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Does resistance exercise with/without a nutrition supplement improve bone and muscle strength in women?

Submission date
03/07/2017

Recruitment status
No longer recruiting

Registration date
07/07/2017

Overall study status
Completed

Last Edited
05/09/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Bone loss and muscle loss can occur together for a number of reasons, including dietary deficiencies and lack of exercise. This can result in osteoporosis (bone weakness), fractures, falls and disability. The aim of this study is to find out whether a simple resistance exercise programme with or without a leucine-enriched essential amino acids (EAAs) and vitamin D supplement, can improve bone and muscle health.

Who can participate?
Community-dwelling women aged 65 or over

What does the study involve?
Participants are randomly allocated to one of three groups. The first group takes part in a home-based exercise intervention. The second group also takes part in the same exercise intervention but is also asked to consume an amino acid and vitamin D supplement alongside this. The third group does not need to do anything different (control group). The exercise programme consists of progressive resistance exercises with the aim of strengthening the dominant wrist and forearm. The exercise intervention is 20-30 minutes, three times a week. The dietary supplement is a unique leucine-enriched essential amino acid (EAA) protein and vitamin D blend, taken twice daily (with breakfast and with lunch). The interventions end at 6 months. Bone density, body composition, muscle strength and function are measured at the start of the study and after 3 and 6 months. One blood sample is taken to test important markers including bone turnover at the start and at 3 months.

What are the possible benefits and risks of participating?
At the third appointment (week 24), participants receive feedback on all of their results. If they are found to have low bone density or deficient bone turnover, participants are advised to make an appointment with their GP and take their results with them to that appointment. Lifestyle advice is provided by the study team. At the end of the study (week 24), everyone is given information on the exercise programme and the overall results of the study. There is a chance for some slight discomfort with the blood test, although this will be very brief and feel more like

a sharp scratch. A trained and experienced phlebotomist conducts the blood test and all regulatory procedures are followed. Because measuring bone density uses x-rays, this involves a small dose of radiation. The total dose from participation in this study is about 28µSv, which is equivalent to about 4 days of natural background radiation. As with all exercise, there is a risk of injury with the exercise programme and tests. The exercise programme is home-based and to minimise the risk of injury, participants are provided with instructions on how to perform the exercises safely (e.g., perform the exercises where it is safe and there are no trip hazards). The programme is also progressive and matched to participant ability at their first appointment.

Where is the study run from?
Leeds Beckett University (UK)

When is the study starting and how long is it expected to run for?
October 2016 to June 2018

Who is funding the study?
Leeds Beckett University (UK)

Who is the main contact?
Dr Karen Hind

Contact information

Type(s)
Scientific

Contact name
Dr Karen Hind

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Protocol serial number
1

Study information

Scientific Title

Efficacy of a targeted resistance exercise programme with and without leucine and vitamin D-enriched protein supplementation for preventing bone loss and improving muscle strength in older women: a randomised controlled trial

Acronym
ELDAS

Study objectives
Bone loss with advancing age is exacerbated by muscle loss, sedentary lifestyle and dietary deficiencies. Leading to increased fragility fracture risk and disability, age-related bone loss represents a significant challenge to current and future health systems. Interventions that can improve both bone and muscle strength or slow their rate of decline with age are urgently needed. Bone strength is augmented by mechanical loading through exercise and direct muscle force. Regarding nutrition, the positive effects of essential amino acids (EAAs) on muscle function and early animal model studies suggest bone anabolic potential through effects on bone metabolism.

The study hypothesis is that targeted resistance exercise will show positive effects on bone turnover at 3 months and bone density and muscle strength at 6 months, and that these effects will be augmented in women who also take the leucine and vitamin D supplement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds Beckett University Research Ethics Committee, 29/03/2017, ref: DW2017001

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Sixty women aged 65+ years will be randomised to one of three groups. The minimisation method of randomisation will be employed. The first participant will be fully randomised to an intervention and thereafter, further participants will be randomised so that the groups are matched for age and bone mineral density. This minimises the imbalance between groups at baseline.

Group A: Home-based exercise intervention
Group B: Home-based exercise intervention and leucine and vitamin D enriched supplement
Group C: No intervention (no treatment)

The dietary supplement comprises of a unique leucine-enriched essential amino acid (EAA) protein and vitamin D blend, taken twice daily (with breakfast and with lunch). The exercise programme consists of progressive resistance exercises with the aim of strengthening the dominant wrist and forearm. The exercise intervention is 20-30 minutes, 3 x week and unilateral for the upper body. As such the non-dominant forearm and wrist will be exercised, with the dominant forearm being the within-person control. The interventions end at 6 months.

Intervention Type
Mixed

Primary outcome(s)
1. Biochemical markers (serum measures of osteocalcin (bone turnover), C-terminal telopeptide (bone resorption), pro-collagen 1 intact N-terminal (bone formation), 25[OH] D (vitamin D), insulin-like growth factor-1), measured at 0 and 3 months
2. Bone mineral density of the forearm, measured using DXA at 0, 3 and 6 months

Key secondary outcome(s))
1. Bone mineral density of the spine and hip, measured using DXA at 0 and 6 months
2. Lean and fat mass, measured using DXA at 0, 3 and 6 months
3. Senior Fitness Test (hand grip, sit to stand test, gait speed over 6 m, and 6 minute walk test), measured at 0, 3 and 6 months
4. Wrist strength, measured using 30 sec wrist curl test at 0, 3 and 6 months

Control outcomes
1. Lifetime physical activity and physical activity in the last 12 months, measured using the bone specific physical activity questionnaire at 0, 3 and 6 months
2. Dietary evaluation using a self-report 3-day diary at 0, 6, 12 and 18 weeks

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Community-dwelling women aged 65 or over
2. Not currently engaged in upper body exercise training (within last 6 months)
3. Not using any medications for osteoporosis and not using any medications that can affect bone metabolism
4. Do not have an underlying disease that impairs bone metabolism, such as hyper /hypoparathyroidism, renal disease and malabsorptive conditions

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Senior

Sex
Female

Key exclusion criteria
1. Currently engaged in upper body exercise training (or within last 6 months)
2. Using medications for osteoporosis
3. Using any medications that can affect bone metabolism
4. Have an underlying disease that impairs bone metabolism, such as hyper/hypoparathyroidism, renal disease and malabsorptive conditions
5. Recent forearm fracture (within the last 6 months)

Date of first enrolment
24/06/2017

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Beckett University
Headingley Campus
Leeds
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Sponsor information

Organisation
Leeds Beckett University

ROR
https://ror.org/02xsh5r57

Funder(s)

Funder type
University/education

Funder Name
Leeds Beckett University

Alternative Name(s)
Leeds Beckett

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Karen Hind.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	case study of one patient in this study	13/06/2023	05/09/2023	Yes	No