex, body mass, height, Body Mass Index (BMI), education level, type of work, active smoking, workplace accident, time since pain onset, Oswestry Disability Index (ODI), Fear-Avoidance Belief questionnaire (FABQ), Hospital Anxiety and Depression Scale (HADS).

## **Data management, and statistical analysis**

A physiotherapist, acting as the rater, will record baseline characteristics, as well as hamstrings flexibility and stiffness measurements. The data will be initially recorded on a paper version of the case report form and then transcribed into an electronic case report form using REDCap electronic data capture tools hosted at our University Hospital. The transcription will be performed by a clinical research assistant and further data management and statistical analysis will be conducted by an independent statistician.

Statistical analyses will be performed using Stata V.15 (StataCorp). Continuous variables will be presented as mean and standard deviation, subject to the normality of their distribution (Shapiro-Wilk test). In case of non-normality, they will be presented as median and interquartile range. The main analysis will rely on a Student's t-test or a non-parametric Mann-Whitney test if the conditions for the t-test are not met. Equality of variances will be assessed using the Fisher-Snedecor test. The results will be expressed in terms of effect size and a 95% confidence interval. Subsequently, this analysis will be complemented by a multivariate approach such as multiple linear regression, with the dependent variable being the gain in the AKE angle. Covariates will be selected based on univariate analysis results and their clinical relevance (including sex, age, BMI and other recorded participants' characteristics). Special attention will be given to multicollinearity. Comparisons between groups regarding secondary quantitative outcomes (FTF, SLR, hamstring stiffness, pelvic tilt) will be studied in a similar manner. Anchor-based method will be used to estimate MCID for all above mentioned hamstring flexibility measures. The relationship between the anchor question (yes/no) regarding the perceived change in flexibility and the changes in flexibility measures (AKE, SLR, FTF, pelvic tilt) following the intervention will be analyzed using Spearman rank-order correlation and receiver operating characteristic (ROC) curves.

Data monitoring will occur when half of the planned sample is enrolled (45 participants) and again upon study completion (90 participants). The data monitoring committee, organized by our university hospital clinical research service, will comprise clinical research assistants who are not involved in the study.

## **Harms and adverse effects**

Harms and adverse effects will be documented in both the paper and electronic versions of the case report form. The interventions in this study will be administered by experienced physiotherapists who specialize in managing patients with CLBP. We will strictly adhere to the

described procedures, particularly adjusting the ROM for stretching based on each participant's pain tolerance. It is important to emphasize that stretching exercises are commonly used in the management of CLBP, and numerous previous studies have reported no serious harms or adverse effects.(Dobija et al., 2023; Kim and Yim, 2020; Medeiros et al., 2016; Mizoguchi et al., 2022; Shamsi et al., 2022) Therefore, the risk of experiencing harms and adverse effects in this study protocol is minimal. Participants may, at most, experience slight discomfort, delayed muscle soreness, or minor, temporary variations in pain intensity.

## **Ethics and dissemination**

The local ethic committee have approved the study protocol (Comité de Protection des Personnes, Number: XXX) Written informed consent will be obtained from participants before any study-related procedures. The information sheet and consent form will be given by investigator which is physiotherapist. To protect the participants' personal information, an individual code will be used instead of their first and last names in both paper and electronic case report forms. The physiotherapists administering the interventions and those acting as raters will have access to personal and medical information of participants. The statistician and clinical research assistant will have only access to anonymised data.

## **Discussion**

This study protocol represents the first opportunity to determine whether the combination of passive and active hamstring stretching interventions is superior to passive stretching alone in achieving an immediate and clinically important improvement in active flexibility ROM in CLBP patients. The design of a randomized controlled trial with an adequate sample size will enable us to establish robust conclusions. Recruiting participants from multiple centers, including university hospitals and private clinics, will enhance the representativeness of the study sample and the generalizability of the study results. Choosing to evaluate the immediate effect rather than the cumulative effect of stretching sessions allows us to address the study



question in a time-efficient manner. This choice is based on the premise that if an intervention results in immediate improvement, it is highly likely that cumulative effects will also occur. Our previous study (Dobija et al., 2023) and those realized by other authors (Aye et al., 2017; Moon et al., 2017; Nishikawa et al., 2015) observed an immediate effect of hamstring stretching interventions in both healthy individuals and those with CLBP. However, none of them have reported a clinically important improvement on the active ROM measured by AKE and FTF movements. The need to develop a stretching intervention that efficiently restores active hamstring flexibility is currently crucial. Therefore, the results of our study will provide valuable insights for the development of more comprehensive rehabilitation programs in both clinical and research settings. Additionally, estimating the MCID for hamstring flexibility measurements will enhance the interpretation of the changes obtained in the present study and, more broadly, in clinical practice.

## **Trail registration number**

ClinicalTrial.gov Identifier: XXX

## **Competing Interests**

The authors declare that no competing interests exist.

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## GENERAL CONCLUSION

Hamstring muscle flexibility assessment in both active (AKE, FTF) and passive (SLR) manners has acceptable measurement properties in patients with CLBP. A statistically significant increase in both passive and active flexibility was recorded immediately after passive HM stretching. However, only passive flexibility could be considered clinically relevant based on the range values of  $MDC_{95}$ . The flexibility improvement is not associated with psychosocial factors measured with FABQ and HADS questionnaires. Responders and Non-responders to passive HM stretching have similar clinical and demographic characteristics, except for a higher BMI in the Non-responders group. There is still a need for a clinically significant improvement in active flexibility in CLBP patients. Therefore, a combination of passive and active stretching exercises is proposed and will be evaluated in a randomized controlled study (EFIM2). Additionally, the presented patient-reported, anchor-based MCID estimation will improve the interpretation of the changes obtained in the proposed study and, more broadly, in clinical practice.

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