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Fascia manipulation for the treatment of muscle pain

Submission date	Recruitment status	[X] Prospectively registered
11/12/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/01/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/02/2023	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Muscle pain (myofascial pain) is a clear problem whose source is not fully understood. It may be a consequence of wrong fascial tension. It is assumed that restoration of the right fascial tension using manual methods, including deep massage (Fascia Manipulation [FM]), can reduce the patient's pain sensation.

Who can participate?
People of 18-40 years old of all genders with musculoskeletal pain for at least 1 week or healthy people for the control group

What does the study involve?
Participants will be randomly allocated to one of three therapies of Fascial Manipulation (different methods in different groups) or no treatment at all (control group).

What are the possible benefits and risks of participating?
Possible benefits: Reduction in myofascial pain and improvement in quality of life.
Risks: local pain caused by deep friction massage.

Where is the study run from?
The Jerzy Kukuczka Academy of Physical Education in Katowice, Poland

When is the study starting and how long is it expected to run for?
January 2020 to July 2021

Who is funding the study?
The Jerzy Kukuczka Academy of Physical Education in Katowice, Poland

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
(1/2017)

Study information

Scientific Title
Evaluation of Fascial Manipulation method on effectiveness in treatment of myofascial pain: a randomised controlled trial of various treatment protocols and their influence on pain levels, the reactivity of soft tissues, change in USG imaging (including elastography), EMG, range of motion, function, and Neurac's tests

Study objectives
Standard treatment protocol of Fascial Manipulation method has better effects than modified protocols or controls

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved DATE, The Jerzy Kukuczka Academy of Physical Education Ethics Committee (Uczelniana Komisja Bioetyczna AWF Katowice, ul. Mikołowska 72a, 40-065 Katowice, Poland; +48 322075152; a.smykla@awf.katowice.pl) ref: (1/2017)

Primary study design
Interventional

Study design
Double-blinded randomized control trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Myofascial pain

Interventions
Patients will be randomly allocated (using a computer program) to one of three groups, where each group will have a different therapy protocol and there will be a control group with no therapy as well. Each protocol will involve three treatments at intervals of 7-10 days, and a follow-up examination after 30 days. Study will be single-centre, and will take place at the premises of The Jerzy Kukuczka Academy of Physical Education.

Patients in treatments groups will undergo a Fascial Manipulation therapy (with different protocols), while the control group will not have any treatment. Patients will be randomly allocated to each group, using a computer program. Each protocol group will involve three treatments at intervals of 7-10 days, and a follow-up examination after 30 days.

Group 1: fascial manipulations according to the Stecco's concept (manipulation of 2 most densified myofascial trains, that stand in opposition to each other)
Group 2: fascial manipulations according to modified Stecco's protocol (manipulation of 2 myofascial trains, that stand in opposition to each other, but not that much densified as points of first group)
Group 3: fascial manipulations of random Stecco's centers of coordination
Control group: no treatment was provided

Intervention Type
Other

Primary outcome(s)
Measured before and after first therapy, after third therapy and after 30 days (follow-up):
1. Pain levels - VAS scale
2. Reactivity of soft tissues - MyotonPro device

Key secondary outcome(s)
Measured before and after first therapy, after third therapy and after 30 days (follow-up):
1. Change in USG imaging (including elastography) (USG Device)
2. EMG (EMG device)
3. Range of motion (digital inclinometer)
4. Function (FMS)
5. Proprioception (kinesthesia tests)
6. Neuromuscular activation test using Neurac test protocol.

Completion date
31/07/2021

Eligibility

Key inclusion criteria

1. Age 18-40
2. Presence of musculoskeletal pain for at least 1 week or healthy with no pain (for control group)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
All

Total final enrolment
54

Key exclusion criteria
1. Coexistence of a chronic or systemic disease
2. Pregnancy
3. Taking steroids, anti-inflammatory drugs or drugs that change blood coagulability
4. Acute injuries
5. Acute surgical interventions
6. The use of other therapeutic forms
7. Serious neurological disorders

Date of first enrolment
15/01/2020

Date of final enrolment
20/04/2021

Locations

Countries of recruitment
Poland

Study participating centre
The Jerzy Kukuczka Academy of Physical Education
Mikołowska 72A

Katowice
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Sponsor information

Organisation
The Jerzy Kukuczka Academy of Physical Education

ROR
https://ror.org/05wtrdx73

Funder(s)

Funder type
University/education

Funder Name
The Jerzy Kukuczka Academy of Physical Education in Katowice

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethics restriction on sharing data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/08/2022	27/02/2023	Yes	No