

Evaluation of Bone Health among Type 2 Diabetes Mellitus Patients: An Application of Health Belief Model

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Abstract:

Background: Type 2 diabetes mellitus (T2DM) and osteoporosis remain one of the major public health problems worldwide with a considerable burden on society. Health belief toward osteoporosis is fundamental to all osteoporosis management programs and is often a pre-requisite for initiating desired behavioral changes. The aim of this study was to assess: the level of the Malay version of the Osteoporosis Health Belief Scale (OHBS-M) among T2DM patients; the relation of socio-demographic characteristics, clinical data with OHBS-M level and the correlation between OHBS-M score and T-score.

Methods: An observational, cross-sectional study design was conducted among T2DM patients. Socio-demographic and clinical data were collected using a convenient sampling method. All T2DM patients underwent the bone mineral density measurement using a quantitative ultrasound scan (QUS).

Results: The result showed the average age of the participants was 62.67 ± 9.24 years. The study findings revealed that the average total score of OHBS-M 143.08 \pm 24.22 (median 141.50) with 85.60% of T2DM patients had a low level of osteoporosis health belief. Moreover, a significant correlation was found between the QUS T-scores and osteoporosis health beliefs.

Conclusions: The study findings revealed that the assessment of T2DM patients' bone health and health belief toward osteoporosis is crucial to improve an osteoporosis preventive strategy for high-risk populations.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a heterogeneous, chronic metabolic disorder with substantial morbidity and mortality [1]. Over the last decades, the incidence of T2DM has escalated dramatically across the world [2]. Malaysia is a rapidly developing multiracial country that shows the change in dietary habits and adoption of a more sedentary lifestyle that is associated with more overweight and obesity [3], and an increase in the prevalence of diabetes in recent decades [4]. Furthermore, many previous studies in Malaysia reported that a large proportion of diabetic patients have poor or suboptimal glycaemic control [5,6]. On the other hand, osteoporosis is a progressive, potentially debilitating skeletal disease, which can be prevented [7]. It is widely recognised as one of the major worldwide public health problems, especially in women and elderly people [8]. Moreover, osteoporosis in Asian ancestry is considered a significant public health problem [9], as Asian populations is considered a risk factor for developing osteoporosis with low bone mineral density (BMD) compared to other ethnic groups [10].

In spite of universal healthcare, osteoporosis continues to be an underdiagnosed and underestimated problem among the general population [11] and diabetic patients [12,13] and remains undetected until fractures occur. In addition, previous studies have shown that diabetes is a common risk factor for compromised bone health and developing osteoporosis [14,15]. Moreover, there is increasing evidence that T2DM patients have an increased risk of certain types of osteoporotic fractures [16]. In Asia, few studies have shown that Asian populations with diabetes were at increased risk of osteoporosis and fracture than those without diabetes [17,18]. However, the relationship between diabetes and osteoporosis remains controversial and needs extensive investigation.

In osteoporosis management, an enormous challenge is to identify the lack of osteoporosis health beliefs towards preventive health behaviours [19]. To address issues related to lack of awareness, the health behaviour theory was largely used. The health behaviour theory is the most effective way for assessing osteoporosis health beliefs and developing education efforts [20]. Moreover, the Health Belief Model (HBM) can be used to elucidate personal health behaviours and understand the reasons for noncompliance related to osteoprotective behaviours [21]. Management of diabetes and prevention of osteoporosis requires continuous efforts from both healthcare professionals and patients lifelong. However, the patient is the true key in any successful prevention program. Moreover, there is a paucity of research that assesses the level of health belief towards osteoporosis among diabetic patients and explores the association between osteoporosis health belief with quantitative ultrasound scan (QUS) measurement. Therefore, the aim of this study was to assess: 1) the level of osteoporosis health belief- Malay version (OHBS-M) among T2DM patients; 2) the relation of socio-demographic characteristics, clinical data with OHBS-M; 3) the correlation between OHBS-M subscales; 4) the correlation between QUS parameters (T-score) and OHBS-M score.

METHODS

Study Design and Setting

An observational, cross-sectional study design was conducted among T2DM patients. The data was collected using a self-report structured questionnaire and retrospective collection of clinical data from patients' medical records at Diabetes Outpatient Clinic of Penang General Hospital (PGH), Malaysia for seven months, from August 2011 to February 2012.

Population and Sampling Method

The study population was recruited using a convenient sampling method with an ethic approval number (NMRR-11-28-8209)/Medical Research Ethics Committee of the Ministry of Health, Malaysia). The inclusion criteria were: patients diagnosed with T2DM at least two years before inclusion in the study, patients receiving oral hypoglycemic agents with or without insulin for at least one year before inclusion in the study, age \geq 30 years old, participants competent to read and write Bahasa Malaysia with no speech or hearing problems and willing to give written informed consent before participation in the study. A total of 500 patients were recruited from the outpatients' diabetes clinic. Out of the 500 patients approached, 50 patients were excluded due to lack of some clinical data (n=31) or incomplete responses from the patients (n=19). The final convenience sample of 450 patients with T2DM was included in the analysis of this study.

Sample Size Calculation

To estimate the sample size of T2DM patients, a prevalence based sampling technique was used. The

T2DM prevalence in Malaysia is 14.90% according to the third National Health and Morbidity Survey (NHMS III) [22]. A total sample size of 450 T2DM patients was included in the final analysis of this study with an accepted margin of error of 5% and a 99% confidence interval.

Research Tools

Socio-demographic, clinical and laboratory data were collected. Validated Osteoporosis Health Belief Scale-Malay version (OHBS-M) was used to assess osteoporosis health belief in this study. The OHBS-M consisted of forty-two items within seven subscales: perceived susceptibility of osteoporosis, perceived seriousness of osteoporosis, perceived benefits of exercise, perceived benefits of calcium intake, perceived barriers to exercise, perceived barriers to calcium intake, and health motivation. The OHBS is rated using a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). The possible range of scores for each subscale is 6-30 with a possible total score range of 42-210. All participants have completed the questionnaire then underwent the bone mineral density (BMD) measurement using QUS.

Quantitative Ultrasound (QUS) Measurements

The bone mineral density (BMD) of the participants was determined using QUS (SONOST 3000) at the calcaneus. Subjects were classified as normal, osteopenic and osteoporotic based on the QUS T-scores using the World Health Organisation (WHO) criteria [23].

Statistical Analysis

Predictive Analytics Software (PASW) version 19.0 was used for data analysis and the level of statistical significance was set at P<0.05 for all analyses. Frequencies (percentages), mean ± standard deviation (M±SD) (median), Mann-Whitney U test, Kruskal-Wallis test, independent t-test and one-way analysis of variance (ANOVA) were conducted when necessary. To measure the correlation, Pearson and Spearman's correlations coefficients were used.

RESULTS

Demographic Characteristics in Relation to Osteoporosis Health Belief Levels

Four hundred and fifty T2DM patients were recruited; 231 (51.30%) were males. The average age of the

participants was 62.67 ± 9.24 years and ranged from 33 to 87 years. Among the racial distribution, the proportion of Chinese patients (204, 45.30%) was higher than Malay (127, 28.20%) and Indian patients (119, 26.40%). The average body mass index (BMI) was 26.36 ± 4.39 kg/m² and the majority of patients were obese (352, 78.20%), as shown in Table **1**.

A significant relationship between OHBS-M levels and education groups, marital status, monthly income, employment status, family history of fracture, smoking habit, and the alcoholic habit was found (P<0.05). Moreover, the results showed significant differences in the total OHBS-M score between the education groups, marital status, monthly income, employment status, family history of osteoporosis, family history of fracture and smoking habit (P<0.05), as shown in Table **1**.

Diabetes-Related Variables in Relation to Osteoporosis Health Belief Levels

The T2DM patients had a mean diabetes duration of 8.65±5.97 years (range 3-32 years). The majority of patients was on combination anti-diabetic therapy (335, 74.40%), did not use insulin (383, 85.10%) for their diabetes management, had at least one diabetic complication (330, 73.30%) and had comorbidity with T2DM (426, 94.70%). The most common macrovascular and microvascular complications were ischemic heart disease (IHD) (18.70%) and peripheral neuropathy (52.40%), respectively. Furthermore, the majority of T2DM had suboptimal glycaemic control (343, 76.20%), as shown in Table 2.

No significant association (*P*>0.05) between OHBS-M levels and diabetes-related variables was found. However, the Spearman's correlation coefficient showed a low but significant positive correlation between OHBS-M and diabetes duration (n = 450, r_s = 0.107, *P* = 0.024). Furthermore, significant differences in the OHBS-M scores were found among the diabetic complications group (*P*<0.05), as shown in Table **2**.

Osteoporosis Health Belief Assessment

The average total score of OHBS-M was found to be 143.08±24.22, with a median score of 141.50. Only 14.40% of the study populations were found to have high OHBS-M levels according to the cut-off point [24]. The results showed low perceived susceptibility and moderate perceived seriousness toward osteoporosis. Furthermore, the results showed few barriers to either physical activity or calcium intake. In contrast, a highly

Variable	Frequency (Percent, %)	Osteoporosis health belief level N (%)				
		Low OHBS-M level	High OHBS-M level	P†	OHBS -M scores Mean± SD (Median)	<i>P</i> ‡
		385 (85.60%)	65 (14.40%)	-		
Age (years)**				0.337		0.638
<45	11 (2.40%)	10 (90.90%)	1 (9.10%)		137.18±23.66 (134.00)	
45-54	78 (17.30%)	71 (91%)	7 (9%)		140.55±21.09 (141.50)	
55-64	166 (36.90%)	137 (82.50%)	29 (17.50%)		145.98±23.08 (143.00)	
≥65	195 (43.30%)	167 (85.60%)	28 (14.40%)		141.96±26.19 (141.00)	
Gender*				0.214		0.681
Male	231(51.30%)	193 (83.50%)	38 (16.50%)		142.40±25.11 (142.00)	
Female	219 (48.70%)	192 (87.70%)	27 (12.30%)		143.81±23.28 (141.00)	
Race**				0.924		0.263
Malay	127 (28.20%)	108 (85%)	19 (15%)		145.40±21.79 (142.00)	
Chinese	204 (45.30%)	176 (86.30%)	28 (13.70%)		140.91±26.45 (141.50)	
Indian	119 (26.40%)	101 (84.90%)	18 (15.10%)		144.34±22.50 (141.00)	
Educational levels*				0.011 ª		0.032 ^a
<12 years	285 (63.30%)	253 (88.80%)	32 (11.20%)		141.04±22.88 (141.00)	
≥ 12 years	165 (36.70%)	132 (80%)	33 (20%)		146.62 ±26.06 (143.00)	
Marital Status*				0.004 ^a		0.029 ^ª
Single	70 (15.60%)	52 (74.30%)	18 (25.70%)		149.96±23.23 (146.00)	
Not single	380 (84.40%)	333 (87.60%)	47 (12.40%)		141.82±24.22 (141.00)	
Monthly income*				0.003 ª		0.029 ª
Less than RM 2000	330 (73.30%)	292 (88.50%)	38 (11.50%)		141.57±22.81 (140.50)	
More than RM 2000	120 (26.70%)	93 (77.50%)	27(22.50%)		147.24±27.42 (146.00)	
Menopausal status (N=219)*				0.484		0.173
Premenopausal	25 (11.40%)	23 (92%)	2 (8%)		137.24±22.71 (135.00)	
Postmenopausal	194 (88.60%)	169 (87.10%)	25 (12.90%)		144.65±23.28 (142.00)	
Employment status*				0.049 ^a		0.028 ª
Working	192 (42.70%)	157 (81.80%)	35 (18.20%)		145.46±25.65 (145.00)	
Not working	258 (57.30%)	228 (88.40%)	30 (11.60%)		141.32±22.99 (140.00)	
Family history of osteoporosis*				0.147		0.033 [°]
No	392 (87.10%)	339 (86.50%)	53 (13.50%)		142.17±24.31 (141.00)	
Yes	58 (12.90%)	46 (79.30%)	12 (20.70%)		149.28±22.89 (150.00)	
Family history of fracture*				0.004 ^a		0.000 ^a
No	359 (79.80%)	315 (87.70%)	44 (12.30%)		140.71±24.31 (140.00)	

 Table 1:
 Socio-Demographic Characteristics of the Study Population in Relation to Osteoporosis Health Belief Levels (N=450)

21 (23.10%)

152.44±21.57 (152.00)

70 (76.90%)

Yes

91 (20.20%)

Variable	Frequency (Percent, %)	Osteoporosis health belief level N (%)				
		Low OHBS-M level 385 (85.60%)	High OHBS-M level 65 (14.40%)	P†	OHBS -M scores Mean± SD (Median)	<i>P</i> ‡
Not smoking	318 (70.70%)	286 (89.90%)	32 (10.10%)		140.36±23.34 (139.00)	
Smoking	132 (29.30%)	99 (75%)	33 (25%)		149.65±25.12 (148.50)	
Alcohol habit*				0.014 ^ª		0.084
Non alcoholic	356 (79.10%)	312 (87.60%)	44 (12.40%)		141.95±23.57 (141.00)	
Alcoholic	94 (20.90%)	73 (77.70%)	21 (22.30%)		147.39±26.23 (145.00)	
BMI (Kg/m ²)*				0.784		0.700
Non-obese (BMI ≤23 kg/m²)	98 (21.80%)	83 (84.70%)	15 (15.30%)		144.44±25.78 (141.50)	
Obese (BMI >23kg/m ²)	352 (78.20%)	302 (85.80%)	50 (14.20%)		142.71±23.79 (141.50)	

† Association, Chi-square test, ^a P<0.05; ‡ Difference; *Mann-Whitney U test; **Kruskal-Wallis test; BMI: Body mass index; SD: standard deviation.

Table 2: Diabetes-Related Data of the Study Population in Relation to Osteoporosis Health Belief Levels (N=450)

Variable	Frequency (Percent, %)	Osteoporosis health belief level N (%)			OHBS -M scores	
		Low OHBS-M level 300 (66.7%)	High OHBS-M level 150 (33.3%)	Pt	Mean± SD (Median)	<i>P</i> ‡
Diabetes Duration (years)**				0.801		0.191
< 5	175 (38.90%)	149(85.10)	26(14.90)		142.46±24.27 (140.00)	
5 – 9	125 (27.80%)	109(87.20)	16(12.80)		140.89±23.59 (139.00)	
10 – 14	89 (19.80%)	77(86.50)	12(13.50)		144.08±24.63 (144.00)	
≥ 15	61 (13.60%)	50(82)	11(18)		147.92±24.61 (143.00)	
Therapy type*				0.905	. ,	
Mono therapy	115 (25.60%)	98(85.20)	17(14.80)		141.79±25.23 (141.00)	
Combined therapy	335 (74.40%)	287(85.70)	48(14.30)		143.53±23.88 (142.00)	
Insulin use*				0.211		0.243
With insulin	67 (14.90%)	54(80.60)	13(19.40)		147.48±25.67 (142.00)	
Without insulin	383 (85.10%)	331(86.40)	52(13.60)		142.32±23.91 (141.00)	
Diabetic complication (DC)*				0.613		0.002 ^ª
Positive (with DC)	330 (73.30%)	284(86.10)	46(13.90)		144.95±23.13 (143.00)	
Negative (without DC)	120 (26.70%)	101(84.20)	19(15.80)		137.95±26.43 (136.00)	
Co-morbidities*				0.75		0.790
Positive (with Co- morbidities)	426 (94.70%)	365(85.70)	61(14.30)		143.37±23.79 (141.50)	
Negative (without Co- morbidities)	24 (5.30%)	20(83.30)	4(16.70)		137.96±31.02 (141.50)	
Glycaemic control (HbA1c)*				0.886		0.111
Good HbA1c (< 6.5)	107 (23.80%)	92(86)	15(14)		139.60±22.37 (139.00)	
Poor HbA1c (≥ 6.5)	343 (76.20%)	293(85.40)	50(14.60)		144.17±24.70 (142.00)	

† Association, Chi-square test, ^a P<0.05; ‡ Difference; *Mann-Whitney U test; **Kruskal-Wallis test; SD: standard deviation.

Construct	Mean ±SD (Median)	Potential range	Belief %	
Perceived susceptibility	18.14±7.15 (18.00)	6-30	60.46%	
Perceived seriousness	20.86±6.63 (22.00)	6-30	69.53%	
Perceived benefits of exercise	24.90±4.72 (26.00)	6-30	83%	
Perceived benefits of calcium intake	24.37±4.19 (24.00)	6-30	81.23%	
Perceived barriers to exercise	15.57±7.26 (13.00)	6-30	51.90%	
Perceived barriers to calcium intake	15.03±5.86 (14.00)	6-30	50.10%	
Health motivation	24.22±4.17 (25.00)	6-30	80.73%	
Total OHBS-M	143.08±24.22(141.50)	42-210	68.13%	

Table 3: Description of Osteoporosis Health Belief Scale (OHBS-M) Total Constructs and the Seven Subscales (N=450)

positive view of perceived benefits constructs of physical activity, calcium intake and health motivations were observed, as shown in Table **3**.

In summary, the frequency of answers for certain questions in OHBS-M includes the following: 1) barely half of the participants strongly agree and agree with the statements (item 1-4). On the other hand, almost half of the participants strongly disagreed and disagreed with the statements (item 5-6). Moreover, participants generally perceived a moderate perception of seriousness for osteoporosis with just over half of the participants agreed and strongly agreed with the statements (item 7-12). Based on the OHBS, participants believe that regular physical exercise can help to prevent the onset of osteoporosis with more than three-quarters of participants agreed and strongly agreed with the statements of taking exercise as protective toward osteoporosis in this subscale (item 13-18). In addition, More than 75% of participants believed that a high dietary calcium intake would be beneficial for the prevention of osteoporosis (item 19-24). Based on the response of items 25-30, participants perceived few barriers to exercise with more than 50% of all participants disagree and strongly disagree that they were facing barriers to exercise with all statements in this subscale. As well, participants generally perceived few barriers to calcium intake as a high percentage of participants disagree and strongly disagree with facing barriers to items 31-36. In addition, participants reported a very high health motivation in preventing the development of osteoporosis based on the response from items 37-42 with at least 70% of participants agreeing or strongly agreeing with all of the items in this subscale.

Correlations between Osteoporosis Health Belief Subscales Scores and T-Scores

Significant negative correlations were found between the perceived benefits to exercise and perceived barriers to exercise (n=450, r_s =-0.106*, *P*<0.05). In addition, a significant negative correlation was found between T-scores and the perceived barrier to exercise (r_s = -0.103, *P*<0.05).

DISCUSSION

From a comprehensive literature review, it is evident that this is the first study that examines osteoporosis health beliefs among T2DM patients which involved a wider range of age groups for both genders with different races in a hospital-based study. In this study, the degree of osteoporosis health belief among T2DM patients was assessed using a validated tool of OHBS-M [24]. The OHBS was selected for use in the current study as it is one of the most widely used instruments to assess osteoporosis health beliefs [25]. By applying the cut-off value of (169), more than three quarters (85.60%) of T2DM patients had a low level of health belief regarding osteoporosis with the average value of 136.37±18.69. Additionally, in this study, T2DM patients identified osteoporosis as a serious condition with low personal susceptibility, a positive view regarding the benefits of exercise and dietary calcium intake, as well as having few barriers to either exercise and calcium intake and they demonstrated overall high health motivation. Moreover, in this study, the belief percent of OHBS-M was 68.13% which was similar to other findings in community-based studies [26,27]. In contrast, a study of young U.S students demonstrated a lower belief percent of OHBS of 58% [28]. Based on the health belief model, if people believe they are at risk of a disease with a negative impact on their health and that a certain health behaviour will improve their quality of life, they are more likely to be motivated to take a healthier behaviour action [29]. A better understanding of T2DM patient's health beliefs toward osteoporosis will allow healthcare professionals and educators to develop culturally sensitive and targeted messages to promote bone health. Future research in this area and the development of culturally specific interventions are needed.

Perceived Susceptibility of Osteoporosis

The T2DM patients perceived low susceptibility to osteoporosis with less than half of all participants agreeing with statements in this subscale. Other studies showed lower susceptibility scores as most participants did not believe that they were susceptible to osteoporosis [30,31]. In the present study, low belief scores in the susceptibility subscale were possible due to the lack of knowledge regarding the risk factors of osteoporosis [32,33]. Another possible explanation for low perceived osteoporosis susceptibility could be the absence of any physical symptoms of osteoporosis. It has been postulated that most individuals do not perceive themselves to be at risk of osteoporosis disease until they begin to experience physical symptoms [34].

Perceived Seriousness of Osteoporosis

The T2DM patients perceived a moderate seriousness to osteoporosis with more than half of all participants agreeing with all statements in this subscale. Many studies showed comparable moderate perceived seriousness [35,36]. In contrast, other studies demonstrated lower perceived seriousness of osteoporosis [30,37]. It was not surprising that T2DM patients perceived moderate seriousness as they perceived low susceptibility to osteoporosis.

Perceived Benefit of Exercise

The T2DM patients believed in the beneficial effect of physical activity performance in the prevention of osteoporosis and more than three-quarters of all participants agreed with all statements in this subscale. Similarly, several studies showed that the majority of their participants agreed and were aware of the benefit of adequate performance of a physical activity in preventing osteoporosis problems [27,38]. In contrast, other studies revealed a lower perceived benefit of exercise [30,39]. The perceived benefits of exercise impact whether an individual will engage in a healthpromoting behaviour or not [40].

Perceived Benefit of Dietary Calcium Intake

The patients believed that a high dietary calcium intake would be beneficial for the prevention of osteoporosis, with more than three-quarters of all participants agreeing with all statements in this subscale. Other studies showed the comparable perceived benefit of calcium intake scores [27,38]. In contrast, other studies demonstrated a lower perceived benefit of dietary calcium intake [30,39]. In summary, T2DM patients generally perceive many benefits of a diet rich in calcium for the prevention of osteoporosis.

A Perceived Barrier to Exercise

The results showed a low perception barrier of exercise with more than half of all participants disagreeing with all statements in this subscale. Similarly, many studies found a lower perceived barrier to exercise scores [28,35]. However, understanding the influence barriers in daily life physical activity is important for osteoporosis prevention behaviour [26]. Limited knowledge of osteoporosis may lead some people to misinterpret the barriers to healthy behaviour lifestyle. This belief was supported by results from previous studies. In those studies, even in participants with high knowledge and belief regarding the role of physical activity, 26 to 58% of the participants thought that people with osteoporosis should not engage in exercise due to the threat of falling and suffering a fracture [41,42].

Perceived Barrier to Dietary Calcium Intake

The results showed a low perception barrier of calcium intake, with more than half of all participants disagreeing with all statements in this subscale. Similarly, several studies found a lower perceived barrier to calcium intake [27,38]. Moreover, it appeared that almost half of the patients in this study did not perceive the cost of calcium-rich foods as a barrier to calcium intake (item 31). Similarly, another study found that most women (82.7%) disagreed that cost was a barrier [43]. However, other studies showed that the income and, hence, the cost were an obstacle for the selection of calcium-rich foods [44,45].

Health Motivation

In this study, T2DM patients reported a high level of health motivation, with more than three-quarters of all

participants agreeing with all statements in this subscale. These patients reported greater importance of keeping healthy, a tendency to look for new healthrelated information, having regular health check-ups, and following recommendations to keep them healthy. Likewise, other studies reported high health motivation scores [28,46]. In contrast, other studies showed lower health motivation scores toward osteoporosis [31,36]. The health motivation subscale evaluates the beliefs regarding learning about health-related behaviours and staying healthy, as well as assessing the general tendency for an individual to engage in health behaviours [47].

Correlations between T-Scores and the Osteoporosis Health Belief (OHBS-M) Scores

The results showed a significant negative relationship was found between T-scores and perceived barriers to exercise; as the barriers to exercise activity increased, the T-scores decreased. In contrast, other studies demonstrated health beliefs about osteoporosis were not correlated with T-score [48,49].

However, previous research findings revealed that receiving the results of the T-score would change general knowledge and health beliefs about osteoporosis by seeking medical consultation or information about osteoporosis [50]. Thus, emphasizing the health beliefs toward osteoporosis were significant predictors of calcium intake and exercise behaviour that eventually lead to improved bone health.

CONCLUSIONS

Overall, this study showed a valuable insight into the health belief toward osteoporosis, and its relation to bone loss among T2DM patients. The study spotlighted that a high proportion of patients were found to have low health beliefs toward osteoporosis (85.60%). In addition, the study results findings highlight the potential importance of these components in the overall understanding of why a person with T2DM may not adopt osteoporosis preventive behaviours. Also, it identified the areas where further research would provide a more comprehensive picture. Such information will be critical for the future development of effective health education programme an for osteoporosis prevention.

CONFLICTS OF INTEREST

All contributing authors declare that no conflicts of interest exist.

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