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Title:
TENDER POINT COUNT AND TOTAL MYALGIC SCORE IN FIBROMYALGIA: CHANGES OVER A 28-DAY PERIOD

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Abstract

Tender point count (TPC) is central to fibromyalgia syndrome (FMS), and with total myalgic score (TMS) is often used to monitor the patient's condition. This study aimed to determine the stability of TPC and TMS over time, and to examine how well these measures reflected patients' perceptions of their condition. Twenty four patients with FMS completed the Fibromyalgia Impact Questionnaire (FIQ) and a visual analogue scale (VAS) measuring wellbeing, at entrance into the study, and 7 and 28 days later. There was no significant change in TPC ($p = 0.074$), FIQ score ($p = 0.291$) or VAS ($p = 0.079$) of wellbeing with time. However, mean TMS score did change over time ($p = 0.021$). There was no correlation between total FIQ score and the other measures (all p values > 0.05). The significant change in TMS over time may reflect the natural fluctuation in the clinical presentation of FMS.

Key words: fibromyalgia, pain, tender point count, pressure pain threshold.

Introduction

Fibromyalgia (FMS) is a well-recognized if somewhat controversial syndrome, for which there are broadly accepted diagnostic criteria endorsed by the American College of Rheumatology [1]. These criteria require widespread non-specific musculoskeletal pain of at least 3 months duration, with pain on mechanical pressure of approximately 4kg or less at 11 of 18 specified anatomical locations, commonly referred to as 'tender points'[1].

Tender point count (TPC) is central to the diagnosis of FMS, and with total myalgic score (TMS, i.e. the summed total pressure pain threshold (PPT) over tender points) these measures are commonly used to monitor the severity of the condition and as outcome measures in clinical trials [2-7]. However, there is ongoing debate in the FMS literature as to the extent to which experimentally induced pain accurately reflects clinical status of patients with FMS [8]. Indeed for either TPC or TMS to be considered reliable and valid indicators of clinical change, they must be stable when a patient's FMS remains quiescent, but sensitive to change when it worsens or improves. It is surprising, therefore, that there has been little investigation of the stability of either TPCs or PPTs over time in patients with FMS.

Some early work carried out by Tunks et al. [9] demonstrated the stability of tender points measured by dolorimetry, in that they had high test-retest and intra-tester reliability (generalisability coefficients = 0.85 in each case) in small groups of patients with (n = 5) and without (n = 5) FMS. However, this study predated the Wolfe et al. [1]

criteria and many of the points used are not considered standard in FMS. Work by Cott et al. [10] demonstrated reasonable inter-rater reliability of both manual (kappa = 0.51, $p < 0.0001$) and dolorimetric TPC (kappa = 0.62, $p < 0.0001$) in 15 patients with FMS. These authors did not, however, explore changes in TPC over time. Work on TMS is also limited, but several studies have found that people with FMS had significantly lower TMS values than those without, supporting the discriminatory potential of the TMS [11-13].

The relationship between symptom severity (as indicated by TPC and TMS), and quality of life (QoL) in FMS is also unclear. Marques et al. [14] found no correlation between a pain visual analogue scale (VAS), the Fibromyalgia Impact Questionnaire (FIQ [15]), and a pain threshold index in 124 people with FMS. In contrast, Jensen et al. [16] reported significant correlations between FIQ scores, and pain VAS, TMS and TPC. More recently Tastekin et al. [7] reported a significant correlations between manual TPC and FIQ scores ($r = 0.38$; $p = 0.022$), however, this relationship was only investigated at one point in time and the extent to which this correlation persists over time is not known. Given the limited amount of work and the contrasting results obtained in this area, there is a need for further investigation of the relationship between TPC, TMS and QoL in FMS. Hence, this study aimed to assess, in patients with FMS, the stability of TPC and TMS over time, and to examine the extent to which these measures correlated with measures of QoL.

Method and materials

This prospective study involved three consecutive assessments of a cohort of patients with FMS over a 28-day period. The University of Ulster's Research Ethics Committee approved the study.

Sample

A sample of convenience of 24 patients with FMS attending an outpatient rheumatology clinic at the Royal Hospitals Trust (RHT), Belfast was recruited over a 6-month period between June and December 2002. Participants were eligible for inclusion if they were diagnosed with FMS according to the ACR 1990 criteria [1] by a consultant rheumatologist (MBF), were aged between 18 and 65 years, and were willing to attend for repeated tender point examination. Participants were excluded from the study if they had a significant concomitant medical condition (e.g. ischemic heart disease, cerebrovascular accident, rheumatoid arthritis), were currently under the care of a psychiatrist, or had received physiotherapy in the previous 3 months.

Outcome measures

The outcome measures – assessed at baseline, Day 7 and Day 28 – were TPC [1], TMS [17], a 10cm VAS measuring self-rated wellbeing [18-19], and QoL as measured within the FIQ [15].

Tender point assessment

A dolorimeter (Dillon Advanced Force Gauge DILN850-006-V04; Fairmont, MN, USA) was used to measure TPC and TMS at 18 tender points according to the ACR criteria [1]. The TPC and the TMS were determined by applying increasing pressure with the dolorimeter to each tender point, perpendicular to the tissue, at a rate of approximately 1kg/s in the manner recommended by Fischer [20]. Participants were asked to say 'stop' the moment pressure became painful. A tender point was considered positive if participants reported 'pain' at or below a pressure of 4kg; the total of such positive tender points was recorded as the individual's TPC. Individual tender point scores (i.e. the PPT) at each tender point were also recorded and summed to give the TMS.

Self-rated wellbeing

Two measures of self-rated wellbeing were used. First, a VAS was used to record wellbeing for that day (0 = 'the best I have ever felt' and 10 = 'the worst I have ever felt'). Second, participants were also asked at their 7th and 28th day visits whether they felt 'the same', 'better' or 'worse' than at their first visit.

Fibromyalgia Impact Questionnaire

The Fibromyalgia Impact Questionnaire (FIQ) has been demonstrated to be a reliable and valid measure of health status in FMS [15, 22-23]. It is a short self-administered 10-item questionnaire that measures physical function, job difficulty, depression, anxiety, sleep, pain, stiffness, fatigue, and well-being. Scores on the FIQ range from 0–100, where a higher score indicates a greater impact of FMS on the individual. When compared to a

range of other commonly used outcome measures in FMS, Dunkl et al. [21] reported that the FIQ was the most responsive outcome measure to perceived clinical improvement (from the patients' perspective) and recommended its use as a primary outcome measure in clinical trials in this population.

Procedure

Participants were interviewed and enrolled in the study after affirming understanding of the protocol and providing written informed consent. Demographic information (i.e. age, gender, time since diagnosis, duration of FMS, and receipt of disability benefits) was recorded at the first visit. Each patient then underwent a standardized assessment – conducted by an investigator (JMcV) who was experienced in the administration of all outcome measures – in the following sequence: FIQ, self-rated wellbeing measures, TPC, and TMS. Participants and the assessor were blinded to all previous scores.

Pilot study

A pilot was conducted to standardize the procedure and test the feasibility of the proposed study. Twelve consecutive patients with FMS (3M: 9F; mean age = 49 years, range 33-65) and five volunteers without FMS (1M: 4F; mean age = 25 years, range 24–27) from physiotherapy and occupational therapy departments at the primary research centre were recruited, and followed up at Days 3, 7, and 28. Due to poor follow-up rates (60%; n = 3, of healthy volunteers and 75%; n = 9, of those with FMS missed at least one follow up assessment), and in discussion with the patients, the protocol was changed to

remove the Day 3 follow-up point. For the main study subjects were therefore requested to attend for follow-up at Day 7 and Day 28 only.

Statistical analysis

Data were entered into spreadsheets and checked for errors prior to analysis using SPSS Version 12. Where parametric assumptions were met, repeated measures ANOVA was used to compare scores across the three time points for each outcome measure; where parametric assumptions were not met, the Friedman test was used. Following these analyses, pairwise a posteriori contrasts with the Bonferroni correction were completed. Variation in individual tender point scores was assessed using eta-squared (η^2), which represents the proportion of variance of tender point scores that is explained by time. Values of η^2 range from 0 to 1, where 0.01 = small effect, 0.06 = moderate effect, and 0.14 = large effect [24]. The relationships between TPC and TMS, and total FIQ scores and self-rated wellbeing VAS, were investigated using the Pearson product-moment correlation coefficient (r).

Statistical significance was set at $p \leq 0.05$ (two-tailed); p values reported for the a posteriori analyses incorporate the Bonferroni adjustment and should therefore also be evaluated against this threshold.

Results

Of the 24 participants who were initially entered into this study, 21 (87.5%) returned on Day 7, and 17 (70.8%) on Day 28. The baseline demographic profile of subjects is presented in Table 1. Participants' mean age was 44.3 years (range 25–65), most were women, and half reported receiving statutory disability benefits (n = 2M; n = 10F). While most patients (n = 17) reported that they had been recently diagnosed with FMS, two thirds stated that they had experienced symptoms for more than 6 years (Table 1). One patient reported being involved in ongoing litigation. Table 2 outlines medication use by participants at baseline; it can be seen that patients were on multiple medication, with more than half the patients taking antidepressants and, or non-steroidal medications, and just under half the patients taking narcotic based analgesic medications. The mean number of medications used by participants was 4.1.

Insert Table 1 and 2.

Table 3 outlines participants mean total FIQ scores and individual sub-scale scores at the three points of evaluation. It can be seen that participants were severely affected with FMS, as reflected by their total FIQ scores; additionally, from the anxiety and depression subscales it appears participants also suffered considerable psychological distress.

Insert Table 3

Variability of outcome measures over time

Table 4 displays TPC, TMS, well-being VAS and FIQ total scores at the different time points for the 17 participants with no missing data. While there was no difference in median TPC values (Friedman test $\chi^2 = 5.20$; $p = 0.074$), there was a significant change in mean TMS scores over time ($F_{2, 32} = 4.40$; $p = 0.021$). This represents a large effect ($\eta^2 = 0.22$), with the mean value decreasing by 22% between baseline and Day 7, and increasing by 15% between Day 7 and Day 28. A posteriori analysis with Bonferroni correction revealed a significant difference between baseline and Day 7 TMS ($p = 0.023$); other pairwise differences were non-significant. Individual tender point scores (i.e. PPT) are detailed in Table 5; individual values were very low, indicating high sensitivity to pressure, with a maximum mean tender point score of only 3.48 kg/cm^2. It can also be seen that there is some variation in tender point scores due to time, with time having a large effect ($\eta^2 > 0.14$) at nine of the 18 tender points.

Insert Table 4

While reports of self-rated wellbeing on the 10-point VAS did not alter significantly with time ($F_{2, 32} = 2.76$; $p = 0.079$), almost half (48%) of participants reported feeling 'worse' at Day 7 compared to baseline, nine (39%), stated they felt the 'same', and only three (13%) felt 'better'. At Day 28 the findings were: 'worse' (n = 6; 35%), 'same' (n = 4; 24%), and 'better' (n = 7; 41%). Median FIQ scores did not vary with time (Friedman test $\chi^2 = 2.47$; $p = 0.291$).

Correlations between outcome measures

There were no statistically significant correlations between TPC and total FIQ score at baseline ($r = 0.32$; $p = 0.133$; Figure 1), Day 7 ($r = 0.37$; $p = 0.085$), or Day 28 ($r = 0.14$; $p = 0.581$), nor between TMS and total FIQ score: baseline ($r = –0.33$; $p = 0.115$; Figure 2), Day 7 ($r = –0.31$; $p = 0.155$) and Day 28 ($r = –0.19$; $p = 0.478$). Similarly there was no significant correlation between TPC and wellbeing VAS at baseline ($r = 0.328$; $p = 0.117$; Figure 3), Day 7 ($r = –0.06$; $p = 0.776$), or Day 28 ($r = 0.478$; $p = 0.053$). For TMS and wellbeing VAS similar levels of correlation were detected: baseline ($r = –0.29$; $p = 0.177$; Figure 4), Day 7 ($r = 0.07$; $p = 0.746$), Day 28 ($r = –0.47$; $p = 0.055$). The above correlations were based on $n = 24$ at baseline, $n = 23$ at Day 7, and $n = 17$ at Day 28.

Insert Figures 1,2,3,4

Discussion

This study was designed to assess the stability of TPC and TMS over time, and to examine the extent to which these variables correlated with measures of QoL and self-rated wellbeing. Findings indicate that TPC ($p = 0.074$), FIQ scores ($p = 0.291$) and VAS of patient wellbeing ($p = 0.079$) were stable over time; there was, however, a significant change in TMS ($p = 0.021$) over the same period. These results suggest that these patients with well-established FMS symptoms were – for the most part – consistent in their clinical presentation over a 28-day period. The variation in TMS over time may reflect changing patterns of PPT not readily captured by outcome measures commonly used in FMS. It is also worth comment that the fairly severe symptoms experienced by patients

remained stable even though they were taking multiple medications for their condition; the effectiveness of these medications in this patient group needs further examination.

In the current study no relationship between either TPC or TMS and FIQ scores and VAS of patient wellbeing was demonstrated. This is consistent with the findings from a recent study by Tastekin et al. [7] who also found no relationship between TPC (as elicited by dolorimetery), TMS and FIQ scores for a group of patients with FMS (n = 36). These authors did however report a significant correlation ($r = 0.38$; $p = 0.022$) between TPC elicited manually and total FIQ score. This led these authors to contend that manual TPC was a better indicator of disease severity than either TMS or TPC elicited by dolorimetery.

The findings from the current study are, however, in contrast to those of Jensen et al. [16], who investigated the relationship between TPC, TMS and the 'activities of daily living' items of the FIQ (FIQ-ADL) (n = 221). These authors reported weak correlations between TPC and FIQ-ADL ($r = 0.2$; $p = 0.003$) and between TMS and FIQ-ADL ($r = 0.3$; $p < 0.001$). However, there were significant methodological differences between their study and the current study. For example, in Jensen et al's study [16], TPC was evaluated manually by 'laboratory technicians', without comment on the training received by these technicians. Furthermore, myalgic score was expressed by pain severity score (range 0–3) multiplied by the respective number of tender points. These methodological differences may have accounted for the contrasting findings compared to the present study.

The absence of any relationship between measures of tenderness and other dimensions of FMS identified in the current study, echo to some extent the recent findings of Geisser et al. [8] and Harris et al. [25]. Harris et al. [25] studied patients (n = 65) participating in a randomized controlled trial of acupuncture in FMS. They evaluated the relationship, over time, between various measures of experimental pain (i.e. manual TPC, dolorimeter PPT, dolorimeter pressure pain tolerance, and pressure pain stimuli presented in a random fashion (multiple random staircase; MRS)), and measures of clinical pain (a numerical rating scale (NRS), and the Short Form McGill Pain Questionnaire (SF-MPQ)). Harris et al. [25] reported that while there was some improvement in clinical pain over the 15 weeks of the trial (NRS, $p = 0.032$; SF-MPQ, $p = 0.001$), only pressure pain presented via MRS demonstrated a significant change over time ($p = 0.001$). Further, when the change scores between the experimental and clinical pain measures were correlated there was no correlation between TPC, dolorimeter (PPT and tolerance) and the NRS, or between MRS, dolorimeter (PPT and tolerance) and the SF-MPQ. Similarly, Geisser et al. [8] found no correlation between measures of pressure pain (dolorimeter and MRS) and a VAS of 'pain today'. Both Harris et al. [25] and Geisser et al. [8] concluded that the random method of eliciting pain scores, using the MRS method, may be less biased than either TPC or dolorimetery. Harris et al. [25] however, reported significant methodological issues using the MRS method, including the time taken to obtain scores, which may preclude its use in a clinical setting.

The stability of FMS symptoms as measured by TPC, FIQ scores and wellbeing VAS found in this study supports previous findings [26-27]. Patients in the current study, however, may be among those more severely affected by FMS (Table 3 and Table 4); Bennett [28] reported that the 'average' patient with FMS will commonly have an FIQ score of around 50, with those severely affected scoring 70 or more. It has been demonstrated that in FMS, patients with high levels of fear of pain and activity report greater disability ($p < 0.001$) than those with less apprehension [29]; it is possible that for this relatively severely affected group of patients, the stability of outcome scores represents well-established pain beliefs and pain behaviours that are unlikely to change over the short term.

The significance of TPC in FMS has been the subject of much discussion, and it has been argued that TPC represents distress [30-32] or pain behaviour [33] in FMS. Indeed, Schochat and Raspe [34] recently demonstrated that high TPC was independently associated not only with pain but also with high somatic symptom count. While the purpose of this study was not to explore the relationship between TPC and anxiety, distress or pain behaviour, some might speculate that the lack of change of TPC over time found here suggests that the anxiety and distress levels of these subjects were relatively stable over the period of the study, indeed Table 3 demonstrates that based on the anxiety and depression subscales of the FIQ there was little variation in anxiety and depression over the duration of the study.

Pressure pain threshold in FMS is significantly lower than that recorded in healthy volunteers [35, 12-13]; participants in the current study demonstrated the expected low levels of PPT. The changes in TMS over time may represent spontaneous variation in PPT rather than any substantial change in clinical presentation. Indeed it is worth noting that Maquet et al. [12] reported that for healthy volunteers the intra-individual coefficient of variation between two consecutive PPT measurements (3 days apart) reached 17% for females and 13% for males, while in patients with FMS it reached 24%. Given the results of the current study, the clinical utility of measuring PPT in FMS therefore must be questioned.

There were some limitations to this study, including the sample size of 24, with only 17 participants completing all follow-up assessments. However, similar problems were encountered by Harris et al. [25] who reported an even higher dropout rate with only 57% of participants (65/114) completing their study. Nevertheless, the dropout rate from the current study means that it is possible that differences in TPC, FIQ score and wellbeing VAS may not have been detected. Also, although dolorimetry examination of tender points has been demonstrated to have good reliability [10-11], the intra-rater reliability of tender point examination was not investigated in this study. Even though a pilot was conducted to standardize the procedure, it is possible that variations in TMS were due to examination technique.

Conclusions

Tenderness and tender points are an integral component of FMS. We have established the stability of TPC over time, therefore supporting its use as an outcome measure in clinical research. The relationship between TPC, TMS, and other commonly used outcome measures in FMS has been explored, and the lack of correlation between measures of tenderness (TPC and TMS) and measures of QoL, perhaps suggests that TPC and TMS represent a phenomenon that is independent from other symptom expression in FMS. Further research is warranted to investigate tenderness in FMS and the contribution this has to the overall patient experience in FMS.

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Table 1. Participants characteristics (n = 24)

Gender (n)	
Female	19
Male	5
Mean age (SD)	44.3 (10.4)
Disability benefits recipients (n)	12
Time since diagnosis (years) (n)	
<1	17
1 – 5	4
6 – 10	3
>10	
Duration of symptoms (years) (n)	
<1	0
1 – 5	8
6 – 10	4
>10	12

Table 2. Participants' (n=24) medication use at baseline; mean number of drugs per person was 4.1.

	n	(%)
Analgesics	5	(20.8)
Analgesics narcotic	11	(45.8)
NSAIDS	14	(58.3)
Antidepressants	13	(54.2)
Anxiolytic	10	(41.7)
Hypnotic	1	(4.2)
Other drugs	15	(62.5)

Table 3. Mean (SD) Fibromyalgia Impact Questionnaire Scores

	Baseline (n = 24)	Day 7 (n = 21)	Day 28 (n = 17)
Total FIQ score	78.2 (16.2)	85.5 (9.4)	84.6 (11.4)
Physical impairment	6.5 (1.8)	7.7 (1.6)	8.1 (1.3)
Feeling good	8.0 (2.6)	8.3 (2.0)	8.2 (1.9)
Missed worked	6.6 (3.6)	17.9 (3.2)	9.0 (1.4)
Problems with work	7.1 (2.9)	8.3 (1.8)	8.5 (1.7)
Pain	8.3 (1.8)	8.7 (1.6)	8.1 (2.4)
Fatigue	9.0 (1.4)	9.8 (0.7)	9.2 (1.6)
Awaked rested	9.3 (1.3)	9.3 (1.2)	9.4 (1.4)
Stiffness	8.1 (2.3)	8.2 (1.7)	8.5 (1.8)
Anxiety	8.1 (2.3)	9.2 (1.3)	7.8 (2.3)
Depression	6.8 (2.9)	8.2 (1.9)	7.8 (2.4)

Table 4. Outcome scores across time for participants with no missing values (n=17)

	Baseline	Day 7	Day 28	p value
TPC; median (IQR)	16 (15 – 18)	18 (17 – 18)	18 (16 – 18)	0.074*
TMS; mean (SD)	40.4 (13.2)	31.6 (11.2)	36.4 (19.2)	0.021#
Self-rated wellbeing VAS; mean (SD)	6.18 (1.71)	7.35 (1.88)	7.41 (2.11)	0.079‡
FIQ; median (IQR)	84.1 (77.2 – 91.6)	86.5 (77.8 – 94.8)	87.5 (73.9 – 97.6)	0.291*

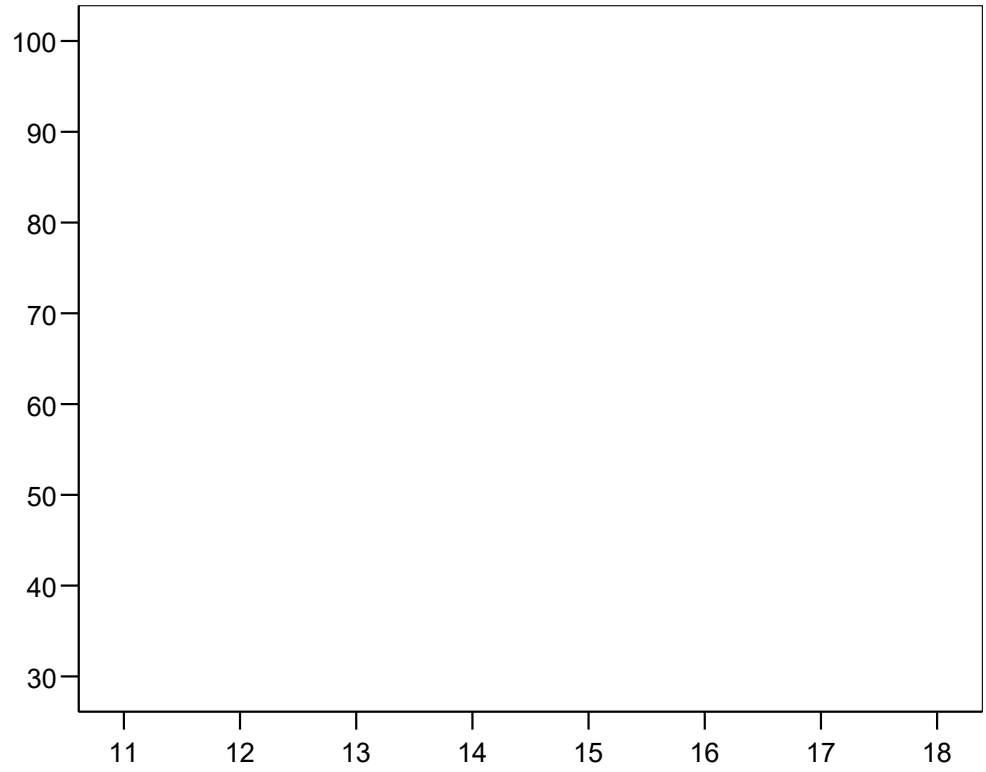
TPC = tender point count; TMS = total myalgic score; FIQ = total score on Fibromyalgia Impact Questionnaire; VAS = visual analogue scale. * Friedman test, # repeated measures ANOVA with square root transformation, ‡ repeated measures ANOVA with squared transformation.

Table 5. Mean (SD) tender point scores (PPT, kg/cm^2) across time (n = 17)

Tender Points*	Baseline		Day 7		Day 28		eta squared (η^2)
TP 1	1.43	(0.62)	1.12	(0.47)	1.21	(0.73)	0.13
TP 2	1.40	(0.62)	1.16	(0.49)	1.29	(0.77)	0.08
TP 3	1.00	(0.38)	0.81	(0.37)	0.97	(0.52)	0.10
TP 4	1.09	(0.34)	0.81	(0.50)	0.94	(0.50)	0.17
TP 5	1.95	(0.69)	1.79	(0.60)	1.86	(1.04)	0.02
TP 6	1.97	(0.93)	1.77	(0.74)	1.95	(1.17)	0.02
TP 7	2.17	(1.04)	1.65	(0.94)	1.99	(1.09)	0.11
TP 8	2.12	(0.95)	1.71	(0.79)	1.97	(1.01)	0.08
TP 9	1.73	(0.73)	1.32	(0.72)	1.75	(0.90)	0.16
TP 10	2.14	(1.05)	1.47	(0.71)	1.78	(1.00)	0.27
TP 11	2.44	(0.91)	1.59	(0.78)	1.98	(1.46)	0.21
TP 12	2.51	(1.11)	2.14	(0.98)	2.57	(1.44)	0.09
TP 13	3.32	(1.08)	2.55	(0.92)	2.96	(1.63)	0.15
TP 14	3.48	(1.34)	2.57	(1.04)	2.72	(1.49)	0.27
TP 15	2.92	(1.59)	2.81	(1.53)	2.94	(1.87)	0.01
TP 16	3.41	(1.40)	2.36	(1.22)	2.86	(1.81)	0.32
TP 17	3.10	(1.42)	2.28	(0.72)	2.51	(1.64)	0.18
TP 18	2.20	(1.25)	1.78	(1.01)	2.12	(1.34)	0.17

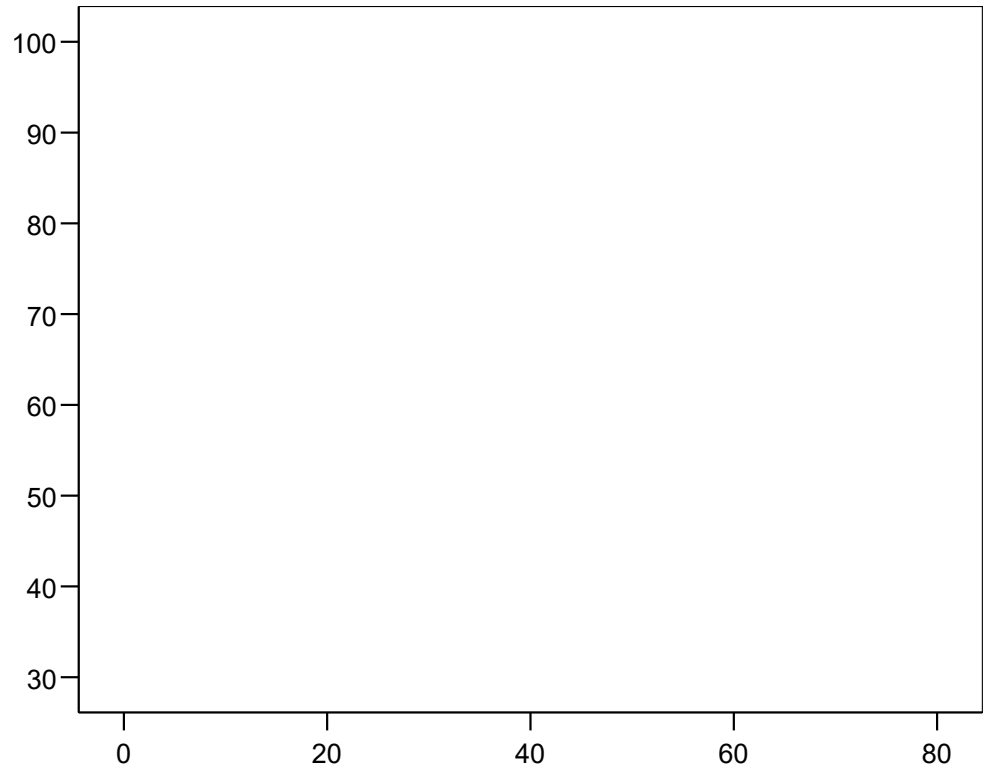
*TP 1 & 2, occiput; TP 3 & 4, anterior cervical; TP 5 & 6, trapezius; TP 7 & 8, supraspinatus; TP 9 & 10, second rib; TP 11 & 12, lateral epicondyle; TP 13 & 14, gluteal; TP 15 & 16, greater trochanter; TP 17 & 18, knee.

Figure 1. Relationship between tender point count (TPC) and total Fibromyalgia Impact Questionnaire (FIQ) score at baseline



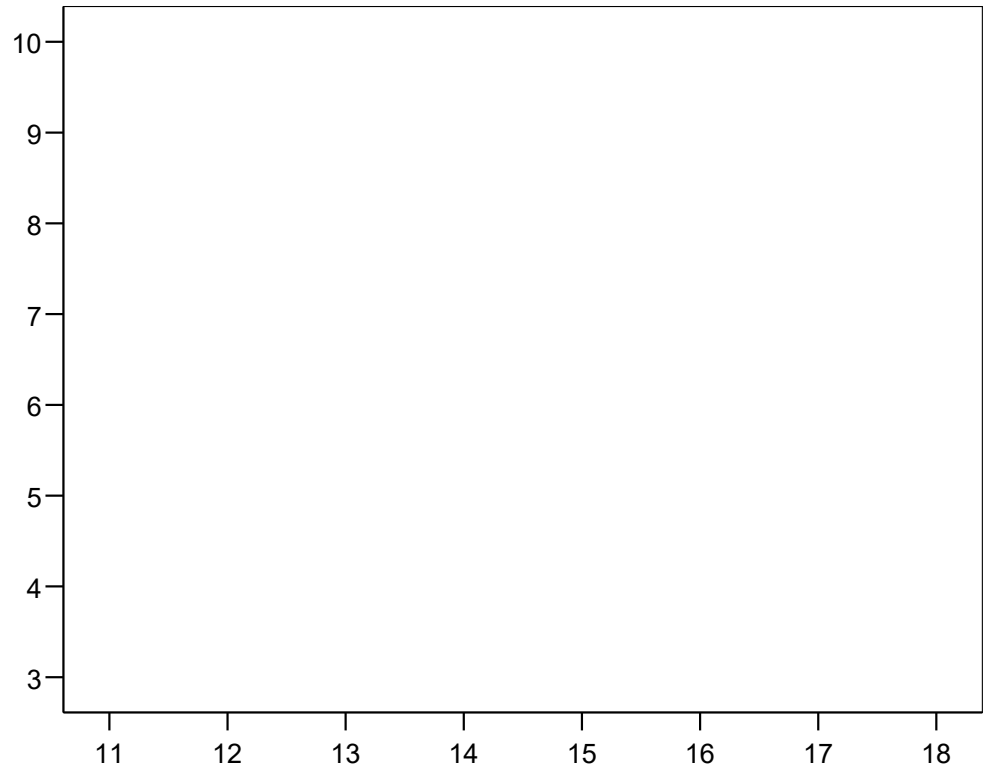
r = 0.32; p = 0.133

Figure 2. Relationship between total myalgic score (TMS) and total Fibromyalgia Impact Questionnaire (FIQ) score at baseline



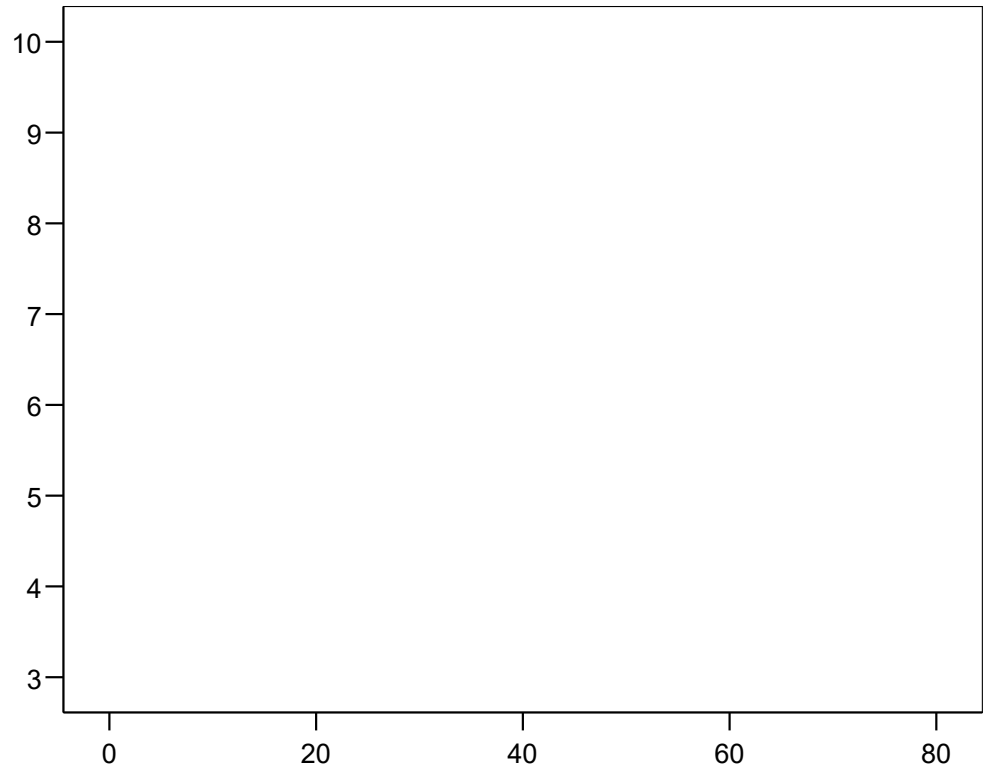
r = −0.33; p = 0.115

Figure 3. Relationship between tender point count (TPC) and wellbeing visual analogue scale at baseline



r = 0.328; p = 0.117

Figure 4. Relationship between total myalgic score (TMS) and wellbeing visual analogue scale at baseline



r = −0.29; p = 0.177