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Improving bone health in paediatric cancer survivors through exercise

Submission date 27/03/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/04/2020	**Overall study status** Completed	
Last Edited 19/09/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Despite a 13% increase in childhood cancer incidence over the last 40 years, the 5-year survival rate has now been set up at 80%. However, curing cancer has important consequences. One of the most common issues in paediatric cancer survivors is a reduction of the bone mineral density. Recent evidence highlights the survivorship phase (rather than the treatment one) for performing interventions to improve bone health. Exercise can improve bone health in healthy children; however, this effect has not been studied yet in this population.
This intervention will analyse the influence of a 9-month exercise intervention on bone mass in growing paediatric cancer survivors.

Who can participate?
Paediatric cancer survivors 6 to 18 years of age at recruitment, ≥1 year from diagnosis and not currently receiving treatment for cancer.

What does the study involve?
Participants will be randomly allocated to the intervention or control group. The intervention will involve a combination of strength and jumping activities. Likewise, the intervention will aim to improve muscular fitness before implementing mechanical loading through jumping exercises. This exercise program will be completed at home and delivered through an online platform. The control group will not perform the exercise program, but they will be offered the same program at the end of the intervention. Nutritional and sun exposure counselling will also be given to both groups.

What are the possible benefits and risks of participating?
The main expected benefit of participating in this study is the improvement in bone mass which lowers the risk of having future bone diseases, such as osteoporosis. The risks of participating are similar to those derived from exercise practice.

Where is the study run from?
1. Virgen de las Nieves Hospital (Spain)
2. Reina Sofía Hospital (Spain)

When is the study starting and how long is it expected to run for?
May 2020 to January 2023

Who is funding the study?
1. “la Caixa” Foundation (Spain)
2. Ministry of Science and Innovation (Spain)

Who is the main contact?
Dr Luis Andrés Gracia Marco, lgracia@ugr.es

Study website
http://profith.ugr.es/?lang=en

Contact information

Type(s)
Public

Contact name
Dr Luis Andrés Gracia Marco

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LCF/ BO/PR19/11700007

Study information

Scientific Title
Effect of an online exercise program on bone health in paediatric cancer survivors

Acronym
iBoneFIT

Study objectives
A 9-month plyometric-exercise intervention improves bone health in paediatric cancer survivors

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/01/2020, Review Committee for Research Involving Human Subjects of Andalucía (Comite de Etica de Investigación de Cordoba. Avda. Menéndez Pidal s/nº 14004-Córdoba, Spain; no tel. provided; no email provided), ref: 4500

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Paediatric cancer survivors at risk of endocrine dysfunction

Interventions
iBoneFIT is a multicentre randomized controlled trial. Participants will be allocated into two groups: an intervention group (a 9-month exercise intervention) and a control group (no exercise program for 9 months; updated 11/08/2020: no exercise intervention). Specific dietary advice regarding calcium and vitamin D will be given to both groups. Simple randomization will be applied using an online tool.

Intervention group: The program will be delivered via an online platform. Nutritional and sun exposure counselling will also be given. The 9-month intervention will involve 3 to 4 days/week of a home-based jumping programme. The jumping programme takes approximately 10 min/day and all activities will be performed on hard surfaces. In brief, the jumping intervention will consist of 3 stages and the volume of each stage will increase progressively. In stage 1 (2 months), participants will perform body mass-based squats; in stage 2 (3 months), participants will perform squat jumps; in stage 3 (4 months), participants will perform countermovement jumps.

Furthermore, five behavior change techniques were used to increase participants' engagement (i. e. action planning and goal setting, provide instructions and demonstrations of how to perform the behavior, self-monitoring of behavior, provide feedback on performance and information about health consequences). Likewise, a gamification design (i.e. points, rankings and rewards) was included to improve the interest, incentive and purposiveness of this non-game program.

Control group: no exercise program will be delivered. At the end of the intervention, the exercise program will be offered to all participants in the control group.

Educational advice and leaflets about the importance of healthy lifestyles, nutrition and sun exposure will be given to both groups on a monthly basis.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 20/06/2022:
1. Bone mineral density measured using Dual-energy X-ray Absorptiometry (DXA) at baseline and post-intervention
2. Bone architecture and geometry measured using specific software for Hip Structural Analysis at baseline and post-intervention
3. Spine Trabecular Bone Score measured using the software iNsight at baseline and post-intervention
4. Volumetric bone parameters measured using the software 3D-SHAPER at baseline and post-intervention

Previous primary outcome measures from 11/08/2020 to 20/06/2022:
1. Bone mineral density measured using Dual-energy X-ray Absorptiometry (DXA) at baseline, post-intervention and follow-up (4 months post-intervention)
2. Bone architecture and geometry measured using specific software for Hip Structural Analysis at baseline, post-intervention and follow-up (4 months post-intervention)
3. Spine Trabecular Bone Score measured using the software iNsight at baseline, post-intervention and follow-up (4 months post-intervention)
4. Volumetric bone parameters measured using the software 3D-SHAPER at baseline, post-intervention and follow-up (4 months post-intervention)

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1. Bone mineral density measured using Dual-energy X-ray Absorptiometry (DXA) at baseline, post-intervention and follow-up (4 months post-intervention)
2. Bone architecture and geometry using specific software for Hip Structural Analysis Trabecular Bone Score at baseline, post-intervention and follow-up (4 months post-intervention)

Secondary outcome measures
Current secondary outcome measures as of 20/06/2022:
1. Anthropometric measurements measured using an electronic scale for body mass and a precision stadiometer for body height (body mass index is also calculated). Body composition measured using DXA and a bioimpedance scale. Additionally, somatic maturation measured using the prediction of years from peak height velocity using validated algorithms for children. All of these parameters are assessed at baseline and post-intervention.
2. Physical fitness measured using the ALPHA fitness test battery at baseline and post-intervention. In addition, perceived physical fitness measured by the International Fitness Scale

3. Physical activity and sedentarism measured using tri-axial accelerometers at baseline and post-intervention. Furthermore, these variables are measured using the Youth Activity Profile questionnaire. Additionally, the influence of previous physical activities on bone is measured using the bone-specific physical activity questionnaire.
4. Calcium intake measured using a food-frequency questionnaire at baseline and post-intervention. Vitamin D status measured using the vitamin D questionnaire at baseline and post-intervention
5. Biochemical markers measured using venous blood samples between 8:00 and 10:00 after an overnight fast at baseline and post-intervention
6. Psychological distress measured using State-Trait Anxiety Inventory for Children (STAIC-T), Children Depression Inventory (CDI) and Positive Affect Schedule for children (PANAS-C) at baseline and post-intervention
7. Well-being measured using Subjective Happiness Scale (SHS), Life Orientation Test-Revised (LOT-R) and Positive Affect Schedule for children (PANAS-C) at baseline and post-intervention
8. Quality of life measured using the Paediatric Quality of Life Inventory (PedsQLTM 4.0 Generic Core Scales) at baseline and post-intervention

Previous secondary outcome measures from 11/08/2020 to 20/06/2022:
1. Anthropometric measurements measured using an electronic scale for body mass and a precision stadiometer for body height (body mass index is also calculated). Body composition measured using DXA and a bioimpedance scale. Additionally, somatic maturation measured using the prediction of years from peak height velocity using validated algorithms for children. All of these parameters are assessed at baseline, post-intervention and follow-up (4 months post-intervention).
2. Physical fitness measured using the ALPHA fitness test battery at baseline, post-intervention and follow-up (4 months post-intervention). In addition, perceived physical fitness measured by the International Fitness Scale.
3. Physical activity and sedentarism measured using tri-axial accelerometers at baseline, post-intervention and follow-up (4 months post-intervention). Furthermore, these variables are measured using the Youth Activity Profile questionnaire. Additionally, the influence of previous physical activities on bone is measured using the bone-specific physical activity questionnaire.
4. Calcium intake measured using a food-frequency questionnaire at baseline, post-intervention and follow-up (4 months post-intervention). Vitamin D status measured using the vitamin D questionnaire at baseline, post-intervention and follow-up (4 months post-intervention)
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8. Quality of life measured using the Paediatric Quality of Life Inventory (PedsQLTM 4.0 Generic Core Scales) at baseline, post-intervention and follow-up (4 months post-intervention)

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1. Biochemical markers measured using venous blood samples between 8:00 and 10:00 after an overnight fast at baseline, post-intervention and follow-up (4 months post-intervention)
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3. Physical fitness measured using the ALPHA fitness test battery at baseline, post-intervention and follow-up (4 months post-intervention)

4. Psychological distress measured using State-Trait Anxiety Inventory for Children (STAIC-T), Children Depression Inventory (CDI) and Positive Affect Schedule for children (PANAS-C) at baseline, post-intervention and follow-up (4 months post-intervention)
5. Well-being measured using Subjective Happiness Scale (SHS), Life Orientation Test-Revised (LOT-R) and Positive Affect Schedule for children (PANAS-C) at baseline, post-intervention and follow-up (4 months post-intervention)
6. Quality of life measured using the Paediatric Quality of Life Inventory (PedsQLTM 4.0 Generic Core Scales) at baseline, post-intervention and follow-up (4 months post-intervention)

Overall study start date
01/05/2019

Completion date
25/01/2023

Eligibility

Key inclusion criteria
1. Paediatric cancer survivors 6 to 18 years old
2. ≥1 year from diagnosis
3. Have been exposed to radiotherapy or chemotherapy
4. Not currently receiving treatment for cancer

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
A minimum of 116 participants (58 per group)

Total final enrolment
116

Key exclusion criteria
1. Simultaneous participation in another study
2. Previous diagnosed anorexia nervosa/bulimia; known pregnancy, alcohol or drug abuse
3. Children requiring chronic oral glucocorticoid therapy or pharmacologic agents for reduced BMD other than calcium or vitamin D
4. Presence of an injury (before inclusion) that may affect daily life activities and can be

aggravated by exercise
5. Have a lower limb prosthesis

Date of first enrolment
01/09/2020

Date of final enrolment
21/03/2022

Locations

Countries of recruitment
Spain

Study participating centre
Virgen de las Nieves Hospital
Ribera del Beiro, s/n
Granada
Spain
18014

Study participating centre
Reina Sofía Hospital
Menendez Pidal, s/n
Córdoba
Spain
14004

Sponsor information

Organisation
University of Granada

Sponsor details
Cuesta del Hospicio s/n
Granada
Spain
18071
+34 958 243 000
informa@ugr.es

Sponsor type
University/education

Website
http://www.ugr.es/

ROR
https://ror.org/04njjy449

Funder(s)

Funder type
Charity

Funder Name
“la Caixa” Foundation

Alternative Name(s)
Caixa Foundation, Fundación Caixa, 'la Caixa', Fundación Bancaria Caixa d'Estalvis i Pensions de Barcelona, Fundación 'la Caixa', Fundação 'la Caixa', Fundación Bancaria Caixa d'Estalvis i Pensions de Barcelona, 'la Caixa'

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

Funder Name
Ministerio de Ciencia e Innovación

Alternative Name(s)
CienciaGob, Ministerio de Ciencia e Innovación de España, Ministry of Science and Innovation, Spanish Ministry of Science and Innovation, Ministry of Science and Innovation of Spain, Spain, Ministry for Science and Innovation, Ministeri de Ciència i Innovació, MCIN, MICINN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan

The exploitation of iBoneFIT results will concern the following steps: (i) identifying the exploitable results, (ii) identifying the best exploitation strategy for every result, (iii) monitoring the market needs and the target users, and (iv) establishing a good communication channel among industry, academia and market. The host institution will consider open source exploitation strategies in order to gain visibility. The Research and Knowledge Transfer office (OTRI) (http://otri.ugr.es/), provides professional support for researchers, evaluating the research and outputs and managing the University research's strategy. iBoneFIT will promote Open Access publications, according to the 2003 Berlin Declaration. Publications will be uploaded to the Universities open access repositories.

Intention to publish date

31/05/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/10/2020	14/10/2020	Yes	No