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Orthostatic hypotension, diabetes, and falling in older patients:

a cross-sectional study

Abstract

Background
Although orthostatic hypotension (OH) is more prevalent in old age, and in patients with diabetes, the prevalence of OH in older patients with type 2 diabetes mellitus is unknown.

Aim
To establish the prevalence of OH, and its association with falling, in home-dwelling older participants with and without type 2 diabetes.

Design and setting
A cross-sectional study in primary care in the Netherlands.

Method
A total of 352 patients with type 2 diabetes, and 211 without participated in this study. OH was defined as a fall in blood pressure of at least 20 mmHg systolic or 10 mmHg diastolic after either 1 or 3 minutes in an upright position. Feelings of dizziness, light-headedness, or faintness during the standing period were documented as orthostatic complaints. Fall risk was assessed with a validated risk profile instrument.

Results
The prevalence of OH was 28% (95% CI = 24% to 33%) and 18% (95% CI = 13% to 23%) in participants with and without type 2 diabetes, respectively. OH was not related to falling, while the presence of orthostatic complaints in itself was associated with both previous fall incidents as well as a high fall risk, even after adjustment for OH. The adjusted odds ratios were 1.65 (95% CI = 1.00 to 2.72) and 8.21 (95% CI = 4.17 to 16.19), respectively.

Conclusion
OH is highly prevalent in home-dwelling older people with and without type 2 diabetes. Those with orthostatic complaints had an increased risk for falling, whereas those with OH were not.

Keywords
aged; diabetes mellitus type 2; falling; orthostatic hypotension; primary care.

INTRODUCTION

Orthostatic hypotension (OH) is increasingly recognised as an important risk factor for cardiovascular disease and mortality.[1–5] Many fall prevention programmes are based on the assumed association between OH and falling, although the evidence regarding this association is conflicting.[6–12] The reported prevalence of OH varies widely in literature, probably because its presence is influenced by many factors, including setting, age, definitions of OH, medications used and comorbidity.[6,13,14] In patients with diabetes, OH is considered to be a clinical manifestation of diabetic autonomic neuropathy. However, other risk factors for OH, such as hypertension and cardiovascular disease, also cluster in patients with type 2 diabetes mellitus. The estimated prevalence of OH in home-dwelling older people, aged ≥70 years, is approximately 30%.[1,15,16] Although OH is more prevalent in old age,[6] and in patients with diabetes,[17] the actual prevalence of OH in older patients with type 2 diabetes is unknown.

The primary objective of this cross-sectional study was to establish the prevalence of OH in home-dwelling older patients with type 2 diabetes. Associated factors of OH, and the prevalence of OH in participants without type 2 diabetes were also investigated. Because of the high fall rate in older people, especially in those with diabetes,[18] and the conflicting evidence whether OH should be considered a risk factor for falling, the association of OH with fall incidents and fall risk was also investigated.

METHOD

Study population

Patients with type 2 diabetes participating in this cross-sectional observational study were recruited from 35 general practices, predominantly located in the north eastern region of the Netherlands. Recruitment and all study procedures took place between January 2009 and May 2010. Eligible patients with diabetes were either selected by practice nurses during the periodical diabetic check-up, or by the authors using the GPs' patients information systems. All participating nurses were visited and trained by the authors for trial procedures. The initial selection included patients with a diagnosis of type 2 diabetes, aged ≥70 years, and the ability to follow the study protocol. Exclusion criteria were known autonomic dysfunction, neurodegenerative diseases, active malignancy, irregular pulse, and residing in a nursing home. Patients with irregular pulse were excluded because of the difficulty establishing 'real' OH in

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Submitted: 28 June 2011; **Editor's response:** 2 September 2011; **final acceptance:** 31 October 2011.

This is the full-length article (published online 1 Oct 2012) of an abridged version published in print. Cite this article as: **Br J Gen Pract 2012; DOI: 10.3399/bjgp12X656838**

How this fits in

Although orthostatic hypotension (OH) is more prevalent in old age, and in patients with diabetes, the prevalence of OH in older patients with type 2 diabetes is unknown. OH is also considered as an important risk factor for falling, however, the evidence regarding this association is conflicting. This study showed that OH is highly prevalent in home-dwelling older patients with type 2 diabetes. No association was found between falling and OH. Remarkably, orthostatic complaints were associated with previous falling and high fall risk, even after adjustment for OH. Perhaps, actively inquiring for orthostatic complaints, instead of measuring OH, as part of the care for patients with type 2 diabetes and/or cardiovascular disease, may be a useful step.

these patients, due to the high variability of blood pressure. Although all practices were asked to participate in recruiting the control group, only a few practices were willing to do so. As a result, participants in the control group, with no history of diabetes, were selected from only seven of the 35 general practices. These participants were either selected during a consultation with the GP, or by the authors using the GPs' patient information systems. The same selection criteria as in the diabetes group were used. For the participants in the control group selected by using the patients information system, one additional criterion was used: a consultation with the GP in the last 6 months. This criterion was used to select a group that would be comparable to the patients who were selected during a consultation with the GP. Those who were selected using the GPs' patient information systems, were sent an invitation to participate in the study.

Data collection

Demographic characteristics, medical history, and medication use were assessed using a standard structured questionnaire. The risk of falling was measured using a self-administered validated risk profile developed to identify community-dwelling older people at high risk of recurrent falling.[19] This risk profile assesses fall risk on the basis of previous fall incidents, body weight, functional limitations, handgrip strength, use of alcohol, presence of pets, level of education, and fear of falling. A high risk of falling was defined as a score of ≥10 points on the risk profile and can be interpreted as a 50% chance of falling at least twice in the upcoming 3 years.

Measurements were performed by either the investigating authors or the practice nurses. Height, body weight, and blood pressure were measured in all participating participants. All participants were asked whether they had consumed a meal or drink within 1 and 2 hours, respectively, prior to the measurements. Blood pressure was measured following a standardised protocol, using a validated A&D digital blood pressure monitor, model UA-767 plus 30.[20] Two supine measurements were performed after 5 minutes of rest, followed by two measurements after 1 minute standing and two measurements after 3 minutes standing. Mean values of the baseline, 1-minute and 3-minute measurements were calculated. During standing, the forearm of the participant was supported at heart level on an adjustable table or on the shoulder of the sitting investigator.[21] The definition of OH was a fall in blood pressure of at least 20 mmHg systolic or 10 mmHg diastolic after either 1 or 3 minutes of standing after the participant changed from the supine to the upright position.[22,23] After orthostatic testing, the participants were asked about feelings of dizziness, light-headedness, or faintness during standing (orthostatic complaints).

Statistical analyses

Based on an estimated prevalence of OH of 30%, the required sample size to obtain a 95% confidence interval (CI) +/–5% around the estimated prevalence, was 341. Therefore, the aim was to include 350 participants with type 2 diabetes. To enable a comparison of the results to those of participants without type 2 diabetes, the aim was to include approximately half the number of the study group: at least 150 participants.

First, univariate binary logistic regression analyses were performed to assess the association of the baseline characteristics with OH and orthostatic complaints. Multiple binary logistic regression analyses were performed to assess the association between OH, orthostatic complaints, and type 2 diabetes. Model 1 was adjusted for age and sex. Model 2 was additionally adjusted for body mass index (BMI), a history of hypertension, previous macrovascular complications, supine systolic blood pressure, the number of antihypertensive medications used, and consumption of a meal or drink before blood pressure measurement.

Finally, the relationships between OH and orthostatic complaints, and previous

fall incidents and high fall risk were investigated in four different models, in which fall incidents and high fall risk were the outcome variables. Model 1 was adjusted for OH, model 2 for orthostatic complaints, model 3 for OH and orthostatic complaints, and model 4 for symptomatic OH, defined as OH combined with the presence of orthostatic complaints. All models were additionally adjusted for the following possible predictors of fall incidents and fall risk: age, sex, BMI, type 2 diabetes, previous macrovascular complications, and the number of antihypertensive medications used. Since body weight is part of the risk profile by which fall risk was defined, body mass index (BMI) was not included in the models for high fall risk. All analyses were performed with SPSS software (version 18). This study was registered at clinicaltrials.gov, NCT00807976. The manuscript was written based on the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement.[24]

RESULTS

Study population

A total of 352 patients with diabetes and 211 participants without type 2 diabetes participated in this study. The number of participants who were invited initially by either the practice nurses, GPs, or the authors, is unknown. This number is only known for the participants selected by the authors: 218 (55%) of the 398 invited to participate actually took part in the study. The non-responders were older (78.6 versus 75.5 years, $P<0.001$), but no significant sex difference between the responders and the non-responders was found (43.6% versus 35.6% males, $P = 0.104$).

Baseline characteristics and the results of the univariate regression analyses are presented in Table 1. There was a univariate association between both macrovascular complications and the total number of drugs and OH and orthostatic complaints. Experiencing orthostatic complaints was related to a higher risk of OH. Higher blood pressure and not having consumed a meal or drink were associated with a higher prevalence of OH, but not with the presence of orthostatic complaints. Female sex, hypertension, and the number of antihypertensive agents were only related to experiencing orthostatic complaints. A total of 169 out of the 553 (30.6%) patients had fallen at least once in the previous year.

Type 2 diabetes and orthostatic hypotension

The prevalence of OH was 28% (95% CI

Table 1. Baseline characteristics and results of univariate logistic regression analyses with orthostatic hypotension and orthostatic complaints as dependent variables, (*n* = 563)

Characteristic	*n*[a]	OR (95% CI)	
		OH	Orthostatic complaints
Demographics			
Median age, years (IQR)	75 (72–79)	0.99 (0.95 to 1.03)	0.99 (0.95 to 1.05)
Male sex (%)	265/563 (47.1)	1.06 (0.72 to 1.56)	0.56 (0.35 to 0.91)
Mean body mass index, kg/m^2 (SD)	28.0 (4.2)	0.97 (0.93 to 1.02)	1.00 (0.95 to 1.06)
Type 2 diabetes mellitus (%)	352/563 (62.5)	1.87 (1.22 to 2.85)	2.16 (1.27 to 3.69)
Median duration of diabetes, years (IQR)	6 (4–10)	1.00 (0.96 to 1.05)	1.00 (0.96 to 1.05)
Hypertension (%)	438/563 (77.8)	1.37 (0.84 to 2.24)	2.11 (1.08 to 4.11)
Macrovascular complications (%)	175/563 (31.1)	1.71 (1.15 to 2.56)	2.13 (1.33 to 3.41)
Family history of CVD (%)	141/563 (25.0)	1.09 (0.70 to 1.69)	1.05 (0.62 to 1.79)
Measurements			
Consumption meal or drink (%)	394/558 (70.6)	0.40 (0.27 to 0.60)	0.82 (0.50 to 1.35)
Mean systolic BP lying, mmHg (SD)	142.1 (20.5)	1.31 (1.19 to 1.44)	0.89 (0.79 to 1.00)
Mean diastolic BP lying, mmHg (SD)	76.1 (9.9)	1.33 (1.09 to 1.62)	0.85 (0.67 to 1.08)
Mean pulse frequency (SD)	67.0 (10.8)	0.99 (0.97 to 1.01)	1.00 (0.98 to 1.02)
Score risk profile (IQR)	3 (1–6)	1.02 (0.97 to 1.08)	1.26 (1.19 to 1.33)
Orthostatic complaints (%)	85/563 (15.1)	2.02 (1.23 to 3.29)	NA
Medication			
Median number of pharmacological agents (IQR)	5 (3–6)	1.12 (1.04 to 1.20)	1.17 (1.08 to 1.27)
Median number of antihypertensive agents (IQR)	2 (0–3)	1.14 (0.99 to 1.32)	1.19 (1.01 to 1.41)
Antihypertensive medication	418/563 (74.2)	1.39 (0.88 to 2.21)	1.74 (0.96 to 3.15)

[a]n unless otherwise stated. A high risk of falling was defined as a score of ≥10 points on the risk profile and can be interpreted as a 50% chance of falling twice or more often in the upcoming 3 years. The ORs for systolic and diastolic blood pressure refer to a pressure increase of 10 mmHg. BP = blood pressure. CVD = cardiovascular disease. IQR = interquartile range. NA = not applicable. OH = orthostatic hypotension. OR = odds ratio. SD = standard deviation.

Table 2. Adjusted ORs for the effects of clinical variables on the risk of orthostatic hypotension and orthostatic complaints

	Orthostatic hypotension, OR (95% CI)		Orthostatic complaints, OR (95% CI)	
Variable	**Model 1**	**Model 2**	**Model 1**	**Model 2**
Diabetes: diabetes versus control	1.89 (1.23 to 2.90)	1.89 (1.16 to 3.08)	2.34 (1.36 to 4.02)	2.08 (1.17 to 3.72)
Age	0.99 (0.94 to 1.03)	0.95 (0.91 to 1.00)	0.98 (0.93 to 1.04)	0.98 (0.93 to 1.03)
Sex: male versus female	1.00 (0.68 to 1.48)	0.97 (0.63 to 1.50)	0.52 (0.32 to 0.85)	0.38 (0.23 to 0.65)
BMI	–	0.95 (0.90 to 1.01)	–	0.96 (0.91 to 1.03)
Hypertension	–	0.85 (0.42 to 1.69)	–	1..78 (0.75 to 4.24)
Macrovascular complications	–	2.14 (1.33 to 3.45)	–	2.29 (1.33 to 3.92)
Systolic blood pressure	–	1.33 (1.20 to 1.48)	–	0.87 (0.76 to 0.98)
Antihypertensive medication	–	1.03 (0.84 to 1.27)	–	0.93 (0.74 to 1.19)
Consumption of meal or drink	–	0.46 (0.30 to 0.72)	–	0.76 (0.45 to 1.29)

The ORs for systolic blood pressure refer to a pressure increase of 10 mmHg. The ORs can be interpreted as a measure of the association of the various variables to either orthostatic hypotension or orthostatic complaints (the dependent variables). BMI = body mass index. OR = odds ratio.

= 24% to 33%) and 18% (95% CI = 13% to 23%) in participants with and without type 2 diabetes, respectively. The results from the multivariate logistic regression analyses show that the association between type 2 diabetes and OH is independent from other clinical variables (Table 2). In these models, a history of macrovascular complications, higher supine systolic blood pressure, and no consumption of a meal or drink before measurements were also independently associated with a higher risk of OH. The prevalence of orthostatic complaints was 18% (95% CI = 15% to 23%) and 10%

Table 3. Adjusted ORs for the effect of clinical variables on the risk of previous fall incidents and high fall risk

	Previous fall incidents as the dependent variable, OR (95% CI)			
Variable	**Model 1**	**Model 2**	**Model 3**	**Model 4**
OH	0.94 (0.61 to 1.46)	–	0.90 (0.58 to 1.40)	–
Orthostatic complaints	–	1.63 (0.99 to 2.68)	1.65 (1.00 to 2.72)	–
Symptomatic OH	–	–	–	1.99 (0.93 to 4.23)
Age	1.02 (0.98 to 1.07)	1.03 (0.98 to 1.07)	1.02 (0.98 to 1.07)	1.03 (0.98 to 1.07)
Sex: male versus female	0.50 (0.34 to 0.75)	0.53 (0.36 to 0.79)	0.53 (0.36 to 0.78)	0.53 (0.36 to 0.78)
BMI	0.98 (0.93 to 1.03)	0.98 (0.94 to 1.03)	0.98 (0.94 to 1.03)	0.98 (0.94 to 1.03)
Diabetes: diabetes versus control	1.08 (0.72 to 1.62)	1.02 (0.68 to 1.54)	1.03 (0.68 to 1.55)	1.06 (0.71 to 1.59)
Macrovascular complications	1.06 (0.68 to 1.64)	0.99 (0.64 to 1.54)	1.00 (0.64 to 1.56)	0.99 (0.64 to 1.54)
Antihypertensive medication	1.07 (0.92 to 1.25)	1.07 (0.91 to 1.25)	1.07 (0.92 to 1.25)	1.07 (0.92 to 1.25)
	High fall risk as the dependent variable, OR (95% CI)			
	Model 1	**Model 2**	**Model 3**	**Model 4**
OH	0.80 (0.38 to 1.65)	–	0.61 (0.28 to 1.34)	–
Orthostatic complaints	–	7.77 (3.98 to 15.17)	8.21 (4.17 to 16.19)	–
Symptomatic OH	–	–	–	2.87 (1.09 to 7.55)
Age	1.07 (1.01 to 1.14)	1.09 (1.02 to 1.16)	1.09 (1.02 to 1.16)	1.07 (1.01 to 1.14)
Sex, male versus female	0.47 (0.24 to 0.92)	0.61 (0.30 to 1.23)	0.59 (0.29 to 1.20)	0.53 (0.27 to 1.04)
Diabetes: diabetes versus control	1.75 (0.83 to 3.68)	1.38 (0.64 to 2.98)	1.39 (0.65 to 3.01)	1.69 (0.80 to 3.56)
Macrovascular complications	1.61 (0.82 to 3.17)	1.16 (0.57 to 2.39)	1.24 (0.60 to 2.57)	1.39 (0.70 to 2.77)
Antihypertensive medication	1.20 (0.94 to 1.54)	1.21 (0.94 to 1.57)	1.21 (0.94 to 1.57)	1.21 (0.94 to 1.55)

Model 1 was adjusted for OH, model 2 for orthostatic complaints, model 3 for OH and orthostatic complaints, and model 4 for symptomatic orthostatic hypotension. All models were additionally adjusted for the following possible predictors of fall incidents: age, sex, BMI, type 2 diabetes, previous macrovascular complications, and the number of antihypertensive medications used. BMI was not included in the models with high fall risk as the dependent variable, since body weight is used in the risk profile by which high fall risk was defined. The ORs can be interpreted as a measure of the association of the various variables to either previous fall incidents or high fall risk (the dependent variables). BMI = body mass index. OH = orthostatic hypotension. OR = odds ratio.

(95% CI = 6% to 14%) in participants with and without type 2 diabetes, respectively. In multivariate analyses, the association between orthostatic complaints and type 2 diabetes was confirmed. Female sex, a history of macrovascular complications, and lower supine systolic blood pressure increased the risk of orthostatic complaints.

Fall incidents and fall risk

Table 3 presents the multivariate regression analyses with previous fall incidents and high fall risk as the dependent variables. OH was not related to previous fall incidents and high fall risk, in both univariate (data not shown) and multivariate analyses. The unadjusted odds ratios (ORs) of orthostatic complaints for fall incidents and high fall risk were 1.79 (95% CI = 1.11 to 2.88) and 8.60 (4.57 to 16.19), respectively. In multivariate analyses, the ORs were 1.63 (95% CI = 0.99 to 2.68) and 7.77 (95% CI = 3.98 to 15.17). After additionally adjusting for OH, orthostatic complaints remained associated with previous fall incidents and a high fall risk. Female sex was independently related to previous fall incidents. Higher age was associated with high fall risk only.

DISCUSSION

Summary

The prevalence of OH in older home-dwelling patients with type 2 diabetes was 28%, which was significantly higher than the prevalence of 18% in the patients without type 2 diabetes. Besides type 2 diabetes, there were independent associations with a history of macrovascular complications, higher systolic blood pressure, and no consumption of a meal or drink before orthostatic testing. OH was not related to either previous fall incidents or a high fall risk. Only the presence of orthostatic complaints was associated with more fall incidents and an increased risk of falling, even after adjustment for OH. Orthostatic complaints were more prevalent in patients with type 2 diabetes or cardiovascular disease, and in females.

Strengths and limitations

The main limitation of the study is potential selection bias. Participants were either selected by practice nurses during the periodical diabetic check-up, or by the authors using the GPs' patient information systems. Since the majority of the patients in the diabetes group were selected by practice nurses (77%), and the majority of the control group by the authors, this may have led to a selection bias. However, baseline characteristics of patients with type 2 diabetes did not differ between those recruited by the practice nurses and those recruited by the authors (data not presented). Therefore, this gives some reassurance that differences between the nurses and authors have not led to an important selection bias. It is also possible that the patients who were willing to participate had some characteristics that could not be adjusted for in the analyses. Unfortunately, data of the non-responders were only known for the participants selected by the authors. Since the responders in this study were younger than the non-responders, the results on prevalence of OH may be an underestimation. Differences between the seven general practices, in which the control group was recruited, and the other 28 practices may also have led to selection bias. However, the characteristics of patients with type 2 diabetes who were selected in the seven practices were not different from the patients in the other 28 practices (data not presented). Furthermore, patients with an irregular pulse were excluded from the study. Therefore, the results are not applicable to patients with an irregular pulse/atrial fibrillation.

Another limitation of this study may be the possibility of recall bias. As fall incidents were assessed retrospectively, it is very likely that the actual number of fall incidents was higher. Finally, there was a poor correlation between OH and orthostatic complaints. Of the 137 patients with OH, only 31 patients had typical orthostatic complaints. Perhaps differences in the definition of OH may explain the poor correlation between OH and orthostatic complaints. However, the correlation between OH and orthostatic complaints was not different for various definitions of OH in the current study (data not presented). The majority of studies, such as the study by Rutan *et al*,[6] did not describe either the number of patients with OH and complaints, nor the number of patients experiencing complaints without measuring OH, making it difficult to compare the poor correlation found in the current study to those studies. A recent study using continuous non-invasive orthostatic blood pressure measurements showed that only initial orthostatic hypotension (during the first 15 seconds) was related to orthostatic complaints and falls, whereas this relationship was not found for orthostatic hypotension after 3 minutes.[25] This could also be the explanation for the poor correlation between OH and complaints/falls in the current study. Unfortunately, blood pressure was not measured within the first seconds upon standing in this study.

This study has some notable strengths. Firstly, the mean of two blood pressure measurements was calculated at baseline, after 1 minute of standing, and after 3 minutes of standing. This allowed for correction of the imprecision inherent to a single blood pressure measurement. Secondly, all measurements were performed using the same validated automatic blood pressure monitoring device. Thirdly, unlike many other studies data were collected on consumption of meals or drinks before orthostatic testing.

Comparison with existing literature

In previous reports, the prevalence of OH in home-dwelling older people, aged ≥70 years, was estimated to be approximately 30% in the general population.[1,15,16] This is comparable to the prevalence in patients with type 2 diabetes observed in the current study. However, the prevalence in this study's control group was much lower. Higher mean age, lower BMI, and higher blood pressure may be the explanations for the higher prevalence of OH observed in previous studies.[1,15,16] Only one previous population-based study by Wu *et al* specifically investigated the prevalence of OH in type 2 diabetes before, and reported a prevalence comparable to this study, namely 25.5%.[17] In Wu *et al*'s study, mean age was lower and fewer patients were on antihypertensive medication. All measurements were performed between 8.00 and 10.00 am in the morning, unlike in the current study in which measurements were performed throughout the day. Since the prevalence of OH is higher when measured in the morning, especially before breakfast, this may have caused an underestimation of the prevalence of OH in the current study.[26] The associations observed between OH and macrovascular complications, higher systolic blood pressure, and not having consumed a meal or drink before testing confirm data from previous studies.[1,6,17,26]

A prospective study on fall risk showed that withdrawal of cardiovascular drugs led to lower fall risk and a reduction in OH.[27,28] Although a relationship between OH and falling was suggested in this study, causality was not proven. Observational studies show conflicting evidence regarding the association between OH and fall incidents.[6–12] Except for the study by Rutan *et al*,[6] all other studies, which reported a positive association between falling and OH, were performed in nursing homes or homes for older people.[7–10] In the community-based study by Rutan *et al*, orthostatic testing was only performed after 3 minutes of standing. The age- and clinic-adjusted OR of OH for frequent falls was 1.52 (95% CI = 1.04 to 2.22) in Rutan *et al*'s study.[6] The relationship between OH and fall incidents is probably influenced by many factors, including study population (such as, nursing home versus community-dwelling older people) and definition of OH (such as, blood pressure drop after 1 minute versus blood pressure drop after 1 or 3 minutes). Furthermore, in contrast to the current study that assessed fall incidents retrospectively, previous studies that showed positive associations had a prospective study design. However, based on the current study's results it can be hypothesised that it is not OH, but the presence of orthostatic complaints that is predictive of previous fall incidents and high fall risk in a home-dwelling older population.

Implications for practice and research

This study shows that OH is highly prevalent in older patients with and without type 2 diabetes. The results suggest that falling is only related to orthostatic complaints, and not to OH. Confirmation in other studies is necessary, and if confirmed, it may be as simple as just asking some questions instead of following a time-consuming protocol to select those patients with an increased risk of falling.

Funding

This study had no external funding source.

Ethical approval

This study was approved by the local medical ethics committee (reference: 08.1168). Written informed consent was obtained from all participants.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

Acknowledgements

The authors would like to thank all 35 participating general practices.

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