ISRCTN17982776 https://doi.org/10.1186/ISRCTN17982776

Exercise and bone health in adolescents engaged in different sports

Submission date
27/08/2015

Recruitment status
No longer recruiting

Registration date
28/08/2015

Overall study status
Completed

Last Edited
26/11/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoporosis, which literally means “porous bone”, is a common condition which makes bone weak, brittle and more likely to break. This progressive illness is difficult to treat and so prevention is considered to be the most effective approach. There is a great deal of evidence that some forms of exercise support the development of strong bones because the strain put on bones causes them to become more dense (osteogenic). Activities that include running and jumping, for example football or basketball, are thought to be osteogenic. However, sports which do not put this strain on bones, such as cycling or swimming, are not thought have an osteogenic effect. Further research is needed to investigate whether added short bouts of weight-bearing (osteogenic) exercise can be used to help strengthen bones for people who only do non-osteogenic exercise. Plyometric jump training (PJT) has been suggested as a good way of strengthening bones in teenagers. The aim of this study is to find out whether PJT can affect the bone strength in adolescents who take part in osteogenic and non-osteogenic exercise, over a three year period.

Who can participate?
Males between 12-14 years old who engage in at least 3 hours of osteogenic (football) or non-osteogenic (cycling or swimming) sports per week in the last three years, and aged matched boys who have not engaged in these sports in the last three years.

What does the study involve?
Participants who play football, cycle or swim are randomly assigned to one of two groups, intervention or control. Those in the intervention group perform the plyometric jump training (PJT) 10 minutes per day, three to four times a week, for a period of nine months, as well as continuing to play sports. Those in the control group do not have any additional activities and play their sports only for the length of the study. Participants who do not play sports do not do any additional activity, and will have the same measurements as the children in the sport groups for comparison. Information about the participants bone health, body fat, diet and physical fitness is gathered one year before the intervention, just before the intervention and immediately after the intervention. Follow up assessments are also completed six months after the intervention, and again after a further six months.

What are the possible benefits and risks of participating?
The benefits that are associated with PRO-BONE are the early detection of poor bone health and improved bone mineralization development (the strengthening of bone with minerals such as calcium) during growth. The following risks have to be considered: The technique used to obtain bone outcomes uses ionizing radiation. However, this technique uses a minimal radiation dose (similar to spending a day outside in the sunshine), and has been widely used for research purposes with child participants worldwide. In addition, passing soreness in the legs might appear because of the jumping exercises. The staff involved in the research team will show the participants some stretching exercises to help this to disappear.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
April 2014 to March 2018

Who is funding the study?
European Union Seventh Framework Programme (Belgium)

Who is the main contact?
Dr Luis Gracia-Marco

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
“Effect of a PROgram of short bouts of exercise on BONE health in adolescents involved in different sports”: the PRO-BONE study

Acronym
PRO-BONE

Study objectives
The objectives of the PRO-BONE study are:
1. To longitudinally assess bone health and its metabolism in adolescents engaged in osteogenic (football) and non-osteogenic (cycling and swimming) sports.
2. To examine whether a short and inexpensive plyometric jump training programme is positively associated with bone mineral content (BMC), bone mineral density (BMD) and bone turnover in adolescent footballers.
3. To examine whether a short and inexpensive plyometric jump training programme is positively associated with BMC, BMD and bone turnover in adolescent cyclists and swimmers, and if so, to examine if this stimulus is enough to counteract the expected negative consequences of these non-osteogenic sports in bone health.
4. To follow-up BMC, BMD and bone turnover over 12 months after plyometric jump training.

The proposed research will provide important data about the association between a simple, feasible and inexpensive plyometric jump training and bone health in adolescents engaged in different sports. In addition, it will show if the effect of this intervention also differs between sports, expecting a greater effect in cyclists and swimmers than footballers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Review Sector of Directorate-General of Research (European Commission), 27/08 /20013, ref:618496
2. Sport and Health Sciences Ethics Committee (University of Exeter), 27/11/2013, ref: 2014/766
3. National Research Ethics Service Committee South West – Cornwall & Plymouth, 23/04/2014, ref: 14/SW/0060

Study design
Mixed longitudinal design that involves four cohorts of males aged 12–14 years at the beginning of the study. This is a single-centre trial that recruits footballers, cyclists, swimmers and controls from sport clubs/schools who will be followed over a period of 33 months with measurements at five timepoints.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Osteoporosis

Interventions
Following 12 months of sport specific training, the randomisation process will start in each sport group and participants will be divided into two sub-groups to perform a plyometric jump training (PJT) programme as follows:
1. Intervention programme groups (sport + PJT)
2. Sport groups (sport only)
It has been shown that 7 to 9 month PJT programmes can effectively improve BMC and/or BMD at different skeletal sites in children and adolescents and to maintain the benefits for 3 years after the intervention. Therefore, a progressive PJT (~10 min/day) will be performed by intervention groups 3 to 4 times/week (depending on progression).
An additional group of control patients (who do not do any sport) will be measured at the same timepoints as the rest of the participants, to compare them with the intervention programme groups and sport groups.

Before the intervention, trained staff will ensure that participants fully understand and correctly execute the different jumps and a research assistant will meet with the participants to observe, demonstrate and review the jumps.

Participants are instructed to perform a number of counter-movement jumps (CMJ) and squat jumps (SJ) on a hard surface. Jumps will be performed before and after school and before going to bed. The CMJ will be performed by bending the knees immediately prior to the jump. The CMJ activates the stretch-shortening cycle in the muscles, resulting in greater power production in the legs compared to a SJ. For the SJ participants will squat down until the knees are bent at 90 degrees, then they will immediately jump vertically as high as possible, landing back on the ground on both feet simultaneously. For this technique, the participant starts from a stationary semi-squatting position, or pauses at the lower level of the squat before jumping upwards. This removes the factor of the stretch-shortening cycle. The reliability and validity of the CMJ and SJ has been previously reported.

These jumps are associated with important ground reaction forces, i.e. for a counter-movement it is about 5 times body weight (BW), compared to 3.5 times BW for jumping jacks. Similarly, the highest rates of change in force are 493 times BW/s for the CMJ, as shown in an independent sample of boys and girls. A diary will be used to record the number of jumps performed each day. Both the intensity and number of jumps will be increased progressively in 3 levels of 12 weeks each. Intensity will be modified using ankle weights (no weight at level 1, 1 kg at level 2 and 2.5 kg at level 3 at each foot). With this an increase in BW between 2 to 5 kg will be achieved.

Intervention Type
Other

Primary outcome measure
Primary outcomes will be measured at baseline, after 12 months (before the intervention starts), nine months later (once the intervention ends, six months after the third timepoint (as a follow-up), and after a further six months (as a second follow-up).
1. Bone mineral content, density and area of different regions and sub-regions will be obtained after performing a whole body, hip (left and right) and lumbar spine scans. Dual-energy x-ray absorptiometry scanner (GE Lunar Healthcare Corp., Madison, WI, USA) will be used to scan participants at these four sites due to the evidence of site specific impact of sports participation. All DXA scans and analyses will be performed using the GE enCORE software (2006, version 14.10.022).
2. Stiffness index will be measured using qualitative ultrasound with a Lunar Achilles Insight and the OsteoReport PC software version 5.x + (TM Insight GE Healthcare, Milwaukee, WI, USA). This portable device measures bone stiffness using ultrasound waves and is considered a valid and radiation-free method to assess bone health in children.
3. Bone turnover markers will be measured using serum procollagen type 1 aminoterminal propeptide (P1NP) and isomer of the Carboxi-terminal telopeptide of type 1 collagen (CTX-1) as markers for formation and resorption, respectively.
4. Vitamin D will be measured by measuring the serum 25-hydroxyvitamin D [25(OH)D] in the blood. For the scope of the present study 25(OH)D will be analysed as it has been shown to interact with PA to improve bone mass in adolescents. Blood samples will be collected between 8:00 am and 9:00 am following a 12-hour fast period. A research team experienced in sampling techniques will collect capillary blood samples (~1.2 mL) from a pre-warmed hand into heparin fluoride coated microvettes (CB 300 tubes, Sarstedt Ltd, Leicester, UK) that will be placed immediately on ice. The microvettes will be centrifuged at 1000 x G per min for 15 minutes at 4° C and plasma will be separated in Eppendorf tubes of at least 60 µL, 110 µL and 60 µL and stored at −80°C for future analysis of P1NP, CTX-1 and 25(OH)D respectively.

Secondary outcome measures
1. Anthropometry and sexual maturation will be measured using a number of techniques. Stature (cm), seated height (cm) and body mass (kg) will be measured by using a stadiometer (Harpenden, Holtain Ltd, Crymych, UK; precision 0.1 cm; range 60–210 cm), a sitting height table (Harpenden, Holtain Ltd., Crymych, UK; precision 0.1 cm; range 32–109 cm) and an electronic scale (Seca 877, Seca Ltd, Birmingham, UK; precision 100 g; range 2–200 kg) respectively. Body mass index (BMI) will be calculated as body mass (kg) divided by the height (m) squared. Waist circumference will measured at the midpoint between the lowest rib cage and the top of the iliac crest. Hip circumference will be measured around the widest portion of the buttocks. All measurements will be undertaken by the same trained researcher using the type Seca 201 measuring tape (Seca Ltd, Birmingham, UK; precision 0.1 cm; range 0–205 cm). All anthropometrical measurements will be performed three times and the mean will be calculated. Pubertal maturation will be self-reported by the participants using adapted drawings of the five stages (Tanner) of pubertal hair development.
2. Fat and lean body mass will be measured using a dual-energy x-ray absorptiometry scanner. The body will be segmented in accordance to standard procedures to evaluate not only regional bone mass, but also lean mass and fat distribution. Information about hip strength index, fat mass ratios (trunk/total, legs/total, arms and legs/trunk), android and gynoid regions will also be obtained and have been previously validated in adolescents.
3. Body volume will be measured with BodPod (Body Composition System, Life Measurement Instruments, Concord, California, USA) as it can effectively predict visceral adipose tissue in

children and determine the changes of body fat percentage over time. Two measurements will be performed and if there is a difference of more than 150 mL in body volume, a third measurement will be taken.
4. Percentage body fat will be measured using the portable Bioelectrical impedance (BIA) device (Tanita BF-350, Tokyo, Japan; range 2–200 kg; precision 100 g; body fat % range 1-75%; body fat% increments 0.1%). Participants will be measured in a fasting state and will remove any metal objects and socks prior the measurements. They will be positioned on the posterior surface barefoot according to manufacturer's instructions.
5. Physical fitness will be measured using a number of tests. Cardiorespiratory fitness (aerobic performance) will be obtained using the 20 m shuttle run test, which has been shown to be both reliable and valid in youth. The participants will be tested at the end of the day following a standardized warm up. The standing long jump test and the Abalakov jump test will be performed at least half an hour before the 20 m shuttle run test and following a standardized warm up and with 2 minutes rest between the two tests. Participants will perform the Abalakov jump test on a jump mat (Probotics Inc., Huntsville, USA). For both muscular tests the participants will perform 1 familiarization effort and 2 maximal effort jumps. The mean height and distance (in cm) of the maximal efforts will be used as criterion of measure. The reliability of both tests in adolescents was previously described and is acceptable to be used in this population.
6. Physical activity will be measured using two different methods: 1) International Physical Activity Questionnaire and 2) a wrist accelerometer (GENEActiv, GENEA, UK). The validity and reliability of the accelerometer and of the International Physical Activity Questionnaire has been established previously in children and adolescents.
7. Assessment of dietary intakes of calcium and vitamin D will be completed by using 24-h dietary recall questionnaires. CompEat Pro software (Nutrition systems, VIS Visual Information Systems Ltd., UK) will be used for the analysis.

Overall study start date
01/04/2014

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Males aged between 12–14 years who engage (≥3 h/week) in osteogenic (football) and/or non-osteogenic (swimming and cycling) sports in the last 3 years or more
2. Males aged between 12–14 years who do not engage in any of these sports (≥3 h/week) in the last 3 or more years (control group).

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
12 Years

Upper age limit

14 Years

Sex
Male

Target number of participants
A minimum of 105 participants will be recruited. This includes 30 swimmers, 30 cyclists and 30 footballers (all of them will continue with their regular training and competition but 15 of each group will additionally perform the jumping intervention). Finally, a control group (n=15) will also be recruited

Key exclusion criteria
1. Participation in another clinical trial
2. Any acute infection lasting until < 1 week before inclusion
3. Medical history of diseases or medications affecting bone metabolism or the presence of an injury (before inclusion) that may affect participation in their respective sports and/or any variable considered in the present study (i.e. doing the PJT)
4. Non-Caucasian participants

Date of first enrolment
01/05/2014

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
CHERC (Children’s Health and Exercise Research Centre)
College of Life and Environmental Sciences
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Sponsor type
University/education

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Not defined

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
1. We aim to publish a descriptive manuscript about baseline bone health and metabolism differences among participants (raw and adjusted analyses) at the end of 2015
2. A manuscript with 1-year follow-up differences between groups will be published by mid 2016
3. A manuscript to analyze the effect of the jumping intervention will be published at the beginning of 2017

4. Follow up results will be published in 2017 and 2018
5. Further publications will be published throughout the duration of the study by using other variables included (i.e. physical fitness, fat mass, etc)

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol :	11/04/2015		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	results	01/04/2018		Yes	No
Results article	results	10/10/2018		Yes	No
Results article	results	17/11/2018		Yes	No
Results article	results	01/03/2019		Yes	No
HRA research summary			28/06/2023	No	No