

Challenges and opportunities to improve fracture liaison service attendance

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Challenges and opportunities to improve fracture liaison service attendance: fracture registration and patient characteristics and motivations

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Abstract

Summary This questionnaire-based study evaluated the reasons for attendance or non-attendance at the fracture liaison service in patients with a recent fracture. Frailty, male sex, living alone, and low education were associated with non-attendance, and the information perceived by the patient was associated with attendance.

Introduction The purpose of this study was to evaluate hospital registration- and patient-related factors associated with attendance or non-attendance to the Fracture Liaison Service (FLS).

Methods Out of 1728 consecutive patients registered with a recent fracture at hospital entry, and after exclusion of 440 patients because of death, residence in a nursing home, already on osteoporosis treatment, or recent DXA, 1288 received an FLS invitation. We evaluated the hospital registration of fractures at entry and exit of the hospital. A questionnaire was sent to all invited patients to evaluate factors related to non-attendance (including age, gender, frailty, living alone, income, education, extrinsic motivations (impact of perceived information) and intrinsic motivations (patient's own perceived views and opinions) and to attendance (personal impact of clinical professionals' advice).

Results There were 278 more hospital exit codes than entry codes. Of the 1288 invited patients, 745 returned analyzable questionnaires (537 attenders and 208 non-attenders). Non-attendance was associated with male gender (OR: 2.08, 95% CI: 1.35, 3.21), frailty (OR: 1.62, CI: 1.08, 2.45), living alone (OR: 2.05, CI: 1.48, 2.85), low education (OR: 1.82, CI: 1.27, 2.63), not interested in bone strength (OR: 1.85, CI: 1.33, 2.63), and being unaware of increased subsequent fracture risk (OR: 1.75, CI: 1.08, 2.86). Information perceived by the patient was significantly associated with attendance (OR: 3.32, CI: 1.75, 6.27).

Conclusion Fracture entry registration inaccuracies, male gender, frailty, living alone, having low general education, or low interest in bone health and subsequent fracture risk were independently associated with FLS non-attendance. Adequately perceived advice (to have a bone densitometry and attend the FLS) was strongly associated with FLS attendance.

Keywords Attendance · FLS · Non-attendance

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Introduction

The Fracture Liaison Service (FLS) is widely considered the most effective model of care for the prevention of subsequent fractures [1–4], and fully coordinated, intensive strategies are the most effective approach to secondary fracture prevention [5] and treatment adherence [6, 7].

However, there is still a large evaluation and treatment gap in secondary fracture prevention [1–3, 8, 9], in spite of available treatments to prevent subsequent fractures [10].

The reasons for this low attendance are unclear, but patients' views and opinions about osteoporosis and the consequent underestimation of subsequent fracture risk might be of strong influence [11–14]. Besides person-related considerations, there may be administrative pitfalls to be evaluated.

Patient information is a key component of effective self-management [11], but it was not always clear whether the studies involved primary or secondary fracture prevention.

Also, patient characteristics can be involved in FLS attendance. Between FLSs, there is a high variability of selected patients according to age or sex [12]. In a study in the UK, socio-economic factors did not play a role in FLS participation [13]. Patient characteristics that could play a role in not attending the FLS include illness perception, frailty, living alone, and low education [14–17]. We therefore evaluated the association of administrative fracture registration, patient characteristics, and patient information with FLS non-attendance and attendance.

The first objective was to study the accuracy of the administrative fracture registration process on the proportion of patients that was or was not invited to the FLS. The second objective was to study the impact of demographic aspects, patients' views, and motivations on attending.

Patients and methods

Patients

This study was performed in patients older than 50 years who presented because of a clinical fracture between January 1st and December 31st in the year 2016 at the Reinier de Graaf Hospital, Delft, The Netherlands.

Identification of patients with a recent fracture was based on the administrative fracture registration that was registered by the clinical professional at the time of hospital entrance. Registrations were monthly reconciled by one of the FLS officers.

After exclusion of patients who had deceased, following patients were also not invited according to the local FLS protocol: permanent residents in a nursing home and patients with medical conditions in need of anti-osteoporotic treatments (not including calcium or vitamin D) or who had a DXA

within 2 years before fracture. All remaining patients were subsequently invited to attend the FLS.

We used two strategies to identify these patients to invite them for a FLS visit, in line with the Dutch Guideline on Osteoporosis and Fracture prevention as implemented in our hospital protocol [18]. Strategy 1 was to invite personally as many patients as possible by the clinical professional at the plaster department. Strategy 2 was to send an invitation letter to all patients who were not personally contacted by the clinical professional at the plaster department or who, in spite of this, had not made an FLS appointment. To accomplish strategy 2, we screened all entry fracture code registrations from the database of the Emergency Department once every month.

Questionnaire

In June 2017, all these patients, whether or not they had accepted the invitation to attend the FLS, were sent a questionnaire by post mail. The content of this questionnaire is available in the [Appendix](#).

The questionnaire consisted of (1) patient characteristics included age, sex, marital status, education, country of birth, income, and fracture location; (2) therapy: use of calcium and vitamin D supplements and having osteoporosis treatment; (3) patient views and opinions: intrinsic motivations (5 questions): about fracture and bone, general health, and questions about patients' views on bone quality and extrinsic motivations (11 questions): perceived advice to attend the FLS and have a DXA scan and motivations why they had decided to attend or not to attend the DXA and FLS; and (4) various aspects of frailty were evaluated, using the validated Tilburg Frailty Indicator (TFI) questionnaire [19]. The TFI has a scoring range between 1 and 15, frailty is defined by a score ≥ 5 but < 10 and being very frail by a score ≥ 10 with the highest limit of 15 points.

Motivations for attending the FLS were evaluated for extrinsic and intrinsic factors. Extrinsic motivations were considered to arise from information by clinical professionals, for example the inclination to follow instructions by the health professional to attend the FLS. Intrinsic motivations originate from self-reflection, such as personal judgment to strive for a better bone health.

Administrative registration of patients with a recent fracture

Reimbursement of treatments in Dutch hospitals is based on administrative fracture registration by the clinical professional. This is firstly done at the time of hospital admission because of a fracture (“entry registration”) [20–22], using the hospital electronic patient management system ChipSoft HiX 6.1 [23]. In this study, the FLS invitation process was based on entry registrations from the Emergency Departments

database, which is common practice among many Dutch FLSs [8, 9]. During the process of fracture care, this entry registration is reconciled by the Hospital Financial Dept., based on the automated collection of fracture registrations from all medical departments. In case of incomplete entry registration, the Hospital Financial Dept. was entitled to make adjustments before the final registration was sent to the health insurance company for reimbursement (“exit registration”). The fracture registration accuracy was evaluated by comparing all entry fracture registration codes with all exit fracture registration codes.

Fracture types (according to exit registrations) were subdivided into non-vertebral non-hip (NVNH) minor fractures ($n = 855$, 43%), NVNH major fractures ($n = 740$, 37%), hip fractures ($n = 312$, 15%), or clinical vertebral fractures ($n = 99$, 5%), based on the level of subsequent fracture risk as previously reported [24].

Statistical analysis

Data were analyzed using Statgraphics Centurion XVII software (Version 17.2.05 for MS-Windows; Statpoint, Inc., Warrenton, VA, USA).

Analyses were performed on two age strata (< 70 and ≥ 70 year) in line with the Dutch VMS [25], gender, and on dichotomized variables of the 745 questionnaires. Medians of age (year) with respect to gender were compared with the Wilcoxon rank-sum test and the Micceri normality test. Associations were assessed via crosstabulation, using two column-dependent variables Attending (Yes/No) and Frailty (Yes/No) using TFI.

After bivariate crosstabulation, a multivariate logistic regression model was fitted to identify any possible association between the binary outcome variable attending (Yes/No) and independent predictive variables, i.e., demographics as age and gender and extrinsic or intrinsic motivations. We tried to decipher model enhancing and significant interactions applying R TREE package. The association was assessed by direction and absolute value of adjusted residuals. Evidence of any association in the population from which the sample was drawn was assessed with unconditional, uncorrected Pearson’s Chi-squared test; if significant, the association was measured using odds ratios and 95% confidence intervals. Multivariate odds ratios were estimated with logistic regression, with non-attendance as dependent outcome and demographics, frailty, and motivations as independent outcome variables after exclusion of those independent variables that were not significant in the univariate analysis and after testing for interaction between variables. Where applicable, 95% confidence intervals and correlation coefficients were used. A p value $< .05$ was considered statistically significant.

Ethics

The study was carried out in accordance with the declaration of Helsinki and the guidelines of the International Conference on Harmonization Good Clinical Practice (GCP) after a certificate of no objection approved by the regional Medical Ethical Review Board (METC Zuidwest Holland) no. NL 17.109.

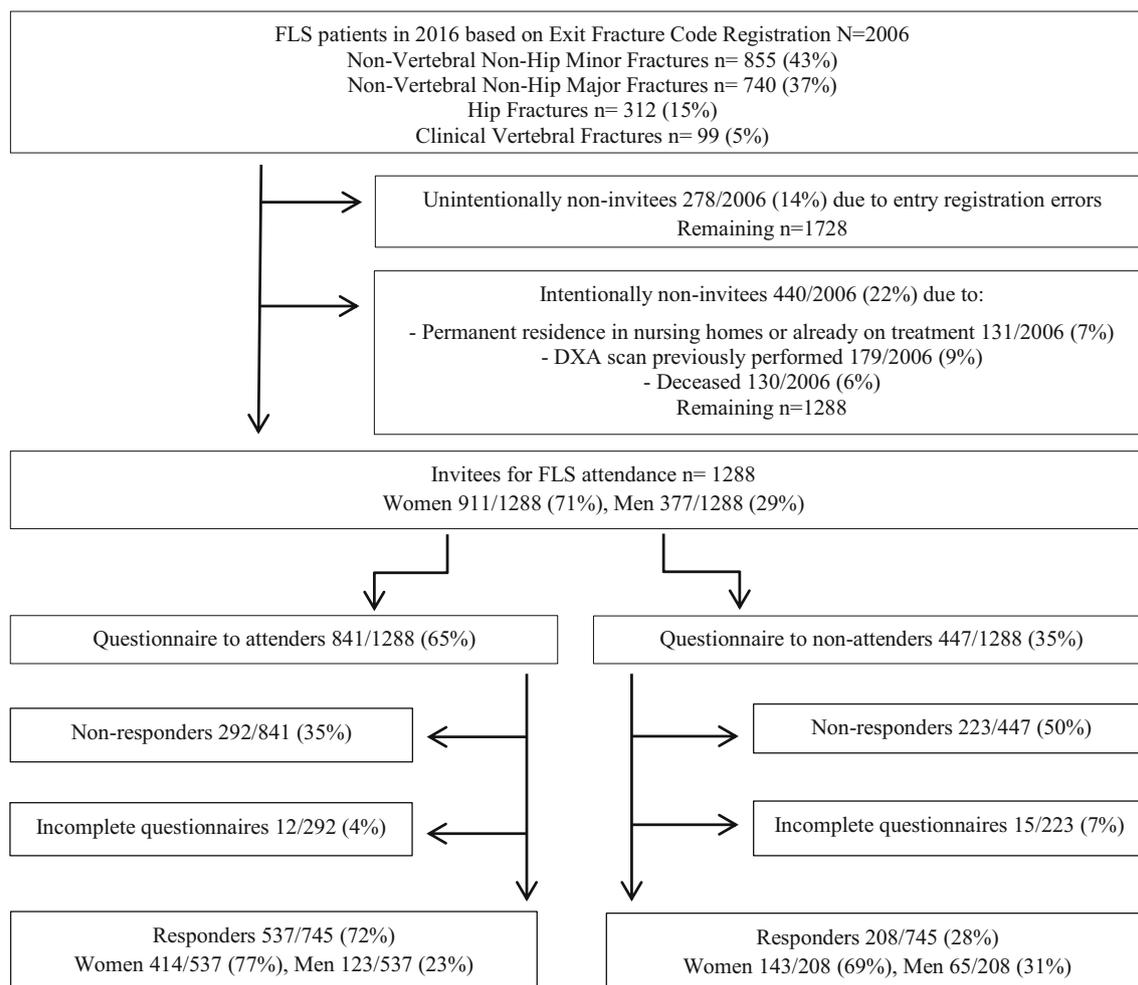
Results

A total of 2006 patients of 50 years or older had a validated exit fracture code registration. As patients were only invited to attend the FLS based on entry fracture code registrations, we calculated that 278 (14%) were missed and therefore had not received the FLS invitation by post mail. Of the remaining 1728 patients, 440 patients were excluded from invitation because they had died or were excluded based on our local FLS protocol (Fig. 1). Therefore, only 1288 patients were invited. This resulted in 841 attenders and 447 not attenders meaning 65% of all invited patients (Fig. 1).

From these 1288 patients, we received 772 questionnaires (27 not analyzable). The remaining 745 evaluable questionnaires came from 537 attenders (72%) and from 208 non-attenders (28%).

The characteristics of attenders and non-attenders are presented in Table 1. Using univariate analysis (Table 2), non-attendance was significantly associated with age > 70 years, being male, living alone, having low income or low education, and being frail. Out of the five questions concerning extrinsic and 11 questions concerning intrinsic motivations, one extrinsic motivation and two intrinsic motivations showed significant associations. The extrinsic motivation “the clinical professional did not advise me to go for DXA” was significantly associated with non-attendance as well as the following two intrinsic motivations (1) “I am not interested in my bone strength” and (2) “I do not think that my fracture risk is increased after sustaining this fracture”. On the other hand, patients’ perceived advice by the clinical professional to go through DXA and visit the FLS was significantly associated with attendance (Tables 2 and 3).

In multivariate analysis, all factors that were significant in univariate analysis remained significant, except age and low income (Table 3). Non-attendance was independently associated with being male, living alone, low education, frailty (OR: 1.62, CI: 1.08, 2.45), no perceived advice to go through DXA, and visit the FLS as well as “I am not interested in my bone strength” and “I do not think that my fracture risk is increased after sustaining this fracture” with non-attendance but not with age, neither as bivariate ≤ 70 - and > 70 -year groups, nor per decade, or categorized for highest versus lowest quartiles or per age category in standard deviation subgroups



Legends:

DXA: Dual Energy X-ray Absorptiometry; FLS: Fracture Liaison Service.

Fig. 1 Flowchart of FLS patients in 2016 based on entry and exit fracture code registration and response to questionnaires. Legends: DXA: dual energy X-ray absorptiometry; FLS: Fracture Liaison Service

(Table 3). Perceived advice to go through DXA and to visit the FLS was positively and significantly associated with attendance, with an OR of 3.32 (CI: 1.75, 6.27).

Discussion

The aim of our study was to gain more insight into reasons of FLS non-attending or attending. We identified failures in administrative fracture entry registration as well as being male, frail, having low general education, living alone, and lack of extrinsic and intrinsic motivations as independent risks for FLS non-attending. Extrinsic motivation was an independent FLS attending factor.

There was an invitation gap of 14% in our hospital due to administrative errors. This finding may provide opportunities to improve this as yet unidentified factor for non-

attending the FLS. According to a previously reported study, this improvement may have nationwide implications for FLS attendance and consequences for fracture reduction and cost savings [6, 26].

The Fracture Liaison Service (FLS) is considered the most effective approach for secondary fracture prevention, but attendance is heterogeneous [1, 8, 9]. Therefore, we evaluated the invitation process, including registration and patients' personal views. It is of note that there is no reported systemic audit on FLS registration. However, there is literature on patients' views and considerations after fracture, highlighting the importance of the lack of information and low awareness to be at high risk for subsequent fracture [11, 27]. Since there are different degrees in FLS structures and populations, studies have been conducted to look for common phenotypes and socio-economic factors in order to better predict FLS non-attendance [5, 16, 17]. In addition to these factors, we found

Table 1 Characteristics of 745 FLS patients that responded to the questionnaire

<i>Pooled data for men and women</i>	Attending <i>n</i> = 537 (72%)	Not-attending <i>n</i> = 208 (28%)
<i>Demographics</i>		
Age at fracture	69 (50–96)	75 (50–95)
Women	414 (77%)	143 (69%)
Men	123 (23%)	65 (31%)
<i>Fracture type:</i>		
Minor fracture	207 (39%)	68 (32%)
Major fracture	250 (46%)	99 (48%)
Hip fracture	54 (10%)	25 (12%)
Vertebral fracture	26 (5%)	16 (8%)
<i>Marital status:</i>		
Living together (married/shared living)	343 (64%)	98 (47%)
Not married	47 (9%)	18 (9%)
Divorced	43 (8%)	17 (8%)
Widow/widower	104 (19%)	75 (36%)
<i>Education:</i>		
No response	5 (1%)	4 (2%)
Primary/secondary school vs. High school/university	342 (64%)	154 (74%)
	190 (35%)	50 (24%)
<i>Country of birth</i>		
The Netherlands	507 (94%)	194 (93%)
Indonesia	6 (1%)	2 (1%)
Surinam and Antilles	5 (1%)	0
Turkey and Morocco	19 (4%)	6 (6%)
<i>Income (in € per month)</i>		
Low (€ 601–€ 1200)	67 (12%)	34 (16%)
Normal (€ 1200–€ 1800)	96 (18%)	49 (24%)
High (\geq € 2100)	275 (51%)	70 (33%)
No response	99 (19%)	55 (27%)
<i>Are you satisfied with your living/housing environment?</i>		
Yes	519 (97%)	200 (96%)
No	12 (2%)	6 (3%)
No response	6 (1%)	2 (1%)
<i>Use of calcium and vitamin D supplementation and use of osteoporosis medication</i>		
<i>Use of calcium tablets?</i>		
Yes	113 (21%)	62 (30%)
No	396 (74%)	137 (66%)
No response	28 (5%)	14 (4%)
<i>Use of vitamin D?</i>		
Yes	299 (56%)	74 (36%)
No	217 (40%)	116 (56%)
Do not know	10 (2%)	8 (4%)
No response	11 (2%)	10 (4%)
<i>Do you take oral bisphosphonates?</i>		
Yes	106 (20%)	38 (18%)
<i>Patients' views and opinions</i>		
<i>What caused your fracture?</i>		
Osteoporosis	65 (12%)	23 (11%)
The fall	240 (45%)	79 (38%)

Table 1 (continued)

<i>Pooled data for men and women</i>	Attending <i>n</i> = 537 (72%)	Not-attending <i>n</i> = 208 (28%)
The accident	85 (16%)	36 (17%)
Bad physical condition	9 (2%)	3 (1%)
Imbalance/dizziness	30 (6%)	23 (11%)
No response	108 (19%)	82 (39%)
<i>I think that my fracture risk is not increased although I had a fracture.</i>		
Yes	99 (18%)	24 (12%)
No/do not know	432 (82%)	181 (88%)
<i>Perceived advice to attend the FLS</i>		
Perceived advice to attend = Yes	428 (80%)	61 (29%)
Perceived advice to attend = No	109 (20%)	147 (71%)
<i>Taking interest in bone quality</i>		
Yes	63 (12%)	15 (7%)
No	236 (44%)	118 (57%)
Somewhat	229 (43%)	64 (31%)
No response	9 (1%)	11 (5%)
<i>Various aspects of health and frailty</i>		
<i>How healthy is your lifestyle?</i>		
Healthy	400 (74%)	138 (66%)
Not healthy, not unhealthy	134 (25%)	65 (31%)
Unhealthy	3 (1%)	5 (3%)
<i>Self-reported level of health</i>		
Good	408 (76%)	145 (70%)
Poor	101 (19%)	44 (21%)
No response	28 (5%)	19 (9%)
<i>Do you suffer from 2 or more chronic diseases?</i>		
Yes	173 (32%)	72 (35%)
No	352 (66%)	131 (63%)
No response	12 (2%)	8 (2%)
<i>Do you take 4 or more tablets every day?</i>		
Yes	179 (33%)	84 (40%)
No	336 (63%)	112 (54%)
No response	22 (4%)	12 (6%)
<i>Frailty (Tilburg Frailty Indicator scores)</i>		
Women	414 (77%)	143 (69%)
<i>TFI score</i> \geq 5 (<i>frail</i>)	167 (40%)	60 (42%)
<i>TFI score</i> < 5 (<i>not frail</i>)	247 (60%)	83 (58%)
Men:	123 (23%)	65 (31%)
<i>TFI score</i> > 5 (<i>frail</i>)	16 (13%)	24 (37%)
<i>TFI score</i> < 5 (<i>not frail</i>)	107 (87%)	41 (63%)

Results are presented as median (range) or numbers (percentage). A Tilburg Frailty Indicator score \geq 5 represents frailty

being male, frail, living alone, and being lower educated independently and significantly contributed to non-attendance.

Being male revealed a significant factor for non-attending. This finding has been previously published in another FLS study [28]. In a recent review on osteoporosis in men, it was found that after low trauma men are less likely to be screened

due to men's reluctance to be screened, although their lifetime risk of osteoporotic fractures is between 13 and 25% after the age of 50 [29]. Although women have a higher risk for a first fracture than men, the relative risk of a subsequent fracture is higher in men, so that the absolute subsequent fracture risk is similar between men and women [30].

Table 2 Univariate associations of demographics, extrinsic and intrinsic motivations, and frailty with FLS non-attendance and attendance

	Measure of association: OR (95%CI)	Test of association: Pearson's Chi-square <i>p</i> value
FLS non-attendance		
<i>Demographic factors contributing to be a non-attender</i>		
Male	1.67 (1.17; 2.42)	.002
Living alone	1.98 (1.43; 2.74)	< .001
Age > 70 years	1.87 (1.35; 2.60)	< .001
Low income	3.03 (2.00; 4.55)	< .001
Low education	3.03 (2.00; 4.55)	< .001
<i>Extrinsic motivations contributing to be a non-attender</i>		
No advice was perceived to have a DXA and to visit the FLS	9.1 (6.7; 12.5)	< .001
<i>Intrinsic motivations contributing to be a non-attender</i>		
I am not interested in my bone strength*	2.08 (1.50; 2.94)	< .001
I do not think that my fracture risk is increased after sustaining this fracture**	1.72 (1.08; 2.86)	.024
<i>Frailty: Tilburg Frailty Indicator (TFI)</i>		
Frailty	2.12 (1.51; 2.98)	.002
FLS attendance		
<i>Extrinsic motivation contributing to be an attender</i>		
Advice was perceived to have a DXA and to visit the FLS	5.9 (3.7; 9.1)	< .001

OR odds ratio, 95%CI 95% confidence interval, *p* value < .05 is considered significant. Frailty: Tilburg Frailty Indicator (TFI) dichotomized: < 5 = not frail vs. ≥ 5 = frail, living alone: dichotomized Yes/No meaning living with other individual(s) vs. living alone; age: dichotomized ≤ 70 years or > 70 years; income: dichotomized highest monthly income \geq €2100 vs. < € 2100; education: dichotomized high school or university grouped vs. other levels of education. Statistical analysis (applying R package: tree) revealed no interaction between variables

*I am not interested in my bone strength; grouped data: I am not interested in my bone strength vs. somewhat interested and interested in my bone strength

**I do not think that my fracture risk is increased after sustaining this fracture; grouped data Yes vs. No and I do not know

Table 3 Multivariate logistic regression of demographics, extrinsic and intrinsic motivations and frailty with FLS non-attendance or attendance

	Measure of association: OR (95%CI)	Test of association: Pearson's Chi-square <i>p</i> value
FLS non-attendance		
<i>Demographics contributing to be a non-attender</i>		
Male	2.08 (1.35; 3.21)	.002
Living alone	2.05 (1.48; 2.85)	< .001
Low education	1.82 (1.27; 2.63)	.0014
<i>Extrinsic motivations contributing to be a non-attender</i>		
No advice was perceived to have a DXA and to visit the FLS	3.23 (1.96; 5.56)	< .001
<i>Intrinsic motivations contributing to be a non-attender</i>		
I am not interested in my bone strength.	1.85 (1.33; 2.63)	< .001
I think that my fracture risk is not increased although I had a fracture	1.75 (1.08; 2.86)	.002
<i>Frailty: Tilburg Frailty Indicator (TFI)</i>		
Frailty	1.62 (1.08; 2.45)	.002
FLS attendance		
<i>Extrinsic motivation contributing to be an attender</i>		
Advice was perceived to have a DXA and to visit the FLS	3.32 (1.75; 6.27)	<.001

OR odds ratio, 95%CI 95% confidence interval, *p* value < .05 is considered significant

Frailty leads to a negative spiral with an increase in fall risk, hospital admissions, and death [31–33] and was a significant determinant of non-attendance in this study. Frailty is operationalized into phenotypes via psychometric clinical descriptions [34–36] or via a scoring system according to validated indicators [37]. In this study, the Tilburg Frailty Indicator (TFI) was used because the TFI is also designed to point insight into demographic variables. TFI has been propagated previously for its robust validation properties, showing favorable outcomes for the relationship between phenotypical and psychometric properties [37]. In an intentionally similar survey on the use of osteoporosis medication after fracture and women's motivation, it was found that frailty was 44% according to the TFI [27]. Moreover, 25–50% of people older than 85 years comply with the accepted definition of frailty [31, 36, 37]. In the current study, frailty was found in 40% of non-attenders (42% women and 37% men) who were younger (median 70 years). This underlines the importance of frailty including its associated functional restrictions in the prediction of fracture risk [38, 39]. Importantly, frailty and functional restrictions are not only associated with non-attendance but also with high imminent fracture risk [38, 39].

In this FLS study, we found a univariate association between age (> 70 years) and non-attendance but the association was not significant in the multivariate model, indicating that other risk factors were dominant over age. This finding, although intuitively perceived to be associated, is not new in the field of osteoporosis. For example, in the Study of Osteoporotic Fractures among women of 65 years and older, age predicted 1-year subsequent risk of hip and non-vertebral fractures, however, this predictive factor diminished after adjusting for functional and cognitive restrictions [39].

Low education was accounted as an independent associated factor of non-attendance in support with two previous studies from Canada and the UK. These studies point to the important role of someone's capability for self-reflection, health literacy, and self-management [11, 16].

Living alone was also found to be a significant determinant for non-attending. In Western European countries, e.g., The Netherlands, the number of adult people living alone is gradually increasing. Recent Dutch data show 43% of the elderly adult population to live alone (21% after divorce and 22% after death of a loved one [40]. Living alone should not be interpreted synonymous with loneliness but stands for increasing odds of losing social contacts and also the reluctance to ask support in general and for medical care [41].

Adequate motivation or the lack of it was a strong determinant associated with FLS attendance or non-attendance. Moreover, motivating patients for FLS attendance by health care professionals should take place shortly after sustenance

of fracture [1, 9]. Therefore, successful patient–health care professional interaction may well resolve part of the widely observed treatment gap. In this perspective, interfering factors like health professionals' self-assurance and the need in general for up-to-date training and uniformity in the field of fracture prevention remain essential [7]. The beneficial effect of face to face FLS promotion immediately post fracture has been shown effective in the current and in a previous study [8]. More than a third of all fracture registrations is attributable to osteoporosis [26]. Such a high proportion prompted to the conviction that all available instruments should be deployed to prevent new fractures as we have the insight, methods, and medications [10, 27]. Physicians, cast technicians, and FLS nurses/nurse practitioners are encouraged to embrace this part of treatment to put effort in gaining patients' attention to accept treatment to prevent subsequent fractures.

The relatively high response rate of 60% to this questionnaire study is remarkable. Usually, lower response rates of pencil and paper studies and of anonymous internet surveys have been reported [42].

This study has limitations. In this retrospective study, information regarding fracture treatment, either conservatively or surgery, exact time between fracture and questionnaire and duration of in- and outpatient treatment, was not available.

In addition, we were not able to correlate treatment modalities and complications and time of rehabilitation to attendance. To ensure statistical power demographics were analyzed as groups, i.e., living alone, income, and level of education. These latter factors are probably different per country, region, or neighborhood.

In conclusion, failures in administrative fracture entry registration as well as frailty, male gender, having low general education, living alone, and low interest in bone health and subsequent fracture risk were independent determinants for FLS non-attendance. Adequate motivation of patients by the healthcare professional shortly after the fracture, or the lack of, was the strongest determinant associated with both FLS attendance and non-attendance, respectively. We advocate to increase attention on the fracture registration process and to put effort on a personal tailored approach to help patients to make an informed decision. Apart from these aspects, alternative strategies may be needed for those individuals who are frail, are living alone, and have low education in order prevent subsequent fractures.

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Author's contributions PVDB, DHS, and PVH are responsible for the study design. PVDB and DHS were the authors, supported by PVH, who also performed all statistical analyses. PG and JVDB supported the process with important scientific contributions.

Compliance with ethical standards

Ethics The study was carried out in accordance with the declaration of Helsinki and the guidelines of the International Conference on Harmonization Good Clinical Practice (GCP) after a certificate of no objection approved by the regional Medical Ethical Review Board (METC Zuidwest Holland) no. NL 17.109.

Conflicts of interest None.

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