

The effect of Rolf Method of Structural Integration therapy on physical and mental characteristics

Submission date 28/11/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/12/2019	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/10/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Structural integration (SI) is a movement education and manual therapy that manipulates muscle and soft tissues to loosen tissue layers, reposition muscles, and facilitate alignment. The practitioner's main aim is to improve the biomechanical function, increase stability, improve balance, joint mobility, and put the body into proper alignment to facilitate improved motor patterns. The sensations of SI, when processed by the brain, may result in changes in emotion, mood, and mental wellbeing.

The aim of this study is to investigate the effects of SI on muscle and on measures of mental health.

Who can participate?

People aged 30 – 60 years with myofascial pain.

What does the study involve?

Participants will be randomly placed into three groups. One group will receive 10 weekly sessions of SI, one group will receive 10 weekly sessions of massage, and one group will not receive additional treatment. Before and after the treatment period, measurements of muscle will be taken and participants will be asked to fill out questionnaires.

What are the possible benefits and risks of participating?

Structural Integration Therapy gives optimally positioned in relation to the vertical gravity line acting on it, moves with greater freedom, fluidity, efficiency and grace. Movement becomes pleasure, breathing is easier, maintaining good posture comes easily. In addition, more efficient use of muscles allows the body to preserve energy and create more sophisticated and economical movement patterns. This is manifested by a decrease in feelings of stress, mental relaxation, increased energy and joy of life.

Where is the study run from?

Opole Medical School, Poland

When is the study starting and how long is it expected to run for?
January 2020 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Grzegorz Jędrzejewski
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Study website
<http://wsm.opole.pl/3210/5723/projekty-badawcze.html>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
Nil Known

Study information

Scientific Title

Assessing the elastic properties, postural stability, blood perfusion of soft tissues and selected psychological values after Structural Integration

Study objectives

1. Ten-session structural integration intervention causes observed improvement of the soft tissue elasticity, posture, blood perfusion and postural stability parameters
2. Ten-session structural integration intervention causes observed impact on psychological indicators

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/11/2019, Opole Medical School Bioethics Committee (68 Katowicka Street; 45-065; Poland; +48 774410882; biurorektora@wsm.opole.pl) ref: KB/205/FI/2019

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Myofascial pain, musculoskeletal disorders

Interventions

This will be a multicentre interventional study evaluating the effect of Structural Integration (SI) on soft tissue elastic properties, blood perfusion and postural stability parameters in women and men. The patients qualified to participate in the study will be randomly assigned to 1 of 3 groups (using Random Allocation Software 2.0):

1. SI-treated group – 10 sessions of Structural Integration treatment
2. SI-blinded group – 10 sessions of classic massage instead of SI
3. Control group without therapy

The target group of this study will include women and men with musculoskeletal disorders.

The research procedure will consist of several stages. First, an interview will be conducted with each participant and basic data (anthropometric measures) and psychological questionnaires will

be collected. Then, postural stability, blood perfusion and elastic properties of soft tissue will be measured. Then, each patient will undergo 10 SI session intervention (or not- according to their assigned group), one session a week. After 10 SI session, the patients will give another postural stability, blood perfusion and soft tissue elasticity examination.

The main outcomes will be to compare the results of postural stability (COP movement track data in mm), blood perfusion (perfusion units, PU), posture (Kineod), and soft tissue elasticity and stiffness (N/mm) before and after ten-sessions of intervention. All the participants of the project will be informed of the purpose of the study and the procedures to be conducted, and they will express their written consent for participation and processing of their data.

SI therapy and data collection will be conducted by certified therapists from Poland, Czech Republic and Italy. Moreover, all psychological questionnaires will be sent by e-mail to certified therapists from Germany, Switzerland, Great Britain, USA, Brazil and Japan affiliated in European Guild for Structural Integration (EGSI). All psychological questionnaires will be sent by e-mail to the project manager before and after 10 SI session.

10 series of the Structural Integration:

Session 1: Increase length and pliability of soft tissues on the anterior aspect of torso, allowing freer respiratory movement of ribs, of soft tissues connecting shoulder girdle to rib cage, and hips to pelvis. Areas: Lateral aspect of hips and thigh, hamstrings, lateral and frontal aspect of shoulders, front of rib cage.

Session 2: Increase consistency of soft-tissue pliability in feet, ankles, and knees, increasing the support they provide the upper body. Areas: Feet, ankles, and legs to knee inclusive.

Session 3: Increase anterior-posterior and cephalic-caudal pliability in soft tissues of the lateral aspect of the body, left/right and anterior/posterior balance, increase independence of thorax from pelvis. Areas: Lateral aspects of body from hip to shoulder inclusive.

Session 4: Increase pliability, left/right and anterior/posterior balance of soft tissues of the medial aspect of legs and floor of pelvis. Areas: Medial aspect of legs and deep outward rotators of hip.

Session 5: Increase pliability and left/right and surface to deep balance in soft tissues spanning the anterior aspect of the pelvis and lumbar spine. Areas: Quadriceps femoris, abdominals, psoas, and iliacus.

Session 6: Increase pliability and left/right and surface to deep balance in soft tissues spanning posterior aspect from heel to midback. Areas: Posterior aspect of feet, ankles, knees, legs, hips, pelvis, sacrum, lumbar and lower dorsal vertebra.

Session 7: Increase pliability and left/right and anterior/posterior balance in soft tissues of the cranium and cervical spine. Areas: All aspects of neck and cranium including jaw.

Session 8: Increase soft-tissue pliability and left/right balance in the hands, wrists, elbows, and arms; increase biomechanical flow between upper extremities and spine. Areas: Hands, wrists, forearms, elbows, upper arm, and shoulders.

Session 9: Increase soft-tissue pliability spanning the lower extremities through hips and pelvis; increase biomechanical flow between lower extremities and spine. Areas: Feet, ankles, legs, and pelvis.

Session 10: Further optimize biomechanical flow through extremities, shoulder, and pelvic girdles to spine; increase overall uniformity of tonus. Areas: as needed to optimize biomechanical integration.

Intervention Type

Other

Primary outcome measure

At baseline and 10-weeks:

1. Myofascial tissue stiffness and elasticity measured using the MyotonPro device (Myoton AS, Tallinn, Estonia) and IndentoPRO Tissue Compliance Meter
2. Muscle blood perfusion measured using Laser Speckle Contrast Analysis (LASCA)

The following skeletal muscles will be measured in supine position:

Mm. brachio-radialis (BR): forearm in intermediate position. The measurement point will be between the lateral epicondyle of the humerus and the styloid process of the radial bone- 5 cm below the lateral epicondylitis, on the previously marked line.

Mm. biceps brachii, caput longum (BB): forearm in supine position. The measurement point will be between line connecting the medial epicondyle of the humerus and acromion- 7 cm above the medial epicondyle, on a previously determined line.

Mm adductores: The measurement point will be between line connecting base of patella and ischial tuberosity- 20 cm above the ischial tuberosity.

The following skeletal muscles will be measured in prone position:

Mm. Triceps surae- medial head: feet hang freely behind the table. We determine the line connecting the calcaneus with the medial epicondyle of the femoral bone. We measure 10 cm below the epicondyle on the previously designated line

Mm. Erector spinae: 3 cm laterally from the L3 spinous process. Forehead based on the dorsal side of the hand

Mm. Trapezius: 3 cm from the Th3 spinous process. Forehead based on the dorsal side of the hand

3. Balance and gait analysis measured using the Body balance - Accu Gait - Dynamographic platform

3.1. Measurement of forces (Fx, Fy, Fz) and forces moments (Mx, My, Mz) in statics and dynamics

3.2. Measurement of the center of pressure on the platform (COP) parameter and all its derivatives

Secondary outcome measures

At baseline and 10-weeks:

1. General health measured using the General Health Questionnaire-28 (GHQ-28)
2. Mood measured using the Mood Adjective Check List – (UMACL)
3. Emotion measured using the Emotional Intelligence Questionnaire (INTE)
4. Posture and line curvature measured using Kineod (three-dimensional analysis)
5. Body image perception measured using the Body Image Questionnaire (BIQO)
6. Locus of control measured using the delta questionnaire

Overall study start date

01/01/2019

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Age between 30-60 years
2. Consent of the patient to participate in the study
3. Permission of the attending therapist
4. The general state of well-being of the patient on the day of examination assessed by the therapist

Participant type(s)

All

Age group

Adult

Lower age limit

30 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

500

Key exclusion criteria

1. Pregnancy (in all stages)
2. BMI>30
3. The occurrence of pain during sessions
4. Active cancer or a cancer history of <1 year after the end of treatment
5. Psychosomatic disorders
6. Rheumatoid arthritis
7. Acute connective tissue disorders

Date of first enrolment

01/01/2020

Date of final enrolment

30/06/2025

Locations**Countries of recruitment**

Poland

Study participating centre

Opole Medical School

Physiotherapy Department

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Opole

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Sponsor information

Organisation

Opole Medical School

Sponsor details

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Sponsor type

University/education

Website

<http://wsm.opole.pl/1/strona-glowna.html>

ROR

<https://ror.org/000bjk220>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal, also plan on preparing abstracts for conference papers.

Intention to publish date

01/01/2022

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2020	13/10/2020	Yes	No