ABSTRACT

Objectives Aboriginal and Torres Strait Islander Australians have a substantially greater fracture risk, where men are 50% and women are 26% more likely to experience a hip fracture compared with non-Indigenous Australians. Fall-related injuries in this population have also increased by 10%/year compared with 4.3%/year in non-Indigenous Australians. This study aims to determine why falls and fracture risk are higher in Aboriginal and Torres Strait Islander Australians.

Setting All clinical assessments will be performed at one centre in Melbourne, Australia. At baseline, participants will have clinical assessments, including questionnaires, anthropometry, bone structure, body composition and physical performance tests. These assessments will be repeated at follow-up 1 and follow-up 2, with an interval of 12 months between each clinical visit.

Participants This codesigned prospective observational study aims to recruit a total of 298 adults who identify as Aboriginal and Torres Strait Islander and reside within Victoria, Australia. Stratified sampling by age and sex will be used to ensure equitable distribution of men and women across four age-bands (35–44, 45–54, 55–64 and 65+ years).

Primary and secondary outcome measures The primary outcome is within-individual yearly change in areal bone mineral density at the total hip, femoral neck and lumbar spine assessed by dual energy X-ray absorptiometry. Within-individual change in cortical and trabecular volumetric bone mineral density at the radius and tibia using high-resolution peripheral quantitative computed tomography will be determined. Secondary outcomes include yearly differences in physical performance and body composition.

Ethical approval Ethics approval for this study has been granted by the Monash Health Human Research Ethics Committee (project number: RES-19-0000374A).

Trial registration number ACTRN12620000161921.

INTRODUCTION

Background and rationale

Aboriginal and Torres Strait Islander Australians have a substantially greater fracture risk than non-Indigenous Australians. For minimal trauma fractures, defined as fractures that result from trauma equal to or less than a fall from standing height, Aboriginal and Torres Strait Islander men and women are 50% and 26%, respectively, more likely to experience such fractures compared with non-Indigenous Australians. Hip fractures also occur at a much younger age in Aboriginal and Torres Strait Islander people compared with non-Indigenous Australians, for men, this is 65 versus 81 years, while for women, this is 74 versus 83 years, respectively. Additionally, over a 10-year period (1999–2009), there was a disproportionate increase in age-related hip fracture rates by 7.2% per year for Aboriginal and Torres Strait Islander Australians, while rates declined by 3.4% per year in non-Indigenous Australians. The occurrence of minimal trauma fractures in older people has been associated with an increased risk of subsequent fracture and premature
mortality. Prevalence of chronic disease, such as cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD), is also higher in Aboriginal and Torres Strait Islander Australians; these comorbidities are associated with increased risks of osteoporosis, falls and fracture. However, currently, there are no data or studies that explain the mechanisms for increased fall and fracture risk in Aboriginal and Torres Strait Islander Australians.

One of the primary causes of fracture is falls, with several studies reporting a greater number of falls among Aboriginal and Torres Strait Islander people compared with non-Indigenous Australians. The number of fall-related injuries increased by an average of 10% per year in Aboriginal and Torres Strait Islander Australians compared with 4.3% per year in non-Indigenous Australians during years 2007–2011. In a 9-year follow-up study (2003–2011), the rates of hospitalisation for fall-related fractures were increased by 3.0% annually for Aboriginal and Torres Strait Islander people compared with 0.7% annually for non-Indigenous Australians.

To date, only two studies have reported areal bone mineral density (aBMD) among Aboriginal and Torres Strait Islander Australians—both in relatively small samples. The first study measured whole-body aBMD in 16 Aboriginal and 16 non-Indigenous women in Sydney, Australia and reported no significant differences between the two groups. The second study measured hip and spine aBMD in a group of 166 Aboriginal and Torres Strait Islander Australians aged ≥17 years (58% women) living in very remote and regional (outer) locations. It showed greater femoral neck aBMD in Aboriginal and Torres Strait Islander adults compared with non-Indigenous adults (n=36). No differences were reported in lumbar spine aBMD, even after adjusting for body composition. Despite higher aBMD being reported for Aboriginal and Torres Strait Islander Australians in this study, their fracture prevalence is higher compared with non-Indigenous Australians. The findings from that study were limited as the participants were not representative of the Aboriginal and Torres Strait Islander population (12% live in very remote and 19% live in outer regional areas) and data were from two studies that were not empirically designed to examine aBMD, but instead to assess CKD, metabolic and inflammatory associations with body composition. Small group numbers and recruitment of participants from two diverse regions (Darwin, Northern Territory and Thursday Island, Queensland) may have further increased the variance in the study sample. In addition, body composition (fat and lean mass) of the non-Indigenous group was not provided, which may have influenced the data, as fat and lean mass have differing effects on aBMD.

Dual-energy X-ray absorptiometry (DXA) is the current clinical gold-standard tool used to predict fracture risk and measures aBMD (g/cm²). A T-score (SD from young adult mean aBMD) ≥−2.5SD is defined as osteoporosis by the WHO. Although DXA has many advantages, with good precision, very low radiation and providing measurements at sites prone to osteoporotic fracture, DXA cannot fully account for bone size or measure trabecular and cortical bone density—known contributors to bone strength and fracture risk. These components of bone strength may be compromised in Aboriginal and Torres Strait Islander Australians, contributing to their higher fracture rates. In particular, the separate bone compartments (cortical vs trabecular), bone geometry (shape and size), microarchitecture (organisation of trabecular bone) and bone strength (buckling vs strain). However, with advancements in bone imaging technology, these components of bone strength can now be measured using high-resolution peripheral quantitative computed tomography (HR-pQCT). Evidence shows that bone microarchitecture and estimates of bone strength from HR-pQCT using microfinite element analysis (µFEA) are more accurate at determining minimal-trauma fracture risk than DXA-derived aBMD.

It should be noted, the utility of DXA scans go beyond musculoskeletal outcomes. Specifically, DXA scans of the lateral spine can also be used to assess abdominal aortic calcification (AAC), a marker of advanced vascular disease, also linked to measures of atherosclerosis at other vascular beds, greater cardiovascular disease risk, poorer muscle strength, greater injurious fall and fracture risk. Collectively, these studies demonstrate a critical nexus between the vascular and musculoskeletal systems, which warrant investigation in Aboriginal and Torres Strait Islander Australians.

During 2008–2012, CVD was the leading cause of death among Aboriginal and Torres Strait Islander Australians, with an age-standardised death rate of 1.5 times that of non-Indigenous Australians. CVD, particularly atherosclerosis, and osteoporosis are common in the ageing population. There is an overlap in the risk factors for CVD and osteoporosis, which may partly explain the higher prevalence of CVD and fractures among Aboriginal and Torres Strait Islander Australians. Recently, associations between AAC, lower aBMD, greater bone loss over time and fragility fractures have been reported. Peripheral artery disease is associated with peripheral vascular calcification (PVC) in the legs, with a greater prevalence reported in people with diabetes. A novel quantitative method using HR-pQCT can now not only assess the presence of PVC but also the severity, as the density of the calcified vessels can now be measured.

The prevalence of T2DM is three times greater among Aboriginal and Torres Strait Islander people compared with non-Indigenous Australians, with diabetes-related mortality almost seven-fold greater in the Aboriginal and Torres Strait Islander population. Those with T2DM are more prone to falls due to reduced balance caused by complications such as peripheral neuropathy, retinopathy and reduced muscle strength, all of which are well-recognised risk factors for falls. Despite generally demonstrating higher aBMD, fracture risk is increased in those with T2DM due to decreased bone strength.
specifically increased cortical porosity and cortical pore volume.\textsuperscript{23} 30 Shared factors may result in a higher risk of both T2DM and osteoporosis among Aboriginal and Torres Strait Islander Australians, independent of each other.

The prevalence of CKD is high among Aboriginal and Torres Strait Islander Australians\textsuperscript{31} as national data reported one in five Aboriginal and Torres Strait Islander people had indicators of CKD and an estimated glomerular filtration rate (eGFR) <90 mL/min/1.73 m\textsuperscript{2} with albuminuria.\textsuperscript{32} End-stage kidney disease is reported to be 10–15 times higher in Aboriginal and Torres Strait Islander Australians compared with non-Indigenous Australians.\textsuperscript{33} 34 There are also other contributing risk factors with CKD in Aboriginal and Torres Strait Islander Australians, such as social disadvantage, remoteness and lifestyle differences.\textsuperscript{31} Renal osteodystrophy in CKD is multifaceted and encompasses increased fibroblast growth factor 23,\textsuperscript{35} secondary hyperparathyroidism\textsuperscript{36} and abnormal calcium-phosphate metabolism.\textsuperscript{37} Muscle wasting and sarcopenia is highly prevalent in those with CKD,\textsuperscript{38} increasing frailty and falls risk,\textsuperscript{39} and consequently increasing fracture risk.

There is sparse data on musculoskeletal health knowledge and/or attitudes of Aboriginal and Torres Strait Islander people. Chronic pain is frequently associated with chronic diseases, such as osteoporosis and other musculoskeletal disorders. A qualitative study on the perceptions of pain among Aboriginal people from a rural region in southeast Queensland revealed that Aboriginal people were reluctant to report their pain due to negative experiences within the healthcare system.\textsuperscript{40} This study also reported that participants had expressed difficulties in communicating their pain with healthcare professionals, and, in turn, understanding what they were being told due to use of jargon by healthcare professionals.\textsuperscript{40} An educational programme that is culturally appropriate and codesigned with community will not only increase musculoskeletal health knowledge among Aboriginal and Torres Strait Islander Australians but also empower them to communicate their pain.

Objectives
The primary aim of this study is to provide the first-ever data regarding the prevalence of osteoporosis across the ageing spectrum in Aboriginal and Torres Strait Islander Australians over a 2-year period. This will be done by assessing within-individual yearly change in skeletal and muscular characteristics known to exacerbate falls and fracture risk. Secondary aims are to (1) identify lifestyle (dietary intake, physical activity) and comorbidity (CVD, T2DM, CKD) determinants of bone and muscle strength loss during ageing and (2) improve health literacy in musculoskeletal health with a community-based educational programme.

Study design
This will be a prospective observational study with three time points (baseline, follow-up 1 and follow-up 2) with 12-month intervals between each study visit. This study will be conducted at the Monash Medical Centre, School of Clinical Sciences, Translational Research Facility Precinct of Monash University, Melbourne Australia. In total, we will recruit 298 Aboriginal and Torres Strait Islander Australians residing in Victoria and will stratify our recruitment by age-band (35–44, 45–54, 55–64, 65+ years) and sex.

METHODS
Patient and public involvement statement
This study arose from hospital data, which highlighted the missing gaps in musculoskeletal health and discussions with community across diverse settings and has been developed through extensive consultation. The Study of Indigenous Muscle and Bone Ageing (SIMBA) has been codesigned using a bottom-up approach with Aboriginal and Torres Strait Islander community members to ensure that the study is culturally sensitive and appropriate. Over the past 4 years, study investigators have established a long-standing and strong relationship with the Bunurong Health Service nestled within the Dandenong & District Aborigines Cooperative Limited (DDACL), who are in full support of SIMBA. Elders were consulted and all suggestions have been incorporated into the study design. In particular, discussions with Elders (who are respected leaders within the community) and community members explained their own personal mobility disabilities, fractures and musculoskeletal pain. As they have had personal experience with these, they expressed how important a study like this is for their people, as they articulated similar situations among family and friends (online supplemental text 1). All clinical assessment procedures and each question in the questionnaires have been individually checked and modified by Aboriginal investigators (JO and TW) to ensure appropriate use of language and suitability. JO is not only the CEO of the DDACL and has over 20 years’ experience in the Aboriginal health service but is also a Wurundjeri Woi-Wurrung Elder in the Aboriginal community. TW is a Yorta Yorta man who has expertise in the skeleton and human movement as he is a practising chiropractor and strength and conditioning coach as well as a scientist in the musculoskeletal field. The introductions and semistructured questions for the focus group sessions have been developed and modified with Aboriginal community members and then checked and approved by Aboriginal investigators (JO and TW). Study governance mechanisms will ensure that engagement is ongoing throughout the implementation of the study, and during data analysis and interpretation. Benefits to community have been discussed and identified by Aboriginal and Torres Strait Islander people during the consultation process (online supplemental text 2).

Study setting
This study will be conducted in community-dwelling Aboriginal and Torres Strait Islander men and women,
aged +35 years, recruited from the general population in Victoria. Participants will be recruited using various methods, including: advertising posters displayed at various locations, screening the patient database at the Bunurong Health Service, referrals from clinicians at Monash Health; engagement with Aboriginal communities, Yarning circles and Gathering places and word of mouth originating from any of the above methods. Potential participants will then contact study staff to undergo eligibility screening.

Eligibility criteria
A screening questionnaire over the telephone will be performed by research study staff, and eligibility will be assessed based on the inclusion/exclusion criteria. Participants who are eligible and willing to proceed will be scheduled for a study visit; after screening participants will be mailed or emailed a copy of the Participant Information Consent Form (PICF) with all the study details. Written informed consent will be taken at the time of the study visit.

Inclusion and exclusion criteria
Participants included will be Aboriginal and Torres Strait Islander adults, defined as an individual who identifies as being Aboriginal and/or Torres Strait Islander; aged 35 years or older; body weight less than 160 kg (maximum rating of imaging machines); not pregnant, not lactating and not breast feeding in the last 6 months (applicable to women only); at least one side of the body must be free from any metal or other material in limbs or surrounding locations that could interfere with imaging; fluent in written and spoken English, has capacity to provide informed consent and can communicate effectively with researchers; and no other medical condition that in the opinion of the investigators may deem inclusion unsafe or inappropriate, for example, recent exposure to nuclear medicine; pregnancy; conditions that may reduce ability to remain supine during bone imaging (eg, vertigo); conditions that may reduce ability to remain still during scans (eg, Parkinson’s disease, motor-neuron disease).

ASSESSMENTS
The study flowchart is summarised in figure 1. At baseline, all participants will attend their study appointment and all the assessments detailed in figure 1 and table 1 will be performed. Participants will then be scheduled for a follow-up visit 12 months later to repeat all assessments except the health awareness questionnaire and blood tests. Six months following the follow-up 1 study visit, all participants will be invited (but not required) to attend the community-based educational programme. Participants will be scheduled for the follow-up 2 visit 12 months after follow-up 1. The first study participant attended the baseline visit on 17 December 2020; the anticipated date for the final follow-up 2 visit is December 2024 (due to disruptions caused by COVID-19 lockdowns).

Community-based educational programme
After attending the follow-up 1 appointment, study participants will be invited to attend the community-based educational programme on bone and muscle health. Musculoskeletal health literacy will be measured by a questionnaire at baseline and after the educational programme, to measure any improvement in musculoskeletal health literacy.

To help determine the most effective and beneficial community educational programme, four focus groups (or until data saturation) will be conducted with an aim to develop the educational curriculum. Data from the focus groups will be synthesised, which will allow for codesign of the educational programme to pilot it in this study, using a bottom-up approach to ensure that the programme is effective in delivering the content in a culturally sensitive way that is appropriate for the Aboriginal and Torres Strait Islander community. The focus groups, each comprising of approximately 5–6 Aboriginal and Torres Strait Islander community members representing each of the four age bands in the study sample, will be conducted in a round table open discussion format. The focus groups will be a shared discussion with cultural moving parts and will be overseen and sat-in with Aboriginal study investigators (JO and TW) and other Aboriginal and/or Torres Strait Islander community champions. Storytelling is a feature of Aboriginal culture, a method of information sharing, where this style of informal and relaxed dialogue is called yarning. With the consent of the focus group attendees, the sessions will be recorded to allow review following the session, and to ensure no information is overlooked when finalising the content and delivery method of the educational programme.

The focus group sessions will aim to identify knowledge gaps that currently exist among Aboriginal and Torres Strait Islander people; what they think they should learn; the existing barriers to osteoporosis screening; an effective format for the educational seminars (eg, PowerPoint presentations, separate groups for men and women, small group sizes); whether question prompt lists regarding osteoporosis and sarcopenia written specifically for Aboriginal and Torres Strait Islander Australians would be beneficial, and if so, what questions would be most suitable and what the best location would be for the seminars (with regards to access). On evaluation of the needs analysis, every aspect, including content and the delivery format of the educational programme, will be codesigned (see online supplemental text 3). An example of the topics that could be covered is listed in table 2, which will be used as a guide during the focus group sessions. Codesigning the educational programme with Aboriginal and Torres Strait Islander community members will provide important insight into how best to design the programme that will most effectively fill their knowledge gap in musculoskeletal health. So, if during the focus group sessions, participants suggest other topics that they deem more relevant than those considered by researchers, then the programme will be developed accordingly.
Use of culturally appropriate and sensitive language during the programme will be a key focus for researchers, since it will be of utmost importance in realising the best possible educational outcomes in combination with the curriculum design. Once developed, the educational programme will be scheduled to commence within 1 month of follow-up 1 measurements being concluded. Process evaluation and implementation will be conducted throughout the duration of the programme (eg, quarterly if focus groups reveal once per month frequency over 1 year). This will allow research staff to monitor the progress of how well the content and delivery is being received and will subsequently provide early indications as to whether certain aspects require modification to better suit the needs of the community members. The quality appraisal tool from the Centre of Research Excellence in Aboriginal Chronic Disease Knowledge Translation and Exchange (CREATE) will be used as a framework to report key elements of the focus groups through an Aboriginal and Torres Strait Islander cultural lens.

**Measurements**

Participants will attend the Bone and Muscle Research Group’s imaging facility located within the Monash Health Translation Precinct at Monash Medical Centre in Melbourne, Australia. The total duration of each appointment will be approximately 2–3 hours.
Participants’ weight (kg) will be measured to the nearest 0.1 cm, using a wall-mounted stadiometer (Seca 213, Seca, Germany).

**Blood pressure**
Blood pressure measurements will be taken three times each for systolic and diastolic blood pressure and pulse rate after using an automated device (Omron HEM-907, Omron Australia, Australia) after the participant has been supine for 10 min. The ankle-brachial index will then be measured, which is a non-invasive measure for peripheral artery disease, calculated from the systolic blood pressure from the ipsilateral arm and ankle. It is calculated as ankle systolic blood pressure divided by arm systolic blood pressure. \(^{43,44}\)

**Blood biochemistry**
Fasting blood samples will be collected to measure clinical indicators of key risk factors for falls and fractures. These include T2DM (glycated haemoglobin, HbA1c; fasting blood glucose), CKD (urea, electrolytes, creatinine, eGFR), CVD (high-density lipoproteins, low-density lipoproteins, very low-density lipoproteins, triglycerides, total cholesterol) and chronic liver disease. Vitamin D will also be measured using the gold-standard liquid chromatography–mass spectrometry method. Additional aliquots of samples will be collected and stored for testing of further analytes when funding becomes available (eg, bone turnover markers, cytostatin C). Non-fasting blood samples will be collected when fasting is not feasible.

**Questionnaires**
Participants will complete the questionnaires at various times during their study visit, to ensure that they are not overburdened with completing the questionnaires all in the one sitting. The following questionnaires are designed to assess demographic, medical and lifestyle factors that are known to influence musculoskeletal health. Data collected will include the following: general demographics (including history on fractures and falls); medical history; reproductive history (women only); medical history; sarcopenia and quality of life; \(^{45,46}\); Cancer Council of Victoria food frequency questionnaire; short form of health. Data collected will include the following: general demographics (including history on fractures and falls); medical history; reproductive history (women only); medical history; sarcopenia and quality of life; \(^{45,46}\); Cancer Council of Victoria food frequency questionnaire; short form of

Table 1: Bone imaging assessments

<table>
<thead>
<tr>
<th>Imaging modality and site</th>
<th>Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA (Hologic)</td>
<td>Whole-body: aBMD; whole body lean and fat mass; compartmental fat mass (android and gynoid), appendicular lean mass (arms+legs lean mass)</td>
</tr>
<tr>
<td></td>
<td>Total hip: aBMD at the total hip and femoral neck; hip structural analysis</td>
</tr>
<tr>
<td></td>
<td>Lumbar spine scan: aBMD; TBS</td>
</tr>
<tr>
<td></td>
<td>Lateral vertebral assessment: Abdominal aortic calcification score; vertebral fracture</td>
</tr>
<tr>
<td></td>
<td>pQCT (Stratec)</td>
</tr>
<tr>
<td></td>
<td>4% radius: Total vBMD, trabecular vBMD</td>
</tr>
<tr>
<td></td>
<td>33% radius: Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference</td>
</tr>
<tr>
<td></td>
<td>66% radius: Cross-sectional muscle area, muscle density</td>
</tr>
<tr>
<td></td>
<td>4% tibia: Total vBMD, trabecular vBMD, presence of PVC</td>
</tr>
<tr>
<td></td>
<td>38% tibia: Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference, presence of PVC</td>
</tr>
<tr>
<td></td>
<td>66% tibia: Cross-sectional muscle area, muscle density, presence of PVC</td>
</tr>
<tr>
<td></td>
<td>HR-pQCT (Xtreme-CTII, Scanco)</td>
</tr>
<tr>
<td></td>
<td>4% radius: Total vBMD, trabecular vBMD</td>
</tr>
<tr>
<td></td>
<td>30% radius: Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference</td>
</tr>
<tr>
<td></td>
<td>4% tibia: Total vBMD, trabecular vBMD, presence of PVC</td>
</tr>
<tr>
<td></td>
<td>30% tibia: Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference, presence of PVC</td>
</tr>
</tbody>
</table>

aBMD, areal bone mineral density; DXA, dual-energy x-ray absorptiometry; HRpQCT, high-resolution CT; pQCT, peripheral quantitative CT; PVC, peripheral vascular calcification; TBS, trabecular bone score; vBMD, volumetric bone mineral density.

**Anthropometry**
Participants’ weight (kg) will be measured to the nearest 0.1 cm, using electronic scales (Seca 804, Seca, Germany). Participants’ height (cm) will be measured to the nearest

Table 2: Potential topics for educational programme

<table>
<thead>
<tr>
<th>Theme</th>
<th>Topics to cover</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone</td>
<td>Fractures and treatment</td>
</tr>
<tr>
<td>Muscle</td>
<td>Weak muscles and falls</td>
</tr>
<tr>
<td>Chronic diseases</td>
<td>Heart disease, kidney disease and diabetes</td>
</tr>
<tr>
<td>Exercise</td>
<td>Different modalities of exercise for example, running, walking, lifting weights (load bearing exercises)</td>
</tr>
<tr>
<td>Healthy living across the lifespan</td>
<td>Across the different phases of life: childhood, adulthood and ageing</td>
</tr>
</tbody>
</table>

the international physical activity questionnaire; osteoporosis knowledge assessment tool and osteoporosis health belief scale.

**Dual-energy X-ray absorptiometry**

Participants will undergo one DXA scan (Hologic Discovery A, Hologic, USA) at each of the four anatomical sites specified in Table 1. Total bone density (mg/cm³) and bone area (mm²) will be measured at each anatomical site using manufacturer’s thresholds, to determine aBMD and bone mineral content. Body composition will be measured for whole body (lean and fat mass), android and gynoid fat mass, and appendicular lean mass (arms plus legs lean mass). The lumbar spine scan will also be used to estimate the trabecular bone score, where a higher value correlates with better skeletal microstructure.

The lateral vertebral assessment will be used to ascertain vertebral fractures and quantify AAC (scored 0 to 24; AAC24). This involves assessing the linear length of the vascular calcification in the aorta relative to the L1–L4 lumbar vertebrae.

**Peripheral quantitative computed tomography**

Participants will undergo one pQCT scan (Stratec XCT 3000, Stratec, Germany) at each of the six anatomical sites specified in Table 1. Total, trabecular and cortical bone density (mg/cm³) and area (mm²), volumetric bone mineral density (vBMD) and muscle and adipose indices will be measured using manufacturer’s thresholds. pQCT scans of the radius and tibia will be performed in the participant’s non-dominant limb. Single 2.5 mm transverse scans will be obtained at 4%, 33%/38% and 66% of limb length measured proximally from the end plate of the tibia or radius, with a voxel size of 0.8 mm and scan speed of 20 mm/s. Scans from pQCT will allow for comparison with other populations, as this imaging modality is widely used, globally.

**High-resolution peripheral quantitative computed tomography**

Participants will undergo one HR-pQCT scan (XtremeCT II, Scanco Medical, Switzerland) at each of the four anatomical sites specified in Table 1. Total, trabecular and cortical bone density (mg/cm³) and area (mm²), vBMD, microarchitecture and µFEA will be measured at each anatomical site using manufacturer’s thresholds. HR-pQCT scans of the tibia will be performed in the participant’s non-dominant lower leg positioned inside the pQCT gantry while seated. Single 10.2 mm transverse scans will be obtained at 4% and 30% of the radius and tibia will be measured proximally from the end plate, with voxel size 0.8 mm and scan speed 20 mm/sec.

**Short physical performance battery**

The short physical performance battery (SPPB) is the most highly validated measure of physical performance and disability in older adults and is widely used in clinical and research settings. A summary score of 0 to 12 (higher score indicates better function) is obtained based on performance in three tasks: five repeated chair stands, standing balance over 10 s (semistand and full tandem) and gait speed over a distance of 4 m. A score of 0–4 is given based on the individual’s performance in each of the three tests.

**Hand grip strength**

Hand dynamometry (Jamar Plus Digital Hand Dynamometer; Nottinghamshire, UK) will be used to test the grip strength of the dominant hand. The participant will sit in the chair with feet flat on the floor and forearms supported by the chair arms. The hand should be positioned neutral with the thumb facing upward. The dynamometer will be adjusted to fit the participant’s hand comfortably when at rest with the tips of the third and fourth fingers aligned between the forward and rear grips. The participant will be instructed to squeeze the handle and breathe out gently. This will be repeated three times in total, with the maximum hand grip strength (HGS; kg) taken as the measurement for analyses.

**Jumping mechanography**

A Leonardo Mechanograph Ground Reaction Force Platform LT (Novotech Medical GmBH, Germany) will measure peak forces and power in the lower limb. It involves real-time recording of force, velocity and power in the leg from a ‘usual’ daily task and is considered a useful addition to other traditional tests. It has been validated as a reproducible tool that enables anatomical site-specific assessment corresponding to loading, falls and fracture in older adults. Tests include (1) a single two leg jump to measure peak muscle power (kW), where the participant will be instructed to jump as high as possible using both legs, bending the knees and using the arms to help create the power and (2) multiple one leg hopping test to measure peak muscle force (kN), where the participant will be instructed to jump, approximately 10 times, as hard and as fast possible on the ball of the foot without the heel touching the platform. Both tests will be repeated three times each in total, where the software will automatically detect which measurement will be taken for analyses.

**Outcome measures**

**Primary outcome measure**

The primary outcome for this study will be within-individual yearly change in aBMD at the total hip, femoral neck and lumbar spine assessed by DXA. In addition to within-individual yearly change in cortical and trabecular bone volumetric mineral density at the metaphysis and diaphysis of the radius and tibia using HR-pQCT.

**Secondary outcomes**

Secondary outcomes will assess yearly changes in: body composition (fat mass and lean mass compartments), physical function (SPPB), muscle strength (force, power and HGS), blood biochemistry including clinical risk factors for chronic diseases (T2DM, CVD and CKD),

lifestyle characteristics (dietary intake, physical activity and quality of life) and blood pressure.

**Sample size**

The required sample size for this study is 298 participants (n=148 men and n=148 women). A power calculation based on 298 participants has been performed to produce a two-sided 95% CI with a width of 0.04, a 20% precision (based on the DXA site with the worst precision, that is, femoral neck), to detect a within-individual change of 2% per year (ie, a rate that has been documented in other populations) and a 20% loss-to-follow-up. In the other DXA skeletal sites and HR-pQCT regions, which can be measured with more precision, smaller rates of change will be detectable with this number of participants. The rates of bone loss will differ between men and women and may alter with age; the greatest bone loss in non-Indigenous Australians occurs in women in the first 5–10 years after menopause. Therefore, the sample size has been determined to allow investigation of bone loss in men and women separately. The time interval of 1 year between scans has been selected to assess bone loss within an individual over 2 years, as the magnitude of bone loss in Aboriginal and Torres Strait Islander adults is unknown; this will ensure the age of osteoporosis (bone fragility) and sarcopenia (decreased muscle function) onset is not missed.

**Data collection, management and analysis**

Study data will be collected using a tablet device and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at Monash University. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for data integration and interoperability with external sources. Online questionnaires have been designed with mandatory answers required to avoid missing data. Data from blood analyses will be entered into a Microsoft Access password-protected database.

**Statistical methods**

Analysis will be performed using Stata V.15.1 (StataCorp, USA). Descriptive statistics will be used to describe the participant characteristics at baseline. Data will be assessed for outliers and normality prior to analysis and log-transformed if necessary. Baseline and follow-up data for outcome measures and between-sex differences across the age-bands will be presented as means and SDs. Linear-mixed models will compare changes in bone and muscle parameters, comparing men and women. Multivariable regression analyses will be performed to determine whether these associations are independent of potential confounders including age, body composition, comorbidities, physical activity and social demographics.

Additionally, data from SIMBA will be compared with age-matched non-Indigenous Australians to elucidate differences in bone and muscle health. Together with Aboriginal investigators, we will work with community representatives to take a strength-based approach in the interpretation and presentation of data. This will be done via an Aboriginal Advisory Group with members formed through JO’s role as CEO of the Bunurong Health Service, TW’s position and strong ties within the community and other community champions. For all analyses, a p value of <0.05 or 95% CI not including the null point will be considered statistically significant. The focus groups will be analysed using a thematic analysis approach, once they have been transcribed. The data will be uploaded and analysed using NVivo Qualitative Data Analysis Software V.20.3 (QSR International).

**ETHICS**

In accordance with the Australian National Statement on Ethical Conduct in Human Research, ethics approval for this study has been granted by the Monash Health Human Research Ethics Committee (project number: RES-19-000374A), registered and certified by the National Health and Medical Research Council (NHMRC) of Australia. We have adhered to the NHMRC Guidelines Framework, which includes the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research and the Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for researchers and stakeholders; we have provided specific details on how SIMBA adhered to all these guidelines (see online supplemental text 4). Briefly, recruitment, study visits and dissemination strategies used in SIMBA are based on best practice for cohort studies of Aboriginal and Torres Strait Islander people.

**DISSEMINATION**

Results will be communicated to study participants and communities in lay language, relevant stakeholders and disseminated in peer-reviewed academic journals and presented in scientific meetings and conferences. In addition to interpretation and presentation of findings, the Aboriginal Advisory Group (mentioned above) will also provide ongoing advice to study investigators, advising on how best to communicate and disseminate findings from SIMBA. Participants can nominate for DXA reports to be sent to their own doctor, and appropriate social and Aboriginal and Torres Strait Islander media and forums will be used to inform participants of study progress and key outcomes. In particular, findings will be presented at Aboriginal community centres and shared with the Victorian Aboriginal Community Controlled Health Organisation—as the peak body for health and well-being of Aboriginal people living across the state of Victoria.
Information regarding consent, confidentiality, access to data and dissemination policy have been disclosed in the PICF.

Author affiliations
1Department of Medicine, School of Clinical Sciences at Monash Health, Monash University, Clayton, Victoria, Australia
2School of Health and Social Development, Faculty of Health, Deakin University, Geelong, Victoria, Australia
3Institute for Nutrition Research, School of Medical and Health Sciences, Edith Cowan University, Joondalup, Western Australia, Australia
4Medical School, Royal Perth Hospital Unit, The University of Western Australia, Perth, Western Australia, Australia
5Centre for Kidney Research, Children’s Hospital at Westmead, School of Public Health, University of Sydney, Sydney, New South Wales, Australia
6Institute for Health Transformation, Deakin University, Geelong, Victoria, Australia
7Australian Institute for Musculoskeletal Science (AIMSS), University of Melbourne and Western Health, St Albans, Victoria, Australia
8Department of Medicine-Western Health, University of Melbourne, St Albans, Victoria, Australia
9Centre for Kidney Research, Children’s Hospital at Westmead, School of Public Health, University of Sydney, Sydney, New South Wales, Australia
10Bunurong Health Service, Dandenong & District Aborigines Co-operative Ltd (DDACL), Dandenong, Victoria, Australia
11Health & Wellbeing, A2B Personnel, Echuca, Victoria, Australia
12Institute for Physical Activity and Nutrition, School of Exercise and Nutrition Sciences, Deakin University, Geelong, Victoria, Australia

Twitter Ayse Zengin @DrAyseZ, Louise Maple-Brown @LMapleBrown and Sharon Lee Brennan-Olsen @Brennan_Olsen

Acknowledgements The investigators thank the organisations and individuals who helped develop, improve and publicise this research project protocol. The investigators would like to acknowledge and thank the various Elders and community members who helped design this research project and provided critical review to ensure cultural sensitivity and suitability. Thank you to Prof. Amanda Vincent of Monash University, for providing critical guidance and advice during the early development phase of SIMBA.

Contributors Development of the study concept, AZ and JO. Assistance in further development and implementation of the protocol, SLB-O, CS-L, PE, DS, LM-B, MS, CS-L, JO, TW and JRL. Writing and draft preparation, AZ, DS, MS, PE, CS-L, TW and SLB-O. Review and editing, all authors. Statistical analysis, AZ, MS, DS. All authors contributed and approved the final manuscript. The authors have no conflicts of interest to declare.

Funding This research is partly funded by competitive investigator-initiated grants from Osteoporosis Australia (now called Healthy Bones Australia), Australia and New Zealand Bone and Mineral Society, and Amgen. MS is supported by a Royal Perth Hospital Research Foundation Career Advancement Fellowship (130/2020), Emerging Leader Fellowship and project grant from the Western Australian Future Health Research and Innovation Fund. DS is supported by a NHMRC Investigator Grant (GNT1174886). JRL is supported by a National Heart Foundation of Australia Future Leader Fellowship. The HRpQCT was purchased with research grants from The Ian Potter Foundation (20180037), National Health and Medical Research Council (GNT6900320) and Faculty of Medicine, Nursing and Health Sciences, Monash University. None of the funding agencies had any role in the conduct of the study; collection, management, analysis, or interpretation of the data; or preparation, review or approval of the manuscript.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Upon completion of study, data sharing will be available through collaborative agreements and initial enquiries should be made to the Principal Investigator Ayse Zengin (ayse.zengin@monash.edu).

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs
Ayse Zengin http://orcid.org/0000-0001-6428-6165
Marc Sim http://orcid.org/0000-0001-5166-0065
Sharon Lee Brennan-Olsen http://orcid.org/0000-0003-3269-5401

REFERENCES


64. National Health and Medical Research Council. Keeping research on track II: a companion document to ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: guidelines for researchers and stakeholders. Canberra: Commonwealth of Australia, 2018.

65. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research. Australian Institute of Aboriginal and Torres Strait Islander Studies Canberra, Australia: ACT, 2020.


Supplementary Information

Text 1: Community Consultation

Findings from the Australian Burden of Disease Study: Impact and causes of illness and death in Aboriginal and Torres Strait Islander people (1) showed that falls had the highest total burden (disability-adjusted life year 56.1). Bone mineral density data was atop the list of key gaps in data to estimate exposure to risk factors for Aboriginal and Torres Strait Islander Australians (1), suggesting musculoskeletal health as a national priority for this population. We have undergone community consultation over several years and have built a strong relationship with several community members and Aboriginal community-controlled organisations including the Bunurong Health Service, Dandenong & District Aborigines Cooperative Limited (DDACL). When musculoskeletal health was discussed with community members who were 40 years and above – these individuals were concerned about their physical function and mobility, so were highly motivated about how to prevent fracture and falls. Discussions with Elders, who are respected individuals within the community, have highlighted that musculoskeletal health of Aboriginal and Torres Strait Islander people is an under-researched area and given all of the physical disability stories they recount during the discussions, this area is of high priority, and they have stated that the community and their people will benefit from this research. They explained that staying within the community and on Country is very important for their people, and so when community members begin to experience physical ailments, they do not want to go to aged-care facilities as this would result in them being away from their community. During these meetings, community members have also explained their culture and traditions. These highlighted the importance of taking a holistic approach when performing a research study with Aboriginal and Torres Strait Islander people.

Equality amongst research partners will be maintained with research transparency – this will not only ensure that all stakeholders are kept informed throughout the study period, but also builds trust, which is critical in research with Aboriginal and Torres Strait Islander people. Quarterly meetings, phone or video calls will be scheduled to discuss the progress of the study with Bunurong Health Service staff and other stakeholders including Elders and community champions (i.e., the Aboriginal Advisory Group). These will enable to modify any research procedures, if necessary, upon feedback from research participants. An Aboriginal Advisory Group (consisting of JO’s role within DDACL, TW’s position within the community, and community champions) will also provide ongoing advice to study investigators regarding...
interpretation and presentation of findings, and how best to communicate and disseminate the findings from SIMBA.

**Text 2: Benefit to Community**

In a more general scope where the findings and health implications will be summarised, we will prepare plain language reports and summaries, infographics/posters, presentations and workshops at community meetings and social events – and make all this available on Aboriginal and Torres Strait Islander media (newspaper, websites, social media). An Aboriginal or Torres Strait Islander person will be employed to design the artwork which will be used for the reports and summaries, and the infographics. There is not a one-size fits all system, and so we will tailor our study outputs to the community’s needs, in line with the guidance from the Aboriginal Advisory Group.

DXA reports will be sent to all the participants’ general practitioners (upon their consent), in order for their doctors to follow-up with treatment if necessary. Furthermore, the age-bands that are listed have been strategically chosen to assist the Bunurong Health Service in their annual reports, as health data is included and summarised according to these age-bands. JO suggested that data on bone mineral density can also be incorporated into the annual reports to further highlight a need to improve screening and diagnosis for osteoporosis.

The described benefits from SIMBA have been discussed and agreed to by Aboriginal or Torres Strait Islander research stakeholders, community champions and Aboriginal investigators. Together, the benefits of SIMBA to community have been planned in accordance with the National Statement on Ethical Conduct in Human Research “The benefits from research should include the enhancement or establishment of capabilities, opportunities or research outcomes that advance the interests of Aboriginal and Torres Strait Islander Peoples” (2). We aim to empower Aboriginal and Torres Strait Islander people with regards to increased health literacy surrounding musculoskeletal health via the community educational program. SIMBA will be involved in capacity building through up-skilling clinicians to screen for osteoporosis and subsequent treatment plans. Additionally, healthcare professionals and other employees of the Bunurong Health Service will have increased knowledge and awareness regarding musculoskeletal health. Through the University’s specific PhD scholarship scheme for Aboriginal and Torres Strait Islander people, SIMBA will provide the opportunity for training in bone imaging and muscle function assessments.
Text 3: Community educational program

Every aspect will be developed together with key community stakeholders. For instance, the content of the program, the delivery (who should deliver it, train personnel if required), creating videos (if required) of key community members telling their own personal story, scheduling invitations of Elders to attend and facilitate the educational program, creating online content – whether it be in text, or various media (videos). Process evaluation and implementation will be conducted throughout the duration of the program (e.g. quarterly if focus groups reveal once per month frequency over one year). This will allow study investigators to monitor the progress of how well the content and delivery is being received and will subsequently provide early indications as to whether certain aspects require modification to better suit the needs of the community members.

Text 4: Ethics

Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities (3) defines six core values — spirit and integrity, cultural continuity, equity, reciprocity, respect, and responsibility. We have applied these values in conjunction with The National Statement on Ethical Conduct in Human Research (2), Australian Code for Responsible Conduct of Research (4), Keeping research on track II (5) and Ethical considerations in quality assurance and evaluation activities (6).

We have detailed how we have addressed each core value below:

1. **Spirit and integrity:** SIMBA study investigators are committed to working in partnership with Aboriginal and Torres Strait Islander people and communities, in the spirit and integrity of Aboriginal and Torres Strait Islander cultural values. We will have ongoing engagement with Aboriginal community members in the research, in a meaningful way. Study investigators are dedicated to ensuring there is transparent communication and respect with Aboriginal people and communities. The SIMBA study investigator team includes two Aboriginal investigators, one of whom is the CEO of an Aboriginal Community Controlled Health Organisation (Bunurong Health Service – JO) and one of who is a chiropractor and musculoskeletal expert (TW).

2. **Cultural continuity:** we have used Aboriginal and Torres Strait Islander standpoints and methodologies when developing research proposals. For instance, we will offer both male and female investigators to perform the scans – whichever the participant
feels more comfortable with. The language in the questionnaires have been modified by Aboriginal study investigators to align with cultural appropriateness.

3. **Equity**: Throughout the consultation process, study investigators have actively engaged community champions in the research topic and methods of research. Our communication strategy (e.g. patient information consent form, questionnaires, feedback and final reports) will be in lay language to ensure all information can be easily understood by participants and community members. There is no exploitation of participants in the conduct of research; the potential benefits and risks of the research is clarified in the patient information consent form and participants are encouraged to ask questions regarding their involvement in the study. Study investigators conduct themselves where there is no judgement, particularly during the telephone screening and the study visit.

4. **Reciprocity**: Study investigators have conducted equitable and respectful engagement with and inclusion of Aboriginal and Torres Strait Islander peoples. In doing so we have prioritised working in partnership and prioritised the voices of Aboriginal and Torres Strait Islander peoples, their values and culture. We have engaged in respectful discussions to understand that the benefits for Aboriginal and Torres Strait Islander people and communities may encompass sharing of knowledge (through educational program and study visits), not be immediate – where the impact of the findings from SIMBA may take time to implement policy changes (for instance Medicare DXA screening specifically for this population), and be of benefit to not only study participants but the wider Aboriginal and Torres Strait Islander people and communities. We have addressed emerging needs articulated by Aboriginal and Torres Strait Islander people, as expressed during the consultation process by various community members, Elders, and community champions. For instance, the impacts of physical disability (due to falls and/or fractures) on community is very unfavourable, as Aboriginal and Torres Strait Islander people have a close connection to community and Country. SIMBA will have both direct (increased musculoskeletal health literacy) and indirect benefits for Aboriginal and Torres Strait Islander people (at the national level – Medicare policy changes for DXA screening). Study findings will also be translated to form the basis of a larger nation-wide study through the roles of co-author PRE as chairman of Healthy Bones Australia. SIMBA will provide evidence for a larger study where the aim is to visit rural and remote communities using a mobile bone imaging vehicle, as these communities do not have access to aBMD assessment. In line
with this, an e-health platform will be developed where experts in metropolitan areas can consult on musculoskeletal assessments in patients who reside in outer regional and remote areas to ensure equitable access to healthcare.

5. **Respect**: The participant information consent form used in SIMBA ensures conditions for consent are satisfied for the research, where the decision to participate is voluntary, participants are fully informed, and understand the information and what being a participant entail. The participant information consent form is written in lay language to ensure everything can be easily understood and has been checked and modified by Aboriginal investigators. Upon the completion of SIMBA individual and collective contributions of Aboriginal and Torres Strait Islander participants and groups will be acknowledged whenever findings are dissemination (e.g. through acknowledgement in final reports, presentations and publications).

6. **Responsibility**: We have demonstrated that SIMBA will do no harm by providing all relevant information for the participants prior to seeking consent during the study visit. We have performed a risk assessment where the research project has been classified as low risk. Additionally, due to the imaging devices utilising radiation, our scanning protocol has undergone a radiation safety assessment by a medical radiation safety officer, who is also a radiologist, and has been classed as low radiation exposure. Nevertheless, all this information is provided in the patient information consent form, which is sent out (either email or hard copy) to the participant prior to scheduling a study visit (where consent is taken). When research results will be published, we have ensured that individuals and/or communities will not identifiable and only aggregate data will be published (e.g. apply privacy-preserving protocols where study ID will be used to label samples, including biological samples, names will be removed from datasets including focus group interview transcripts and field notes).

References

3. National Health and Medical Research Council, Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders. Commonwealth of Australia, Canberra.2018.

5. National Health and Medical Research Council, Keeping research on track II: A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders. Commonwealth of Australia: Canberra. 2018.