The benefits of fasciatherapy for the management of chronic low back pain in physiotherapy: a randomised cluster study

Short title :
Fasciatherapy and chronic low back pain

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Place(s) where the study was carried out :

Multicentric, in a private physiotherapy practice. All practices are located in France.

SUMMARY

Background :

Low back pain is defined as pain located between the thoracolumbar hinge joint and the lower gluteal fold. It may be associated with radicular pain which is pain in one or both lower limbs at the level of one or more dermatomes. Common low back pain is pain in the lower back that has no warning signs (see "red flags"). The term "common" low back pain is preferred to "non-specific" low back pain in everyday practice. Chronic low back pain is defined as low back pain lasting more than 3 months (HAS 2019).

Current knowledge suggests that the causes of common chronic low back pain are multifactorial (Seminowicz & al 2011, Fayt 2010, May and George 2011). Although there are recommendations for physiotherapy for the sub-acute and chronic phases, the care protocol is not well defined (HAS 2000, 2005). New therapeutic models centred on neuro-physiology are gradually replacing models based on biomechanics, and new programmes centred on patient education and a biopsychosocial approach are beginning to emerge (Nijs & al 2011).

Recent research has highlighted the possible involvement of fascia in low back pain (Langevin & al 2011, Willard & al 2012, Schilder & al 2013, Hoheisel & al 2015, Wilke & al 2017) and studies have shown the role of manual fascia therapies in the treatment of low back pain (Tozzi & al 2011, Branchini & al 2016, Harper & al 2015, Gordon & al 2015). To date, there are no studies that have demonstrated the effects of fasciatherapy in the treatment of common low back pain although physiotherapists are increasingly interested in the role of fascia in the management of musculoskeletal pathologies (Kwong and Findley 2014) including low back pain (Viklund & al 2015, Ajimsha & al 2014).

In France, many of them use this type of treatment and more specifically fasciatherapy during the various phases of low back pain (Trudelle 2003), believing that it improves their physiotherapy management of low back pain (Courraud & al 2016). Other studies have also highlighted the effects of the application of fasciatherapy in the management of fibromyalgia pain (Dupuis 2016), the treatment of anxiety (Payrau & al 2017), general discomfort (Angibaud & al 2013) and the body perception Duval & al 2010, Courraud 2007). These findings underscore the multidimensional impact of fasciatherapy and its potential for clinical, functional, and psychosocial benefits in the context of LBP treatment.

Fasciatherapy, like osteopathy from which it derives, is one of the manual therapies that target the fascial system and its various functions. This "patient-centered" therapeutic technique is rooted in a biopsychosocial and humanistic approach to health (Bois 2008). Fasciatherapy focuses on the fascia—defined as a membrane or sheet enveloping and connecting various body structures, such as muscles, joints, viscera, vessels, and nerves (Terminologia Anatomica, code A04.0.00.031, Adstrum et & 2017). This tissue is the subject of numerous scientific investigations and its involvement in various musculoskeletal pathologies such as low back pain is regularly mentioned. The architectural changes (tensions, rigidifications and fascial adhesions) observed by imaging are likely to produce acute and chronic pain. Manual and gestural treatment techniques for the fascial system are therefore among the promising Non-Medicinal Interventions (NMI). Fasciatherapy techniques involve manual and exercice therapy, the aim of which is to restore the contractile, elastic and movement properties of the fascial system in order to bring relief and improve the function and/or quality of life of people suffering from low back pain. These techniques are called 'non-manipulative' because they do not use forced mobilisation of the tissues.

In France, however, fasciatherapy is not included in professional recommendations and is not recognised as a title, specificity or qualification by the Conseil National de l'Ordre des Masseurs-Kinésithérapeutes (CNOMK 2012).

The aim of this study is therefore to highlight the effects of fasciatherapy on low back pain through an assessment of pain, quality of life, functionality and anxiety. It also aims to observe how fasciatherapy could contribute to the management of low back pain in the context of massage and physiotherapy.
This is a randomised cluster study with pain as the primary endpoint, involving 180 participants. The evaluation criteria include pain assessment using the Visual Analogue Scale (VAS), functional assessment using the Dallas Pain Questionnaire, quality of life evaluation with the SF-12 questionnaire, psychological assessment of anxiety using the STAI, and monitoring of medication use based on information provided by patients to the practitioner.

The practical conduct of the study is structured as follows:

- Recruitment of physiotherapists (investigators) by the FasciaFrance association and verification via their Curriculum Vitae of the investigators' inclusion criteria,
- Randomization of investigators into three groups based on the care they will provide: massage-physiotherapy care, combined massage-physiotherapy and fasciatherapy care, and fasciatherapy-only care.,
- Distribution of the investigator's brochure and observation booklet,
- Each investigator recruits their patients and adheres to the protocols outlined in the investigator's guide and observation booklet.
- Submission of anonymized ("coded") data by the investigators to the study sponsor.
- Data entry in the ACCESS database,
- Statistical analysis of the data using STATA software,
- Publication of the results.

CONTENTS

1 General information

1.1 Title of research

The benefits of fasciatherapy for the treatment of chronic low back pain in physiotherapy: a randomised cluster study
Short title : Fasciatherapy and chronic low back pain

1.2 Coordination and monitoring of the study - promoter

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1.3 Coordinating investigator

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The coordinating investigator takes part in drawing up the study design, is in contact with the CPP, collects the questionnaires, takes part in entering the data into the database in ACCESS format, transmits the data to the statisticians, takes part in analysing the data and disseminating the results.

1.4 Co-investigator - scientific collaborator - investigator - statisticians and associate partner

Co-investigator
Cyril Dupuis
Physiotherapist, Master's degree in Perceptive Psychopedagogy
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Scientific collaborator
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The co-investigator and scientific collaborator are involved in drawing up the study design, entering the data into the database in ACCESS format, analysing the data and disseminating the results.

Investigators
The investigators receive and complete the observation booklets, communicate with the primary and secondary investigators, carry out the study sessions, distribute the questionnaires to the patients, collect them afterward, and submit them to the primary investigator.
See list sent in attachment and CV provided on the website: https://cnriph.sante.gouv.fr

Statisticians
Céline Lambert and Bruno Pereira
Clermont-Ferrand University Hospital
Clinical Research & Innovation Delegation
Methodology, Biostatistics and Data Management Unit
bpereira@chu-clermontferrand.fr
The statisticians create the database in ACCESS format, retrieve the data and carry out the statistical analysis.

Partners
Centre for Study and Applied Research in Perceptive Psychopedagogy (CERAP)
Praça 9 de Abril, 349 | 4249-004 Porto (Portugal)
Tel: 06 82 12 09 01

1.5 Study locations

As this is a multi-centre study, patients will be enrolled in the practices of healthcare professionals (investigators) practising massage physiotherapy and fasciatherapy.
Authorisation for research site: not applicable

1.6 Study timetable

CPP submission: 14 December 2020
Study start date: effective start date: 6 May 2021
Recruitment period: 6 May 2021 to 6 June 2023
Patient follow-up period: 3 months maximum
Total duration of the study: 28 months
Anticipated end of study (last patient visit): 6 September 2023
End of study report: May 2024

2 Study rationale and scientific justification

Low back pain is defined as pain located between the thoracolumbar junction nd the lower gluteal fold. It may be associated with radicular pain which is pain in one or both lower limbs at the level of one or more dermatomes. Common low back pain refers to pain in the lower back that occurs without any specific warning signs (see "red flags"). The term "common" low back pain is preferred to "non-specific" low back pain in everyday practice. Chronic low back pain is defined as low back pain lasting more than 3 months (HAS 2019).
Questionnaires can be used to assess the risk of chronic low back pain. The French National Authority for Health (HAS) recommends the use of the STarT Back screening tool (which offers risk-stratified management) and the short version of the Örebro questionnaire (which predicts absenteeism), both of which have a grade B recommendation (scientific presumption).
According to current knowledge, the causes of common chronic low back pain are multifactorial (Seminowicz & al 2011, Fayt 2010, May and George 2011). Although there are recommendations for physiotherapy for the sub-acute and chronic phases, the treatment protocol is not well defined (HAS 2000, 2005). New therapeutic models centered on neuro-physiology are gradually replacing models

based on biomechanics, and new programmes centered on patient education and a biopsychosocial approach are beginning to emerge (Nijs & al 2011).
Recent research has highlighted the possible involvement of fascia in low back pain (Langevin & al 2011, Willard & al 2012, Schilder & al 2013, Hoheisel & al 2015, Wilke & al 2017) and studies have shown the role of manual fascia therapies in the treatment of low back pain (Tozzi & al 2011, Branchini & al 2016, Harper & al 2015, Gordon & al 2015). To date, there are no studies that have demonstrated the effects of fasciatherapy in the treatment of common low back pain although physiotherapists are increasingly interested in the role of fascia in the management of musculoskeletal pathologies (Kwong and Findley 2014) including low back pain (Viklund & al 2015, Ajimsha & al 2014).
In France, many patients opt for this type of treatment, particularly fasciatherapy, during the different phases of low back pain. (Trudelle 2003), believing that it improves their physiotherapy management of low back pain (Courraud & al 2016). Other studies have also highlighted the effects of the application of fasciatherapy in the management of fibromyalgia pain (Dupuis 2016), the treatment of anxiety (Payrau & al 2017), general discomfort (Angibaud & al 2013) and the perception of the body (Duval & al 2010, Courraud 2007). These studies bear witness to the multidimensional action of fasciatherapy and justify its clinical, functional and psychosocial evaluation in the context of its action on low back pain.
Fasciatherapy, like osteopathy from which it derives, is one of the manual therapies that target the fascial system and its various functions. This "patient-centered" therapeutic technique is rooted in a biopsychosocial and humanistic approach to health (Bois 2008). It essentially targets its action on the fascia, an anatomical entity described as a membrane, sheet or envelope that covers, surrounds and compartmentalises the different parts of the human body (muscles, joints, viscera, vessels, nervous system) while linking them together (Terminologia Anatomica, code A04.0.00.031, Adstrum & al. 2017). This tissue is currently considered to be the anatomical element that maintains the shape and architectural unity of the body, while ensuring interaction between the different parts.
It has been the subject of numerous scientific investigations over the last few decades, and its involvement has been demonstrated in various fields. From a biological perspective, inflammation originates in and is managed by the fascia. In biomechanics, fascia acts as the vector for the transmission of muscular force and the organization of movement. It is also involved in neuro-sensory phenomena such as proprioception, nociception, and interoception.
Its role in various musculoskeletal pathologies such as low back pain is also regularly mentioned. The architectural changes (fascial tensions, rigidifications and adhesions) observed by imaging are likely to produce acute and chronic pain. Manuel or exercice therapytechniques for the fascial system are therefore among the promising Non-Medical Interventions (NMI).
Fasciatherapy techniques involve manual and exercice therapy aimed at restoring the contractile, elastic and movement properties of the fascial system, with a view to providing relief and improving the function and quality of life of people suffering from low back pain. The manual and gestural techniques used are "non-manipulative" (no forced mobilisation of tissues). The practitioner applies manual and/or gestural tension to the fascia with the aim of achieving self-regulation of tension and tightness in the various fascial structures. In the treatment of low back pain, fasciatherapy techniques will be applied specifically to the thoracolumbar fascia and its various connections (lower limbs, lumbar, thoracic and cervical spine, shoulder girdle and abdomen).
In France, however, fasciatherapy is not included in professional recommendations and is not recognised as a title, specificity or qualification by the Conseil National de l'Ordre des Masseurs-Kinésithérapeutes (CNOMK 2012).

3 Aims of the study

3.1 Main objective

To evaluate the specific benefits of 5 fasciatherapy sessions, alone or in combination with physiotherapy, on the pain experienced by patients suffering from chronic low back pain.

3.2 Secondary objectives

- Assessing the benefits of fasciatherapy in the physiotherapy and massage treatment of low back pain
- Demonstrate the beneficial impact of fasciatherapy on the various aspects of chronic low back pain (pain, anxiety, function, quality of life)
- Identify the aspect(s) of low back pain for which fasciatherapy is most effective.

4 Study category

4.1 Search category

RIPH category: category 2
Fasciatherapy: non-manipulative manual and gestural therapy.

4.2 Justification for qualification

The interventional research study involves only minimal risks and constraints with regard to the list set by the decree of 03/05/2017.

5 Population studied / concerned

5.1 Inclusion criteria

Patients will be included:

- At the time of the practitioner's first consultation for this condition, the patient had been diagnosed with chronic low back pain and had no red flags.

The judgement criteria used to confirm the chronic nature of low back pain independently of the presence of pain lasting more than 3 months were :

- the STarT Back Screening Tool (Grade B recommendation by the HAS), which identifies the risk of chronicity in a patient with low back pain,
- the VAS scale, which assesses pain intensity,
- Functional Assessment using the DALLAS Self-Assessment Questionnaire (French version of the DRAD validated by the S.F.R. Spine Section), which assesses the impact of pain on quality of life,
- Patients aged between 30 and 60.

5.2 Non-inclusion criteria

Patients should not :

- Present with specific low back pain (systemic rheumatic pathology, compression due to a tumour, neurological pathology of central origin, etc),
- Present with psychiatric pathologies (apart from the usual comorbidities of chronic low back pain),

- Be pregnant or breastfeeding,
- Be under guardianship or curatorship,
- Be deprived of liberty or under a court protection order
- Be incapable of giving consent
- Being unable to complete questionnaires.

5.3 Procedure for early termination of research

The patient cannot participate simultaneously in another study in order to avoid interactions between studies, the cumulative effect of care and to guarantee the homogeneity of the groups. There is no exclusion period, and patients may participate in another clinical research protocol as soon as their participation in this study has ended.

5.4 Recruitment procedures

Patients are included in the protocol by each practitioner participating in the study, as part of their usual practice. Any patient consulting a practitioner participating in the study for chronic low back pain may be included in the study. The practitioner will ensure that the inclusion and exclusion criteria are respected. At the first appointment, the patient is informed about the study and given an informed consent form. A minimum of 48 hours elapses between the consent form being handed over and the patient's consent being collected.

6 Description of the study

6.1 Assessment criteria

6.1.1 Primary endpoint

The main evaluation criterion will be pain, measured using the VAS (visual analogue evaluation) scale (Moquet 1999) to assess pain levels, before and after each session.

6.1.2 Secondary evaluation criteria

- Functional assessment using the DALLAS Self-Assessment Questionnaire (French version of the DRAD validated by the S.F.R. Spine Section) completed at the start of treatment (1st session) and at the end of treatment (5th session);
- Assessment of Quality of Life using the SF-12 Quality of Life questionnaire (short form) completed at the start of treatment (1st session) and at the end of treatment (5th session);
- Psychological assessment using the STAI Y questionnaire (Spielberg's State-Trait Anxiety Inventory). The STAI YA measuring the state of anxiety is completed at the beginning and end of each session. The STAI YB measuring trait anxiety is completed at the start of treatment (1st session) and at the end of treatment (5th session).
- Any changes in the usual/current use of medication (analgesics and psychotropic drugs) prescribed for low back pain, by collecting information at each session.

6.2 Investigation method used

This is a cluster randomised clinical trial.

The methodology is pragmatic:

- Patients with common chronic low back pain were included, regardless of co-morbidities,
- The comparative intervention is physiotherapy,

- The instructions for implementing the experimental or control intervention are flexible, leaving the practitioner considerable latitude in the application of the intervention,
- The experimental and control intervention is deployed under all clinical conditions, with attention paid only to the dose delivered and to side effects,
- There is no follow-up of patients after the end of the study.

Three groups of low back pain patients will be selected:

- A group receiving only conventional physiotherapy;
- A group receiving both conventional masso-physiotherapy and fasciatherapy treatments;
- A group receiving fasciatherapy treatments only.

All patients will receive 5 sessions over a maximum period of 3 months. The frequency of the sessions will be determined by the practitioner, and the duration of each session may vary from 30 to 45 minutes in order to respect the usual ways of practising masso-physiotherapy and fasciatherapy. The study will be limited to 5 sessions because a previous survey of physiotherapists practising fasciatherapy showed that they carried out an average of 5 fasciatherapy sessions for the treatment of a patient with low back pain. In order to be able to compare the groups, we decided to use this number of sessions. As the number of physiotherapy sessions was defined by each physiotherapist following the physiotherapy assessment, there was a risk of differences in the number of sessions between the groups and between practitioners in the same group. For this reason, we also chose to limit the study to 5 sessions. However, patients will of course be able to continue with the sessions if this proves necessary.

The choice of specific techniques used by the practitioner is left to his or her discretion, whether for physiotherapy (massage, physiotherapy, exercises, etc.) or fasciatherapy (manual therapy, exercice, etc.).
The only additional procedures compared with ordinary care are the secondary assessment questionnaires.

6.3 Description of measures taken to reduce and avoid bias

Cluster randomised trial :

- Practitioners will be randomly assigned to one of the three study groups.
- All patients of the same practitioner will be assigned to the same randomisation group.
- Randomisation will be carried out in blocks of random size.

For the duration of the study, the practitioner undertakes to offer all patients eligible for inclusion the opportunity to take part in the study.

The multicentre nature of the study will minimise the practitioner effect inherent in this type of clinical research.

The self-administered questionnaires will be given to the patient in person, and the patient will be left alone while the questionnaire is completed.

Only the analysis of the data will be unblinded. In addition, the data will be anonymised to guarantee confidentiality.

7 Duration and organisation of the research

7.1 Expected duration of participation and description of the trial timeline

Study duration estimated at 28 months
Study start date (first patient included): 6 May 2021
End date (end of follow-up of the last patient in the study): September 2023
Total duration of patient participation in the study: 3 months maximum.
The date of completion of the study will be sent to the competent authority and the CPP within 90 days.
If the study is stopped prematurely, information will be sent to the competent authority and the CPP within 15 days.

7.2 Description of procedures performed on individuals (description of each visit)

7.2.1 Physiotherapy group (Group 1)

The masso-physiotherapy procedures recommended by the HAS (2005) and in accordance with the Nomenclature Générale des Actes Professionnels (NGAP) for the treatment of low back pain are as follows:

- physical exercise,
- massage,
- electrotherapy,
- spinal traction,
- adjuvant treatments (balneotherapy, cryotherapy, etc).

The choice of procedures and their combination is left to the discretion of the practitioner according to his initial assessment, the needs and possibilities of the patient and his therapeutic preferences (in accordance with the principles of EBM).
In this study, practitioners are encouraged to keep to the usual session time of between 30 and 45 minutes.

7.2.2 Masso-physiotherapy and fasciatherapy group (Group 2)

Practitioners carry out both masso-physiotherapy and fasciatherapy procedures at each session. The time devoted to each of these acts, and the order in which they are performed, is left to the discretion of the practitioners, depending on their assessment and clinical progress.
The length of sessions observed (Courraud, 2015) is 30 to 45 minutes. Participating practitioners will be encouraged to respect this time.

7.2.3 Fasciatherapy group (Group 3)

Practitioners only carry out fasciatherapy procedures using manual (myofascial, articular, visceral) and/or gestural treatment techniques. The choice of procedures, their order of application and their combination is left to the discretion of the practitioners, depending on their assessment and the patient's clinical progress.
The length of sessions observed (Courraud, 2015) is 30 to 45 minutes. Participating practitioners will be encouraged to respect this time.
The fasciatherapy techniques used in this study are 'non-manipulative' (i.e. no forced manipulation of joints or soft tissues), manual and gestural (no use of instruments or adjuvant products) and aim to restore the mechanical properties of the fascias (sliding, elasticity, mobility) in order to restore their function (continuity, contractility, sensitivity). The maneuvers are performed very slowly (with each stretch lasting about 15 seconds), resulting in a gradual and global stretching of the fascia in the

lumbar region and its distant connections. During this stretching, the practitioner establishes a support point (holding the stretched fascia) to alter the fascial tone. The practitioner evaluates areas of tension and tightness in the lumbar fascia to guide the treatment plan and identify the specific areas to address.

7.3 Description of the general logistical organisation of the trial

Practitioners will receive an observation booklet by post. Each practitioner will include between 3 and 5 patients in the study.
The promoter is responsible for gathering all the data collected at each phase of the study and at the end of the study. They will compile the data into an Excel file and transmit it to the statistician.

7.4 Inclusion criteria for practitioners

- Qualified physiotherapist,
- Private practice,
- Having a mixed practice combining conventional physiotherapy and fasciatherapy which is outside the scope of conventional practice,
- Having completed at least 105 hours of training in fasciatherapy.

8 Data collected

8.1 Source data

8.1.1 Definition

Source documents, defined as any original document or object making it possible to prove the existence or accuracy of data or facts recorded during the clinical study, will be kept for 15 years by FasciaFrance.

8.1.2 Observation booklet and investigator's brochure

Investigator brochure :

- Cover page mentioning "Investigator Brochure"
- Investigator instruction sheet
- General overview of the study
- Investigator memo: "What to do and when for each patient?"
- Filling instructions
- CV and characteristics sheet of the investigator physiotherapist
- Correspondence table
- A copy of the self-administered questionnaires

Observation book :

- Cover page mentioning "Observation Notebook"
- Patient eligibility sheet (inclusion and exclusion criteria)
- Patient dividers and temporal dividers for the investigator's reference
- Patient information form
- Patient consent form in two copies
- Administrative and medico-social patient sheet
- Anonymized evaluation questionnaires and the Visual Analog Scale (VAS) sheet, distributed according to the study protocol

- Patient follow-up sheet (dates, session description, medications, significant events), divided into five sections
- Serious Adverse Event (SAE) reporting sheet

8.2 Collection of personal data

8.2.1 Origin and nature

Age, sex, living environment, family situation, professional situation, duration of low back pain in months, treatments received, current treatments, leisure activities, sick leave.

8.2.2 Justification for using them

The data collected enables us to check that a patient is not included twice in the study.

8.3 Data circulation

8.3.1 Data capture and processing

The source data will be collected by the investigators and private practitioners, and collated by the investigators. The data will then be entered into the database in ACCESS format.
The people :

1. who will be responsible for implementing automated data processing: Mr Pereira, Ms Lambert data processors;
2. who will have access to the data: Ms Bertrand, Mr Dupuis and Mr Courraud, in charge of data entry

The data entry control procedure consists of a double reading of the data by the principal and secondary investigators, who certify on their honour that they have entered the data honestly as collected.

8.3.2 Data export / Multicentre study

Anonymised data will be collected by the physiotherapists, placed in an envelope and sent by post to the promoter FasciaFrance, 63 boulevard Berthelot 63000 Clermont-Ferrand.

8.3.3 Confidentiality

In accordance with the provisions concerning the confidentiality of data to which the persons responsible for quality control of research involving the human person have access (article L.1121-3 of the Public Health Code).
These people, in the same way as the investigators themselves, are subject to professional secrecy (under the conditions defined by articles 226-13 and 226-14 of the French Penal Code).
During the research or at its conclusion, the data collected on the persons involved and transmitted to the sponsor by the investigators (or any other specialist) will be rendered anonymous. Under no circumstances must the names or addresses of the persons concerned appear in clear text.
The co-ordinating investigator will ensure that each person taking part in the research has given written consent for access to their personal data, which is strictly necessary for the quality control of the research.
Anonymity is ensured by means of a correspondence table supplied to the investigator, filled in and kept by him alone. This correspondence table assigns a coded, completely anonymous identifier to each patient.

8.3.4 Archiving

The following documents will be archived by the name of the study at the FasciaFrance premises, under the responsibility of the coordinating investigator and FasciaFrance for 15 years after the end of the study.
These documents are :

- Protocol, observation book, any amendments,
- Original signed information forms and consents
- Individual data (authenticated copies of raw data)
- Follow-up documents
- Statistical analysis
- Final study report

At the end of the period of practical use, all documents to be archived will be placed under the responsibility of FasciaFrance.

No removal or destruction may be carried out without the agreement of the Developer. At the end of the 15 years, the Promoter will be consulted for destruction. All data, documents and reports may be subject to audit or inspection.

9 Statistical considerations

9.1 Data analysis method

9.1.1 General

Statistical analysis will be carried out using Stata software (version 15, StataCorp, College Station).

Continuous variables will be presented in the form of mean and standard deviation, subject to the normality of their distribution (Shapiro-Wilk test if necessary). In the event of non-normality, they will be presented in the form of median, quartiles and extreme values. Qualitative variables should be expressed in terms of numbers and associated percentages. Wherever possible, graphical representations should be associated with these analyses.

Patients will be described and compared between groups (group receiving conventional physiotherapy only, group receiving both conventional physiotherapy and fasciatherapy and group receiving fasciatherapy only) at inclusion according to the following variables: compliance with eligibility criteria, epidemiological characteristics, clinical characteristics and characteristics of any treatments.

A description of protocol deviations, patients allocated according to these deviations and reasons for drop-out will also be provided. The number of patients included and the inclusion curve will be presented by randomisation group.

The initial comparability of the groups will be assessed on the main characteristics of the participants and potential factors associated with the primary endpoint. Any difference between groups on any of these characteristics will be determined on the basis of clinical and not just statistical considerations.

Comparisons between randomisation groups will be made systematically (1) without adjustment (2) by adjusting for factors whose distribution could be unbalanced between groups.

All statistical tests will be carried out with a risk of error of the first kind α of 5%.

Part of the analyses concerning the secondary evaluation criteria should be mainly exploratory in nature. As discussed by several authors (*Bender, R.; Lange, S. Adjusting for multiple testing-When and how? J. Clin. Epidemiol. 2001, 54, 343-349; Feise, R.J. Do multiple outcome measures require p-value adjustment? BMC Med. Res. Methodol. 2002, 2, 8; Rothman, K.J. No adjustments are needed for multiple comparisons. Epidemiology 1990, 1, 43-46*), adjustment for the risk of error of 1st kind will not be proposed systematically, but on a case-by-case basis in the light of clinical and not purely statistical considerations.

9.1.2 Main analysis

In order to evaluate the specific benefits of fasciatherapy compared with physiotherapy for chronic low back pain in terms of variation in pain before and after each of the 5 sessions considered in this protocol, the main analysis will consider a mixed model approach for repeated data, making it possible to study the fixed group effects (group receiving only conventional physiotherapy, group receiving both conventional physiotherapy and fasciatherapy and group receiving fasciatherapy only), assessment time (session) and their interaction, while taking into account inter- and intra-patient variability (subject taken as a random effect), in addition to the (random) practitioner effect. The results will be expressed in terms of regression coefficient and 95% confidence interval.
It will also be proposed to study the difference between randomisation groups for each of the sessions. The results will be expressed in terms of effect size and 95% confidence interval.

9.1.3 Secondary analyses

The analyses described above for the primary endpoint will be supplemented in a multivariate situation by a mixed linear regression model to take into account the covariates selected on the basis of the results of the univariate analysis and their clinical relevance. The practitioner effect will be measured and taken into account in the statistical analyses as a random effect. The results will be expressed in terms of regression coefficient and 95% confidence interval.

Comparisons between randomisation groups (group receiving only conventional masso-physiotherapy, group receiving both conventional masso-physiotherapy and fasciatherapy and group receiving only fasciatherapy) concerning quantitative assessment criteria (functional assessment by the DALLAS self-assessment questionnaire, quality of life assessment by the SF-12 quality of life questionnaire, psychological assessment by the STAI Y questionnaire) will be carried out by Student's t-test or non-parametric Mann-Whitney test if the test conditions are met, assessment of quality of life using the SF-12 quality of life questionnaire, psychological assessment using the STAI Y questionnaire) will be carried out using Student's t test or the non-parametric Mann-Whitney test if the conditions of Student's test are not met (normality verified by the Shapiro-Wilk test and equality of variances by the Fisher-Snedecor test). Particular attention will be paid to the statistical distributions of the quantitative data under study. Where appropriate, the above analyses may be supplemented by more appropriate generalised linear regressions. The results will be expressed in terms of effect size and 95% confidence interval. In line with the recommendations proposed by Vickers and Altman, an ANCOVA-type analysis will also be proposed in order to compare the scores at the 5th session by adjusting for the values at the 1st session.
The STAI YB measuring anxiety status will be completed at the beginning and end of each session; the statistical analysis will therefore follow the same statistical analysis plan as that described for the primary endpoint.

Comparisons between the randomisation groups (conventional physiotherapy-only group, conventional physiotherapy and fasciatherapy group and fasciatherapy-only group) for categorical variables (e.g. functional assessment scores, quality of life assessment scores and psychological

assessment scores, categorised according to the statistical distribution or thresholds commonly reported in the literature) will be performed by chi-square test or Fisher's exact test. The results will be expressed in terms of absolute difference and 95% confidence interval. In multivariate situations, mixed generalized linear regression models (logit link function) will be considered. The results will then be expressed in terms of relative risk and 95% confidence interval.

Concerning the longitudinal analysis of categorical parameters (for example pain and STAI YB categorised according to statistical distribution or thresholds reported in the literature), the analysis will consider a mixed model approach for repeated data of the generalised linear type (logit link function for a binary dependent variable) making it possible to study the fixed effects of group, assessment time (session) and their interaction, while taking into account inter and intra patient variability (subject taken as a random effect), in addition to the (random) practitioner effect. The results will be expressed in terms of odds ratios and 95% confidence intervals.

9.1.4 Method for taking into account missing, unused or invalid data

A sensitivity analysis will be carried out to study the attrition bias, i.e. the quantity (level of attrition) and nature (independence from the randomisation group) of the missing data, and to propose the most appropriate data imputation method if necessary.

9.2 Justification of the number of subjects / power analysis.

In order to evaluate the specific benefits of fasciatherapy compared with physiotherapy for chronic low back pain in terms of variation in pain before and after each of the 5 sessions considered in this protocol, the estimate of numbers is based on recruitment capacity, the time required for experimentation and simulations concerning the effect size for risks of error of 1st and 2nd kind fixed respectively at 1.7% (two-sided with correction for multiple comparisons: group receiving only conventional physiotherapy, group receiving conventional physiotherapy and fasciatherapy and group receiving only fasciatherapy) and less than 20%.

Thus, if we estimate that a clinically relevant difference in pain assessment is between 1 and 2 points, for a standard deviation of the variation in pain of 1.5 to 2.5 points, we should include 30 to 40 patients for a statistical power of over 80% and an intra-individual correlation coefficient (5 sessions per subject) conventionally set at 0.5.

This proposal must be revised upwards in order to take into account the dropouts inherent in this type of protocol and the inter- and intra-practitioner variability (due to the experimental design of the cluster trial) which can be measured by the intra-class correlation coefficient and which it seems reasonable to estimate in the context of this project to be of the order of 0.05 to 0.2. It is therefore proposed to include 60 patients in each of the study groups.

9.3 Persons responsible for the analysis

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The statistical analysis plan and its successive versions will be kept in the study file. The statistical analysis plan may be revised during the course of the study, to take into account any changes made to the protocol or any other changes in the course of the study which have an impact on the statistical analyses initially planned.

10 Quality control and assurance

10.1 Investigator and sponsor commitment

The coordinating investigator undertakes to ensure that this study is carried out in compliance with the Public Health Act no. 2004-806 of 9 August 2004 as amended by Act no. 2012-300 of 5 March 2012 and by Order no. 2016-800 of 16 June 2016 concerning research involving the human person, implementing decree no. 2016-1537 of 16/11/2016 amending Chapter I^{er} of Title II of Book 1er of Part I of the Public Health Code concerning research involving the human person, as well as the orders in force.
The investigator also undertakes to work in accordance with the World Medical Association's Declaration of Helsinki (Tokyo 2004, revised).

10.2 Quality Assurance

The scientific collaborator appointed by the sponsor will ensure that the study is carried out correctly, that the data generated are collected in writing, documented, recorded and reported, in accordance with the Standard Operating Procedures implemented by the sponsor (*FasciaFrance*) and in compliance with Good Clinical Practice and the legislative and regulatory provisions in force.

10.3 Quality Control

The scientific collaborator guarantees the authenticity of the data collected as part of the study and accepts the legal provisions authorising the study sponsor to implement quality control.
The co-ordinating investigator and the associated investigators therefore agree to make themselves available for the Quality Control visits carried out at regular intervals by the scientific collaborator. During these visits, the following elements will be reviewed according to the predefined monitoring plan:

- Informed consent
- Adherence to the study protocol and the procedures defined within it
- Quality of data collected in the observation notebook: accuracy, missing data, consistency of data with "source" documents (medical records, appointment logs, original laboratory results, etc.)
- Management of any products involved

10.4 Observation booklet

All the information required by the protocol must be recorded in the observation books and an explanation given for any missing data. Data must be collected as it is obtained and transcribed into these notebooks in a clear and legible manner.
Erroneous data recorded in the case report forms should be clearly crossed out, and the new data should be copied next to the crossed-out information, accompanied by initials, the date and, where appropriate, a justification by the coordinating investigator who made the correction.

11 Ethical and regulatory considerations

11.1 Individual Protection Committee

The protocol, the information and consent form and the study observation booklet will be submitted to the designated Comité de Protection des Personnes for their opinion.

Notification of the CPP's favourable opinion and the summary of the research will be sent by the Sponsor to the Agence Nationale de Sécurité du Médicament et des Produits de Santé for information, before the start of the study.

11.2 CNIL

This study falls within the scope of the "Reference Methodology" (MR-003) in application of the provisions of the Act of 6 August 2004 on the protection of individuals with regard to the processing of personal data and amending the Act of 6 January 1978 on Data Processing, Data Files and Individual Liberties. This change was approved by a decision dated 5 January 2006. The study promoter (FasciaFrance) signed a commitment to comply with this "Reference Methodology" on 24 September 2018, its declaration number is 2207468v0.

11.3 Patient information

Patients will be fully and fairly informed, in comprehensible terms, of the objectives of the study and the nature of the information collected, and of their right to object at any time to the use of the data collected. The investigator must also inform subjects of the opinion issued by the Data Protection Committee.
All this information is given on an information form given to the patient. The patient's consent will be collected and recorded by the investigator. These documents have been approved by the Comité de Protection des Personnes and are to be used for the study in question, to the exclusion of any other document.

Two original copies will be co-signed by the investigating physiotherapist and the patient. One copy will be given to the patient, the second copy will be kept in the patient's medical file.

11.4 Feasibility of the study

- Competencies of the teams involved: All practitioners have a state diploma in masso-physiotherapy and must practice fasciatherapy (with a training course of at least 105 hours).
- Recruitment possibilities: A preliminary questionnaire distributed to members of Fascia France showed that 49 practitioners were willing to participate in the study. Of these, 41 could include patients with low back pain. The total number of potential patients for inclusion ranged between 200 and 370.
- Sessions take place in the practitioner’s office, which is the one the patients have contacted.

12 Financing and insurance

12.1 Study budget

- Datamanagement and statistical analysis package: €5,850,
- Management of case report forms and investigator brochures (production, printing, dispatch, etc.): 3,000 euros,
- Insurance: €728.

12.2 Insurance

In accordance with regulatory provisions, the promoter (*FasciaFrance*) has taken out civil liability insurance to cover any damage resulting from the research with the company Biomedic Insure. The policy number is 0100534514058 200123.

It should be noted that failure to comply with the legal conditions of the research (absence of CPP opinion, non-consent of the person, continuation of suspended or prohibited research) is a clause excluding cover.

13 Communication - Publication rules

Data will only be disclosed with the prior joint agreement of the investigator and the sponsor. The results will be communicated and published. The study will be recorded on an open-access website. The authors will be referenced as follows: Principal investigator : I. Bertrand, the co-investigator: C. Dupuis, statisticians: C. Lambert and B. Pereira and scientific collaborator: C. Courraud.

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