Title of Project: The Bone Booster Study (Feasibility)

Researcher name: Dr. Vicky Stiles

Invitation and brief summary:

You are invited to take part in a research study at the University of Exeter.

This study will test how easy it is to use a new app. The app tracks your everyday movement and turns bone-loading impacts into a simple Impact Score. This helps you see how short bursts of movement add up across the day.

Before you decide, please read the following information carefully. It explains why the study is being done and what taking part would involve.

Take time to think about it. You may wish to discuss it with family or friends.

If you have any questions, please contact the research team.

Purpose of the research:

Bones respond to impact. Short bursts of moderate-impact activity can help support bone strength over time.

Stronger bones are linked to a lower risk of osteoporosis (bone thinning) and fractures in later life.

Research suggests that **aiming for around 50 moderate impacts on most days** may help support bone health.

We have developed an app to help people track this type of activity. The app works in a similar way to a step counter, but it focuses on impact activity instead.

This study will help us understand how easy the app is to use and how people interact with it.

Why have I been approached?

We are inviting around 400 healthy men and women aged 40–60 years to take part.

You have been contacted through the PROTECT platform because you have agreed to be contacted about other research studies.

Who can take part?

You may take part if:

- You are aged 40–60 years
- You are generally healthy
- You do not have a muscle, joint, heart, or lung condition that limits physical activity

- You feel able to take part in normal everyday movement
- You own a smartphone (iPhone or Android)
- You use your smartphone in your everyday life
- Your smartphone operating system is between: **iPhone: iOS 18 – 26**; or **Android 11 and above**

Hints for finding this information:

On iPhone (iOS):

- Go to Settings → General → About
- You'll see the iOS version

On Android phones:

- Go to Settings → About phone / Device
- Look for Android version
- On some phones, you may need to tap Software information to see the operating system version

Who cannot take part?

You cannot take part if you:

- Have had surgery in the last 3 or 6 months
- Are pregnant
- Have been told you must only do supervised physical activity
- Have had a blackout, faint, or concussion in the last year
- Have osteoporosis, osteopenia, arthritis, joint or back problems
- Have spinal cord disease
- Have a heart, lung, metabolic, or neurological condition
- Are having cancer treatment
- Have Kidney problems
- Live with two or more ongoing medical conditions
- You do not own and use a smartphone in your everyday life
- The smartphone's operating system is less than iPhone: iOS 18; or Android 11

What would taking part involve?

This study is completed entirely online.

First, you will complete questionnaires through the PROTECT platform. These will ask about your physical activity, health, your awareness of bone health and osteoporosis and your views on using apps for health. There are no right or wrong answers.

You will then download **The Bone Booster** app onto your own smartphone and use it for 3 months. The app uses your phone's built-in sensors to record movement and detect impact activity. It will also record how often you use the app.

The app includes onboarding questions that will ask you your first name (used only to personalise your app), year of birth, age and height. **The app also asks you to confirm that you have no diagnosis of osteoporosis.** It will also ask you some simple activity questions. Based on these responses, **simple guidance** to help you work towards and maintain **50 moderate impacts on most days** of the week is shown at the top of the **activity check-in page**. You can complete activity check-ins to get new guidance whenever you want.

An Impact Score is shown at the top of the homepage. This shows how many moderate impacts you build up each day. Everyday movement is tracked in the background and you can also choose to open the app and complete suggested impact exercises. If you choose to complete any activities outside your home, please do so in familiar pedestrian areas or routes, wearing suitable clothing, and let someone know where you'll be for your own safety. The Impact Score helps you see how your daily activity is adding up compared to a guide of **50 moderate impacts on most days**.

The app also includes a **Bone Boost graph**. This **shows how your impacts build across the day**. Each bar represents a short time period, making it easy to see when your most active bursts of movement occurred.

The Bone Boost score itself is still under development and is not currently displayed. This is intentional and part of the ongoing research.

Depending on app use, the app may send you 1–2 notifications per day.

Because the app runs on your smartphone, it will use a small amount of battery power. **Please ensure your phone is sufficiently charged** during the day, especially when you are away from home.

At the end of the 3-month period, you will delete the app on your smartphone and complete the questionnaires again. This will help us understand whether using the app has changed your awareness of bone health and your views on using digital tools to support it.

You will also have the **option to take part in an online focus group** to share your experience and feedback.

What are the possible benefits of taking part?

We cannot promise that taking part will benefit you directly. However, you may find it interesting to learn more about your everyday impact activity and how it adds up across the day. The app also includes information about bone health and osteoporosis, which may help you better understand how impact activity relates to your bones.

By taking part, you will help us understand how easy the app is to use. Your feedback will help improve digital tools designed to support awareness of bone-loading activity.

What are the possible disadvantages and risks of taking part?

As the app encourages impact activity, taking part in this study involves movements such as walking, marching, heel drops, short bursts of running (10–20 steps), or small jumps. The choice of activity is up to you.

For most people, these activities are safe. You may notice mild muscle soreness, especially when trying something new. This is usually temporary. Only do what feels comfortable for you. You can stop at any time.

If you experience any problems, you can report them through the PROTECT platform. The research team will monitor all reports. If a serious issue is thought to be related to the study, it will be reviewed and the study may be stopped.

What will happen if I don't want to carry on with the study?

Taking part is voluntary. You can withdraw from the study at any time, without giving a reason.

If you choose to withdraw, no new data will be collected from you.

If you withdraw before the data are combined and analysed, any identifiable or coded data we hold about you will be deleted from our study records.

Data that have already been anonymised and included in analysis will not be able to be removed. This will occur 3 months after the testing period has concluded.

Withdrawing will not affect your involvement in the PROTECT study or your relationship with the University of Exeter.

How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing informationgovernance@exeter.ac.uk. or at https://www.exeter.ac.uk/departments/cgr/ig/

Data will be managed in accordance with UK GDPR, the Data Protection Act 2018, and University of Exeter policies (https://www.exeter.ac.uk/departments/cgr/ig/policy/).

App data will be coded so that you cannot be directly identified. Data are encrypted when transferred and stored securely on University systems. If you take part in a focus group, it will be held using a secure University Zoom account. The sessions will be recorded and transcribed. Once the transcripts have been checked for accuracy, all recordings will then be permanently deleted, resulting in anonymisation of the transcripts.

Files that contain personal details (such as your name or contact information) will be deleted three months after the study analysis is complete. When results are reported, data will be combined so that individuals cannot be identified. Anonymised data will be stored securely and may be used in future ethically approved research. Your identifiable data will not be shared outside the research team.

Will I receive any payment for taking part?

Following completion of the 3-month testing period & follow up questionnaires, you will receive a £20 Love2shop voucher. The voucher will be sent to your email address through the PROTECT platform. If you choose to take part in the follow-up focus group, you will receive an additional £25. This will be paid by bank transfer from the University of Exeter.

What will happen to the results of this study?

The results will help us decide whether the app and the technology behind it should continue to be developed.

A summary of the findings may be published in academic journals and presented at conferences. No individual participants will be identified in any reports.

Additionally, the anonymised data will be securely stored indefinitely and used in future research projects exploring bone health, osteoporosis, or similar areas of digital technology.

Who is organising and funding this study?

This study is organised by researchers at the University of Exeter.

It is funded by the Medical Research Council (MRC) through a gap fund that supports early-stage development of new health technologies.

Who has reviewed this study?

This project has been reviewed by the Public Health and Sport Sciences Research Ethics Committee at the University of Exeter (Reference Number 12397718).

Contact for any questions or requests regarding your participation in this research:

If you have any questions about the study or your participation, please contact the research team:

Email: bonebooster@exeter.ac.uk

If you need to **report a problem or side effect during the study,** please log in to your study area on the PROTECT platform and complete the reporting form.

To contact the Research Ethics Committee please email shs-ethics-admin@exeter.ac.uk

You can also contact the University Research Ethics and Governance Team if you wish to make a complaint or comment
please email cgr-reg@exeter.ac.uk,

or

Dr Sean Jennings
Head of Research Governance, Ethics and Compliance
University Research Services, University of Exeter
Innovation Centre, Rennes Drive Exeter, EX4 4RN
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Thank you for your interest in this project.

Consent to Take Part

- I confirm that I have read the information sheet (version 1.1_24_02_26) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
- I understand that relevant sections of the data collected during the study, may be looked at by members from the research team, other individuals from The University of Exeter, and I give permission for these individuals to have access to my records.
- I understand that taking part involves the collection of acceleration data from an app downloaded to my smartphone, which will be stored separately from my personal data, meaning the data cannot be directly linked to me.
- I understand that taking part involves the collection of data on year of birth, weight, height & phone model.
- I understand that taking part involves me logging into an App I've downloaded via a link in an email from the project team and sharing data collected by the App to a cloud-based storage facility when the App is linked to Wi-Fi (link-anonymised storage of data).
- I understand that taking part involves me completing questionnaires about my health and background, my knowledge of osteoporosis and bone health, my experience with digital health tools and my experience of the smartphone app.
- I understand that my anonymised raw data & results will be:
  a. Stored indefinitely on the project database;
  b. Shared with other researchers for use in future research projects (secondary data analysis);
  c. Included in publications in academic journals, project websites, media publications;
  d. Included in teaching or training materials for use in university activities and public engagement activities.
- I agree to take part in the above study.