### Clinical Pain Research

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# Pain experience in an aging adult population during a 10-year follow-up

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#### **Abstract**

**Objectives:** This 10-year follow-up study aimed to examine the persistence of SF-36 pain intensity and pain-related interference and to identify baseline factors that may relate to pain experience among community-dwelling aging adults. **Methods:** Questionnaire and clinical data on a total of 1,954 participants (mean age at baseline 63 years) were collected in 2002, 2005, 2008, and 2012. Based on pain reports, four pain intensity, pain interference (PIPI) groups were formed at each time point: PIPI group I: none to mild pain intensity and interference; II: moderate to extreme pain intensity, none to mild pain-related interference; III: None to mild pain intensity, moderate to extreme pain-related interference, IV: Moderate to extreme pain intensity and interference.

**Results:** Participants with the most pain at baseline improved their pain situation the most during the follow-up. Higher BMI was associated with pain interference, and metabolic syndrome (MetS) and musculoskeletal diseases with both pain intensity and interference (p<0.05, statistically significant interaction between pain intensity and pain interference) at baseline. According to multivariate logistic regression analysis the following baseline characteristics were associated with remaining in PIPI group I throughout

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the follow-up: presence of musculoskeletal disease (OR 0.22 [95% CI 0.16–0.30]), high BMI (OR 0.93 [95% CI 0.90–0.97]), high household income (OR 1.46 [95% CI 1.07–1.98]), good childhood home environment (OR 1.03 [95% CI 1.00–1.05]). **Conclusions:** Multiple factors may affect pain persistence in late adulthood with varying effect on pain intensity and pain-related interference. Pain situation of even those with most pain may be improved.

**Keywords:** aging; elderly; middle-aged; pain; pain intensity; pain interference; pain persistence.

## Introduction

The economic burden imposed on society by chronic pain is enormous [1, 2]. On an individual level, the burden may be even heavier, as chronic pain is a major factor affecting the health-related quality of life (HRQoL) [3, 4]. Chronic pain is common among older adults [5–8], and the population is aging rapidly.

The importance of separate evaluation of pain intensity and pain-related interference has been highlighted [9–11]. In pain management, to become completely free of pain is rarely a priority, however, adaptation may occur. To minimize the interference, however, is always the goal and, with appropriate pain management, also achievable in many cases. Studies evaluating the persistence of pain-related interference in community-dwelling older adults are scarce. The existing studies present rather short follow-up periods and long-term conclusions have emerged as difficult to be drawn [12, 13]. To experience persistent highly interfering pain is particularly destructive in terms of the quality of life [14]. On the other hand, relatively high prevalence (12%) of long-term non-interfering pain has also been reported among aged population [15].

Further studies have suggested for example older age, male sex, better self-reported health, not being obese, fewer medications, and fewer depressive symptoms as protective factors from persistent pain [16]. Higher prevalence of concomitant anxiety, depression, co-morbidity and obesity; female sex; older age; low education and income; and low

social class, have been suggested to associate with persistence of interfering pain in older adults [12, 15]. In 2005–2007, in a study on Finnish community-dwelling older adults, persistent pain for over 3 years was reported to be highly prevalent and associated with poor self-related health, mobility difficulties, and rheumatoid arthritis [17]. Further knowledge is needed to evaluate whether the several physical, psychological, and social factors presented above rather have an influence in pain intensity or interference, and whether the effects reach a clinical significance in long-term.

Longitudinal studies are essential in pain research. Especially among older adults who report a high pain prevalence, identifying the characteristics of those individuals whose pain becomes persistent may markedly improve the targeting of pain management, thus preventing the pain from becoming chronic. The research questions of the present study were as follows: 1) What was the persistence of older adults' pain experience (pain intensity and pain-related interference) over a 10-year follow-up? 2) Which of the several factors (demographics, health-lifestylemetrics, standard clinical chemistry, concomitant morbidities) examined were related to pain intensity and/or pain interference of the study participants at baseline?

# Methods

The present study was a part of the 10-year follow-up multidisciplinary Good Ageing in Lahti Region (GOAL) cohort study executed in the Päijät-Häme Hospital District in Southern Finland in 2002–2012 [18]. The GOAL introduced a stratified (age, sex, 14 municipalities) random sample of community-dwelling Finnish adults born in 1926-30, 1936-40, and 1946-50. Thus, at the end point in 2012, the participants were 62-66, 72-76, and 82-86 years of age.

At baseline (2002) and at each of the three follow-up visits (2005, 2008, and 2012), an extensive questionnaire (overall health, attitudes, quality of life, etc.) was applied and blood samples and physical data collected. The inclusion criteria were as follows: 1) sufficient data regarding reported pain intensity and interference (490 excluded) and 2) attendance at baseline in 2002 and at least one additional follow-up point (371 excluded). Therefore, the total number of subjects included in the analyses was 1,954. Seniors in hospital care or in need of institutional care did not participate in the study. Figure 1 presents the study flow chart.

All data on the study participants' pain, demographics, lifestyle, morbidity, and symptoms were based on the GOAL questionnaire. Regarding pain, the two-item Bodily Pain section of the SF-36 questionnaire was used [19, 20]. The participants indicated 'How much bodily pain have you had during the past 4 weeks' (intensity; 100=none, 80=very mild, 60=mild, 40=moderate, 20=severe, 0=very severe) and 'During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?' (interference; 100=not at all, 75=a little, 50=moderately, 25=quite a bit, 0=very much). SF-36 bodily pain was calculated as the mean of both pain intensity and interference reports. Four pain intensity, pain interference (PIPI) groups (I-IV) with combined pain intensity and interference

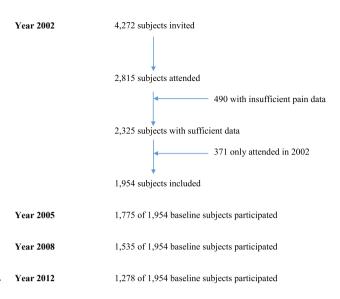


Figure 1: Study flow chart presenting participant inclusion and the number of participants who attended the study through the 10-year follow-up.

reports were formed using a foursquare model. The formation of the PIPI groups is presented in Figure 2.

Interaction between pain intensity and pain-related interference was calculated to examine whether these two present synergy, or whether the effects of variables on pain intensity and interference may be regarded as main effects. Thus, if p-value for interaction is <0.05, the baseline variable has an effect on pain intensity and interference.

Several factors were examined in relation to pain. Variable selection was based on multidisciplinary evaluation taking previous literature into account. Household income was determined as the taxable household income divided by the square root of the number of people living in the household indexed to the year 2018 [21]. Weekly alcohol consumption was measured with the three-item AUDIT-C [22] instrument. Leisure-time physical activity (LTPA) was determined as activities lasting over 30 min that make the participant sweat and puff at least to some degree (high [6-7 times a week], moderate [3-5 times a week], low [1-2 times a week or less, or not possible due to injury or illness]) [23]. Laboratory test data (fP--Glucose, fP-Triglyceride, high-density lipoprotein [fP-HDL], low-density lipoprotein [fP-LDL], fP-Cholesterol), and blood pressure were considered. The morbidities examined included cardiovascular, pulmonary, and musculoskeletal diseases, as well as diabetes mellitus type II and depression. Metabolic syndrome (MetS) was determined as the presence of three or more of the following components: 1) waist circumference ≥102 cm for men and ≥88 cm for women; 2) fP-Triglycerides ≥1.7 mmol/L, or treatment for dyslipidemia; 3) fP-HDL ≤1.03 mmol/L for men and ≤1.29 mmol/L for women, or treatment for dyslipidemia; 4) systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥85 mmHg, or antihypertensive medication; and 5) fP-Glucose ≥5.6 mmol/L or the use of medication for hyperglycemia [24]. Smoking and cohabitation were self-reported. Pain medication administration was based on self-report reflecting whether a participant has used some prescribed analgesic during the last week. The Childhood Index was calculated as the sum of responses to nine questions regarding the childhood home environment. The participants were asked to evaluate how well the following adjectives reflected their childhood home environment (on a scale of 0-4, with 0=the most negative alternative and 4=the most positive): warm/caring; inspiring/supportive;

#### **Pain Intensity**

		None to mild	Moderate to very severe		
	None to mild	PIPI group I	PIPI group II		
Pain-related		$N_I = 1,380 (71\%)$	$N_{II} = 133 (7\%)$		
Interference	Moderate to	PIPI group III	PIPI group IV		
	extreme	$N_{III} = 77 (4\%)$	$N_{IV} = 364 (19\%)$		

Figure 2: A foursquare model of pain intensity, pain interference (PIPI) group formation among 1,954 Good Ageing in Lahti Region (GOAL) participants. PIPI group I: None to mild pain intensity, none to mild pain-related interference; PIPI group II: Moderate to very severe pain intensity, none to mild pain-related interference; PIPI group III: None to mild pain intensity, moderate to extreme pain-related interference, PIPI group IV: Moderate to very severe pain intensity, moderate to extreme pain-related interference. The participants indicated 'How much bodily pain have you had during the past 4 weeks?' (intensity; 100=none, 80=very mild, 60=mild, 40=moderate, 20=severe, 0=very severe) and 'During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?' (interference; 100=not at all, 75=a little, 50=moderately, 25=quite a bit, 0=extremely, SF-36).

contentious; understanding/trusting; harsh; open; unequal; happy; careless. Also, regarding childhood, participants were asked to report whether their childhood family had ever had long-term financial problems, whether they had ever feared a family member, and whether there had been alcoholism in the family.

All-cause mortality was examined. The 10-year survival data of the participants were retrieved from Statistics Finland.

The descriptive statistics include means and SDs for continuous variables and numbers and percentages for categorical variables. Statistical comparisons between groups at baseline were drawn using generalized linear models (analysis of variance and logistic models). Tests for interactions between interference (with and without interference) and intensity (with and without intensity) were conducted by adding a multiplicative term between the interference level and the intensity level.

Longitudinal measures were analyzed using generalizing estimating equations (GEE) models with the unstructured correlation structure. GEE models take into account the correlation between repeated measurements in the same participants; the models do not require complete data and can also be fitted for individuals for whom observations at all time points are not available. A multivariate logistic regression model was used to investigate factors related to participants remaining in PIPI group I (baseline for comparison=participants who stayed in PIPI group 1 throughout the follow-up, comparator group=participants who moved out of PIPI group 1). The normality of variables was evaluated graphically and with the Shapiro-Wilk W test. The Stata 16.0, StataCorp LP (College Station, TX, USA), statistical package was used for the analyses.

The Regional Ethics Committee of Helsinki University Hospital gave the approval for the study (HUS 1748/2019). The principles of the Declaration of Helsinki were observed. All participants gave their written informed consent prior to the data collection.

## Results

Study flow charts are shown in Figure 1. The mean age of all participants at baseline in 2002 was 62.6 years. The proportion of women was 52%. Of a total of 1,954 participants,

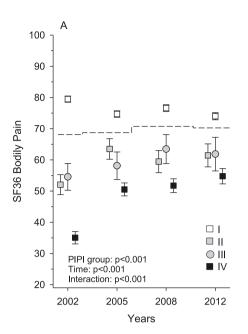
1,380 (71%) comprised PIPI group I, 133 (7%) comprised PIPI group II, 77 (4%) comprised PIPI group III, and 364 (19%) comprised PIPI group IV (Figure 2).

The reported mean SF-36 bodily pain scores of the whole sample at each follow-up visits were as follows: 68 (SD 24) in 2002, 69 (SD 24) in 2005, 71 (SD 24) in 2008, and 70 (SD 23) in 2012.

After adjusting for sex, age, education, smoking, alcohol consumption, LTPA, and the number of morbidities, the changes in pain experience in the four PIPI groups were calculated (Figure 3A).

The proportion of participants who had shifted to a different PIPI group at the follow-up visits compared to their baseline PIPI group were as follows: 29% in 2005, 29% in 2008, and 30% in 2012. The percentages of participants whose pain intensity and pain-related interference had not improved at the follow-up visits (i.e., those who had not moved to or not remained in PIPI group I) are presented in Figure 3B. To summarize Figure 3A, B, those with the poorest pain situation at baseline improved their pain situation the most during the follow-up.

Participant characteristics and factors in relation to four PIPI groups at baseline are presented in Table 1. Higher BMI was associated with pain interference, and MetS and musculoskeletal diseases with both pain intensity and interference (p<0.05, statistically significant interaction between pain intensity and pain interference) at baseline. The p-value for interaction presents whether pain intensity and interference interact with each other. For example, for MetS, p-value was statistically significant for both pain intensity and interference. p-value for interaction was also <0.05, supporting that prevalence of MetS elevates with more interfering pain regardless of intensity.



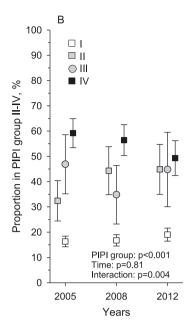


Figure 3: (A) Change in SF-36 bodily pain during the 10-year follow-up in terms of four PIPI groups (I-IV). (B) Percentage of participants whose SF-36 pain intensity and interference did not improve (did not move to or remain in PIPI group I) at the follow-up points in comparison to their baseline value (year 2002).

Table 1: Characteristics of 1,954 GOAL participants at baseline in 2002 by four pain intensity, pain interference (PIPI) groups (I-IV).

	None to mild interference		Moderate to extreme interference		p-Value		
	None to mild intensity (PIPI group I) N=1,380	Moderate to very severe intensity (PIPI group II) N=133	None to mild intensity (PIPI group III) N=77	Moderate to very severe intensity (PIPI group IV) N=364	Interference	Intensity	Interaction
Demographics							
Female sex, n, %	693 (50)	82 (62)	43 (56)	203 (56)	0.96	0.14	0.13
Age, mean (SD)	62 (8)	62 (7)	64 (7)	64 (8)	0.007	0.52	0.97
Education years, mean (SD)	9.8 (3.3)	9.9 (3.0)	8.9 (2.6)	8.8 (2.8)	<0.001	0.90	0.79
Cohabitant, n, %	1,074 (78)	96 (73)	60 (78)	261 (72)	0.91	0.098	0.95
Household income <sup>a</sup> , mean € (SD)	1,333 (885)	1,206 (485)	1,121 (582)	1,145 (705)	0.041	0.44	0.26
AUDIT-Cb, mean (SD)	2.7 (2.3)	2.4 (2.0)	2.5 (2.3)	2.2(2.1)	0.40	0.11	0.99
Smoking, n, %	212 (15)	17 (13)	15 (19)	65 (18)	0.10	0.44	0.80
BMI <sup>c</sup> , mean (SD)	27.4 (4.2)	28.0 (5.6)	29.5 (5.1)	28.1 (4.4)	<0.001	0.27	0.003
MetS <sup>d</sup> , n, %	605 (44)	60 (45)	51 (66)	179 (49)	<0.001	0.042	0.019
LTPA <sup>e</sup> , n, %					<0.001	0.85	0.23
Low	188 (14)	19 (14)	21 (28)	90 (25)			
Moderate	974 (71)	98 (74)	49 (64)	232 (64)			
High	216 (16)	16 (12)	6 (8)	41 (11)			
Laboratory tests, mean (SD)							
fP-Glucose, mmol/L	5.62 (1.02)	5.54 (0.63)	5.66 (0.69)	5.65 (1.15)	0.34	0.59	0.63
fP-Cholesterol, mmol/L	5.80 (1.06)	5.83 (0.90)	5.50 (0.94)	5.69 (1.06)	0.007	0.15	0.32
fP-HDL, mmol/L	1.53 (0.43)	1.57 (0.42)	1.39 (0.32)	1.51 (0.44)	0.004	0.012	0.22
fP-LDL, mmol/L	3.60 (0.94)	3.60 (0.83)	3.39 (0.88)	3.49 (0.97)	0.031	0.48	0.54
fP-Triglyceride, mmol/L	1.50 (1.15)	1.46 (0.69)	1.56 (0.58)	1.53 (0.84)	0.42	0.65	0.93
Blood pressure, mean (SD)							
Systolic, mmHg	145 (18)	143 (17)	145 (16)	145 (18)	0.74	0.59	0.66
Diastolic, mmHg	86 (9)	86 (10)	86 (9)	86 (10)	0.89	0.99	0.41
Morbidity (diagnosed), n, %							
Hypertension	427 (31)	43 (32)	32 (42)	144 (40)	0.015	0.95	0.65
Diabetes mellitus type II	69 (5)	2 (2)	2 (3)	31 (9)	0.28	0.99	0.016

Table 1: (continued)

	None to mild interference		Moderate to extreme interference		p-Value		
	None to mild intensity (PIPI group I) N=1,380	Moderate to very severe intensity (PIPI group II) N=133	None to mild intensity (PIPI group III) N=77	Moderate to very severe intensity (PIPI group IV) N=364	Interference	Intensity	Interaction
Cardiovascular disease	97 (7)	11 (8)	16 (21)	47 (13)	<0.001	0.39	0.11
Musculoskeletal disease	310 (22)	72 (54)	39 (51)	245 (67)	<0.001	<0.001	0.024
Pulmonary disease	60 (4)	15 (11)	10 (13)	36 (10)	0.033	0.14	0.006
Depression	36 (3)	4 (3)	5 (6)	48 (13)	<0.001	0.20	0.38
Pain medication, n, %	205 (15)	60 (45)	20 (26)	215 (59)	<0.001	<0.001	0.69
Childhood							
Childhood Index <sup>f</sup> , mean (SD)	25.6 (6.0)	24.1 (6.2)	23.9 (6.6)	24.1 (6.6)	0.077	0.18	0.080
Financial stress, n, %	902 (65)	97 (73)	60 (78)	266 (73)	0.080	0.80	0.087
Fear of a family member, n, %	369 (27)	43 (32)	29 (38)	136 (37)	0.025	0.43	0.38
Alcoholism in family, n, %	361 (26)	38 (29)	26 (34)	114 (31)	0.14	0.98	0.49

p-values less than 0.05 were considered statistically significant. Data are presented as mean (SD) and as absolute values and percentages. 
<sup>a</sup>Household income, OECD square root–determined household income. 
<sup>b</sup>AUDIT-C, alcohol unit consumption per week. 
<sup>c</sup>BMI, body mass index. 
<sup>d</sup>MetS, metabolic syndrome. 
<sup>e</sup>LTPA, leisure-time physical activity. 
<sup>f</sup>Childhood index, Childhood Index, calculated as a sum of nine question responses regarding the childhood home environment, with higher value indicating a more positive environment. 
fP-HDL, high-density lipoprotein; 
fP-LDL, low-density lipoprotein. 
PIPI group II: None to mild pain intensity, none to mild pain-related interference; 
PIPI group III: None to mild pain intensity, moderate to extreme pain-related interference.

**Table 2:** Variables associated with participant permanence in PIPI group I (none to mild pain intensity, none to mild pain-related interference) throughout the 10-year follow-up. Multivariate logistic regression analysis.

	Remaining in PIPI group I		
	Or (95% CI)	p-Value	
Female sex	1.26 (0.91–1.74)	0.17	
Age	1.01 (0.99-1.04)	0.24	
Education years	0.97 (0.92-1.02)	0.24	
Household income/1,000 €	1.46 (1.07-1.98)	0.019	
Smoking	0.91 (0.59-1.39)	0.64	
AUDIT-C <sup>a</sup>	1.06 (0.98-1.14)	0.16	
LTPA <sup>b</sup>			
Low	1 (Reference)		
Moderate	0.93 (0.59-1.46)	0.75	
High	0.90 (0.51-1.59)	0.72	
BMI <sup>c</sup>	0.93 (0.90-0.97)	<0.001	
Metabolic syndrome	0.95 (0.67-1.33)	0.76	
Musculoskeletal disease	0.22 (0.16-0.30)	<0.001	
Childhood Index <sup>d</sup>	1.03 (1.00-1.05)	0.016	

<sup>&</sup>lt;sup>a</sup>AUDIT-C, alcohol unit consumption per week. <sup>b</sup>LTPA, leisure-time physical activity. <sup>c</sup>BMI, body mass index. <sup>d</sup>Childhood Index, Childhood Index, calculated as a sum of nine question responses regarding the childhood home environment.

Multivariate logistic regression analysis was executed in order to identify variables associated with remaining in PIPI group I throughout the follow-up (Table 2). The following associated factors emerged: presence of musculoskeletal diseases (OR 0.22 [95% CI 0.16–0.30]), high BMI (OR 0.93 [95% CI 0.90–0.97]), high household income (OR 1.46 [95% 1.07–1.98]), and a positive Childhood Index (OR 1.03 [95% CI 1.00–1.05]).

The 10-year survival of the participants of each baseline PIPI group was as follows: 94% (92-95) in PIPI group I, 92% (86-95) in PIPI group II, 87% (77-93) in PIPI group III, and 89% (85-92) in PIPI group IV; p=0.004 after adjustment for sex and age.

## **Discussion**

The current study examined baseline factors in relation to experienced pain (SF-36 pain intensity and pain-related interference) and changes in pain experience in a 10-year follow-up in a sample of community-dwelling Finnish older adults. Several baseline factors were identified in association with remaining pain-free throughout the follow-up and also in relation to either more severe pain

intensity or pain-related interference or both. The pain situation of participants with the most severe pain experience at baseline improved the most.

PIPI group I comprised the majority of the participants. thus, more than two out of three reported none or only mild pain intensity and pain-related interference at baseline. However, almost one in four reported moderate to extreme pain-related interference, which may be considered a marked proportion among home-dwelling citizens, although it is in line with previous studies [25, 26]. The mean SF-36 bodily pain experience remained at a relatively stable level at each followup point (SF-36 bodily pain approximately 70) in the whole sample. However, one third of the participants had shifted to a different PIPI group at each follow-up point. It was encouraging to notice that PIPI group I remained the most stable. and only less than one in five participants reported a worsened pain situation at the follow-up points. This minor deterioration may be explained by an age-related increase in pain or regression to the mean [27, 28]. PIPI group IV participants improved their pain situation the most. Interestingly, the majority of the improvement occurred during the very first years of follow-up (2002–2005). Although the study did not include treatment interventions, it is likely that some of the most disabled participants had not previously had the physiological or physical resources to ask for assistance and treatment, and study participation had brought these individuals under care. It is reassuring to know that even severe pain may be treated effectively, even though regression to the mean, habituation to chronic pain or Hawthorne effect may also explain some of the observed improvement.

A low BMI, low prevalence of musculoskeletal diseases, better financial situation, and a better Childhood Index predicted remaining pain-free throughout the follow-up. The results are somewhat in line with the literature [16, 17]. Musculoskeletal diseases are frequent in older adults [29], and obesity has, in multiple studies, proved to associate with both pain and musculoskeletal conditions [30, 31]. It is well known, that low household income strongly associates with other social and healthrelated problems and overall distress [32, 33] and, further, low socioeconomic status with more experienced pain intensity and interference [5, 10, 11, 34]. Notably, a low household income level does not limit access to treatment for medical problems in Nordic societies which refers to those positive effects of better financial situation need to link to overall well-being and life habits. Additionally, the results provide further evidence to suggest that early childhood circumstances (e.g., affectionless parental bonding and improper development of psychological resources) possibly affect the pain situation in later life [35, 36]. Therefore, high pain interference may result from

ineffective pain coping skills, and on the other hand, sufficient psychological resources may protect against pain becoming chronic. Certainly, herein, childhood index was based on recalled childhood psycho-social events, which may be influenced by current emotions and cognitions.

Several differences were found between the PIPI groups based on the division by pain intensity and interference. Painrelated interference is an important element that is, as presented, not always parallel to either pain intensity or tissue damage but a key aspect in pain-related decrease in the quality of life [3, 14]. Participants who reported higher painrelated interference (PIPI groups III-IV) expressed multiple similarities regardless of the pain intensity. Especially a higher BMI and prevalence of MetS and musculoskeletal disease emerged to cause intensive pain-related interference. possibly at least partially due to impaired overall functioning. On the other hand, persistent pain itself interferes with physical functioning and participation in everyday life activities [37–39]. In the present study, it appears that a major part of the pain was due to musculoskeletal diseases. Remarkably, in musculoskeletal pain conditions less interfering state is relatively often possible to achieve with adequate physical rehabilitation and analgesic support.

The long duration of the follow-up, decent sample size, and the setting of following up on one strictly determined cohort of community-dwelling older adults for a decade may be regarded as the major strengths of the present study. Also, multiple factors were examined in relation to both pain intensity and pain-related interference. Furthermore, the study included both questionnaire and clinical data. Some limitations need to be addressed, however. Firstly, the clinical situation related to the reported pain was not retrievable. Secondly, it was not possible to identify factors that may have been the reason for the improvement or worsening of the pain situation on an individual level between the control visits. Future studies are needed to identify these factors and especially predictors for flow directions going towards cohorts with a worse bodily pain outcome. Possibly trajectory analyses would be able to put more clinical view on the patterns of pain experience over time.

## Conclusions

According to the results herein, changes occurred in the pain experience during the 10-year follow-up. The most improvement in both pain intensity and pain-related interference was achieved by participants with the worst pain situation at baseline. Diverse factors were found to relate to baseline pain experience. 10-year survival was slightly lower in participants with higher pain interference. The absence of musculoskeletal disease, a lower BMI, a better financial situation, and a more positive childhood home environment were associated with remaining in PIPI group I (none to mild pain) throughout the follow-up.

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Ethical approval: Research involving human subjects complied with all relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration (as amended in 2013), and has been approved by the authors' Institutional Review Board or equivalent research ethical committee.

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