

A FEASIBILITY STUDY COMPARING TWO CHIROPRACTIC PROTOCOLS IN THE TREATMENT OF PATELLOFEMORAL PAIN SYNDROME

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ABSTRACT

Objective: The purpose of this pilot study was to determine the feasibility of (1) using the existing clinic, clinicians, interns, faculty, and staff from our college in conducting all components of a planned randomized controlled clinical trial; (2) successfully recruiting patients with patellofemoral pain syndrome (PFPS); and (3) consistently, effectively, and safely implementing the study protocols and therapy.

Methods: Diagnostic, treatment, and blind assessment procedures were carried out while recruitment and administrative techniques for managing long-term storage of data and files were developed. Thirty-one patients were randomized into a local manipulative group (group A) or to a full kinetic chain manipulative therapy group (group B), each combined with exercise and soft tissue treatment. The Anterior Knee Pain Scale, visual analog scale, and Patient Satisfaction Scale were used.

Results: All phases of the feasibility study including use of the clinic, staff, recruitment techniques, treatment protocols, data collection, input, and analysis were effectively and safely carried out.

Conclusions: A feasibility study investigating the ability to conduct a randomized controlled trial of a manipulative therapy protocol for PFPS using available chiropractic college infrastructure was accomplished. A fully powered PFPS trial is feasible and merited. (*J Manipulative Physiol Ther* 2009;32:536-548)

Key Indexing Terms: *Manipulation, Chiropractic; Patellofemoral Pain Syndrome; Knee Injuries; Musculoskeletal Manipulations*

Patellofemoral pain syndrome (PFPS) is generally described as anterior knee pain around or behind the patella aggravated by increased activity, particularly

flexion, and use of the quadriceps muscles.¹⁻⁵ Not a diagnosis but a syndrome, there is no definitive etiology for PFPS. A common diagnosis in sports medicine, PFPS prevalence rates range between 2% and 30%, including 10% of all runners.¹⁻⁸ PFPS has a general incidence rate of at least 7% in athletic young adults, 15% of soldiers, and, within a lifetime, may affect 10% to 40% of the general population ages 18 to 45 as well as older active adults.¹⁻⁸ Surgery is reserved as a last resort.⁹

Exercise alone, applied locally, has been demonstrated useful in the short-term treatment of PFPS at 6 weeks. Exercise with or without manipulative and soft tissue therapy or, combined with other modalities such as orthotics, knee braces, and tape, demonstrates comparable short-term usefulness.^{1-5,10-18} In clinical trials, manipulative therapy (defined as all grades of mobilization I-IV including manipulation or grade V high-velocity low-amplitude thrust) for PFPS has been restricted to patellofemoral joint mobilization with manipulation of lumbopelvic joints occasionally added.^{1-5,8,19-21} A few trials, designed to treat knee osteoarthritis, have also used full kinetic chain (FKC) manipulative therapy for joint dysfunction in the lumbosacral, hip, knee, ankle, and foot. Based on the markedly decreased pain and increased knee function demonstrated in these previous trials, it was decided that FKC would be used

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in this pilot study for PFPS.²²⁻²⁴ This approach is supported by the theory that the locomotor system is a closed kinematic system within which joint dysfunction and change/loss of function are adapted by other joints and/or soft tissue. No chiropractic trials have yet combined these approaches for PFPS. It was decided to compare and contrast manipulative therapy for the knee vs FKC for the lumbosacral, hip, knee, ankle, and foot, each combined with exercise and soft tissue treatment.^{1-5,8,10,13,20,22-29} A large, fully powered (and expensive) chiropractic randomized controlled trial (RCT) with this protocol has not yet been carried out, and with few chiropractic organizations intentioned to support such research (the National Institutes of Health providing funds for few complementary and alternative medicine trials), innovation is required. In addition, no trial of this scope had been previously integrated into or conducted at the Cleveland Chiropractic College Los Angeles (CCCLA) Health Center; therefore, it was decided to complete a pilot study to determine the feasibility of successfully initiating and completing an adequately powered RCT.

The purpose of this study was to determine the feasibility of (1) using the clinic, clinicians, interns, faculty, and staff in conducting all of the various components of a planned randomized controlled clinical trial; (2) successfully marketing/recruiting patients with PFPS from the community; and (3) consistently, effectively, and safely implementing the study protocols and therapy.

METHODS

It was determined that, to meet the specific aims of this pilot study, 10 patients, aged 18 to 45, would be randomized to each study arm. The Anterior Knee Pain Scale (AKPS), visual analog scale (VAS), and Patient Satisfaction Scale (PSS) were used to assess each sample at baseline, after the sixth treatment, and at the 2-month follow-up. The AKPS and VAS are valid and reliable for PFPS.^{1,30,31} Demonstrating that this type of research is feasible and that evaluation, treatment, and reassessment per study protocols could be practically executed and fairly performed, in the midst of an ambulatory health center/teaching clinic otherwise primarily focused on and responsible for more than 30 000 patient health encounters per year, was one of the most important aims of this endeavor.

Diagnosis/Inclusion Criteria^{1,2,4,5}

1. Anterior, peripatellar, or retropatellar knee pain of more than 3 months from at least 2 of the following: prolonged sitting, stair climbing, squatting, running, kneeling, and hopping/jumping or overuse activities with the pain of any of these activities relieved by rest.
2. Insidious or gradual onset of symptoms unrelated to a traumatic incident.
3. Presence of pain upon palpation of the patellar facets, on step down from a 25-cm step, or during a double-legged squat.
4. X-ray or MRI findings were not required as there is no clear correlation between severity of complaints and arthroscopic or radiologic findings.
5. A VAS (worst pain) of ≥ 5.0 and an AKPS of ≥ 50 .
6. The "PARTS" system was used to facilitate determination of concurrent segmental joint dysfunction or "subluxation complex" requiring chiropractic manipulative therapy (CMT).³²

Exclusion Criteria

Exclusion criteria included other disorders such as osteoarthritis, instability, or medial meniscus injuries. Specifically, (1) patellar subluxation/dislocation, locking due to meniscal, internal, and intraarticular derangement or pathology (ie, anterior cruciate ligament injury, ligament tear, laxity, or instability); (2) Osgood-Schlatters or Sinding-Larsen-Johanson syndromes, knee joint effusion, autoimmune or seronegative arthritides, bursitis, patellar tendonitis; (3) previous knee surgery; (4) neurologic disorders that influence gait and similar disorders; (5) illiteracy or the inability to understand and answer questionnaires and/or consent forms; (6) inability to attend all treatment sessions; and (7) previous physical therapy, chiropractic, or massage therapy in the last 3 months. Prescribed and over-the-counter medication use was allowed if initiated before study entry, although patients were requested to not begin using medications or other common treatments, such as injections, during the study. Similarly, foot orthotics were allowed if currently worn but could not be added/modified during the trial.

Baseline Measurement

Diagnosis of joint dysfunction (referred to in chiropractic as a component of a subluxation complex and/or segmental joint dysfunction) was operationalized using the PARTS system; this and similar systems are widely used across professional disciplines to identify a manipulable lesion, composed of various evaluative and observational components in this system including pain or tenderness produced by palpation and or pressure, asymmetry or malalignment of segmental components, detection of limited range of motion (including quantitative, qualitative, and end range barriers), tone/texture/temperature changes (includes muscular tenderness, trigger points, adhesions, spasm, and thermal asymmetries), and other special tests (such as x-ray, neurologic examinations, abnormal motor control, complex kinetic chain dysfunctions and relationships, and other complementary and alternative medicine diagnostic procedures; see Petersen and Bergman 2002).^{3,32-38} PARTS assessment was performed by *unblinded* assessors. At baseline, the first 4 components of "PARTS" were required for identification and diagnosis of joint dysfunction; but at the sixth treatment,

and 2-month follow-up, only 2 components were necessary as per the US Medicare guidelines: a range of motion abnormality and/or asymmetry—misalignment along with one additional PART(S) component.³⁹

Recruitment Procedures and Sample Size

Initially, a sample of males and females 18 to 45 were to be drawn from the college health center, local population, by word of mouth, through advertisements and flyers at local universities, colleges, schools, chiropractic and medical clinics, businesses, and from the community. About 6 months into the study, it was deemed necessary to explore additional recruitment strategies. The most immediately successful of these additional strategies was a large banner, advertising the study, on a highly visible external wall of the college facing a heavily traveled thoroughfare.

Informed Consent

All patients participating provided written consent following the explanation that they would be randomly assigned to 1 of 2 treatment groups; both treatments were believed to be effective. The project was approved by the CCCLA institutional review board before recruitment of any patients.

Intervention Groups and Planned Course of Treatment

Group A received CMT to the knee joints only, exercise, and Graston Technique or Graston Instrument–assisted Soft Tissue Mobilization (Graston Technique, Falmouth, Mass; hereafter GISTM and/or in this article designated soft-tissue treatment or therapy).⁴⁰ Group B received CMT to the FKC, including manipulative therapy, as needed, to the lumbosacral, sacroiliac, and all lower-extremity joints including the knee, exercise, and soft tissue (GISTM) treatment.

Enrolled subjects received 1 to 3 treatments per week for generally 2 to 6 weeks for a total of 6 treatments. The primary end point was the AKPS and VAS assessed at a 2-month follow-up after the sixth or last treatment. The PSS was collected only at the 2-month follow-up.

Treatment Details

Group A received manipulative therapy (grades I through V) to the local knee joints in conjunction with soft tissue (GISTM) and exercise therapy at a dosing level of 1 to 3 times per week for generally 2 to 6 weeks combined with home exercises. Exercises were to be performed twice daily except for Sunday (day off). Two months after the last or sixth treatment, outcome measures were obtained at a final follow-up visit.

Group B received manipulative therapy (grades I through V) to the FKC: lumbosacral, sacroiliac, and (all)

lower-extremity joints including the knee, ankle and foot, and exercise and soft tissue (GISTM) treatment at a dosing level of 1 to 3 times per week for generally 2 to 6 weeks combined with home exercises. Exercises were to be performed twice, daily except for Sunday (day off). Two months after the last or sixth treatment, a follow-up visit obtained outcome measures.

Diagnosis and manipulative therapy for both groups A and B were carried out at the CCCLA health center by the 2 study-designated floor clinicians and/or by 2 to 4 fully supervised, fully vetted and highly trained interns; however, per trimester, most of the treatment was delivered by these highly trained interns, each intern usually participating for 2 trimesters/8 months. Manipulative therapy used the techniques as outlined in Taylor and Brantingham, Petersen et al, Peterson and Bergmann, Tucker et al, Stakes et al, Fish et al, and/or this article using common, diversified procedures (Appendix A).^{3,19,27,32,41,42}

Groups A and B and Soft Tissue Treatment (GISTM). Groups A and B received GISTM procedures as the soft tissue therapy. All providers delivering this modality were required to be trained and certified in GISTM. GISTM was administered to patients with PFPS using methodology as outlined in the Graston Technique Instruction Manual.⁴⁰ Both treatment groups received the same GISTM treatment.

The following structures/soft tissue problems were evaluated using the scanning instrument GT 4 and treated using the instrument appropriate for the lesion: vastus medialis oblique fascial restriction, patellar femoral soft tissue joint restriction, iliotibial band insertion at the patellar attachment, rectus femorus adhesion, and/or restriction of the patellar tendon both suprapatellar and infrapatellar. GISTM was applied for a maximum of 3 minutes per site. For the purposes of this pilot study, ice was not applied after GISTM. Post-GISTM treatment allows for either icing or passive stretching posttreatment, with the latter being applied to the areas that had GISTM after therapy.⁴⁰

Exercises. Exercises commonly prescribed to treat PFPS were given to all patients, with sets, repetitions, and stretching initiated and modified with respect to the age, condition, and fitness of each subject and performed at each clinic visit.^{1,3,5} Patients were strongly encouraged to be compliant with exercise. During treatment and after the sixth visit, home exercises were to be done 2 times everyday (with Sunday off) until the 2-month follow-up. Subjects were asked at the 2-month follow-up to estimate their percentage of home exercise compliance (Appendix B).^{1,3,5}

Outcome Measures for PFPS

The AKPS and the VAS, valid and reliable for PFPS, were chosen as outcome measures for this study.^{1,30,31} The AKPS is a comprehensive survey of 13 questions specifically assessing knee pain, disability and function, antalgic gait, need for support, pain after prolonged walking, pain on

climbing stairs, squatting, running, prolonged standing, generalized pain, swelling, painful movement of the patella, muscle atrophy from disuse, and flexion deficiency^{1,30,31,43} In addition, the PSS was used (at the 2-month follow-up) as a primary measure. The PSS is a simple dichotomous scale labeled “discharge” (D) or “refer” (R).⁴⁴

A clinically meaningful change for the better in the AKPS, a 0- to 100-point scale in which a higher score represents less disability, requires an increase of 8 to 10 points. In the VAS, a decrease of 1.5 to 2.00 cm on a 0- to 10-cm pain scale represents a clinically meaningful lessening of pain.^{1,30,31,43,45} Using the PSS, patients answer a dichotomous question only at the 2-month follow-up: (1) do they now feel they can be discharged (D) as they are satisfied enough that they do not feel the need for further care or, (2) do they feel they need to be referred (R) for further chiropractic care or to another doctor, practitioner, or orthopedist?⁴⁴ The AKPS and VAS but not the PSS were collected at baseline before randomization and by blind assessors after the sixth treatment; all 3 outcome measures were collected at the 2-month follow-up.

Randomization was performed by one of the investigators. A computer-generated list of random numbers was allocated into either group “A” or “B.” These letters were written on slips of paper, folded over, and sealed in envelopes that had no marking on them on the outside and the folded numbers inside were undetectable. These envelopes placed in a locked cabinet were requested for assignment only after a patient was fully accepted into the study and given out by a researcher who had no contact with the patients.⁴⁶ Because of the relatively small size of the pilot (n = 20) and initial a priori failure to use small block randomization, a first block of 30 was randomized (15 per group in consideration of dropouts). Along with other factors discussed below, the 2 treatment arms ended up with slightly more subjects in group B (18) than in group A (13). Smaller blocks of 6 per group were subsequently pre-prepared.⁴⁶

Outcome measures were sent to the Office of Data Management and were entered into a permanent, secure, confidential, compliant, and protected database using a double-entry system to insure accuracy. These data were later available for analysis.

Statistics

Descriptive statistics and other exploratory analyses were calculated using SPSS version 12.0 (SPSS Inc, Chicago, IL).

Clinicians

Training of clinic staff to deal with the special needs of research patients was relatively easy and straightforward, but with doctors and interns over the entire study period, training was repetitive, arduous, labor intensive, but workable. Three training sessions per doctor and/or intern

was adequate. Two clinicians were designated to the study but usually, per trimester, an additional doctor would be trained as backup. Two to four new interns were required to be trained per trimester secondary to graduation. As mentioned earlier, all doctors and interns had to be certified in GISTM and this requirement was met throughout the study.

This study used the CCCLA health center and therefore most of the interventions were delivered by interns; but frequently when an intern encountered a patient who was more challenging with respect to achieving an adjustment or joint cavitations (eg, a patient who was difficult to side posture lumbar manipulate), the designated clinicians were called upon to administer the treatment. A number of the other health center clinicians, who were fully trained in the study protocol, would, on rare occasion, administer treatment secondary to unavailability by the primary treating clinicians. Clinicians and interns were frequently monitored by the study coordinator for their level of engagement in the research study to assess the level of motivation and attention to full compliance with the study protocol.

Blind Assessment

The operational procedure governing blind assessors during this trial was that if the blind assessor became aware of the subject’s group assignment (ie, became unblinded), the assessor was to, without delay, leave the room and immediately report to the project coordinator/or another supervising clinical faculty member. Another blind assessor was then located to make the assessment. Much effort was made to reinforce the importance of this procedure, and blinding was maintained. Blind assessment was successfully carried out by the site.

Begun in June 2006, the pilot was to run 1 year. Initial recruitment was slower than anticipated; and as the study neared the end of this 1-year period, it was determined that there was a need to continue to explore improved recruitment/marketing strategies if a fully powered study was ever to be considered. It was therefore deemed important to extend the pilot for a short period (until December 2007) to allow exploration of additional recruitment strategies. With the successful response after introducing these additional approaches, a greater number of patients than first responded suddenly began to appear.

Recruitment

One hundred forty-one patients were recruited as potential participants for this study. Of these patients who contacted the college, 94 were excluded by the initial phone or in-person interview secondary to not meeting protocol requirements. One objective of this pilot study was to determine if the study site could successfully market/recruit PFPS patients from the community. The most successful

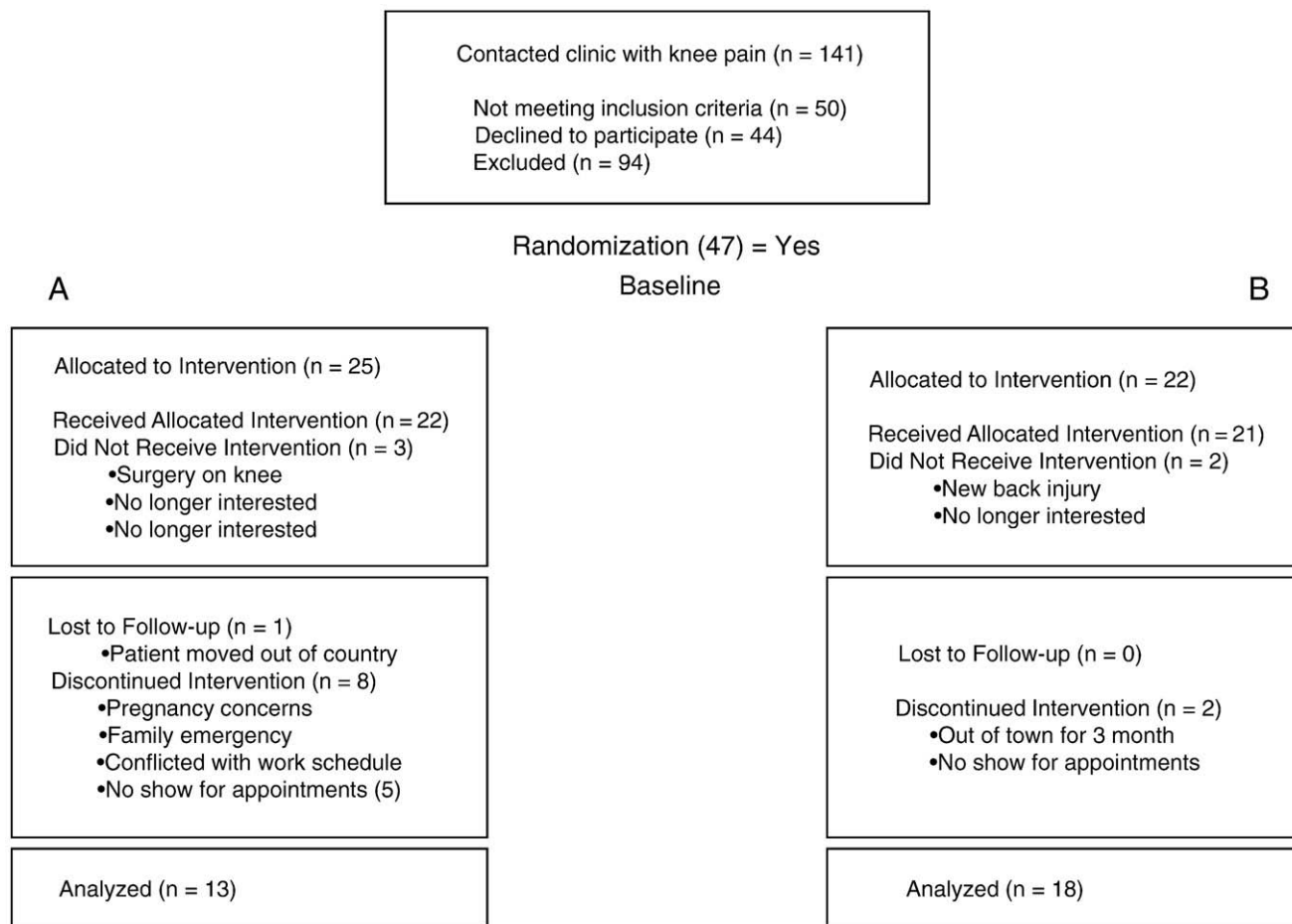


Fig 1. Study flowchart for PFPS treatment.

enhanced marketing/recruitment strategy was the use of a banner that was placed facing the busy thoroughfare that runs north-south along the campus. Practical considerations restricted the size and usable/visible lettering space so the message was limited to “Do You Have Knee Pain?” The banner generated a substantial increase in inquiries regarding the study by interested patients with a variety of knee disorders, many of which, such as knee osteoarthritis, meniscal, or ligament injuries, did not meet the inclusion/exclusion criteria. Some of these patients did meet the protocol requirements and were ultimately allowed to enroll. This resulted in the total number of patients enrolled in this small pilot study being greater than was initially planned. The literature has identified that there is a case to be made that sometimes it is *more* ethical, under these types of circumstances, to include additional patients than to exclude them secondary to closing a study.⁴⁷

RESULTS

Eventually, 47 patients aged 18 to 45 met the inclusion, exclusion, historical, and diagnostic criteria consistent with

PFPS and were randomized to 1 of the 2 study arms with 31 patients completing the full study protocol (Fig 1).

Safety

Review of subjective, objective, analysis, and plans notes, interviews, posttreatment calls, and outcome measures indicated no patients dropped out of the pilot from side effects, although a few reported mild adverse reactions (ie, 1 in group A, 3 in group B) such as stiffness, soreness, and weakness after treatment. There were no reports of serious adverse reactions.

Baseline Characteristics

Group A mean age was 27.92 (SD, 3.16) and group B mean age was 30.72 (SD, 8.07). Analysis regarding baseline characteristics (using the Mann-Whitney *U* and χ^2 tests) revealed that no statistically significant between-group differences were detected regarding age, sex, onset, or with the AKPS or VAS baseline scores ($P > .05$). Group A had PFPS symptoms/and or complaints for an average of 48.48 months and group B, 54.77 months. Further χ^2 analysis

Table 1. Group A demographics

PFPS	Group	Age	Sex	Onset
1	A	30	F	Trauma
2	A	26	M	Gradual
3	A	26	M	Gradual
4	A	33	M	Gradual
5	A	26	M	Gradual
6	A	30	M	Gradual
7	A	27	M	Gradual
8	A	27	M	Gradual
9	A	22	M	Gradual
10	A	33	F	Trauma
11	A	31	M	Trauma
12	A	30	M	Gradual
13	A	22	M	Gradual
	13	27.92	2 F 11 M	3 Trauma 10 Gradual

demonstrated no statistically significant difference between groups with respect to onset (gradual or traumatic) or in male-to-female ratio ($P > .05$) demonstrating that the site was able to implement randomization procedures in this feasibility pilot (Tables 1-5).

Intergroup

Further secondary analyses of the study data were performed to explore for trends/directionality of treatment effects. Using the Mann-Whitney U and χ^2 tests, no statistically significant differences between groups at baseline, after the sixth treatment, or at the 2-month follow-up were detected for VAS (usual or worst), the AKPS, or the PSS ($P > .05$).^{1,31}

Intragroup AKPS

However, the Wilcoxon signed rank test, assessing within-group AKPS change from baseline to the sixth treatment, demonstrated a statistically significant and clinically meaningful change in group A but not group B. From baseline to the sixth treatment, group A increased by 9.46 points and group B by 6.05 points. At the 2-month follow-up, the Wilcoxon signed rank test demonstrated statistically significant and clinically meaningful changes in both groups. From baseline to the 2-month follow-up, group A increased by 13.23 points and group B increased by 13.05 points (Table 3).

Intragroup VAS

Using the Wilcoxon signed rank test, the VAS-usual was statistically significant for improvement for group A, but not group B, at the sixth treatment. However, VAS-worst was statistically significant and clinically meaningful for both groups at the sixth treatment (decreased 1.95 and 1.91 cm, respectively),^{1,31} as presented in Tables 4 and 5.

In addition, VAS-usual was statistically significant and clinically meaningful for group B, but not group A, at the

Table 2. Group B demographics

PFPS	Group	Age	Sex	Onset
1	B	30	M	Gradual
2	B	33	F	Gradual
3	B	28	M	Gradual
4	B	34	F	Trauma
5	B	24	M	Trauma
6	B	21	M	Gradual
7	B	25	F	Trauma
8	B	45	M	Gradual
9	B	29	M	Trauma
10	B	21	M	Gradual
11	B	45	M	Gradual
12	B	41	M	Gradual
13	B	41	M	Gradual
14	B	22	M	Gradual
15	B	36	M	Gradual
16	B	22	M	Trauma
17	B	28	F	Gradual
18	B	28	M	Gradual
	18	30.72	4 F 14 M	5 Trauma 13 Gradual

2-month follow-up (decreased 1.48 and 0.76 cm, respectively), whereas VAS-worst was both statistically significant and clinically meaningful for groups (A and B) at the 2 month follow-up (decreased 2.04 and 2.73 cm, respectively), as shown in Tables 4 and 5.

Intra- and Intergroup PSS

χ^2 analysis of the PSS for both groups A and B failed to demonstrate a statistically significance change within groups ($P = .132$ and $.285$, respectively) or between groups ($P = .496$). However, it is worth noting descriptively that 73% of group A and 64% of group B patients reported that they did not feel the need for further care, preferring discharge over referral.⁴⁴ Nevertheless, in exploring this positive trend, PSS outcomes were compared with those who had, and had not, continued the exercise per protocol after the sixth treatment (comparing percentage estimate collected at the 2-month follow-up). As seen in the trial of Clark et al, so too in this study, more were discharged who continued regular exercise than those who had not (or had exercised less) after the sixth treatment. However, this did not reach statistical significance.⁴⁴

Joint Dysfunction

Joint dysfunction documented for the lumbar spine, sacroiliac, hip, knee, ankle, and foot joints is listed as determined from the pilot trial data. Other data on knee additional joint dysfunctions are listed in Appendix C in relation to group B (Appendix C).^{3,13,19,27,32,42} No claim to validity or reliability is being made, merely a percentage “impression.”

Table 3. Sixth treatment and 2-month follow-up (AKPS)

Sixth Treatment									
AKPS	Baseline (points)	SD (points)	Change after sixth treatment (points)	AKPS-worst sixth (points)	SD (sixth treatment)	Mean	CI	<i>P</i> (usual)	
Group A	71.85	9.745	↑9.46 ^a	81.31	Mean 71.85-81.31	SD (2 mo) ±11.566	2.47 to 16.45	.010	
Group B	75.83	9.024	↑6.05	81.89	75.83-81.89	SD ±12.909	-0.36 to 12.48	.0069	
2-mo follow-up									
AKPS	Baseline (points)	SD (points)	Change after 2-mo treatment (points)	VAS 2 mo (points)	SD (2-mo FU)	Mean	CI	<i>P</i> (usual)	
Group A	71.85	9.745	↑13.23 ^a	85.08	Mean 71.85-85.08	SD (2 mo) ±11.519	-3.718 to -0.358	.003	
Group B	75.83	9.024	↑13.05 ^a	88.88	75.85-88.89	SD ±13.926	-4.229 to -1.135	.003	

FU, Follow-up.

^a Denotes a clinically meaningful change.

Table 4. Sixth treatment and 2-month follow-up for the VAS-usual

Sixth treatment									
VAS-usual	Mean - baseline (cm)	SD (cm)	Change after sixth treatment (cm)	VAS-usual sixth (cm)	CI	Mean sixth treatment (cm)	SD (sixth treatment) (cm)	<i>P</i> (usual)	
Group A	2.56	±2.10	↓1.0	1.56	-1.99 to -0.004	1.64	±1.57	.041	
Group B	3.06	±2.38	↓1.17	1.89	-2.22 to -0.089	1.90	±1.71	.083	
2-mo follow-up									
VAS Usual	Mean - baseline (cm)	SD (cm)	Change after 2-mo treatment (cm)	VAS-usual 2 mo (cm)	CI	Mean 2-mo FU (cm)	SD (2 -month FU) (cm)	<i>P</i> (usual)	
Group A	2.56	±2.10	↓-0.76	1.80	-1.50 to -0.022	2.06	±2.14	.230	
Group B	3.06	±2.38	↓-1.48 ^a	1.58	-2.63 to -0.306	1.59	±1.78	.021	

^a Denotes a clinically meaningful change (1.5-2.0 cm = clinically meaningful change; 0 = best, 100 = worst score).

DISCUSSION

Although difficult to measure, it seems reasonable to assume that, similar to practice-based research, there may have been some minor decrement in the effects and consistency of treatment delivered secondary to using the busy health center staff, clinicians, and interns, particularly use of multiple treating interns throughout the course of the study.⁴⁸⁻⁵⁰ Yet the study overall was successfully completed with the exploratory data analysis indicating positive trends that mirror other studies in the literature. One further reflection in this regard worth considering is that the conditions under which this pilot study was conducted may parallel more accurately the less controlled and consistent environment of private practice. This may actually make the findings developed from this pilot study and future research conducted in this type of environment extrapolate better to the wider chiropractic community.^{51,48}

Dropouts and Adverse Effects

As reported, there were a few mild adverse reactions but no reports of serious adverse reactions (eg, defined as persistent severe knee stiffness, swelling, and/or pain).⁴¹

There were other reasons why patients left the study, for example, one patient received his or her first 2 treatments immediately before a college scheduled 1-week break. This subject did not return despite extensive attempts made to contact the patient; data were carried forward in later analysis. Data from a number of other patients though were excluded. One patient sustained a low back injury unrelated to the study and was excluded; another pregnant patient was excluded by her obstetrician because of concerns about miscarriage, which was unrelated to the study. Ultimately, the *baseline data* from 2 patients in group A, 1 in group B, and 3 in group B from the sixth treatment were carried through all calculations. No patients reported after study that they had begun a new or different treatment (Fig 1).

Comparison of Trends with Previous Manipulative Therapy Studies for PFPS

The widely used AKPS and VAS have been specifically demonstrated valid and reliable for PFPS and were easily understood and completed by study patients. On the other hand, the Patient Specific Functional Scale or PSS selected for inclusion secondary to its use in the highly rated PFPS

Table 5. Sixth treatment and 2-month follow-up for the VAS-worst

Sixth treatment								
VAS-worst	Mean – baseline (cm)	SD baseline (cm)	Change after sixth treatment (cm)	VAS-W sixth (cm)	CI	Mean sixth treatment (cm)	SD (sixth treatment) (cm)	P (usual)
Group A	7.33	±1.49	↓-1.95 ^a	5.38	- 3.32 to - .583	5.37	±2.44	.008
Group B	7.05	±1.43	↓-1.91 ^a	5.14	- 3.11 to - 0.706	4.98	±2.28	.008
2-mo follow-up								
VAS-worst	Mean – baseline (cm)	SD baseline (cm)	Change after 2-mo treatment (cm)	VAS-worst 2 mo (cm)	CI	Mean 2-mo FU (cm)	SD (2-mo FU) (cm)	P (usual)
Group A	7.33	1.49	↓-2.04 ^a	5.29	-3.71 to -0.35	5.29	±2.81	.013
Group B	7.05	1.43	↓-2.73 ^a	4.32	-4.22 to -1.13	4.28	±2.84	.002

^a Denotes a clinically meaningful change (1.5-2.0 cm = clinically meaningful change; 0 = best, 100 = worst score).

study by Clark et al limited and forced a dichotomous choice, and this was difficult/confusing to patients. Interestingly, this may explain why the PSS has failed to achieve a similar level of validity and reliability compared to the other measures.^{1,5,8,11,12,25,31,52,44,53} The PSS Overall Therapy Effectiveness Tool or even a Likert scale (allowing a broader variety and choice of response) is preferred.⁵⁴ Notably, trends in this pilot study are similar and comparable to previous studies.^{1,3,19,5,10,55-57} In this pilot study, exploratory analysis revealed positive change in the AKPS, which appeared to be statistically significant and clinically meaningful at the sixth week and at the 2-month follow-up. At the sixth treatment, group A increased by 9.46 points, and for both groups, the mean increase was nearly 8 points. There was a greater than 13-point increase in both groups at the 2-month follow-up.^{1,3,19,5,10,55-57} This pilot study thus approximates the short-term findings in the PFPS trial of Collins et al.¹⁰ Collins et al, using mobilization of the patella, soft tissue, and exercise therapy (using the protocol of Crossley et al), had an increase in the AKPS of around 11.7 points at 6 weeks and 13.2 points at 3 months.^{1,10} Furthermore, this study correlates to the studies of Stakes et al and Taylor and Brantingham (using different functional scales for PFPS), which also documented statistically significant and clinically meaningful functional improvements using patellar mobilization with either lumbosacral manipulation and/or exercise, respectively.^{3,19,56,57}

In the present study, trends in the VAS-usual data appear statistically significant for group A (with a decrease of 1.0 cm and $P = .041$) but statistically significant and clinically meaningful for FKC group B treatment at the 2-month follow-up (a decrease of about 1.5 cm, with $P = .021$). In the PFPS trial of Collins et al, VAS-usual decreased about 1.29 cm at 6 weeks and 1.4 cm at 3 months.^{1,10} And again, although not directly comparable, these data correlate to the decreased pain seen in the PFPS studies of Stakes et al, Taylor and Brantingham, and Rowlands and Brantingham that used either the NRS-101 usual or the Short-Form McGill Pain Questionnaire.^{2,3,19}

Notably, in this study, VAS-worst was statistically significant and clinically meaningful for both groups at the sixth week and the 2-month follow-up: representing nearly a 2-cm decrease at the sixth treatment. At the 2-month follow-up, the localized treatment group maintained this result, whereas the FKC treatment group B (Table 5) increased to a near 3-cm change ($P = .002$).⁵⁸ This is similar to VAS-worst for Collins et al¹⁰ with about a 2.92-cm decrease at the sixth treatment and 3.45-cm decrease at 3 months. In passing, it should be noted that foot orthotics fared nearly as well as Collins physical therapy (mobilization, exercise, and soft tissue treatment) for PFPS, and serious discussion continues as to the long-term effectiveness of treatment in PFPS; however, it cautiously appears that the trends in this study appear to compare favorably to previous research regarding short-term effects.^{5,10,13}

This study effectively used the CCCLA health center. Use of multiple clinicians and highly trained interns to assess and safely deliver treatment to patients with PFPS is workable (at all times under supervision and fully supervised by the designated study clinicians). If a slightly more difficult manipulation was called for, such as a nuanced side posture lumbar thrust, the designated clinician was called upon to administer the treatment. In a training center environment, such as conducted with this pilot study, it may be necessary to frequently monitor clinician and intern engagement to ensure motivation and full compliance. Although difficult to measure, it seems reasonable to assume that there may have been some minor decrement in the effects and consistency of treatment delivery secondary to using the busy health center staff, clinicians, and interns, particularly utilization of multiple treating interns throughout the course of the study. Yet the pilot study overall was successfully completed with the exploratory data analysis indicating positive trends that mirror other studies in the literature while reflecting the environment of private practice. This may actually make the findings, borne out of conducting future studies in this type of environment, extrapolate better to the wider chiropractic community.^{48,51}

Future Trial Considerations

Overall, interns and doctors reported that they enjoyed participation. Recruitment was slow but increased dramatically in the later part of the study secondary to the use of additional recruitment strategies. As has been learned in this pilot study, a banner and targeted, explicit advertising and other marketing methods such as radio advertising will easily permit a full sample size of 57 per group to be met within a 1-year time frame. One clinician or intern to act solely as a blind assessor perhaps would produce greater consistency.

A future trial has been designed and a fully powered sample size calculated for this potential study with the frequently used AKPS.^{1,11,25,30,31,52} A future fully powered PFPS trial, assessing 2 similar treatments, will need 57 patients per group or an N of 114 to detect an 8- to 10-point clinically meaningful difference between 2 groups using the AKPS at 80% power with a confidence level of 95% and an $\alpha = .05$.^{5,23,59-62} In addition, based on previous published studies, a 10% dropout rate should be considered so that each group should be increased to reach an N = 125 or about n = 62 per group.^{5,23,59-62} Sample size calculations were made with the *nQuery Advisor Release 2.0* (Statistical Solutions, Boston, Mass) and are consistent with similar, previous, and newly planned trials.^{25,44}

Limitations

In this pilot study, FKC treatment did not demonstrate a significant intergroup trend. These results may reflect a decrease in treatment effect due to reliance on multiple, less experienced therapists and/or on the inability to isolate important joint dysfunction. Recently published evidenced-based research better suggests where, when, and how to apply manipulative therapy to the FKC for knee pain and joint dysfunction and will be used in future PFPS trials.^{8,13,23,29} These innovative approaches are currently being applied in a new clinical trial at our college.

Use of multiple doctors and interns as used in this study has been argued as more representative of private practice, more similar to practice-based research, and may at times better reflect actual effectiveness in the field.^{48,49} Along these lines, outcomes in practice-based research are initially slightly lower but, with further practice-based research, scores tend to raise near or even to the same level seen in RCTs; however, the average intern in this study was involved for 2 trimesters. Therefore, this may have negatively affected outcomes and trends.⁴⁸⁻⁵⁰ This study attempted to use a treatment(s) similar to but improve upon, first, the study of Crossley et al and then Rowlands and Brantingham and finally Clark et al.^{1,2,44} The study of Crossley et al and other above-cited studies have been demonstrated superior to placebo/and or standard care.^{1,2,44} Use of a recognized standard care and/or a similar treatment demonstrated to be better than placebo, in place of placebo is considered more ethical (group A was the “standard care”),

and at a minimum equivalent to placebo; a higher or “better” score vs standard care being generally more difficult to achieve.^{1,5,22,10,23,63-65} Nevertheless, the addition of placebo and “wait and see” (natural history) groups may have strengthened this study.⁶³⁻⁶⁵

In this pilot study, subjects could not be treated during school breaks (eg, breaks could extend beyond 2 weeks). Occasionally, patients in the study became ill with, for example, an upper respiratory tract infection such as influenza, thus necessitating missing appointments for a period of up to a week or more. It was decided early in the study that missing a study visit by more than 3 weeks might constitute a compliance problem and result in being dropped from the study. Fortunately, no patients who met this period of leading to potential exclusion required being dropped (as they had valid reasons for the time lapse and agreed to vigilant compliance thereafter), although this did result, in these cases, in a more extended time to completion of the 6 treatments. As this study solely relied on intramural funding, the investigators were not able to compensate patients for reasonable time and expense for their participation. This may have also impacted compliance to some extent. Again, it may be important to note that some patients were slightly delayed in the time to completion of all study visits by 2 to 3 weeks; therefore, some change in outcomes could be due to regression to the mean.⁶⁶ Of 31 patients, a few students (ie, 4 in group A and 2 in group B) presented for treatment, allowing for the possibility of bias; otherwise, patients' occupations ranged across the board from local university students, a newspaper editor, bank teller, professor, hospital workers, an actor, nurses, personal trainers, a construction worker, medical assistants, business people, homemakers, maids, and unemployed. Patients did not have to be naive to chiropractic care, which also may have introduced bias. An ability to provide improved continuity of care in some cases where there was a brief interruption during trimester breaks as well as the ability to compensate patients for time and effort, and therefore increase compliance, may enhance the outcomes in future trials.⁵¹

Later modification of patient recruitment and marketing strategies led to an unexpected increase in sample size, which provided the opportunity to explore descriptive statistics and trends. Using the PSS, descriptively 73% and 64% of patients (ie, groups A and B, respectively) were satisfied with treatment. Using the AKPS, after the sixth treatment, group A increased by 9.46 points, and at the 2-month follow-up, groups A and B increased by 13.23 and 13.05 points, respectively. The VAS-usual for group A decreased 1.00 cm at the sixth treatment and for group B, 1.48 cm at the 2-month follow-up. VAS-worst was, for both groups at the sixth treatment and at the 2-month follow-ups, decreased (ie, 1.95 and 1.91 cm and 2.04 and 2.73 cm, respectively). Using nonparametric analyses, these appear to be clinically meaningful trends for both protocols ($P \leq .05$); cautiously encouraging of positive potential effects and

motivating for conducting a future randomized clinical trial. Performed out of natural interest, but to develop better data collection, management, and analyses, these techniques were completed to guide future trial design. Nevertheless, it should be noted that these trends, calculated from a small sample of 31 patients, should not be extrapolated or generalized to patients or to the general population until a fully powered study can be conducted.

CONCLUSION

The primary aims of this pilot and feasibility study were met. The clinic, clinicians, supervised interns, faculty, clinic personnel, and staff, including blind assessors, successfully worked together, randomized patients, and effectively carried out all tasks and treatments required in conducting a future, full-scale RCT. Group A received manipulative therapy to the knee joints only, exercise, and soft tissue treatment, whereas group B received FKC manipulative therapy with identical exercise and soft tissue treatment. Data collection, storage, and analysis of outcome measures and trends were effectively carried out. Therefore, execution of this complex pilot study suggests that a future fully powered PFPS trial is feasible.

Practical Applications

- Two different chiropractic protocols for the treatment of PFPS were consistently, effectively, and safely implemented.
- Diagnostic, randomization, treatment, outcome, and blind assessment procedures were carried out.
- Pilot aims were met and descriptive statistics and trends appear positive, suggesting that a future fully powered PFPS trial is feasible and merited.

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No conflicts of interest were reported for this study.

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APPENDIX A. CHIROPRACTIC MANIPULATIVE THERAPY PROCEDURES AND DIVERSIFIED TECHNIQUE(S) FOR GROUPS 1 AND 2

Protocol 1 (group A):

CMT procedures included (all grades of mobilization and/or high velocity low amplitude manipulation starting with lesser grades of mobilization and grades increased per PARTS indications, patient age, and tolerance; cavitation is not required nor necessary) the *patellofemoral* joint (patellar mobilization); *tibiofemoral*: axial elongation, AP (anterior to posterior) and PA tibial glide, internal/external rotation tibial glide, and varus or valgus tibiofemoral glide. Proximal fibular (*proximal fibulotibial*) technique included AP and PA, superior (S) to inferior (I) or IS glide.

Protocol 2 (group B):

For those randomized to group B (in addition to the above manipulative procedures as outlined in protocol 1), manipulative procedures to the lumbosacral, sacroiliac, hip, ankle, and foot adjustments were applied.

-Per Taylor and Brantingham, Petersen et al, Peterson and Bergmann, Tucker et al, Stakes et al, Brantingham et al, and/or this article.^{3,13,19,27,32,42}

APPENDIX B. EXERCISE—IDENTICAL FOR GROUPS 1 AND 2

Warm-up is performed at the clinic and at home and consisted of:

Isometrics

Three sets of 10 repetitions held for 5 to 10 seconds

Quadriceps setting

Supine straight leg raising, held at 30° to 45°

Short arc quadriceps extension exercises

Isometric hip abduction while standing (4 sets of a 30-second hold)

Eccentric strengthening

Squats (bilateral) up to 40° of knee flexion combined with isometric gluteal muscle contractions (4 sets of 10 repetitions)

Standing single-leg squat with slow lowering of knee into flexion (with *external rotation* for isolating the vastus medialis = eccentric quadriceps strengthening) up to 40°

Stretching

Hamstrings static stretch held 3 repetitions for 30 seconds each

Quadriceps static stretch held 3 repetitions for 30 seconds each

Static stretches will be appropriate for age and fitness (eg, standing quadriceps stretch for a younger fit subject or kneeling quadriceps stretch with an older subject)

-Per Crossley et al,¹ Taylor and Brantingham,³ and Heities et al⁵

APPENDIX C. JOINT DYSFUNCTION (UNBLINDED)*

*Because of time constraints, concerns with reproducibility, and discrepancies in notation and listing these restricted motions are merely listed as an indication of, and possible correlation to, dysfunction. No causal or degree of importance is claimed at this time. Improved procedures for determining and documenting joint dysfunction are planned for future trials.

Lumbar:

L5/SI restricted extension and left rotation

L5/SI restricted extension and right rotation

L1/L2 restricted extension and left rotation

L4/L5 extension and right rotation

L3/L4 restricted extension and left rotation

L2/L3 restricted extension and right rotation

Sacroiliac:

Restricted extension of the left sacroiliac joint (“PI”)
Restricted extension of the right sacroiliac joint
Restricted flexion of the left sacroiliac joint (“AS”)
Restricted flexion of the right sacroiliac joint

Hip:

Restricted internal rotation of the hip joint

Knee:

Restricted axial elongation of the tibia on the femur
Restricted varus or “adduction” joint play of the tibia on the extended femur

Patella:

Restricted medial to lateral glide of the right patellofemoral joint
Restricted lateral to medial glide of the left patellofemoral joint

Restricted lateral to medial glide of the right patellofemoral joint
Restricted superior to inferior glide of the right patellofemoral joint
Restricted superior to inferior and medial to lateral glide of the right patellofemoral joint
Restricted inferior to superior glide of the left patellofemoral joint
Restricted inferior to superior and lateral to medial glide of the left patellofemoral joint

Ankle:

Right decreased dorsiflexion
Left decreased dorsiflexion
Left decreased anterior to posterior talar glide (*with* decreased dorsiflexion).

-Per Taylor and Brantingham, Petersen et al, Peterson and Bergmann, Tucker et al, Stakes et al, Brantingham et al, and/or this article.^{3,13,19,27,32,42}