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Joint hypermobility: effect of a strength training program on disability and function

Submission date
01/07/2013

Recruitment status
No longer recruiting

Registration date
16/07/2013

Overall study status
Completed

Last Edited
13/08/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Joint hypermobility (some or all of a person's joints have an unusually large range of movement) is often seen in rheumatologic patients (patients suffering from a painful disorder affecting the joints, muscles, tissues around the joints, and bones) and it often remains unclear how disabling the joint hypermobility is for a person. Generally women are more often affected and the hypermobility usually decreases with age. Currently there is not clear which treatment is best. This study aims to explore the effect of a 12-week strength training program on the pain and disability of women with joint hypermobility.

Who can participate?
The study will involve women aged between 20 and 40 years with generalized joint hypermobility who are interested in doing a 12-week strength training program in a medical fitness centre.

What does the study involve?
Participants in the study are randomly allocated to one of the two groups: one group will immediately start with a strength training program, the other will not change lifestyle habits for 12 weeks. The changes in muscle strength, performance in daily life and disability between these two groups will be compared. After the 12 weeks of waiting the second group will also do the training and then for all participants the effects in the long term (three months after training until one year) are compared to the condition at the beginning of the study.
The strength training will involve exercises for thigh and calf muscles, as well as for the back and the abdomen, all performed on fitness machines. The training will be guided by an experienced physiotherapist. Two training sessions each week of about 50 min should be performed during the 12 weeks. In week 1, 3 and 6 an individual instruction session will take place, while the other sessions are performed under general supervision.
To assess the effects, several measurements will take place before the training, after the training or waiting period (12 weeks) and three months after the end of the training. The measurements will test the strength of the knee extension and knee flexion muscles. Stair climbing as daily-life activity and the passive mobility of the knee are also measured. To detect changes in the muscles, the bone and muscle properties of the thigh and lower leg will be measured by means of quantitative computer tomography (pQCT).

For measuring the effects on pain and disability in daily life three questionnaires will be used, which are filled in by the participants. At all measurement points the questionnaires will also be filled in, as well as six and 12 months after the end of the training.

What are the possible benefits and risks of participating?
The benefit for the participant is a guided and supervised 12-week strength training program free of charge. The training and the functional measurements do not involve any more risk for injury or pain than normal daily life or sports activities. The measurements with the pQCT lead to a low radiation dose, comparable to 5% of the dose during a transatlantic flight. The total time for the training will be about 24 hours and for the assessments 10-12 hours per participant.

Where is the study run from?
Bern University Hospital - Department of Physiotherapy, in Collaboration with the Department of Rheumatology, Clinical Immunology and Allergology of the Bern University Hospital, Switzerland.

When is the study starting and how long is it expected to run for?
The study is planned to start in August 2013 and the end of recruitment is estimated to be in Summer 2014. The last follow-up will take place in October 2015. The recruitment is planned for one year or until 50 participants are involved in the study.

Who is funding the study?
The Bern University Hospital, Department of Physiotherapy

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Insel-Nr: 2303

Study information

Scientific Title
Joint hypermobility: effect of a strength training program on disability and function: a randomised controlled trial

Study objectives
Primary aim is to look at immediate effects of a specific strength training program on muscle strength, functional movements, pain and disability in daily-life of hypermobile women, compared to a control group.

Secondary aims are:
1. To evaluate the feasibility of this strength training program for hypermobile women
2. To look at the long-term effects of the training intervention, especially the influence of the strength training on pain and disability in daily-life.

Primary Hypothesis:
A specific 12 week strength training leads to an increase of muscle mass and muscle strength in women with generalised joint hypermobility.

Additional hypotheses:
H1, feasibility: A specific 12 week strength training can be completed by women with generalised joint hypermobility without severe side effects or an increase of pain and disability.
H2, quality of life: A specific 12 week strength training leads to an improved quality of life in women with generalised joint hypermobility, due to less disability and pain in daily-life activities.
H3, mid-term physiological changes: The improvement in muscle mass and muscle strength in women with generalised joint hypermobility due to a specific 12 week strength training is holding on three months after the end of the training.
H4, mid-term quality of life: The improvement in quality of life in women with generalised joint hypermobility due to a specific 12 week strength training is holding on three months after the end of the training.
H5, long-term quality of life: The improvement in quality of life in women with generalised joint hypermobility due to a specific 12 week strength training is holding on six months after the end of the training.
H6, long-term quality of life: The improvement in quality of life in women with generalised joint hypermobility due to a specific 12 week strength training is holding on one year after the end of the training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Canton Bern, 07/02/2013, ref: 222/12

Study design

Single-centre single-blinded randomised controlled trial with waiting list design

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
Joint Hypermobility

Interventions
Strength training for 12 weeks with two training sessions of about 50- 60 minutes weekly in a medical training fitness, totally 24 training sessions.

First two weeks: complex method, two series with 25 repetitions at a resistance of 40-50% of the one repetition maximum (1RM).

Second phase (week 3 to 12): hypertrophy training, three series with 12 repetitions at 80% of 1RM. The Training is instructed and supervised by an experienced physiotherapist.

Exercises: 10 min warm-up on cycle ergometer or stepper, leg-press, knee flexion and knee extension in open chain, hip abductors, triceps surae on the leg press (heel-rise), back extension and abdominals.

Comparator: 12 weeks without changing lifestyle habits

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Effect of strength training is the increase in muscle strength, measured as maximum isometric strength and the rate of force development (RFD) of knee extensors and knee flexors on a custom-built strength measurement table with a force transducer. Measured at baseline, after training respectively waiting period (12 weeks) and three months after end of the training.

Secondary outcome measures

1. Ground reaction forces (GRF) and muscle activity (EMG) during stair ascent and descent: GRF measured with force plates on a custom-built six step standard stair at self-selected speed. EMG of following leg muscles with surface electrodes: vastus lateralis, vastus medialis, biceps femoris and semitendinosus.
2. Passive tibial translation: passive ventral displacement of the tibia against the femur in the ventral direction, measured with an adapted Aircast Rolimeter.
3. Peripheral quantitative computer tomography (pQCT): Muscle and bone variables measured at thigh and lower leg, as well as distal radius: Bone density of tibia, femur and radius, muscle cross-sectional area at thigh, calf and forearm.
4. Three questionnaires for pain and disability, as well as general health: 1. Medical Outcomes Study Short Form 36-Item (SF-36). 2. Arthritis Impact Measurement Scales 2 (AIMS-2). 3. Self-developed questionnaire for pain and disability in functional activities using 5 point likert-scales.
GRF and EMG during stair climbing, tibial translation and pQCT will be measured at baseline, after training respectively waiting period (12 weeks) and three months after end of the training. The questionnaires will be filled in at all these time points and additionally six and twelve months after end of the training.

Overall study start date
08/06/2012

Completion date
14/12/2016

Eligibility

Key inclusion criteria
1. Women with generalized joint hypermobility
2. 20 to 40 years old
3. Normal body mass index (BMI) (between 18-30 kg/m2)
4. At least 6/9 points in the Beighton score
5. Right knee extension beyond 10°
6. Able to understand German questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Female

Target number of participants

50

Total final enrolment
51

Key exclusion criteria
1. Surgery of the legs or lumbar spine in the last two years
2. Doing more than four hours per week of regular intense sports
3. Pregnancy or less than one year after delivery
4. Known genetic diseases of connective tissue like Marfan syndrome and Osteogenesis imperfecta, as well as Ehler-Dahnlos-syndrome I and II

Date of first enrolment
25/10/2013

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
Department of Rheumatology, Clinical Immunology and Allergology
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Sponsor information

Organisation
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Sponsor type

Hospital/treatment centre

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ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bern University Hospital - Department of Physiotherapy (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and analysed during this study are included in the results publication as a supplementary file.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/02/2021	10/02/2021	Yes	No
Abstract results	results presented at the World Congress of Physiotherapy		13/08/2021	No	No