sided medical tape and used to determine each of the three test angles. Participants were first shown one of the angles, which was held for a few seconds, then were asked to close their eyes and attempt to reproduce the angle; this was repeated for all three test angles. We also repeated these assessments at 24 and 48 weeks to test durability of response. The mean error (absolute angle error) between the actual and replicated angles was calculated for each of the three test angles. The Tai Chi and control groups were compared by intention-to-treat using t-tests.

Results: The participants had a mean age of 65y (SD 7.8), mean disease duration 10y (SD 7.6), mean BMI 30.0 kg/m^2 (SD 4.8), and median K/L grade 4; 75% were female, 70% were white. There were no significant differences at baseline in demographics, radiographic score, and outcome measures. Attendance rate was 85% in the Tai Chi versus 89% in the attention control. Participants in the Tai Chi arm exhibited significantly improved proprioception at 30 degrees, but not at 45 and 60 degrees, at 12 weeks (Table 1). Patients who continued Tai Chi practice after 12 weeks also reported no significant improvements in knee proprioception at 24 and 48 weeks.

Conclusion: We were not able to demonstrate in this pilot study that Tai Chi is beneficial for knee proprioception in people with severe KOA. Potential confounders of the test including baseline characteristics, knee pain severity, effusion and function, modified Tai Chi style, changes in joint position and body weight, small sample size may limit data interpretation and evaluation of the results. Standardized and reproducible measures for knee proprioception should be explored in the future research.

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EFFECTS OF NAPROXCINOD AND NAPROXEN ON CHANGE IN JOINT SPACE WIDTH IN THE TIBIO-FEMORAL JOINT: RESULTS OF A 52-WEEK, RANDOMIZED CONTROLLED TRIAL

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Purpose: In previous studies, naproxcinod, a novel cyclooxygenase inhibiting nitric oxide donator (CINOD), has shown efficacy similar to naproxen in the treatment of the signs and symptoms of hip and knee osteoarthritis (OA), but with effects on blood pressure (BP) similar to placebo. The objective of this analysis is to determine if nitric oxide donation from naproxcinod contributes to any difference in change in joint space width in the tibio-femoral joint over one year compared to naproxen.

Methods: Data were analyzed from a 53-week, randomized, double-blind, parallel-group clinical trial of 1020 patients with idiopathic knee OA who were randomized to naproxcinod 750 mg, naproxcinod 375 mg, naproxen 500 mg or placebo (all *bid*) for 13 weeks; patients who had received placebo were then re-randomized to naproxcinod either 750 mg or 375 mg bid. Weight-bearing posterior-anterior (PA) radiographs were obtained in the semiflexed position with a standard protocol by radiology technicians using the SynaFlexer™ positioning device at baseline (between 4 and 10 days prior to randomization) and after 52 weeks in patients who completed the study. All images (either hard copy or digital) were sent to Synarc Inc. (San Francisco, CA) for quality assessment. A single trained and certified radiologist measured minimum joint space width (JSW) using a semiautomatic computer program on digitized images that were paired by subject but randomized and blinded to time sequence. Mean (SD) change in minimum JSW by compartment in the index knee was calculated for each treatment group. No statistical comparisons were performed of this exploratory safety endpoint.

Results: A total of 1020 patients with idiopathic knee OA were enrolled in the study and randomized to one of the four treatment groups: mean (SD) age 59.8 (9.8) years, 709 (71%) women, 789 (79%) white, mean BMI 33.8 kg/m^2. A total of 391 subjects completed 52 weeks on study medication and had paired knee x-rays that were read for minimum JSW at both time points. Mean and median changes in minimum JSW in both the medial and lateral compartments are shown in Table 1.

Table 1

All in Millimeters	Naproxcinod 750	Naproxcinod 375	Naproxen 500
Medial compartment			
Mean change (SD)	0.130 (0.92)	-0.064 (0.812)	0.118 (1.18)
Median change (min, max)	0.00 (-2.06, 3.79)	-0.01 (-4.22, 1.98)	0.00 (-3.73, 6.87)
Lateral compartment			
Mean change (SD)	-0.109 (1.23)	-0.145 (0.98)	-0.153 (1.22)
Median change (min, max)	-0.06 (-5.58, 3.50)	-0.02 (-3.66, 2.00)	-0.08 (-6.15, 3.24)

Conclusions: These data show no significant difference in JSW change for naproxcinod as compared to naproxen over one year. Changes in minimum JSW seen in this study were consistent with data reported in published literature for patients with knee OA.

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RETROSPECTIVIE AND PROSPECTIVE REPORTING OF KNEE PAIN AND DISABILITY AMONG PEOPLE WITH SYMPTOMATIC KNEE OSTEOARTHRITIS

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Purpose: To determine the association between knee pain and physical function (last 48 hours) and health related quality of life (past 4 weeks) and prospective reporting of knee pain and global assessment of knee OA over the following seven day period in a cohort of people with symptomatic knee osteoarthritis participating in the two year Long-term Evaluation of Glucosamine Sulphate (LEGS) study.

Methods: The LEGS study is a 2×2 factorial design randomised placebo-controlled clinical trial allocating participants to glucosamine sulphate (1500mg) and chondroitin sulphate (800mg) or matching placebo for two years. Participants are required to attend annual clinic assessments (including WOMAC and SF-12 questionnaires) and complete a 7-day Participant Diary collecting daily prospective data on knee pain (At its worst, how much pain did you have in your knee today? 0-10 (No pain to worst pain) and a global assessment (Considering all the ways your knee arthritis affects you, how would you say your knees are today? Excellent to Poor). For each participant both the average knee pain score and the highest score reported over 7 days was extrapolated for analysis. For each scale, apart from the SF-12, higher scores indicate more pain or disability.

Results: A total of 605 people with mild to moderate symptomatic knee OA were randomised (October 2007-2009) and completed the baseline clinic assessment and the immediately following 7-day Participant Diary reporting (Table 1).

Table 1. Baseline pain and disability

Clinic Assessment	Mean (sd)
Age	60.3 (8.2)
Female (n,%)	339, 56%
BMI	28.9 (5.8)
Obese (n, %)	214, 35%
WOMAC pain (0-100)	33.2 (17.6)
WOMAC function (0-100)	32.4 (18.2)
SF-12 PCS	41.3 (9.5)
SF-12 MCS	52.8 (10.0)
7-day Participant Diary	**Mean (sd)**
Left knee pain (0-100)	34.1 (18.6)
Right knee pain	33.4 (19.3)
Left highest knee pain	47.2 (20.9)
Right highest knee pain	44.9 (21.1)
• Excellent	23 (4%)
• Very good	93 (16%)
• Good	210 (36%)
• Fair	234 (41%)
• Poor	17 (3%)

The correlation between WOMAC pain and physical function scores was unexpectedly strong (r=0.80). Unsurprisingly, there was no correlation between the SF-12 PCS and the SF-12 MCS score (r=-0.10).

There were meaningful correlations between the WOMAC scores (past 48 hours) and prospective Participant Diary daily pain (r=0.47 to 0.54) and global assessment of arthritis scores (r=0.45 to 0.46). There were smaller corrections between the SF-12 PCS and the Participant Diary daily pain scores (r=-0.31 to -0.34) and little association between the SF-12 MCS and the Participant Diary daily pain scores (r=-0.06 to -0.11).

While the WOMAC pain and physical function scores indicated a mild to moderate level of pain and disability over the past 48 hours, prospective data collection (Participant Diary) detected higher levels of knee pain when the highest score reported of the 7 day period was utilized (highest 7-day knee pain). Further, the prospective 7-day Participant Diary also demonstrated almost half of the study participants (44%) with a mean global assessment of their knees as only 'fair' or 'poor'.
A simple Participant Diary requiring daily recording of knee pain specified as 'at its worst' on a 11 point rating scale over one week may provide an inexpensive, robust and responsive outcome measure in long term clinical trials compared to retrospective reporting of pain (past 48 hours) but without descriptive specificity.

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VALIDATION OF DIGITALIZED HEALTH STATUS QUESTIONNAIRES FREQUENTLY USED IN THE MONITORING OF OSTEOARTHRITIS: A CROSS SECTIONAL STUDY

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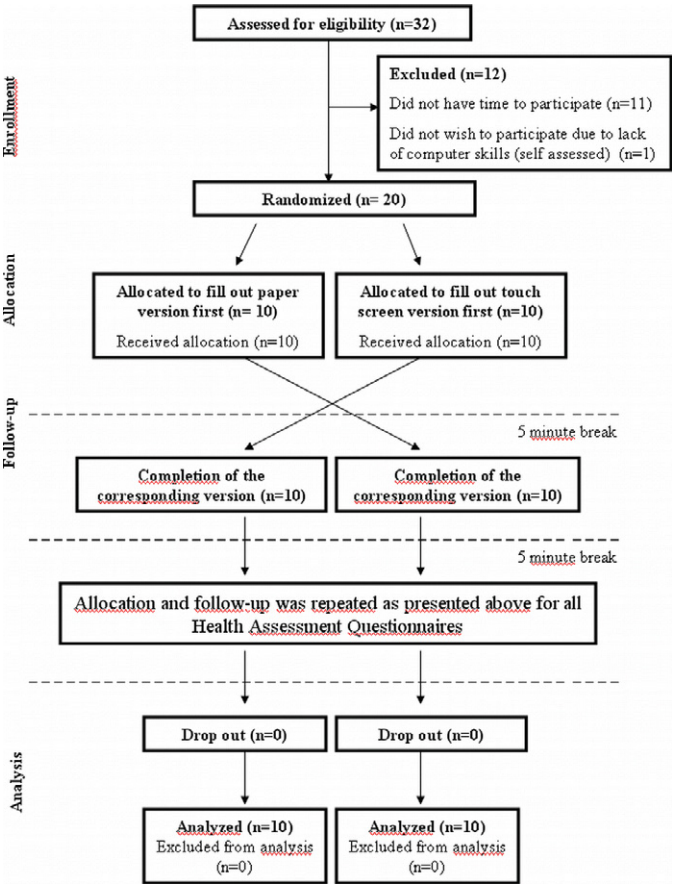
Purpose: To validate digitalized Health Status Questionnaires (HSQs) used for sampling Patient Reported Outcomes for knee osteoarthritis (KOA) patients, employing newly developed freeware on touch screens. Furthermore to examine the effect of patient characteristics on differences between HSQ-versions.
Methods: Touch screen answers were compared to answers on paper versions of the most commonly used HSQs in the clinical management of KOA, and participants were recruited from an ongoing in-house KOA trial (the CAROT-study; ClinicalTrials.Gov Identifier: NCT00655941). 20 female participants, mean age 67 (SD 7), completed KOOS, SF-36, ADL Taxonomy, Physical Activity Scale, VAS pain, function and patient global and Pain Detect, and the trial profile ensured testing of only one HSQ at the time in a repeated randomized cross-over design. The two HSQ versions (paper and touch screen) were completed with a 5 min. interval and between each HSQ patients had a 5 min. break. Mean values for each version, mean differences (95% CI), pooled means, medians, median differences, Minimal Important Differences and Spearman correlation coefficients were calculated for all HSQs including relevant subscales.
Results: Correlations between touch screen and paper version of SF-36 were 0.92 for the physical component summary scale and 0.81 for the mental component summary scale. Similar correlations for KOOS ranged from 0.88 to 0.98, and the other instruments were tested with comparable results. When analysing mean and median differences we found no consistent pattern in differences between the two measures, nor were there any systematic patterns in the differences between HSQ-versions. No significant influence was observed of age, former computer experience or level of education on differences between the two HSQ-versions. The participants did not need further help or explanations when filling out questionnaires on screen and found the process easier than filling in paper versions of the questionnaire. 16 of 20 overall preferred the touch screen version.



Correlation between paper- and touch-screen versions

Paper version	Spearmans Correlation Coefficient	Touch Screen Version
KOOS	0.97	KOOS
VAS pain	0.89	VAS pain
VAS function	0.87	VAS function
VAS patient global	0.78	VAS patient global
SF-36$_{\text{Physical Component Summary Scale}}$	0.92	SF-36$_{\text{Physical Component Summary Scale}}$
SF-36$_{\text{Mental Component Summary Scale}}$	0.81	SF-36$_{\text{Mental Component Summary Scale}}$
Physical Activity Scale	0.84	Physical Activity Scale
Pain Detect$_1$	0.97	Pain Detect$_1$
Pain Detect$_2$	0.96	Pain Detect$_2$
Pain Detect$_3$	0.95	Pain Detect$_3$
Pain Detect$_4$	0.86	Pain Detect$_4$
Pain Detect$_5$	0.88	Pain Detect$_5$
Pain Detect$_6$	0.91	Pain Detect$_6$
ADL Taxonomia	0.95	ADL Taxonomia

Conclusions: The digitalized HSQs on touch screen gave statistically comparable results to answers given on a paper version of the same HSQs. Use of electronic questionnaires gives a safer and more precise data collection due to direct registration of answers, and implementation as well as use of this freeware is feasible for patients

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SHORT FORM-36 (SF-36) AND EUROQOL-5 DIMENSION (EQ-5D) RESULTS FROM RANDOMIZED, DOUBLE-BLIND PHASE 3 STUDIES OF TAPENTADOL PROLONGED RELEASE (PR) IN PATIENTS WITH MODERATE TO SEVERE CHRONIC NOCICEPTIVE AND NEUROPATHIC PAIN

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Purpose: To summarize SF-36 and EQ-5D health survey results from four 15-week, double-blind phase 3 studies of tapentadol PR in patients with osteoarthritis (OA) pain (NCT00421928 [OA study 1] and NCT00486811 [OA study 2]), low back pain (NCT00449176), and pain related to diabetic peripheral neuropathy (DPN; NCT00455520).
Methods: In the OA and low back pain studies, patients received placebo, tapentadol PR (100-250 mg bid), or oxycodone HCl controlled release (CR; 20-50 mg bid) during a 3-week titration period and a 12-week maintenance period. In the DPN study, patients received tapentadol PR (100-250 mg bid) during a 3-week open-label titration period; patients with at least a 1-point improvement in pain intensity (11-point numerical rating scale [NRS]) were randomized to receive placebo or their optimal dose of tapentadol PR (determined in the titration period) during a 12-week double-blind maintenance period. SF-36 and EQ-5D health survey questionnaires were used to assess health status. The SF-36 consists of 8 dimensions (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health) measured on a 0 to 100 NRS (0 = being in poor health to 100 = being in good health) and summarized as physical component and mental component summaries. The EQ-5D consists of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), which are measured using 3 possible levels ("no problems," "some problems," and "extreme problems") and summarized