

# The protocol for the Prospective Urban Rural Epidemiology China Action on Spine and Hip status study

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**Abstract:** The Prospective Urban Rural Epidemiology (PURE) China Action on Spine and Hip status (CASH) study focused on the prevalence of osteoporosis and spinal fracture in China. The aim of the PURE CASH study is to determine the prevalence of osteoporosis and spinal fracture, and explore the potential relationship between spinal fracture and bone mineral density (BMD). This study is a prospective large-scale population study with a community-based sampling and recruitment strategy. The aim is to determine the prevalence of osteoporosis and vertebral fracture in this population, to evaluate the association between vertebral fractures and BMD values, and to assess the prediction power of BMD for incident fractures. Participants in the PURE CASH study are all from the PURE study in China, recruited from 12 centers in 7 Chinese provinces. The inclusion criteria are that participants should be aged more than 40 years and able to give informed consent. Exclusion criteria are pregnant women, individuals with metal implants in the lumbar spine, use of medications or the existence of any disease or condition known to have a major influence on BMD, and inability to give informed consent. A total of 3,457 participants undergo a quantitative computed tomography (QCT) scan of the upper abdomen. The scanning parameters are as follows: 120 kVp at all centers, mAs between 75 and 200, FOV 40 cm×40 cm. The BMD values of L1 to L3 are measured, and the average BMD calculated. The American College of Radiology QCT criteria for the diagnosis of osteoporosis is applied to determine the presence of osteoporosis. The scout view images of T4–L4 vertebrae are reviewed by two experienced radiologists for semi-quantification of vertebral fractures according to Genant's method.

**Keywords:** Osteoporosis; fracture; bone mineral density

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## Introduction

Osteoporosis is a systematic skeletal disorder characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in the fragility of bone and susceptibility to fracture (1). Osteoporotic fractures occur most commonly at the spine, hip, forearm and other sites, while hip fracture is associated with high mortality and morbidity (2,3). Studies have indicated an increasing incidence of hip fracture in Chinese cities (4,5), and this is a significant burden for society. Accurate and reliable knowledge of the prevalence of osteoporosis and osteoporotic fracture throughout China will be critical for policy-making and healthcare planning. A cross-sectional and population-based study conducted in Shanghai in 2010 showed that the prevalence of osteoporotic fractures was 14.9% in females (57.6±9.5 years) and 12.2% in males (58.5±10.1 years) (6). Results of Mister Osteoporosis Study and Miss Osteoporosis Study from 2001 to 2003 suggested that the prevalence of vertebral fractures (defined as grade ≥2 vertebral deformity according to Genant's criteria) in Hong Kong was 5.0% among elderly men (mean age: 72.4 years old) and 12.1% among elderly women (mean age: 72.6 years old) (7).

In the past, dual energy X-ray absorptiometry (DXA) has been widely used to study the epidemiology of osteoporosis, and in the diagnosis and management of osteoporosis. It was demonstrated using DXA that the bone mineral density (BMD) of 85-year-old women reflected a loss of 32% at the spine and 30–35% at the femur measurement sites in China (8). The two-dimensional projection nature of DXA images makes the measurement susceptible to degenerative changes in the spine and aortic calcification. Our previous study verified that a substantial number of patients with osteoporosis were missed by DXA measurements (9). Quantitative computed tomography (QCT) is technically superior to DXA for measuring BMD in the spine and hip, and has attracted increasing attention in recent years (10–17). The diagnosis of osteoporosis by DXA relies on T score measurements at the spine and hip, and the calculation of T scores relies on the use of reference databases provided

by the manufacturers. Therefore, the variations in the prevalence of osteoporosis reported in different studies may be partially due to the differences in the reference databases, and not indicative of true differences in the prevalence of osteoporosis. A diagnostic criterion of osteoporosis by QCT of a spinal trabecular volumetric BMD (vBMD) less than 80 mg/cm<sup>3</sup> was recommended by the International Society for Clinical Densitometry in 2007 (17) and American College of Radiology in 2008 (18). Because the lateral scout view image of the CT scan can be used to assess for prevalent vertebral fractures (19–21), and vBMD measurements can be achieved simultaneously, QCT can provide accurate data on the prevalence of osteoporosis. However, the prevalence of osteoporosis and vertebral fractures using QCT data has not yet been studied in a Chinese population.

The Prospective Urban Rural Epidemiology (PURE) study is an international, large, multi-center, community-based, epidemiological cohort study in 18 countries, including China. The details of this study and the baseline characteristics have been reported (22,23). The details of Chinese participants and their baseline characteristics were reported recently by Peng *et al.* (24). The PURE China Action on Spine and Hip status (CASH) study focused on the prevalence of osteoporosis and osteoporotic spinal fractures in China. The participants in the PURE CASH study are all from the PURE study in China. The objectives of this study are: (I) to determine the prevalence of osteoporosis in this population by QCT vBMD measurement; (II) to determine the prevalence of osteoporotic vertebral fractures and their association with vBMD; (III) to determine the power of vBMD to predict future fractures in a follow-up study.

## Study design

The PURE CASH study (identifier: NCT01758770) is a prospective, multicenter, epidemiological study. The subjects of PURE CASH study are enrolled from 12 centers (Beijing Jishuitan Hospital, Beijing Shijingshan Hospital, Taiyuan Central Hospital, West China Second University

Hospital of Sichuan University, Chengdu Second People's Hospital, the People's Hospital of Dayi County, the 4th People's Hospital of Shenyang, Wujin Hospital of Traditional Chinese Medicine, Affiliated Hospital of Nanjing University of Chinese Medicine, the Second Affiliated Hospital of Nanjing University of Chinese Medicine, Xi'an Honghui Hospital, the Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine). From June 2013 to March 2017, all the subjects underwent QCT scans of the lumbar spine with thoracic and lumbar spine CT scout views. The participants of PURE CASH study will be followed up for incident fractures as required by the protocol of PURE study in the future.

Ethical approval is obtained from the ethics committee of the Beijing Jishuitan Hospital, Peking University (Approval No. 201210-01 and No. 201512-02). The study is conducted in accordance with ethical principles according to the Declaration of Helsinki and is consistent with Good Clinical Practice. Radiation safety and protection measures are strictly implemented in the whole study. Informed consent is obtained from every participant in the study.

The participants are from 12 centers in 7 Chinese provinces including Beijing, Liaoning, Shanxi, Shaanxi, Sichuan, Jiangsu and Jiangxi. The inclusion criteria are that participants should be aged over 40 years old and able to give informed consent. Exclusion criteria are pregnant women, individuals with metal implants in the lumbar spine, use of medications or the existence of any disease or condition known to have a major influence on BMD, and inability to give informed consent.

### The estimation of sample size and the recruitment

When enrollment commenced the estimated number of participants is more than 3,000. Since there is no population based QCT prevalence data available in China, we use the published DXA data for osteoporosis prevalence in China instead. The prevalence of osteoporosis by DXA BMD measurements is between 5% and 20% according to areal measurements (25). Under a two-sided 0.05 alpha level, 500 participants per center is sufficient to ensure a  $\pm 3.5\%$  estimated precision on the osteoporosis rate for each area (the width of the 95% confidence interval will be less than 7.0%). Since QCT is more sensitive than DXA for detecting osteoporosis (9), the detected prevalence of osteoporosis is expected to be higher. Hence the current sample size is sufficient to ensure adequate accuracy.

The assumed prevalence of osteoporotic vertebral

fractures is between 15% and 25% (25,26). Given the sample size per province and the adopted significant level, the precision of the estimate of prevalent osteoporotic vertebral fractures will be less than  $\pm 3.8\%$  (means that the maximum width of 95% CI will not exceed 7.6%).

Recruitment was started in June 2013, and details are shown in *Table 1*. Up to now, a total of 3,457 subjects have been enrolled in the 12 centers. Each subject completed a one-page questionnaire regarding factors that may have an effect on bone (Supplementary file). Full informed consent is obtained before an appointment being made for a QCT scan at the nearest participating imaging center.

### The QCT scan

An abdominal CT scan is performed with a Mindways QCT calibration phantom beneath the spine. The scan parameters are predefined at each installation, and are different at different centers according to the CT scanners (*Table 1*). Radiation protection measures are implemented according to local requirements. A lateral scout view of T4 to L4 vertebrae is obtained for localization.

### Quality control and cross calibration of QCT scan

All QCT scans are performed using the CT scanner available at each center (*Table 1*). The Mindways QCT (QCT Pro, Mindways software Inc., Austin, TX, USA) system is used in each center. Four sets of Mindways QCT Pro systems are rotated between centers. The Mindways QCT system is shipped to the center and installed. The staff are trained by research associates from Beijing Jishuitan Hospital. For cross-calibration, a single European Spine Phantom (ESP-145) is scanned at all centers before scanning the subjects. All QCT data are transferred to Beijing Jishuitan Hospital for analysis and quality control.

### The BMD measurement of vertebral body

The vBMD values ( $\text{mg}/\text{cm}^3$ ) of the L1, L2 and L3 vertebral body are measured according to the Mindways protocol. The average vBMD value of L1–L3 is calculated as the spinal vBMD outcome of each subject.

### The diagnosis of osteoporosis

The diagnostic criteria of osteoporosis for QCT, recommended by the International Society for Clinical

**Table 1** The study centers, CT scanners, scan parameters and subjects' number of PURE CASH study

Geographical regions	Urban/rural sites	Centers	CT scanners	Scan kVp	Scan mAs	Subjects' number (n=3,457)
Beijing	Urban site	Beijing Jishuitan Hospital	Toshiba Aquilion PRIME	120	112.5	441
		Beijing Shijingshan Hospital	GE LightSpeed VCT	120	200	
Liaoning Province	Rural site	The 4th People's Hospital of Shenyang	GE LightSpeed 16	120	135	510
	Urban site	The 4th People's Hospital of Shenyang	GE LightSpeed 16	120	135	
Sichuan Province	Rural site	The People's Hospital of Dayi County	GE Optima 660	120	90	543
	Urban site	West China Second University Hospital of Sichuan University	Philips Brilliance 6	120	150	
Jiangsu Province	Rural site	Chengdu Second People's Hospital	Philips Brilliance 64	120	150	631
		Wujin Hospital of Traditional Chinese Medicine	Siemens SOMATOM Definition AS+	120	90	
	Urban site	Wujin Hospital of Traditional Chinese Medicine	Siemens SOMATOM Definition AS+	120	150	
		Affiliated Hospital of Nanjing University of Chinese Medicine	GE Optima 660	120	150	
Shanxi Province	Urban site	The Second Affiliated Hospital of Nanjing University of Chinese Medicine	Philips iCT 256	120	Automatically	333
	Rural site	Taiyuan Central Hospital	Toshiba Aquilion 64	120	75	
Shaanxi Province	Urban site	Taiyuan Central Hospital	Toshiba Aquilion 64	120	75	177
Jiangxi Province	Urban site	Xi'an Honghui Hospital	Philips Brilliance 16	120	150	316
		The Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine	GE Discovery 750 HD	120	125	

CT, computed tomography; PURE, Prospective Urban Rural Epidemiology; CASH, China Action on Spine and Hip status.

Densitometry in 2007 (17) and American College of Radiology in 2008 (18), is used to classify the subjects as normal if average vBMD >120 mg/cm<sup>3</sup>, osteopenia if vBMD between 120 and 80 mg/cm<sup>3</sup>, and osteoporosis if vBMD <80 mg/cm<sup>3</sup>.

### The vertebral fracture assessment (VFA)

The lateral scout view images from the QCT scans are used to detect vertebral body fractures according to Genant's semiquantitative method (27,28). Each vertebral body is classified as normal (grade 0), mild (grade 1, approximately 20–25% depression in height and a reduction in area 10–20%), moderate (grade 2, approximately 25–40% depression in height and a reduction in area 20–40%), or severe (grade 3, more than 40% reduction in height and

area) fracture (27,28). The digital images are displayed and viewed on a professional work station with the RadiAnt DICOM Viewer software (Version 4.5.9, Medixant Company, Poland); the quantitative diagnosis is performed by two musculoskeletal radiologists with many years' experience of vertebral fracture assessment. The outcomes are determined via consensus opinion. A subject is considered to have a spinal osteoporotic fracture if any one of the T4–L4 vertebral bodies had a VFA score ≥ grade 1. The highest VFA score for each subject will be considered the severity.

### The benefit for the study participants

The vBMD results along with any abnormal CT scan findings will be provided to the participants.

## Conclusions

This study is the first to determine the prevalence of osteoporosis and vertebral fractures in China by QCT measurements in a large-scale, multicenter population. Accurate data on the prevalence of osteoporosis and osteoporotic fracture in China can be obtained, and their association can be assessed. These data may have great significance for future policy-making and the prevention of osteoporosis and osteoporotic fractures in China.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

*Ethical Statement:* Ethical approval was obtained from the ethics committee of the Beijing Jishuitan Hospital, Peking University (Approval No. 201210-01 and No. 201512-02) and informed consent was obtained from every participant in the study.

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## Questionnaire of PURE CASH Study

PURE Identifier: \_\_\_\_\_

Name: \_\_\_\_\_ Gender: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ (mm)/ \_\_\_\_\_ (dd)/ \_\_\_\_\_ (yy)

Age: \_\_\_\_\_ years old Nation: \_\_\_\_\_

Weight: \_\_\_\_\_ kg Height: \_\_\_\_\_ cm

Waist Circumference: \_\_\_\_\_ cm Hip Circumference: \_\_\_\_\_ cm

Blood Pressure: \_\_\_\_\_ (SBP)/ \_\_\_\_\_ (DBP) mmHg

Fasting blood-glucose: \_\_\_\_\_ mmol/L

Age of menopause (if postmenopausal females): \_\_\_\_\_ years old

Fracture History: None \_\_\_\_\_

Yes \_\_\_\_\_ Date of Fracture if any \_\_\_\_\_ Fracture Site if any \_\_\_\_\_

Hip Fracture History of parents: None \_\_\_\_\_ Yes \_\_\_\_\_

Tobacco Use: No \_\_\_\_\_ Yes \_\_\_\_\_ How many cigarettes per day if any \_\_\_\_\_

Glucocorticoids use: No \_\_\_\_\_ Yes \_\_\_\_\_

History of Rheumatic Arthritis: No \_\_\_\_\_ Yes \_\_\_\_\_

History of Secondary Osteoporosis: No \_\_\_\_\_ Yes \_\_\_\_\_

[NOTE: Secondary osteoporosis referred to the osteoporosis caused by Type I diabetes mellitus (insulin-dependent diabetes mellitus), adult osteogenesis imperfecta (idiopathic osteopsathyrosis), hyperparathyroidism, hypogonadism or premature menopause (age <45 years old), chronic malnutrition or malabsorption, and chronic hepatopathy.]

Alcohol Use Amount equal to or more than 3 Units per day: No \_\_\_\_\_ Yes \_\_\_\_\_

[NOTE: One unit means 285 mL beer, 30 mL spirit, 120 mL wine, 60 mL fruit wine, or 60 mL sake.]

Date: \_\_\_\_\_ (mm)/ \_\_\_\_\_ (dd)/ \_\_\_\_\_ (yy)

Signature: \_\_\_\_\_