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Why Aboriginal and Torres Strait Islander Australians fall and fracture: the codesigned Study of Indigenous Muscle and Bone Ageing (SIMBA) protocol

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Why Aboriginal and Torres Strait Islander Australians fall and fracture: the codesigned Study of Indigenous Muscle and Bone Ageing (SIMBA) protocol

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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

Strengths and limitations of this study

► This study has been codesigned using a bottom-up approach with Aboriginal and Torres Strait Islander community members.

► Comprehensive bone and muscle assessments will be performed using the latest cutting-edge imaging technology.

► Data on modifiable lifestyle factors, such as diet, physical activity and quality of life, will be collected through questionnaires.

► Clinical indicators of key risk factors for falls and fractures will be assessed via medical history, blood biochemistry and novel imaging assessments (abdominal aortic calcification).

► The study population will be recruited from one Australian state (Victoria) suggesting limited generalisability to Aboriginal and Torres Strait Islander Australians across the entire country as there may be differences between various regions.

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.[1] 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.[1] 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.[2] The occurrence of minimal trauma fractures in older people has been associated with an increased risk of subsequent fracture and premature

mortality.[3 4] 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.[5] 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.[6] 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.[7]

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.[8] The second study[9] 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.[10] It showed greater femoral neck aBMD in Aboriginal and Torres Strait Islander adults compared with non-Indigenous adults (n=36).[9] No differences were reported in lumbar spine aBMD, even after adjusting for body composition.[9] 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[11]) 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/cm^2). A T-score (SD from young adult mean aBMD)≤−2.5 SD 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[12] 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.[12] 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.[13]

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,[14] greater cardiovascular disease risk,[15] poorer muscle strength,[16] greater injurious fall[17] and fracture risk.[15] 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.[18] 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.[19] Recently, associations between AAC, lower aBMD,[20] greater bone loss over time[21] and fragility fractures[22] 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.[23] 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.[24]

The prevalence of T2DM is three times greater among Aboriginal and Torres Strait Islander people compared with non-Indigenous Australians,[18 25] with diabetes-related mortality almost seven-fold greater in the Aboriginal and Torres Strait Islander population.[26] 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.[27] Despite generally demonstrating higher aBMD, fracture risk is increased in those with T2DM due to decreased bone strength,[28 29]

specifically increased cortical porosity and cortical pore volume.[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[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 m² with albuminuria.[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.[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.[31] Renal osteodystrophy in CKD is multifaceted and encompasses increased fibroblast growth factor 23,[35] secondary hyperparathyroidism[36] and abnormal calcium-phosphate metabolism.[37] Muscle wasting and sarcopenia is highly prevalent in those with CKD,[38] increasing frailty and falls risk[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.[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.[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.[41] 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.
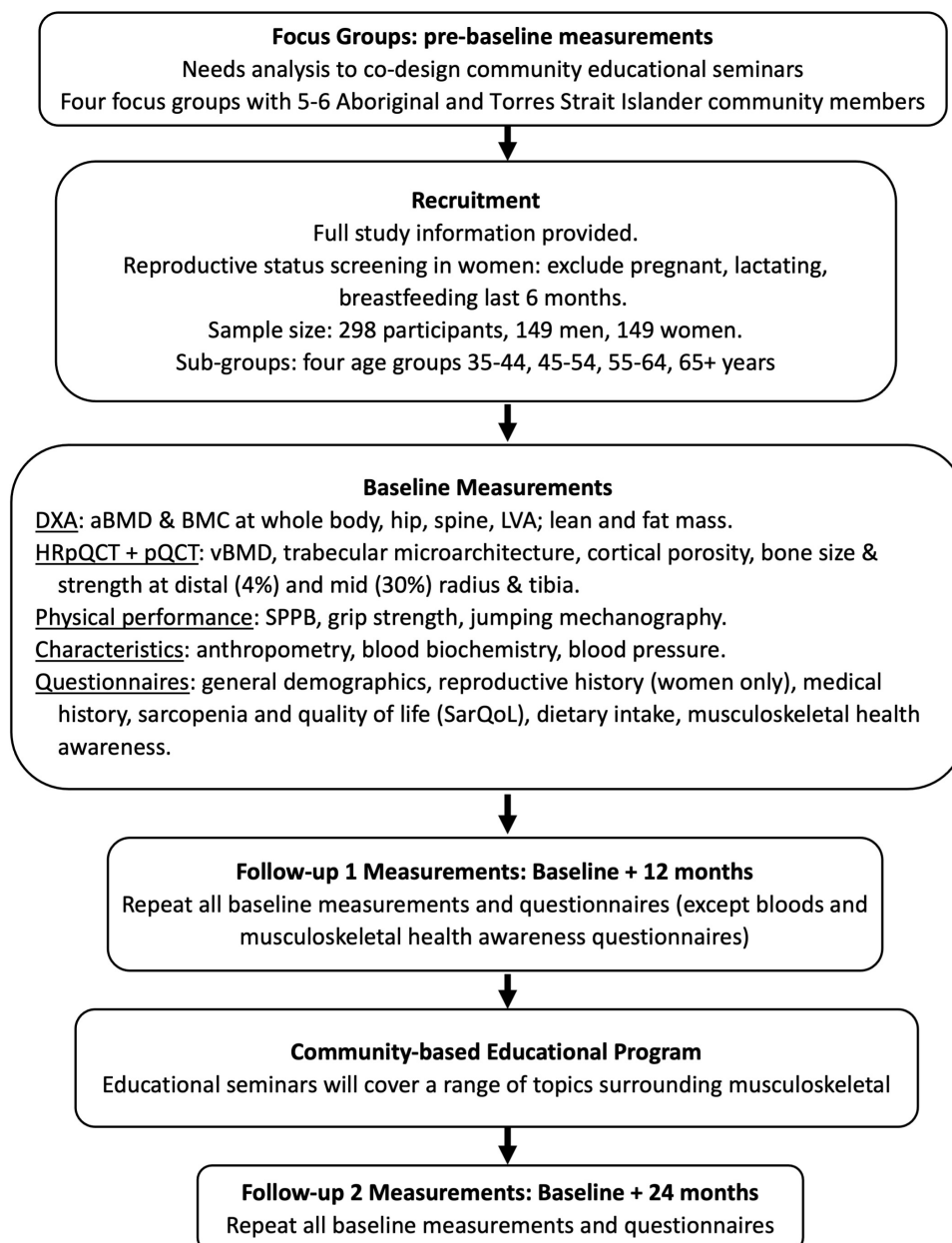
Focus Groups: pre-baseline measurements
Needs analysis to co-design community educational seminars
Four focus groups with 5-6 Aboriginal and Torres Strait Islander community members

Recruitment
Full study information provided.
Reproductive status screening in women: exclude pregnant, lactating,
breastfeeding last 6 months.
Sample size: 298 participants, 149 men, 149 women.
Sub-groups: four age groups 35-44, 45-54, 55-64, 65+ years

Baseline Measurements
DXA: aBMD & BMC at whole body, hip, spine, LVA; lean and fat mass.
HRpQCT + pQCT: vBMD, trabecular microarchitecture, cortical porosity, bone size &
    strength at distal (4%) and mid (30%) radius & tibia.
Physical performance: SPPB, grip strength, jumping mechanography.
Characteristics: anthropometry, blood biochemistry, blood pressure.
Questionnaires: general demographics, reproductive history (women only), medical
    history, sarcopenia and quality of life (SarQoL), dietary intake, musculoskeletal health
    awareness.

Follow-up 1 Measurements: Baseline + 12 months
Repeat all baseline measurements and questionnaires (except bloods and
musculoskeletal health awareness questionnaires)

Community-based Educational Program
Educational seminars will cover a range of topics surrounding musculoskeletal

Follow-up 2 Measurements: Baseline + 24 months
Repeat all baseline measurements and questionnaires

Figure 1 Study flowchart. aBMD, areal bone mineral density; BMC, bone mineral content; DXA, dual energy x-ray absorptiometry; HRpQCT, high resolution peripheral quantitative CT; LVA, lateral vertebral assessment; SarQoL, sarcopenia and quality of life; SPPB, short physical performance battery; vBMD, volumetric bone mineral density.

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)[42] 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.

Table 1 Bone imaging assessments

Imaging modality and site	Measurements
DXA (Hologic)	
Whole-body	aBMD; whole body lean and fat mass; compartmental fat mass (android and gynoid), appendicular lean mass (arms+legs lean mass)
Total hip	aBMD at the total hip and femoral neck; hip structural analysis
Lumbar spine scan (anterio-posterior, L1-L4)	aBMD; TBS
Lateral vertebral assessment	Abdominal aortic calcification score; vertebral fracture
pQCT (Stratec)	
4% radius	Total vBMD, trabecular vBMD
33% radius	Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference
66% radius	Cross-sectional muscle area, muscle density
4% tibia	Total vBMD, trabecular vBMD, presence of PVC
38% tibia	Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference, presence of PVC
66% tibia	Cross-sectional muscle area, muscle density, presence of PVC
HR-pQCT (Xtreme-CTII, Scanco)	
4% radius	Total vBMD, trabecular vBMD
30% radius	Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference
4% tibia	Total vBMD, trabecular vBMD, presence of PVC
30% tibia	Total vBMD, cortical vBMD, cortical area, stress strain index, cross-sectional moment of inertia, endocortical and periosteal circumference, presence of PVC

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 kg, using electronic scales (Seca 804, Seca, Germany). Participants' height (cm) will be measured to the nearest

Table 2 Potential topics for educational programme

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

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); reproductive history (women only); medical history; sarcopenia and quality of life[45 46]; Cancer Council of Victoria food frequency questionnaire; short form of

the international physical activity questionnaire[47]; osteoporosis knowledge assessment tool[48] and osteoporosis health belief scale.[49]

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/cm^3) and bone area (mm^2) 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.[50 51] The lateral vertebral assessment will be used to ascertain vertebral fractures and quantify AAC[14 52] to assess risk factors for CVD. AAC will be scored using a semiquantitative scoring system (scored 0 to 24; AAC24). This involves assessing the linear length of the vascular calcification in the aorta relative to the L1–L4 lumbar vertebra.[52–56]

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/cm^3) and area (mm^2), 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/cm^3) and area (mm^2), 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.[57] A summary score of 0 to 12 (higher score indicates better function) is obtained based on performance in three tasks[1]: five repeated chair stands,[2] standing balance over 10 s (semitandem and full tandem) and[3] 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.[58 59] 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.[60 61] 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).[62] 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,[63 64] ethics approval for this study has been granted by the Monash Health Human Research Ethics Committee (project number: RES-19–0000374A), 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[65] and the Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for researchers and stakeholders[66]; 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.[67–69]

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.

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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).

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