Chapter Overview

Chapter is written based on CONSORT 2010 checklist for reporting randomized control trials. This chapter begins with clinical trial registry details and ethical approval of the trial. It continues with study design, sample size calculation details and inclusion exclusion criteria. Randomization, Blinding and concealment of randomized numbers is explained in detail in subsequent parts. Last part of chapter deals with measurements of the outcome measures and detail procedure of intervention used in the trial. Flow of participants is summarized through CONSORT flow chart at the end of procedure chapter.

3.1 TRIAL REGISTRY:

Study was registered on the Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics, New Delhi. The registration number is CTRI/2013/06/003752 [ANNEX 7]. The trial was also registered on The International Clinical Trials Registry Platform (ICTRP) maintained by the WHO [ANNEX 8]. Registration of the current trial at public platforms has helped to maintain accountability and transparency in the study.

3.2 Ethical approval:

This study was approved by Institutional Ethics Committee of the Pravara Institute of Medical Sciences, Loni, Maharashtra. [PMT/PIMS/RC/2013/234.]

3.3 Study design: The study design used for the research was single blind, randomized control trial.

3.4 Study setting: Pravara Institute of Medical Sciences, Dr. A.P.J Abdul Kalam College of Physiotherapy, Loni and Dr. Vithalrao Vikhe Patil Foundations, College of Physiotherapy, Ahmednagar, Maharashtra.

3.5 Study duration: The duration of trial was from June 2010 till December 2014.
3.6 Sample size: Minimum sample size was calculated based on the pilot study results. Mean and Standard deviation (SD) of intervention and control group was considered for calculation. Based on these readings, precision (0.208) was calculated. Attrition was considered at 10%. Using the following formula the Minimum calculated sample size was 60.

In the current RCT, effectiveness of SNAGS, Maitland’s and conventional physiotherapy in cases of lumbar facet joint syndrome was studied. Primary outcome for the study was pain intensity and it was measured on visual analogue scale (0 – 10).

Subjects included in the study were independent samples and using the intervention 2 sided hypothesis was tested.

The formula used for calculating the minimal sample size,\(^{216}\)

\[
n = 2 \frac{S^2(Z_1 + Z_2)^2}{(M_1 - M_2)^2}
\]

In the formula

- \(M_1\) = Mean for test intervention
- \(M_2\) = Mean for Control intervention
- \(S_1\) = Standard deviation of \(M_1\)
- \(S_2\) = Standard Deviation of \(M_2\)
- \(S\) = Pooled SD

In current study \(M_1\) (SNAGs - Intervention Group) = 2.13, \(S_1 = 0.74\)

\(M_2\) (Conventional Physiotherapy – Control group) = 3.41, \(S_2 = 0.64\)

Absolute precision at 20% calculated using the formula = 20 x(M_1-M_2)/ 100

On calculation the precision was =0.256

Hence the calculated minimum sample size using the formula mentioned above was 57.
Sample size was also calculated using $M_1$ (Mean for Maitland Group – Intervention) and $M_2$ (Conventional Physiotherapy – Control)

$M_1$ (Mean for Maitland group) = 2.37, $S_1 = 0.51$

$M_2 = 3.41, S_2 = 0.64$

Absolute precision at 20 % = 0.208.

Hence the minimum sample size calculated was 60.

From above calculations of sample size using the formula described by Patrikar, it was 57 and 60. Out of this sample size, 60 was taken as the minimum sample size for the current study. 10 % allowance was made for attrition during the study. Hence the sample size projected for the study including attrition was 66 in each group.

3.7 Participants:

3.7.1 Inclusion criteria:

- Participants diagnosed with facetal arthropathy on MRI
- Localized unilateral lumbar pain
- Replication or aggravation of pain by unilateral pressure over the lumbar facet joint
- Pain eased in flexion, pain in extension, lateral flexion or rotation to the ipsilateral side
- Participants those who were willing to participate.

3.7.2 Exclusion criteria:

- Participants with history of spinal surgery
- Trauma to the spine
- Manipulation under general anesthesia (MUGA) for any spinal pathology
- Metabolic disorders involving spine
- Diagnosed cases of spinal tumors.
3.8 **Randomization:** Randomization of the participants to three groups was performed using computer generated randomization method. Random numbers were generated using OpenEpi software.

Group I: Received SNAGs technique along with therapeutic ultrasound and back endurance exercises.

Group II: Received Maitland’s spinal mobilization along with therapeutic ultrasound and back endurance exercises.

Group III: Received therapeutic ultrasound and back endurance exercises.

3.8.1 **Allocation concealment:** Codes obtained from randomization were maintained in opaque envelopes until the intervention began. The allocation was concealed by using consecutively numbered, sealed, opaque envelopes (SNOSE). Eligible participant were allocated to groups by the investigator who opened the next available numbered envelope prior to the first treatment session.

SNOSE were prepared by using 210 opaque, letter-sized envelopes, 210 sheets of standard size papers and rolls of household aluminium cooking foil. Sheet of standard sized paper marked with computer generated code folded to fit in the envelope. Then completed insert was placed into a blank envelope, with the carbon paper closest to the front of the envelope. Completed all the 210 envelopes, sealed each of the envelope and signed over the top of the envelope seal.

3.8.2 **Implementation:** Primary investigator of the trial generated the random allocation sequence, enrolled the participants and assigned participants to interventions.

3.8.3. **Blinding:** It was a single blind trial. In the current trial, the investigator was aware about the interventions given to three groups but the participants involved in the groups were blinded for the intervention which they received.

3.9 **Outcome measurements:** Primary outcome measures for the study were Modified Oswestry Disability Questionnaire (MODQ) which was translated in Marathi language. Pain intensity was measured using Visual Analogue Scale (VAS) and spinal flexion and extension range of motion was measured by using
modified Schober’s test. Secondary outcome measures were pressure pain threshold which was measured using a pressure algometer [Fig. 4] and back muscle endurance was measured using Sorensen’s test.

3.10 Baseline assessment

After eligibility was established, participants were informed about three different interventions which are widely used in physiotherapy. After obtaining the written informed consent, baseline measurements were performed.

3.11 Interventions:

3.11.1 Therapeutic Ultrasound: Sonopuls – 492 equipment was used with the frequency set at 1 MHz and the intensity of 1.5 w/cm². The average duration for ultrasound application to each participant was six minutes. Each participant was instructed to maintain a prone position throughout treatment. Aquasonic gel was used as a coupling medium to facilitate the transmission of the ultrasonic waves. The transducer was moved in a circular fashion at a 90 degree angle to the back during treatment.

3.11.2 Sustained Natural Apophyseal Glides: (SNAGs)

SNAGs for painful or restricted flexion [Fig. 5]

The position adopted in this technique was sitting on a plinth with the legs suspended over one side of the plinth. Mulligan’s belt was placed around the participant’s lower abdomen, below the anterior superior iliac spines and below the hips of a physiotherapist. The ulnar border of physiotherapist right hand was placed under the spinous process of the vertebra above the suspected facet joint level. Each participant was asked to bend forwards until pain was experienced and then straighten back minimally from that position.

A gliding force was applied by the therapist’s right hand along the facet treatment plane while the participant attempted to bend forwards and get erect again. Flexed position was maintained by the participant for a few seconds while the therapist sustained the facet glide until the participant was erect again.

A total of 3 sets of mobilization with 6 repetition in each set, in accordance with Mulligan’s rule of three was administered with a one minute break between sets.
SNAGS for painful or restricted extension:

Each participant was instructed to sit on a plinth with the legs suspended over to one side. Mulligan’s belt was placed around participant’s lower abdomen and it was below the anterior superior iliac spines and below the hips of physiotherapist. The ulnar border of physiotherapist’s right hand was placed under the spinous process of the vertebra above the suspected facet joint level. Participant was asked to extend the spine until pain was felt and then backed off a little from this position. Gliding force was applied upward by the therapist’s right hand along the facet treatment plane as participant extends again. Extension position was sustained by the participant for few seconds while the therapist maintained the facet glide until participant was erect. 3 sets of mobilization with 6 repetitions in each set, were given.223, 224

3.11.3 Maitland’s spinal mobilization[Fig. 6]

The participant was in prone lying position with the hands on either side and the head turned to one side. Investigator stood on the right side of the participant and placed the left hand on the participant’s back so that the ulnar border of the hand between the pisiform and hook of the hamate was directly over the spinous process of the affected facet joint vertebra. The investigators shoulders were directly over the point of contact, and full wrist extension was maintained with the forearm in neutral between supination and pronation. Right hand then reinforced the left by placing the carpus of the right hand over the radial aspect of the left carpus at the base of the left index finger through the approximation of the right thenar and hypothenar eminences. The oscillating movement that accompanied joint mobilization of the vertebra was obtained by a rocking motion of the upper trunk in an up-and-down direction in the vertical plane, with the transmission of pressure coming through the investigators arms and shoulders as they act as springs. The direction of the applied force was downwards, avoiding any variations in either the caudal or cranial directions.

This technique was administered once, with a protocol consisting of grade I and II joint oscillations for 30 seconds each. Grade I joint mobilizations were administered consecutively to the 3 spinous processes that surround the affected facet joint with 30 seconds of rest in between, followed by grade II joint mobilizations performed in the same manner, for a total of 6 repetitions of joint mobilizations.63
3.11.4 Spinal Exercises

Exercise protocol:

All exercises were performed 4 days per week, for 2 consecutive weeks. All participants performed warm-up, stretching exercises for 15 minutes before and cool down exercises for 10 minutes after each session.

Warm up:

It included a light aerobic exercise such as exercise bicycle for 5 minutes at moderate pace.

Stretching exercises:

Each stretch was held for 15-20 seconds and care was taken that the pain wasn’t provoked.

Stretching exercises included:

Back stretches:

- Single and double knee to chest from supine position:
  Participant was in supine position and was asked to use his hands to help lift one/two leg(s) to their chest, bringing the spine into flexion.

- Alternate spinal flexion-extension from 4-point kneeling position (cat and camel):
  The participant slowly arches the spine into maximum flexion and then moved it into maximum extension while in 4-point kneeling position.

- Trunk forward stretching in praying position:
  Each participant was asked to adopt a knee sitting position with their buttocks resting on their heels and their hands placed anterior to the knees. They were further instructed to slide their hands, forward reaching out as far as possible.

- Side bending in standing position with and without contralateral arm elevation:
  Each participant was instructed to perform lateral flexion of the trunk either with arms by side or with 90° shoulder abduction.

- Low back sustained rotation from a supine position:
Each participant was instructed to adopt a supine lying position with one knee 90° flexed and the pelvis rotated to the other side so that the flexed leg is on top and the knee is on other side of body. Participant was then asked to rotate the shoulders in the opposite direction to the rotation of the pelvis.

- **Pelvic/leg stretches:**
  - Quadriceps Stretch:
    Each participant was instructed to adopt prone position. The towel was used which was attached to the foot and it was pulled to towards the buttocks. This stretch was held for 1 min and repeated for 3 times.
  - Hip Flexor Stretch:
    The participant was instructed to adopt a kneel position with knees on the ground, the same side arm was taken back, causing pelvis (hips) to shift forward, and back to extend. This position was held for 20 – 30 seconds and repeated 3 times.
  - Hamstring Stretch:
    The participant was asked to adopt a standing position and instructed to keep the heel up on the table He was then asked to lean forward at the hips. This position was held for 20-30 seconds and repeated for 3 times.

**Cool down period:**

Each participant was asked to perform cool down exercises after spinal exercises which included back stretches and pelvic/ leg stretches exercises.

**Back exercise:**

**Exercise parameters:**

For all exercises with an isometric contraction: Participants were asked to hold the muscle contraction/posture for 10 seconds and repeat 10 times with a short rest (3-4 seconds) between each contraction. A 60-second rest interval was given between each exercise.

Progress: Participant progressed with the exercises when they were able to perform the exercise comfortably and able to perform 25 repetitions of 10 seconds duration successfully.
Procedure:

All exercises were performed consecutively and in the same order. Before each exercise, the physical therapist gave detailed verbal explanation and visual instructions (pictures), regarding the start and end positions.

Exercise 1: Supine abdominal draw exercise with simultaneous upper and lower extremity flexion. [Fig. 7]

The participants adopted supine position and were instructed to maintain the co-contraction and natural lordosis while rapidly alternating the arms and hips into flexion. The procedure involved simultaneously raising the left arm and right lower extremity (LE) followed by raising the right UE and left LE.

Exercise 2: Bilateral shoulder lifts [Fig. 8]

The participants adopted prone position with both arms by the sides of the body. They were instructed to lift the head and upper trunk off the plinth from neutral to extension.

Exercise 3: Contralateral arm and leg lift [Fig. 9]

The participant adopted prone position with a pillow under the lower abdomen. They were instructed to lift the contralateral arm and a leg from neutral to extension.

Exercise 4: Bilateral shoulder lifts with hands behind the head [Fig. 10]

The participants adopted prone position with the hands interlocked at the occiput so that the shoulders were abducted to 90° and the elbows flexed. They were instructed to lift the head and trunk off the plinth from neutral to extension.

Exercise 5: Bilateral shoulder lifts with arms in full elevation [Fig. 11]

The participants adopted prone position with both arms elevated forwards. They were instructed to lift the head, trunk and elevate the arms off the plinth from neutral to extension.
Exercise 6: Quadruped position with co-contraction and simultaneous upper and lower extremity extension.\textsuperscript{99}[Fig. 12]

This exercise involved alternately raising their upper and lower extremities simultaneously (right arm with left leg, then left arm and right leg) while maintaining the co-contraction of the TrA and Multifidus.

Exercise 7: Side bridge exercise while maintaining abdominal draw. [Fig. 13]

Participants were required to lie on one side with the legs extended. The exercise required the individual to lift their hips off the table to a level where their body is straight and supported by their weight-bearing arm and feet. This exercise was performed on both the right and left sides.\textsuperscript{225}
FIGURES

Fig. 4: Measurement of PPT
Fig. 5: SNAGs for lumbar Spine

Fig. 6: Maitland’s Lumbar spine Mobilization
Fig. 7: Supine abdominal draw in with Simultaneous UE & LE Flexion
FIGURES

Fig. 8: Bilateral Shoulder Lifts

Fig. 9: Contralateral Arm & Leg lift

Fig. 10: Bilateral Shoulder lift with hand behind head

Fig. 11: Bilateral shoulder Lift with arm in full elevation

Fig. 12: Quadruped with simult. upper and lower extremity extension

Fig. 13: Side bridge
Fig 14: CONSORT diagram of flow of participants through the trial

Assessed for eligibility
(n=216)

Excluded (n=18)
- Not meeting inclusion criteria (n=08)
- Declined to participate (n=04)
- Other reasons (n=06)

Randomized
(n=198)

SNAGs + Conventional PT
Allocated to intervention (n=66)
- Received allocated intervention (n=62)
- Did not receive allocated intervention (n=04)

Maitland’s Mobilisation + Conventional PT
Allocated to intervention (n=66)
- Received allocated intervention (n=61)
- Did not receive allocated intervention (n=05)

Conventional Physiotherapy
Allocated to intervention (n=66)
- Received allocated intervention (n=63)
- Did not receive allocated intervention (n=03)

Lost to follow-up
- (n=0)
- Discontinued intervention (n=04)

Lost to follow-up
- (n=0)
- Discontinued intervention (n=05)

Lost to follow-up
- (n=0)
- Discontinued intervention (n=03)

Analysed (n=62)

Analysed (n=61)

Analysed (n=63)