Research

Patients' Perception of Care: Comparing Placebo and Manual Therapy Within a Pilot Study

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ABSTRACT

Introduction: Several previous placebo 'treatments' have been developed for chiropractic clinical trials. However, all of the placebos included some form of touch, such as sham massage or manipulation. The objective of this study was to develop and test a placebo treatment that included minimal contact with subjects.

Methods: Subjects were randomized to one of four groups; three groups receiving flexion distraction care (8, 12, or 18 visits) and one receiving placebo care (8 visits) over six weeks. Subjects were asked about their perception of care at the end of the first week of care and at the care completion visit.

Results: By the end of the study, approximately 23% of the subjects in the placebo group believed that the treatment was certainly placebo and another 39% believed that the treatment was possibly placebo. On the other hand, the majority of subjects in the active care groups believed they were receiving active care. Interestingly, more treatments led to a higher percent of subjects who believed that they were in the active treatment group.

Conclusion: Based on these results, it does not appear that our placebo was a successful comparison to the active treatment groups.

INTRODUCTION

The use of placebos in clinical trials originated in the pharmaceutical industry where placebo tablets or capsules were made to look like the therapeutic equivalent, but did not include the active ingredient. Translating this practice to manual medicine has proven to be very difficult. Multiple factors may influence the outcomes of treatment in manual medicine including doctor-patient interaction, physical contact with the patient, manual treatments such as massage or manipulation, and self-care suggestions. It is difficult to determine which feature is the 'active' component, so as to remove it during the placebo therapy.

Several previous placebo 'treatments' have been developed for chiropractic clinical trials.[1-4] However, all of the placebos included some form of touch, such as sham massage or manipulation. The objective of this manuscript and one objective of this pilot study assessing differing dosages of flexion distraction therapy for lumbar spinal stenosis was to develop and test a placebo treatment that included minimal physical contact with subjects and included other components of typical care.

METHODS

An institutional review board approved the trial and all patients provided written informed consent prior to study entry.

Sixty subjects with lumbar spinal stenosis were randomized to one of four groups; three treatment groups including different dosages of flexion distraction care (8, 12, or 18 visits) or placebo care (8 visits) over six weeks. Group differences were assessed in terms of change in perceived pain levels (Visual Analog Scale), general functional health status (Oswestry Disability Index), condition-specific functional health status (Stucki Questionnaire), and walking time to onset of symptoms (Treadmill Test) at the end of six weeks of treatment and at six months post-care follow-up.

At the end of the first week of care and at care completion, subjects were also asked which treatment group they thought they were in: active care or placebo care. Subjects did not know that the placebo care only included 8 visits over the six weeks, so they were not persuaded based on the number of treatments.

Participants

Subjects were eligible if they were at least 50 years old, had lumbar spinal stenosis syndrome defined as anatomical signs of spinal canal narrowing as viewed by MRI, had associated clinical symptoms of current pain in the back and/or one or both legs diagnosed as neurogenic claudication or chronic nerve root compression, and had symptoms for at least six months with an insidious onset. Subjects were excluded based on the criteria in **Table 1**.

Table 1: Exclusion criteria

1. Congenital stenosis or other spine deformities such as current spinal fractures, spinal infections, or tumors of the spine.

2. Prior lumbar spine surgery such as laminectomy, spinal fusion, or discectomy that lacks stability or occurred within the past 3 months. A recent or failed lumbar surgery may not be stable enough to withstand chiropractic manipulation. Previous surgeries will be allowed providing the research clinician is confident that the flexion distraction manipulation will do no harm.

3. Currently pregnant or nursing, although this is unlikely in this older population. While we do not know of any potential risks to unborn children or mother's milk from spinal manipulation, this area has not been adequately studied so we are choosing to exclude this population.

4. Co-morbid conditions that may preclude a person from participating in active care (laying prone on a treatment table or completing exercises) and outcome measures (Treadmill Testing, completion of questionnaires), such as severe cardiopulmonary disorders (i.e.: severe coronary artery disease, recent myocardial infarction, or vascular claudication), neuromusculoskeletal disorders (i.e.: disabling hip or knee arthritis; trochanteric bursitis; piriformis syndrome; need for assisted ambulation), or brain disorders (i.e.: dementia or Alzheimer's Disease).

5. Cauda equina symptoms (i.e.: perianal numbness; loss of bowel and/or bladder control).

6. Not fluent or literate in the English language. We will not be able to provide multiple translators within this pilot study.

7. Current or future litigation for any healthcare problem.

We screened 1211 subjects by telephone and 234 were eligible and interested. Of those, 234 presented for the baseline visit and 60 were randomized. **Figure 1** shows the flow of patients through the trial. **Table 2** shows the baseline characteristics of the randomized subjects in each of the groups.

Figure 1: Flow of subjects through the clinical trial

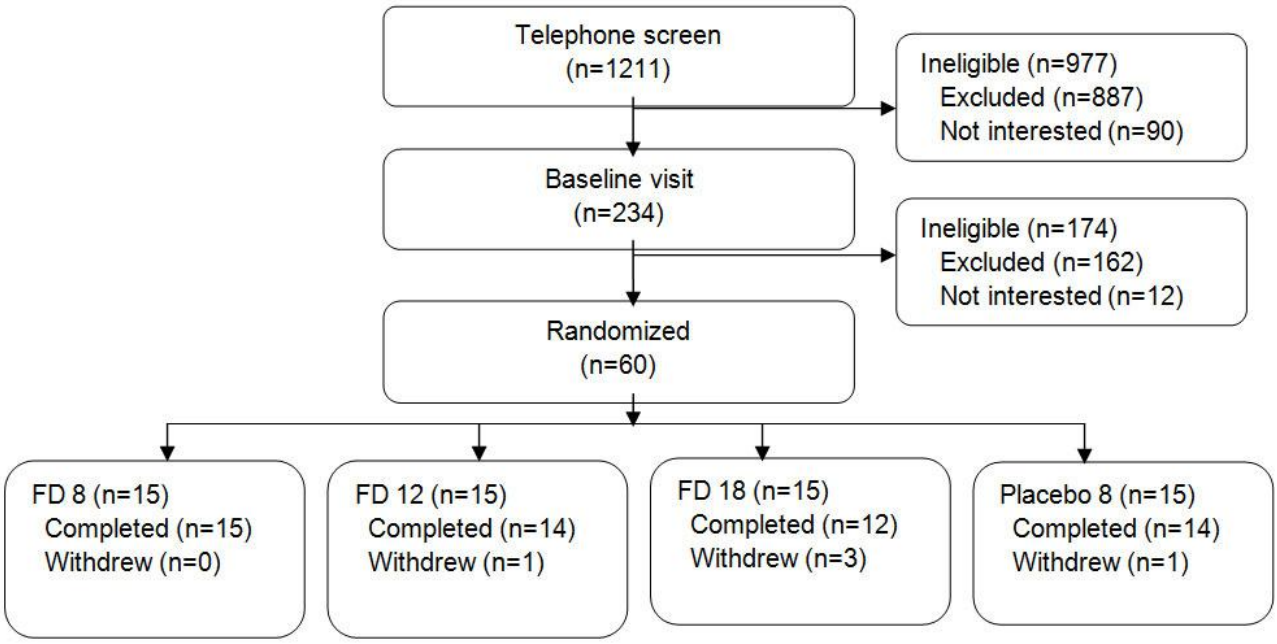

Table 2: Baseline characteristics

	8 placebo (n=15)	8 treatment (n=15)	12 treatment (n=15)	18 treatment (n=15)	Total
Gender					
Male	11 (73%)	7 (47%)	9 (60%)	13 (87%)	40
Female	4 (27%)	8 (53%)	6 (40%)	2 (13%)	20
Age; average	62.2	63.7	59.4	64.5	
Marital status					
Married	9 (60%)	9 (60%)	7 (50%)	12 (86%)	37
Unmarried	6 (40%)	6 (40%)	7 (50%)	2 (14%)	21
Race					
Caucasian	13 (87%)	13 (87%)	14 (93%)	13 (87%)	53

Other	2 (13%)	2 (13%)	1 (7%)	2 (13%)	7
Education*					
≤ HS	6 (40%)	0 (0%)	2 (13%)	3 (20%)	11
Post HS	9 (60%)	15 (100%)	13 (87%)	12 (80%)	49
Self-reported activity level					
Active	3 (20%)	4 (27%)	2 (13%)	5 (33%)	14
Inactive	2 (13%)	0 (0%)	2 (13%)	4 (27%)	8
Somewhat	10 (67%)	11 (73%)	11 (73%)	6 (40%)	38
Leg symptoms					
Both	7 (47%)	9 (60%)	6 (40%)	7 (47%)	29
Left only	4 (27%)	4 (27%)	6 (40%)	5 (33%)	19
Right only	4 (27%)	2 (13%)	3 (20%)	3 (20%)	12

*Statistically significant difference $p<0.05$

Outcome measures

In this study, subjects were asked about their perception of care at the end of the first week of care and at the care completion visit. Specifically, they were asked if they thought that they were definitely in active care, probably in active care, probably in placebo care, or definitely in placebo care. The subjects were also asked for any additional comments on why they perceived that they were in that group.

All other outcome measures will be discussed in the primary manuscript.

Interventions

Subjects were randomized to one of four groups; three groups receiving flexion distraction care (8, 12, or 18 visits) and one receiving placebo care (8 visits) over six weeks. Subjects were informed through the consent process that there were two forms of care. Each type of care was briefly described with the disclaimer that one of the possible forms of care was a placebo that

"looks like a typical chiropractic treatment but may not have a physical effect on the body." We did not disclose to the subjects which form of care was the placebo.

Flexion distraction care included two phases of care depending on the subject's symptoms. The phases were mobilization and traction. Mobilization is described as passive movement within the physiologic joint space. It is the attempted restoration of full painless joint function by rhythmic, repetitive passive movements to the patient's tolerance, in voluntary and/or accessory range and graded according to examination findings. These movements are applied from a specified beginning point, move to a specified end point, and immediately return to the beginning point. Traction is described as a sustained or rhythmically intermittent force, manually or mechanically applied in the longitudinal axis of a body part and thus to all aspects of it. It may also be arranged so that the emphasis of distraction is to the posterior, anterior, or unilateral aspect of an intervertebral joint. These movements are applied from a specified beginning point, move to a specified end point, maintain position at the specified end point, and then return to the beginning point.[5] Maintenance of force at the specified end-point is referred to as the hold time of each repetition. Depending on the patient's symptoms and tolerance, each phase of care could include either Grade III or IV mobilization, as defined by Maitland.[6] Hot packs could be used for 3, 5, or 8 minutes before flexion distraction care and cold packs could be used for 3, 5, or 8 minutes after flexion distraction, depending on patient symptoms. Both forms of hot/cold care were not to exceed 8 minutes total and the total care time was to be approximately 20 minutes.

Placebo care included the use of a low level laser pad placed upside down (lights away from the body) on each subject's low back for 8 minutes while the subject was in the prone position. Plastic bubble wrap surrounded the laser pad, so that the subject felt like the laser lights were touching their skin. This barrier also allowed for an easier to clean surface for hygienic purposes. A towel was placed over the top of the laser pad so that the subject was less likely to notice the upside down placement of the pad. After the pad was removed, care was applied using a hand-held instrument set to zero force so that there was a sound emitted from the instrument during use but no force was received by the subject. Subjects were assessed using leg-length checks at various points throughout the treatment to mimic actual therapeutic assessment. Six possible series of points were 'treated' and included points that were not used during active protocols, including up to three of six paraspinal points (2" lateral to the spinal process of L2, L4, or L5), up to two of four points on the pelvis (1" inferolateral to the PSIS or 1" superior and 2" posterior to the greater trochanter), and up to two of four points on the leg (2" superior to the medial or lateral knee). Total care time was to be approximately 20 minutes.

Both groups included the same types of comments such as "You may experience soreness following care today" in order to better maintain the impression that all subjects were receiving active care.

Randomization Process

A predetermined randomization scheme (blocked randomization) was performed prior to study initiation. Randomization was based on a random numbers table with each individual randomization sequence being placed in consecutively-numbered, sealed envelopes. Subjects were randomized to one of four groups, with 15 subjects ending up in each group.

Blinding

Subjects and research assistants were blind to the treatment allocation of all subjects; whereas it was not possible to blind the clinicians because they were rendering treatment.

Statistical methods

Baseline data were collapsed using descriptive statistics. Perceptions of care and timing of care were also descriptively compared, with emergent themes assessed from the qualitative data.

RESULTS

The average time spent with patients in the active care groups was 20 minutes (ranging from 10 to 45 minutes) and in the placebo group was 21.5 minutes (ranging from 13 to 45 minutes).

When asked what group subjects thought they were in, the placebo group most often responded certainly or possibly placebo **(Table 3)**. In the active group, a higher number of treatments rendered led to a higher percent of subjects who thought they were receiving active care. In both groups, the care completion visit had a more accurate perception of care than at the end of week 1, with more subjects in the placebo group believing they were in the placebo group and more subjects in the active care groups believing they were in the active care group.

There were three major themes found in the qualitative responses **(Table 4)**. First, the subjects were pleased with many aspects of the study such as personnel. Second, the subjects described that their symptoms improved or, third, that there was no change. The subjects in the group with 18 active treatments were most likely to state that they liked the study personnel or the study. Comments included that they were “impressed with the staff, doctors, and facility” and that the doctor “was a good listener.” The 18 active treatment group was also the most likely to describe that they had an improvement in symptoms stating that the study treatment “seems to make me stand straight” and “they helped decrease my back pain.” The 8 visit active care group was most likely to have commented about a lack of improvement stating that “after treatment I don’t feel any better or worse.”

Table 3: Percent of subject responses to which group they perceived they were in

Group	Timing	Certainly placebo	Possibly placebo	Possibly active care	Certainly active care
8 visit placebo group	Week 1	13.3%	40.0%	40.0%	6.7%
8 visit placebo group	Care completion	23.1%	38.5%	38.5%	0.0%
8 visit active group	Week 1	0.0%	40.0%	53.3%	6.7%
8 visit active group	Care completion	0.0%	13.3%	60.0%	26.7%
12 visit active group	Week 1	7.1%	21.4%	42.9%	28.6%
12 visit active group	Care completion	0.0%	14.3%	28.6%	57.1%
18 visit active group	Week 1	0.0%	14.3%	42.9%	42.9%
18 visit active group	Care completion	0.0%	33.3%	41.7%	25.0%

Table 4: Number of comments on given topics in each group of subjects

Group	Liked personnel or study	Improved symptoms	No improvement in symptoms
8 visit placebo group	4	5	1
8 visit active care group	3	7	2
12 visit active care group	2	5	0
18 visit active care group	5	8	1

DISCUSSION

A major aspect of this study was to test a placebo that included minimal therapeutic contact as the sham treatment. By the end of the study, approximately 23% of the subjects in the placebo group believed that the treatment was certainly placebo and another 39% believed that the treatment was possibly placebo. On the other hand, the majority of subjects in the active care groups believed they were receiving active care and these beliefs increased over time. For example, between the week 1 and care completion assessment, there was an increase in the percent of subjects who believed they were "certainly in the active care group" for both the 8-visit (7% to 27%) and the 12-visit active care groups (29% to 57%). This trend was opposite in the 18-visit active care group, dropping from 43% of subjects believing they were certainly in the active care group during week 1 to only 25% during the care completion visit. This may have been an aberrant data point due to the low number of subjects, or perhaps the subjects initially improved and then, when completing the remaining visits, believed that these visits were unnecessary and deemed them as placebo visits. Further study on this topic is necessary before we can say definitively that this occurrence is consistent.

Another interesting finding was that more treatments led to a higher percent of subjects who believed that they were in the active treatment group, particularly in week one with 7% of the 8-visit active care group believing they were 'certainly' in active care, 29% of the 12-visit active care group, and 43% of the 18-visit active care group. Having more groups of placebo care with a higher number of visits would have helped clarify if this was a function of the number of visits or if the subjects were improving over time and therefore determined that they were in the active care group. Overall, it does not appear that we were successful with development of our placebo.

There were several limitations in this study. First, the clinicians were not blind to treatment allocation so may have influenced the manner in which they interacted with the subjects. There

was a considerable amount of training on how to care for all subjects equally (except for the treatment aspect of the visit); and clinicians attempted to follow a semi-structured script in order to discuss the same issues with each subject regardless of their group allocation. Second, the perception data were only collected at two time points and may have been influenced by the believability of the care received that day rather than during the full course of care. Third, the subjects that entered this study may have expected some form of manual therapy rather than a non-touch placebo, possibly leading to the un-blinding of the subjects during the trial. If the subjects in the placebo group did not find their care believable for any reason, their outcomes may have been influenced by this belief leading to issues with data interpretation. Finally, the qualitative data were collected by asking about "any additional comments about your treatment group" rather than asking why the subject believed they were in active or placebo care. The results would have been more beneficial in understanding subjects' perceptions if we had asked the question differently.

Due to the limitations mentioned above and the findings of this study, investigators are encouraged to undertake preliminary studies on the form of placebo care they intend to institute prior to initiating their clinical trial. Such studies can test whether or not the placebo is 'believable' to the subjects thus minimizing the impact on the results of the main study. If ample time cannot be spent on developing an appropriate placebo, then the investigators may want to consider conducting comparative effectiveness trials rather than placebo-controlled trials.

CONCLUSION

An objective of this study was to develop a placebo treatment that involved minimal contact with the subjects because we believe touch may be a major factor in manual treatment. We developed a placebo that included the use of (1) a low level laser pad that was placed upside down on the subject and (2) a hand-held instrument that was clinician administered but emitted zero force. At the end of care completion, the majority of subjects in the placebo group believed that they were in the placebo group and the majority of subjects in the active group believed that they were in the active group; therefore, our placebo treatment was not determined to be a success.

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