

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

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		<input type="checkbox"/> Protocol
Registration date 07/07/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/09/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2016

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

Age group

Senior

Sex

Female

Target number of participants

60

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**

England

United Kingdom

Study participating centre

Leeds Beckett University

Headingley Campus

Leeds

United Kingdom

LS6 3QS

Sponsor information

Organisation

Leeds Beckett University

Sponsor details

Quality and Assurance Governance Officer
Faculty of Health and Social Sciences
City Campus
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United Kingdom
LS1 3HA

Sponsor type

University/education

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

Publication and dissemination plan

1. Cross-sectional findings will be published as soon as available
2. The main trial findings will be submitted for publication in summer 2018
3. All participants and relevant charities/organisations will be invited to an event for public dissemination (fact-sheets, talks and Q&As)

Intention to publish date

30/06/2018

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