

Frequency of sacroiliac malrotation in low back pain and correction with a simple in-home exercise or pelvic support belt. A randomized study comparing those treated immediately to those waiting one month for treatment.

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1.0 Introduction:

1.1 Introduction

In developed countries, back pain ranks among the top 10 complaints that bring participants to see a doctorⁱ yet in 84% of cases, no specific cause can be found.^{ii, iii} Where the pain is of lumbar origin, the diagnosis can usually be established using medical imaging techniques and neurological testing. The sacroiliac joints, just below the lumbar spine, are difficult to visualize using imaging techniques, except in cases of ankylosing spondylitis, and tests for sacroiliac dysfunction are not reliable^{iv, v, vi} nor do these diagnostic techniques suggest therapeutic options.^{vii, viii} This may be why the sacroiliac joints have been neglected as a possible cause for low back pain^{ix}.

In my family practice with a special interest in pain, in order to better determine the cause of this frequent complaint, I developed a new, quick and easy way to examine this joint, the Sacroiliac Forward Flexion Test (SIFFT). This test determines the location of the posterior superior iliac spines (PSISs): many of those with back pain were very tender to pressure applied just below one or both of these PSISs and pointed to this as being where they had the most pain. This corresponds to the long dorsal sacroiliac ligament, which would be painful, should there be a malrotation of the corresponding sacroiliac joint. To assess for malrotation, I put a mark under each of the PSISs, and used a carpenter's level to test whether they were at the same level.^x I also test the participant for leg length discrepancy by measuring from the umbilicus to the medial malleolus bilaterally as this can affect the PSIS levels.

A malrotation of the sacroiliac joints puts excess strain on the muscles stabilizing this joint and these usually develop tendinitis. The gluteus medius and minimus, join the sacrum and ileum to the greater trochanter where malrotation sufferers are often diagnosed as having trochanteric bursitis. The iliopsoas joins the ilium to the lesser trochanter causing groin pain with SI malrotation. The quadratus lumborum joins the ileum to the lumbar lateral processes and the 12th rib, and a malrotation of the ilium can also cause a quadratus lumborum tendinitis. The biceps femoris joins the ischium to the head of the fibula and tendinitis of this muscle is often the cause of pain on sitting and in

the knee for those with sacroiliac malrotation. The presence of tenderness where these pelvic stabilizer muscles attach will be documented in this study.

In 2018 I did a chart review of 180 cases of low back pain in which I tested those who did not have lumbar pain using the SIFFT^x. I treated them with the appropriate exercise depending on the direction of the sacroiliac rotation. From this review, I found 16 cases of pain coming from the lumbar spine (9%). Of the remaining 164 given the appropriate 2 minute exercises, 78% found pain relief of which two thirds left the office entirely pain free. At that time, I also prescribed a pelvic support belt as, generally, a malrotated pelvis is an unstable pelvis^{xi}. As soon as the pelvis becomes malrotated again, the pain recurs. As the corrective exercise and pelvic support belt are two different treatments, the current research project will study them first separately for one month, then on follow-up after they have been used together for one month.

The aim of this study is to determine whether the pain relief and improved back function is temporary or if it can be reproduced and sustained by the patient at home, as needed with these two treatments. In order to test the effectiveness of each treatment alone and when they are combined, two sub-studies will be carried out as follows:

The first study is a superiority trial with a delayed control.

Population: ambulatory people between the ages of 19 and 90 suffering from low back pain, not of lumbar spine or hip origin, for at least three months.

Intervention 1 : teaching participants how to detect pelvic malrotation using the SIFFT then prescribing a two-minute exercise to correct pelvic malrotation, depending on its direction.

Intervention 2: prescribing a pelvic support belt to stabilize the pelvis.

Control: waiting list for one month, using usual treatments such as medications, alcohol and other drugs, chiropractic and other manipulation and physical therapy.

Outcome: a clinically significant change in Brief Pain Inventory (BPI) NRS pain score or in Oswestry disability Index (ODI) for low back pain.

Time: outcomes measured at baseline and after one month of using the assigned treatment at home.

The second study is a one month follow-up of the combined treatments.

Population: all previous study participants

Intervention: teaching all participants how to detect pelvic malrotation using the SIFFT then a two-minute exercise to correct pelvic malrotation depending on its direction followed by prescription of a pelvic support belt.

Control: BPI NRS pain severity score and ODI at one month assessment

Outcome: a clinically significant change in BPI NRS pain severity score or ODI

Time: outcomes measured at the one month assessment and after one month of using the combined treatments at home.

The effects of the SIFFT and associated exercises are important to investigate as they may prove to be both diagnostic and therapeutic. When someone experiences back

pain relief from an exercise to correct sacroiliac malrotation, this indicates that their back pain is not coming from their lumbar spine, but from a malrotated sacroiliac joint. The knowledge and relief from this simple test may help avoid unnecessary medical imaging and spinal surgery. If back pain relief is sustained with the use of a pelvic support belt, then the pain can be ascribed to pelvic instability^{xii} ^{xiii}. A better understanding of the potential sustained effects of these two treatments has great potential to improve care and reduce costs for patients with low back pain^{xiv}.

1.2. Hypotheses

The first study aims to find out if the recently developed exercises or the use of a pelvic support belt provide more than short term pain relief in the doctor's office:

Primary Hypotheses for the first study:

1. At 1 month, there will be significantly greater improvement in the ODI for low back pain score: at least 10% greater in those who are in treatment group 1 and are immediately taught how to perform the SIFFT followed by the appropriate exercise when compared to those on the waiting list for one month prior to being treated.
2. At 1 month, there will be significantly greater improvement in the ODI for low back pain score: at least 10% greater in those who are in treatment group 2 and are immediately given the pelvic support belt when compared to those on the waiting list for one month prior to being treated.

Secondary Hypotheses for the first study:

- 1 At 1 month, there will be significantly greater improvement in the BPI NRS pain severity score in those who are in treatment group 1 and are immediately taught how to perform the SIFFT followed by the appropriate exercise when compared to those on the waiting list for one month prior to being treated.
- 2 At 1 month, there will be significantly greater improvement in the BPI NRS pain severity score in those who are in treatment group 2 and are immediately fitted with a pelvic belt when compared to those on the waiting list for one month prior to being treated.

The follow-up study aims to find out if the recently developed exercises together with the use of a pelvic support belt provided more pain relief than each individual treatment:

Primary Hypothesis for the follow-up study:

- 1 At 2 months, there will be significantly greater improvement in the ODI for low back pain score compared to their one-month score in all participants.

Secondary Hypothesis for the follow-up study:

- 1 At 2 months, there will be significantly greater improvement in the BPI NRS pain severity score compared to their one-month score in all participants.

2.0 Recruitment:

Participants making a first appointment at the clinic for back pain will be in contact with my medical office assistant, Lori Molleken, and invited to participate in this study. If they would like to participate, she will send them the consent form and eligibility questionnaire. If they are eligible, she will schedule them for their first visit.

If not enough potential participants present at the office spontaneously, an email will be sent to all family physicians, rehabilitation specialists, neurosurgeons and neurologists associated with Lions Gate Hospital with information about the study.

Information about the study will also be posted on Facebook, Instagram and Twitter, which will refer potential participants to a website about the study. People will be warned that if they choose to post to the page, or “like” the page, they will be publicly identified with the study and instructed to consult the website instead.

2.1 Randomization and group assignment

. After a potential participant has been examined, determined to be eligible and consents to participate they will be randomly assigned to treatment group 1, 2 or 3 according to the randomization scheme developed using “research randomizer”. Group 1 for immediately teaching the participant the SIFFT and appropriate exercises, group 2 for fitting of the pelvic support belt and group 3 for delayed treatment.

2.2 Sample Size

This study will recruit 20 participants per treatment group (60 participants overall). This sample size will allow the researchers to pilot this design.

2.3 Inclusion Criteria

- Age 19 to 90 Participants present with pain in their low back (below the waist) or their buttock.
- Able to attend all 3 study visits at the participating physician’s office (assessment visit, exercise and pelvic belt visit and one- month follow-up visit)
- Able to attend the first two visits with someone willing to assist them in assessing their back and help them with the necessary exercise if need be.
- Willing to perform the corrective exercise at home as needed
- Their PSISs are not level on initial examination.

- The long dorsal sacroiliac ligament below at least one of the PSISs is tender to palpation on initial examination.

2.4 Exclusion Criteria

- Pain experienced is lumbar in origin
- Pain secondary to hip or other pathology
- PSISs are level at initial examination
- No tenderness to pressure under the PSISs
- Severe pain elsewhere in the body, making the assessment of back pain difficult.
- Presence of ankylosing spondylitis (seen on x-ray, pain worse at night, relieved by exercise, abnormal CRP or ESR)
- Obvious leg length discrepancy ($> 1 \frac{1}{2}$ cm) when measured umbilicus to medial malleolus.
- Location of PSISs cannot be assessed accurately due to back mice or obesity.

3.0: Procedures

3.1 Prior to First Treatment Appointment

On first contacting the office, people with low back pain will be told about the research project. If they wish to participate, they will be sent a consent form, together with a questionnaire to determine their suitability for the study, by mail or email. They will be told about the www.low-back-pain.info website and given an appointment. They will be told that, preferably, they should be accompanied at this visit by someone able to help them with their back pain.

3.2 Randomization and First Treatment Visit

- Prospective participants presenting with pain in their low back (below the waist) will be given a questionnaire about medications, alcohol and marijuana as well as the other therapies they currently use for pain relief. They will be given the BPI NRS pain severity questionnaire and ODI questionnaire .
- To rule out lumbar origin pain, physical examination will include straight leg raise, knee and ankle reflexes, Babinski, and tests for sensitivity to touch, pinprick and vibration below the knee. If these tests indicate lumbar origin pain, they will be eliminated from the study and replaced by another participant, but their number and data will be retained.
- Range of motion of the hips will then be tested and those with painful limitation of hip range of motion will also be eliminated and their data entered into the study.
- All participants will be tested for hypermobility using the Beighton score as, in the chart review, 15% of those with sacroiliac joint sprains were also hypermobile.

- The active straight leg raising test will be carried out to assess sacroiliac dysfunction^{xv}.
- Obvious leg length discrepancy (greater than 1½ cm) will be assessed as this causes scoliosis and sacroiliac strain as well as making it impossible to test the PSISs levels. The shorter leg will be prescribed a heel lift, participants will be sent for x-ray evaluation of leg length and excluded from the study.
- The lower back and buttocks will be examined for back mice or excess fat, making the exact location of the PSISs difficult to assess. If this is the case participants will be excluded but their data will be entered in the database.
- As gluteus medius and minimus as well as the piriformis muscle are major stabilizers, iliopsoas, biceps femoris and quadratus lumborum are secondary stabilizers of the sacroiliac joints, these may develop a compensatory overuse tendinosis in response to the sacroiliac malrotation, we will check for tenderness to palpation where these muscles insert on the ilium, the greater and lesser trochanter, the ischium, the head of the fibula and the edge of the sacrum.

3.2.1 Sacroiliac Forward Flexion Test (SIFFT)

Everyone of the “idiopathic” low back pain participants is asked to stand, with their belt undone, leaning on one of the office counters with their legs vertical and their body, flexed at the hips, horizontal (Figure 1). This causes the innominate bones to be tilted forward with the horizontal body and lifted-up by the vertical legs while the weight of the torso brings down the spine and the sacrum. In this position, the PSISs (posterior superior iliac spines) face the examiner and are easier to palpate. The examiners then run their hands down the iliac crests to



Figure

locate the PSISs. Once these are located, they press down below the PSISs with the ulnar side of their thumbs abutting against the PSISs. They then ask the participants whether and on which side they feel pain. The pain may be due to pressure on the overstrained long dorsal sacroiliac ligaments which stabilize this joint. This is called the sacroiliac forward flexion test (SIFFT).

1: sacroiliac forward flexion test (SIFFT)

- Using a surgical marker, the examiner marks the area between his/her thumb and the PSIS on each side and writes the letter B (for before) on the painful side, on both sides if they have pain on both sides. He/she then asks the participant to stand and places a horizontal level on the lowest mark (Figure 2). He/she then measures the distance between the level and the highest mark in centimetres (Figure 3).

Figure 2: using a level on the lowest PSIS

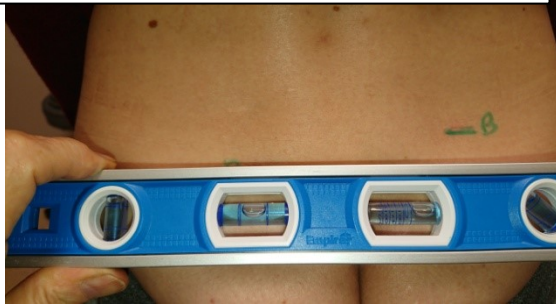
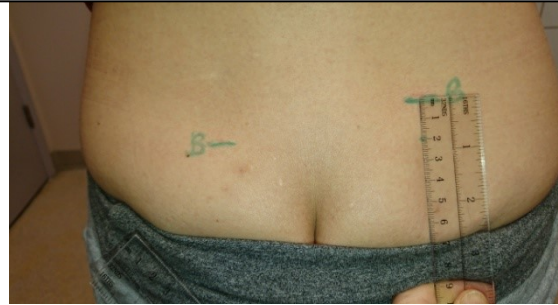


Figure 3: measuring the distance between levels



The marks indicate the direction and extent of the malrotation:

- if the PSIS on the painful side is higher than that on the asymptomatic side, there is an anterior malrotation of the painful side ileum on the sacrum.
- If it is lower, there is a posterior malrotation of the painful side ileum on the sacrum.

The physician will record the degree of malalignment and its direction. If the participant is part of group 3 they are given a return appointment to be treated with both the exercises and the pelvic support belt one month later.

3.2.2 Corrective Exercises

- Participants assigned to Group 1 will be treated to correct the malrotation depending on whether the ileum is anteriorly or posteriorly malrotated on the sacrum.
- **In order to correct an anterior malrotation of the ilium on the sacrum**, the participants are asked to face a chair and place the foot on the affected side on the chair. They bend the knee on the unaffected side to lean it on the front of the chair, helping to stabilize the unaffected joint. Each hand then grabs the side of the chair and they lean back to force the thigh on the affected side against the ASIS. They then pull up hard to push the thigh against the ASIS, rotating it posteriorly (Figure 4).



They must hold this position without pausing for 2 minutes. This exercise is tiring and a 2-minute timer is used to ensure they hold the position for that amount of time. It is also advisable to also speak to them continuously in order to distract them while they are performing the exercise. The exercise and the reason for it is explained in the following YouTube video:

www.youtube.com/watch?v=NXNS6PNKRPo

Figure 4: correcting an anterior malrotation of the ileum on the sacrum If there is an anterior or a posterior malrotation of the affected ileum on the sacrum, if the participant is unable to perform the first corrective exercise or if the posterior sacroiliac ligaments under both the PSISs are tender, a different corrective exercise is used. This exercise requires help from someone else: in dorsal decubitus, with the knee on their anteriorly rotated side bent against their chest and their foot on the examiner's sternum, the examiner leans forward to push the thigh on the anteriorly rotated side against the ASIS. At the same time they lean on the extended thigh corresponding to the posteriorly rotated ilium on the sacrum just above the knee. This uses the sartorius which is attached to the ASIS and the rectus femoris which is attached to the AIIIS to pull the affected ilium anteriorly. When correcting an anterior sprain, lean forward forcibly, and simply stabilize the extended opposite thigh. When correcting a posterior sprain, stabilize the flexed thigh and lean heavily on the extended thigh (Figure 5). For bilateral sprains, one anterior and one posterior, force needs to be used bilaterally. Again, the position is held for 2 minutes.



anteriorly rotated side bent against their chest and their foot on the examiner's sternum, the examiner leans forward to push the thigh on the anteriorly rotated side against the ASIS. At the same time they lean on the extended thigh corresponding to the posteriorly rotated ilium on the sacrum just above the knee. This uses the sartorius which is attached to the ASIS and the rectus femoris which is attached to the AIIIS to pull the affected ilium anteriorly. When correcting an anterior sprain, lean forward forcibly, and simply stabilize the extended opposite thigh. When correcting a posterior sprain, stabilize the flexed thigh and lean heavily on the extended thigh (Figure 5). For bilateral sprains, one anterior and one posterior, force needs to be used bilaterally. Again, the position is held for 2 minutes.

Figure 5: Correcting a posterior malrotation of the affected ileum on the sacrum or a right anterior, left posterior malrotation



For those who have no one to help them, I ask them to genuflect and lean forward against their thigh on the anterior malrotated side with their hands on other side of their foot, while extending the posteriorly malrotated leg with their knee on the floor on a cushion, and, once again, to hold this position for 2 minutes. (Figure 6)

Figure 6: self correction of an anterior right, posterior left malrotation of the ileum on the sacrum.



Following the exercise, the sacroiliac joints are once again examined and the level of the PSISs is marked with the letter A for after. (Figure 7)

Figure 7: levels of the PSISs, before and after correction.

- The participants are then asked if they are still experiencing pain or tenderness to palpation in their back. Usually, if they are still symptomatic the PSISs are not entirely level. If this is the case, the pelvis is re-examined and the corrective exercise is repeated for a further 2 minutes.
- Those who accompany the patient are instructed on how to examine the PSISs to find their level and how to correct an anterior or a posterior sprain. Participants are sent home with instructions to do the exercises whenever their back pain recurs and to come back as needed.
- If the participants are unaccompanied, they are taught how to palpate their PSISs and to locate them in a full-length mirror. If they are unable to do this, they will be taught to locate their ASISs and check for their level in a full-length mirror, with the lower ASIS indicating an anterior sprain and the higher ASIS indicating a posterior sprain.
- This being done, they will be sent home for one month with instructions to repeat the SIFFT test and use the appropriate corrective exercises whenever their back pain recurs.

3.2.3 Fitting for a pelvic support belt

- A pelvic support belt is a device capable of stabilizing their pelvis^{xvi}, ^{xvii}. The fact that the sacroiliac joint is malrotated indicates a laxity of the ligaments holding this joint in place. This laxity can be the result of old age, a strain, sprain, tear, the presence of relaxin in pregnancy or defective collagen as occurs in Ehlers Danlos syndrome, Marfan's syndrome and hypermobility syndrome. The sacroiliac joint would not be displaced if the ligaments stabilizing it were functioning properly^x. Unless a pelvic belt is worn, particularly during activities where the sacroiliac joints are stressed, there is a very high likelihood of a recurring malrotation. As the goal of this treatment is to provide sufferers with long-term solution for their unstable pelvis, the pelvic belt is a necessary adjunct.

- Participants assigned to group 2 will be fitted for a pelvic support belt and instructed on how to use it: the belt has to be positioned at the level of the sacrum in the back, immediately below the ASISs in front and just above the greater trochanters on the side. It has to be fitted tight, but not excessively^{xvi}, in order to ensure pelvic stability. Preferably it should be worn on top of an undershirt or a crotchless underpant to avoid skin irritation. This being done, they will be sent home for one month with instructions to use the pelvic support belt as needed, whenever they are performing activities which would normally precipitate more back pain.

3.3 Assessment Visit (One Month after the Treatment Visit)

- Participants will answer the questionnaire about the medications, alcohol and marijuana as well as the other therapies they use for pain relief.
- They will be given the BPI NRS pain severity scales and the ODI questionnaire.
- They will once again be assessed, marked, measured and treated: this time participants in all treatment groups will be instructed on how to do the SIFFT and the corresponding corrective exercises. All of them will also receive the pelvic support belt.
- Those in group 1 will report on their use and effectiveness of the corrective exercises. They will then be fitted with a pelvic support belt.
- Those in group 2 will report on their use and the effectiveness of the pelvic support belt. They will then be taught the SIFFT and how to use the exercise corresponding to the direction of their sacroiliac malrotation.
- Those in group 3 will be instructed on how to do the SIFFT and the corresponding corrective exercises. They will also receive the pelvic support belt.
-

3.5 Withdrawal Procedure, Dropouts

- Participants with uneven sacroiliac joints who do not experience any relief after doing the correction exercises and/or trying out the pelvic support belt will probably not want to continue to try these exercises or wear the pelvic support belt at home.
- They will, however, be asked to try the exercise and belt at home and return in 1 month to be retested and fill out the questionnaires. At that time, all the procedures associated with the first treatment visit will be repeated.
- For those who decide to withdraw from the study, every effort will be made to contact them and ask them the questionnaire relevant to the time they withdrew,
- unless, at the time they withdraw they notify us that they do not want to answer any more questionnaires, in which case the last data collected will be entered in the database.

3.5.1 Lost to Follow up Procedure

- When a participant is lost to follow-up, the last data collected will be entered in the database for each missed subsequent visit.

4.0 Data to be Collected

4.1 Data Collected on All Participants

- Date of assessment visit
- Number of participants presenting with back pain
- Month and year of birth of participants
- Sex of participants
- Duration of back pain
- Concomitant pain medications
- Cannabis and alcohol intake in the past 24 hours
- BPI NRS pain severity score (appendix 1)
- ODI questionnaire (appendix 2).
- presence of lumbar pain or hip pain
- Beighton hypermobility score
- Piriformis, gluteus medius or minimus biceps femoris and quadratus lumborum tenderness
- Size of leg length discrepancy, if present

4.2 Data Collected on All Participants with Nonaligned PSISs

4.2.1 At all visits

- Date of questionnaire (randomization and first treatment visit, one month assessment visit and two month reassessment visit)
 - Use of medications, cannabis, alcohol.
 - Use of other treatments: acupuncture, yoga, core exercises, chiropractic manipulation, massage, physiotherapy and other treatments.
 - The (ODI) questionnaire (appendix 2)
 - the BPI NRS Pain Severity Scale (appendix 1): On a scale of 0 (no pain) to 10 (worst imaginable pain) pain in the last 24 hours compared to previous recorded pain level (the participant will have this information available)
 - on average
 - at its worst
 - at its best
 - right now

the average of these values as well as the pain "right now" will be recorded.

4.2.2 At the Treatment visit and the One Month Follow-Up Visit:

- On which side the painful sacroiliac sprain is located and whether it is anteriorly or posteriorly rotated.
- Distance in centimetres between the lowest and the highest PSIS: before and, for group 1 participants, after the corrective exercise.
- Pain score 0 (no pain) to 10 (worst imaginable pain) following the exercise, for group 1 participants.
- Impression of pelvic support belt for group 2 participants

4.2.3 At the One Month Assessment Visit

- For group 1 participants Frequency of exercise use (0 = not at all, or number of times per week)
- Effectiveness of the corrective exercise in correcting pain (0 = not at all, 1 = sometimes, 2 = most of the time, 3 = always)
- Side effects of the corrective exercise

For group 2 participants

- Satisfaction with use of the pelvic support belt (0 = not at all, 1 = mildly satisfied, 2 = moderately satisfied, 3 = very satisfied)
- Was the pelvic support belt worn during the day? (0 = not at all, 1 = sometimes, 2 = most of the time, 3 = always)
- Was the pelvic support belt worn at night? (0 = not at all, 1 = sometimes, 2 = most of the time, 3 = always)
- Side effects of the pelvic support belt

For all participants

- Perceived need for further treatment 0 = not at all, 1 = possibly, 2 = probably, 3 = certainly)

4.2.4 At the Two Month Reassessment Visit

- Frequency of exercise use (0 = not at all, or number of times per week)
- Effectiveness of the corrective exercise in correcting pain (0 = not at all, 1 = sometimes, 2 = most of the time, 3 = always)
- Side effects of the corrective exercise
- Satisfaction with use of the pelvic support belt (0 = not at all, 1 = mildly satisfied, 2 = moderately satisfied, 3 = very satisfied)

- Was the pelvic support belt worn during the day? (0 = not at all, 1 = sometimes, 2 = most of the time, 3 = always)
- Was the pelvic support belt worn at night? (0 = not at all, 1 = sometimes, 2 = most of the time, 3 = always)
- Side effects of the pelvic support belt
- Perceived need for further treatment 0 = not at all, 1 = possibly, 2 = probably, 3 = certainly)

5.0 Statistics

5.1 Outcome Measures

5.1.1A Primary Outcomes For the First Study

- difference in the change in ODI score in the initial treatment visit questionnaire and at the assessment visit one month later in the control group compared to the change from the treatment visit questionnaire to the 1 month assessment follow-up visit in the immediate SIFFT and exercise treatment group.
- difference in the change in ODI score in the treatment visit questionnaire and at the assessment visit, one month later, in the control group compared to the change from the treatment visit questionnaire to the 1 month assessment follow-up visit in the immediate pelvic support belt treatment group.

5.1.2A Secondary Outcomes For the First Study

- difference in the change in BPI NRS pain severity scores in the treatment visit questionnaire and at the assessment visit, one month later, in the control group compared to the change from the treatment visit questionnaire to the 1 month follow-up assessment visit in the immediate SIFFT and exercise treatment group.
- difference in the change in BPI NRS pain severity scores in the treatment visit questionnaire and at the assessment visit, one month later, in the control group compared to the change from the treatment visit questionnaire to the 1 month follow-up assessment visit in the immediate pelvic support belt treatment group.

5.1.1B Primary Outcome For the Follow-up Study

- difference in the change in ODI score in the assessment visit questionnaire and at the reassessment visit, two months later, for all groups.

5.1.2B Secondary Outcome For the Follow-up Study

- difference in the change in BPI NRS pain severity scores in the assessment visit questionnaire and at the reassessment visit, two months later, for all groups.

5.1.3 Other Measurements

- Change in pain level, immediately before and after the corrective exercises at
 - the treatment visit for members of group 1
 - the one-month follow-up assessment visit.
 - the two month reassessment visit
- Change in average pain level between the
 - treatment visit
 - and the one-month follow-up visit.
- Number of times the exercise was used per week
- Perceived effectiveness of the exercise
 - when first used with the physician
 - one month later,
 - and two months later for group 1
- How often the pelvic support belt was used during the day at the one month follow-up assessment visit for group 2.
- How often the pelvic support belt was used during the day at the 2 month reassessment visit for all participants.
- How often the pelvic support belt was used during the night at the follow-up assessment visit for group 2.
- How often the pelvic support belt was used during the night at 2 month reassessment visit for all participants.
- Perceived effectiveness of the pelvic support belt when first used and after one month of use for all participants.
- perceived effectiveness of the pelvic support belt when first used and after two months of use for group 2.

5.2 Statistical Analysis

Data will be analyzed using PASW Statistics 18, Release 18.0.0, IBM. Analysis will be performed by intention-to-treat. Descriptive statistics (mean value \pm standard deviation (SD)) will be calculated for outcome variables at each time point. Baseline between-group data will be analyzed for significant differences by t-tests for nominal variables and Pearson chi square tests for categorical variables. Baseline characteristics will be included in the model as covariates for those variables with a significant between group difference. Analyses of covariates will be applied to compare the groups for magnitude of change in the 0-10 NRS pain score and Oswestry Disability Index between baseline and each follow-up time point (0, 1 and 2 months). A two-tailed P value $<.05$ will be used as the statistical significance level.

- a Pearson's chi-square-test will be done to assess the significance of the difference in Oswestry low back disability score over a 1 month period between

those who are treated with the immediate SIFFT and exercise treatment group, the immediate pelvic support belt group and those who are in the observation group.

- A second Pearson's chi-square will be done to assess the significance of the difference in BPI NRS pain severity score over a 1 month period between those who are treated with the immediate SIFFT and exercise treatment group, the immediate pelvic support belt group and those who are in the observation group.
- A student t-test will be done to assess the significance of the difference in ODI score over a one month period when both treatments are used simultaneously.
- A student t-test will be done to assess the significance of the difference in BPI NRS pain severity score over a one month period when both treatments are used simultaneously.
- The average and standard deviation for all the other data will be calculated and reported on.

Appendix 1: Brief Pain Inventory Pain Severity Scale

3.	Please rate your pain by circling the one number that best describes your pain at its <u>worst</u> in the last 24 hours.										
	0	1	2	3	4	5	6	7	8	9	10
	No										Pain as bad as
	Pain										you can imagine
4.	Please rate your pain by circling the one number that best describes your pain at its <u>least</u> in the last 24 hours.										
	0	1	2	3	4	5	6	7	8	9	10
	No										Pain as bad as
	Pain										you can imagine
5.	Please rate your pain by circling the one number that best describes your pain on the <u>average</u> .										
	0	1	2	3	4	5	6	7	8	9	10
	No										Pain as bad as
	Pain										you can imagine
6.	Please rate your pain by circling the one number that tells how much pain you have <u>right now</u> .										
	0	1	2	3	4	5	6	7	8	9	10
	No										Pain as bad as
	Pain										you can imagine

Appendix 2: Oswestry Low Back Disability Questionnaire

- **Section 1 – Pain intensity**
- 0 I have no pain at the moment
- 1 The pain is very mild at the moment
- 2 The pain is moderate at the moment
- 3 The pain is fairly severe at the moment
- 4 The pain is very severe at the moment
- 5 The pain is the worst imaginable at the moment

- **Section 2 – Personal care (washing, dressing etc)**
- 0 I can look after myself normally without causing extra pain
- 1 I can look after myself normally but it causes extra pain
- 2 It is painful to look after myself and I am slow and careful
- 3 I need some help but manage most of my personal care
- 4 I need help every day in most aspects of self-care
- 5 I do not get dressed, I wash with difficulty and stay in bed

- **Section 3 – Lifting**
- 0 I can lift heavy weights without extra pain
- 1 I can lift heavy weights but it gives extra pain
- 2 Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- 3 Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- 4 I can lift very light weights
- 5 I cannot lift or carry anything at all

- **Section 4 – Walking***
- 0 Pain does not prevent me walking any distance
- 1 Pain prevents me from walking more than 1 km
- 2 Pain prevents me from walking more than 500 m
- 3 Pain prevents me from walking more than 100 m
- 4 I can only walk using a stick or crutches
- 5 I am in bed most of the time

- **Section 5 – Sitting**
- 0 I can sit in any chair as long as I like it
- 1 I can only sit in my favourite chair as long as I like
- 2 Pain prevents me sitting more than one hour
- 3 Pain prevents me from sitting more than 30 minutes
- 4 Pain prevents me from sitting more than 10 minutes
- 5 Pain prevents me from sitting at all

- **Section 6 – Standing**
- 0 I can stand as long as I want without extra pain at
- 1 I can stand as long as I want but it gives me extra pain
- 2 Pain prevents me from standing for more than 1 hour
- 3 Pain prevents me from standing for more than 30 minutes
- 4 Pain prevents me from standing for more than 10 minutes
- 5 Pain prevents me from standing at all

- **Section 7 – Sleeping**
- 0 My sleep is never disturbed by pain
- 1 My sleep is occasionally disturbed by pain
- 2 Because of pain I have less than 6 hours sleep
- 3 Because of pain I have less than 4 hours sleep
- 4 Because of pain I have less than 2 hours sleep
- 5 Pain prevents me from sleeping at all

- **Section 8 – Sex life (if applicable)**
- 0 My sex life is normal and causes no extra pain
- 1 My sex life is normal but causes some extra pain
- 2 My sex life is nearly normal but is very painful
- 3 My sex life is severely restricted by pain
- 4 My sex life is nearly absent because of pain
- 5 Pain prevents any sex life at all

- **Section 9 – Social life**
- 0 My social life is normal and gives me no extra pain
- 1 My social life is normal but increases the degree of pain
- 2 Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- 3 Pain has restricted my social life and I do not go out as often
- 4 Pain has restricted my social life to my home
- 5 I have no social life because of pain

- **Section 10 – Travelling**
- 0 I can travel anywhere without pain
- 1 I can travel anywhere but it gives me extra pain
- 2 Pain is bad but I manage journeys over two hours
- 3 Pain restricts me to journeys of less than one hour
- 4 Pain restricts me to short necessary journeys under 30 minutes
- 5 Pain prevents me from travelling except to receive treatment

Appendix 3: Beighton hypermobility score

Joint	Finding	Points
left little (fifth) finger	passive dorsiflexion beyond 90°	1
	passive dorsiflexion ≤ 90°	0
right little (fifth) finger	passive dorsiflexion beyond 90°	1
	passive dorsiflexion ≤ 90°	0
left thumb	passive dorsiflexion to the flexor aspect of the forearm	1
	cannot passively dorsiflex thumb to flexor aspect of the forearm	0
right thumb	passive dorsiflexion to the flexor aspect of the forearm	1
	cannot passively dorsiflex thumb to flexor aspect of the forearm	0
left elbow	hyperextends beyonds 10°	1
	extends ≤ 10	0
right elbow	hyperextends beyonds 10°	1
	extends ≤ 10	0
left knee	hyperextends beyonds 10°	1
	extends ≤ 10	0
right knee	hyperextends beyonds 10°	1
	extends ≤ 10	0
forward flexion of trunk with knees full extended	palms and hands can rest flat on the floor	1

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