CHAPTER 3
MATERIALS AND METHOD
This study was conducted in two phases

3.1 Phase I

Period of study for this phase was from September 2011 to December 2012.

3.1.1 Objectives

Objectives of this phase were

1. To estimate the prevalence of the musculoskeletal disorders among medical laboratory professionals in Udupi district.
2. To identify the risk factors for these disorders.

3.1.2 Methodology

Before starting the study, ethical clearance was obtained from institutional ethical committee (Appendix-1)

3.1.3 Study design

Cross-sectional study

3.1.4 Study population

All the laboratory professionals in the medical laboratories of Udupi district.

3.1.5 The inclusion criteria

All laboratory professionals (lab technicians, pathologists, microbiologists, biochemistry technologist)

- In age group between 19 to 60 years
- Working in the profession for at least past one year.
3.1.6 Exclusion criteria

- Subjects who gave history of unhealed fractures, recent dislocations, inflammatory arthritis, tumors, diagnosed psychiatric illness, recent traumatic soft tissue injuries, diagnosed disc lesion.
- Those who refused to participate.

3.1.7 Sampling method

Complete enumeration of all the medical laboratory professionals in Udupi district.

3.1.8 Instruments

3.1.8.1 Validated Questionnaire to screen for disorders (section A) and the risk factor associated with laboratory workstation (section B).

*Questionnaire section A (Appendix 6)*

This questionnaire was used to check 12 month prevalence of musculoskeletal disorders in nine body regions (neck, upper back, shoulder, elbow, hand/wrist, lower back, hip, knee, ankle/foot).

*Questionnaire section B (Appendix 7)*

This questionnaire was used to get information on personal and workstation risk factors.

The personal risk factors were comprised of demographic data, occupational case history in terms of years of experience and number of hours of work, involvement in any physical activity, and individual perception of their general health.
Risk factors in workplace was evaluated by “workstation evaluation” component of this questionnaire. This had nine component i.e. laboratory bench top, lab chairs, pipetting, microscopes, working in standing position, micromanipulation, microtome/cryostat, miscellaneous, computer work.

3.1.8.2 Visual Analog scale

Was used to assess the severity of musculoskeletal disorders

VAS is a tool measuring subjective characteristics. When responding to an item of VAS the participants were asked to mark the amount of pain/discomfort that they feel on 10 cm scale. Where 0 indicated no symptoms and 10 indicated worst symptom. The subject had to mark on the line at the point that they feel represents their perception of their current state.

3.1.8.3 Disability of arm shoulder and hand (DASH)

Was used to check the upper quadrant function.

The DASH is a 30-item questionnaire with a five-item response option for each item. The test has a maximum score of 100, where higher scores reflect greater disability. This questionnaire enquired about subject’s symptoms as well as the ability to perform certain activities. DASH disability score was calculated as follows [(sum of n responses) - 1] x 25 divided by n, where n is equal to the number of completed responses.

It also has work module which is optional. The questions in this section ask about the impact of discomfort or pain of arm, shoulder or hand on the individual's ability to work.
3.1.8.4. Neck disability index (NDI)

Was used to check the upper quadrant function.

The NDI is a 10-item scaled questionnaire. The 10 items addressed in the NDI include effect of pain on personal care activities, lifting, reading, work-related activities, driving, sleeping and the level of participation in the recreational activities. Each section contains 6 statements representing a different level of severity. Each section is scored on a 0 to 5 scale, with 5 designating the greatest disability. The scores of each section are summated for a total score of 50. The NDI score was finally transformed into percentage for analysis.

3.1.8.5 Short form 36 (SF-36)

Was used to assess the quality of life among the laboratory professionals.

It consists of eight health scales to measure the generic health related quality of life. Eight health component of scale were 1- Physical function (10 items) 2- Role limitation due to physical problem (4 items), 3- body pain (2 items), 4- general health (5 items), 5- Social function (2 items) 6-Vitality/energy (4 items), 7- role limitation due to emotional problems (4 items), 8- mental health 95 items). The standard SF36 asks question regarding past 4 weeks. The health components of SF 36 were summarized in two summary scales: the physical component summary scale (PCS) and the mental component summary scale (MCS).
The questionnaire to screen for symptoms (section A) and the risk factor associated with laboratory workstation (section B) was developed and content validated.
3.1.9. Development and Content validation of the questionnaires to check the prevalence of WRMSD in laboratory (Section A) and to identify the risk factors i.e. Personal risk factor and Workstation risk factors (Section B)

3.1.9.1 Literature search and item generation

English language literature was searched in PubMed, Proquest, MD consult, Cochrane Library and EbscoHost data base in time frame between January 1970 and 2010. The keywords used were MSD, questionnaire, screening WRMSD for section A and Laboratory ergonomics, laboratory checklist, musculoskeletal injury, and musculoskeletal disorder in Laboratory for section B.

The questionnaire relevant to check the presence of musculoskeletal disorder and assess risk factors were identified from the literature and documented. The items identified from the literature were compiled and used for framing the questionnaire. For section A questionnaire, most of the items were generated from Nordic musculoskeletal questionnaire and Dutch musculoskeletal questionnaire. The items relevant for the present study were picked and organized.

For section B questionnaire, the items identified from the literature mainly the laboratory ergonomics checklist were compiled and used for framing the questionnaire. Personal visit to the laboratory workstation was done to understand the various tasks that the professionals carried out as a routine. Also informal interview of some professionals working on various task in the laboratory was done to understand the frequency and pattern of task. This procedure was chosen to yield maximum number of items which the laboratory professional felt the need to be checked or taken care off.
After generation of items from the literature and interviews, the items were pooled together, corrected for duplication and grouped into various domains. Grouping of items under the domain was followed by its content validation by the panel of experts.

3.1.9.2 Content validation

Content validation was done by a panel of experts. Ten experts validated the questionnaire. The panel consisted of health professionals who were specialized and experienced in the field of ergonomics and Physiotherapy in Musculoskeletal orthopedics, as well as the laboratory professionals specialized in the area of pathology, biochemistry, microbiology. The experts from laboratory professionals were identified and approached from the respective departments of Kasturba Medical College Manipal. The experts were contacted individually and explained about the purpose of the study with a request to participate for the content validation.

3.1.9.3 Sample size - Not Applicable

3.1.9.4 Procedure

All the experts identified were given an information letter explaining the purpose of the study along with the consent form. Content validation form with the list of domains and item generated was given to the experts. They were asked to judge each item and the domain based on its appropriateness, relevance and accuracy (appendix 2). They were also provided with the column of additional comment/suggestion.
Percentage level of agreement between the experts was used to evaluate the content validity of the items and the domains. The criteria to include the item in the domain was fixed at 80% i.e., the items and the domain was included only if eight or more experts score it as relevant. The filled content validation form were collected from the experts and the data was compiled and analyzed. The items and the domains were accepted, modified or deleted based on the level of agreement between the experts as well as the suggestion given by them.

Experts were also requested to provide the comments in comment column regarding the items, domain and fit of the items under the domains. The comments were discussed, clarified and analyzed with the individual experts.

3.1.9.5. Data analysis

Descriptive statistics was used to summarize the percentage of agreement for each item and domain in the questionnaire
Table 3.1 Characteristics of experts

<table>
<thead>
<tr>
<th>S.no</th>
<th>Expert field</th>
<th>Experience in years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Physiotherapist in Musculoskeletal specialty</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>Physiotherapist in Musculoskeletal specialty</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Physiotherapist in Musculoskeletal specialty</td>
<td>8</td>
</tr>
<tr>
<td>4</td>
<td>Physiotherapist specialized in Occupational health and ergonomics</td>
<td>15</td>
</tr>
<tr>
<td>6</td>
<td>Physiotherapist specialized in Occupational health and ergonomics</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>Pathologist</td>
<td>15</td>
</tr>
<tr>
<td>8</td>
<td>Biochemist</td>
<td>14</td>
</tr>
<tr>
<td>9</td>
<td>Microbiologist</td>
<td>13</td>
</tr>
<tr>
<td>10</td>
<td>Biochemist</td>
<td>20</td>
</tr>
</tbody>
</table>

3.1.9.6 Observations on content validation of Section A questionnaire

It was observed that the level of agreement for each question was 100%. However few errors in the sentence framing was pointed out by the experts which was rectified based on the suggestion.

3.1.9.7 Observations on content validation of Section B questionnaire

The level of agreement between the experts for each item and the domains under which these items were grouped is enclosed in appendix 3.

Out of 63 items, 59 items had 100% agreement between experts in the respective domains. In the domain of working in standing position, the item asking “do you experience any pain, fatigue, stiffness after working for long” had 40%
agreement so it was removed. The reason was the repetition of the question in the earlier (section A) questionnaire for prevalence estimation.

In the domain of miscellaneous, the item asking “Does contact stress exist between your forearm, wrist and/or elbow on work benches” only 60% agreement was seen because of duplication of the information, so it was eliminated. In the same domain one item (do you use Gloves?) was added based on the suggestion given by 3 experts.

In the domain of computer work, the item “Do you experience any work related discomfort” had 50% agreement. Because of repetition of the information in section A questionnaire, this item was removed.

After validation of questionnaire, pilot testing was done on ten laboratory professionals.

3.1.10. Procedure for Phase I

Permission from the District Health Officer was taken (Appendix-4), following which the details regarding the list of medical laboratories with the number of laboratory professionals was obtained. These laboratories were visited and laboratory personnel working were enlisted.

260 subjects were identified and screened for inclusion and exclusion criteria. Of which, 10 were excluded (6- less than one year experience, 4-diagnosed disc lesion). Total of 250 subjects participated in the study. After taking informed consent, the participant were interviewed using Section A questionnaire (Appendix 6) and Section B questionnaire (Appendix 7).
List of Laboratories procured
Laboratory professionals were identified (n= 260)

Excluded n = 10
(Had less than 1 year experience, and diagnosed disc lesion of cervical or lumbar)

250 laboratory professionals agreed to participate in the study

Written Informed consent was obtained from the participants included

Participants were interviewed using
• Section A questionnaire
• Section B questionnaire.

Data was summarized and analyzed using descriptive statistics

Figure 3.1 Flow diagram of procedure for Phase I
Workstation Risk Factor analysis

For analysis of Workstation risk factor, workstation was divided into six components (General Workstation, pipetting Workstation, microscope workstation, Microtome workstation, standing workstation and Computer workstation). Each workstation was assessed based on the activities carried out at the station. Each activity was scored 1 if favorable and 0 if not favorable. The scores were summed up and value was generated for each workstation.

No risk- < 20% of workstation activities are not favorable
Low risk- 20-60% workstation components are not favorable
High risk- >60% workstation items are not favorable

3.1.11 Data analysis

• All the data collected were analyzed by SPSS version 15.0 software.
• Frequency and percentage was used to summarize all categorical variables.
• Univariate logistic regression analysis was used to study the risk factors for WRMSD.
• Multivariate logistic regression analysis was used to study the independent risk.
3.2 Phase II

Phase II was initiated after one month of completion of phase I (February 2013 to July 2014).

3.2.1 Objectives

To determine the effect of structured ergonomic intervention on upper quadrant function and QOL among laboratory personnel.

3.2.2 Study Design

Quasi–Experimental design

3.2.3 Study center

The study was conducted in the various medical laboratories of Udupi District and Mangalore city.

3.2.4 Study Participants

Laboratory professionals (lab technicians, pathologists, microbiologists, biochemistry technologist).

3.2.5 Inclusion criteria

Laboratory professionals

- In age group between 19 to 60 years
- Reported musculoskeletal symptom in one or more anatomical areas in upper quadrant
- Working in the profession for at least past one year
3.2.6 Exclusion criteria

- Subjects who gave history of unhealed fractures, recent dislocations, inflammatory arthritis, tumors, diagnosed psychiatric illness, recent traumatic soft tissue injuries, diagnosed disc lesion.
- Those who refused to participate.

3.2.7 Sampling Method: Purposive sampling

3.2.8 Sample Size

Sample size was calculated based on the outcome measure i.e. neck disability index.

Anticipating a standard deviation of 9 for NDI with minimum clinically important difference of 5 units, for a power of 80% at 95% confidence level.

It was calculated based on the following formula

\[ n = \frac{(Z\alpha + Z\beta)^2 \sigma^2}{d^2} \]

A minimum of 32 subjects needed to be enrolled in each arm of the study.

Where n is the total number of subjects
\( \sigma = \) standard deviation of the baseline score of the scale, which is taken as 9 approx.
\( d = \) minimum improvement in the mean score from baseline taken as 5 unit
\( Z\alpha = 1.96 \)
\( Z\beta = 0.84 \)
3.2.9 Procedure

Twenty five medical laboratories were identified from Udupi district and Mangalore city. From these laboratories, 76 subjects fulfilled the eligibility criteria. Of the 76, five subjects refused to participate. Total 71 subjects were included in the study. Written informed consent was obtained from all the participants. They were then allocated into intervention and control group by convenient sampling.

Group Allocation

The subjects were allocated into intervention and control group based on convenience. It was ensured that the eligible participants from the same laboratory were allocated into the same arm to prevent contamination.

At the end of the study there were 3 dropouts in the intervention group and 4 dropouts in the control group. Study duration for this phase was 12 weeks. Total 32 subjects in each group was analyzed for the study. Enrollment and final flow of the participants is shown in the flowchart 2.
Subjects satisfied the eligibility criteria N=76

Informed consent form administered
(Refused to participate in the study n=5)

Subjects Recruited
N=71

Group allocation

Intervention group
N=35

Intervention

Drop outs n= 3

Completed Study
n=32

Data Analyzed

Control group
N=36

No intervention

Drop outs n=4

Completed Study
n=32

Figure 3.2 Flow diagram of procedure for Phase II
Table 3.2 Details of the number of Laboratories and professionals with musculoskeletal pain.

<table>
<thead>
<tr>
<th>Number of laboratory Professionals with Symptoms</th>
<th>Number of Laboratories (Intervention group)</th>
<th>Number of laboratories (Control group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>14</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Above table depicts the total number of laboratories in intervention and control group with respect to number of symptomatic laboratory professionals recruited in the study.

3.2.10 Methodology

Baseline data was collected from all the participants in the intervention and control group using following tool

- Section A questionnaire
- Section B questionnaire.
- Visual Analog Scale.
- DASH and NDI scales based on area of complain given by the participant. (Appendix 8 & 9)
- SF-36 (Appendix 10)
After baseline data collection ergonomic intervention was given to the intervention group. Control group did not receive any intervention.

**Operational definition**

“Ergonomic intervention”- for this study ergonomic intervention was defined as the combination of Education, workstation/work style readjustment and exercise.

**Ergonomic intervention**

The ergonomic intervention consisted of three components namely Education, workstation/work style readjustment and structured exercise. All the 3 components were given/demonstrated to the participants on one day. Total time for intervention was 35 to 40 minutes.

**Follow Up**

To maintain the compliance, regular follow up was done through phone calls and visit at interval of two weeks. During follow up, log book was checked and any doubts related to intervention was clarified.

**Reassessment:**

At the end of 6 and 12 weeks, changes in the symptom severity, Upper quadrant function and quality of life was assessed in both intervention and control arm using following outcome measures.

- Visual Analog Scale.
- DASH and NDI scales based on area of complain given by the participant.
- SF-36
The intervention included-

1. **Education (approx. 15 minutes)**
   - This included education about lab workstation risk factors (awkward postures, repetitive movements, eyestrain) b) Education about effect of bad posture c) Guidelines to follow for injury prevention for e.g. rest breaks, worker positioning (Appendix 11)

   **Method**: Participants were educated using a power point presentation as well as verbal explanation by the principal investigator. Appropriate pictures as well as live demonstration to understand the concept of bad posture & repetitive movement and effect of these on their health was explained.
   - **Duration**: Education session was 15 minutes
   - **Frequency**: It was given only once during first contact with the participant.

2. **Work station/work style readjustment guidelines (5-10 minutes)**
   - This included a) Workstation adjustment e.g. Lumbar support, adjustment of chair, adjustment of work surface, foot rest. b) Task modification e.g. rest break.
   - Subjects were taught to adjust the height of the chair and optimal working height while sitting and standing work was explained to them, need and frequent use of footrest was told to them.
   - Use of blocks was advised while doing standing work.
   - Adjusting the computer screen height and optimal height of the screen for individual subject was explained.
• Optimal height of stool/chair while viewing the microscope was explained and was advised to use that.

• For this phase, participants in the study group were asked to follow the workstation re-adjustment guidelines for all the task carried out by them in the laboratory throughout their working duration.

3. **Structured Exercise programs (10-15 minutes)**

This included Structured Exercise program which was customized for each participant.

There was overlap of the exercise in some participants, as the exercise was given based on the symptoms reported by the participants as well as the need felt by the investigator. The exercises given were Cervical range of motion exercise, Posture correction/Chin tuck exercise, Deep cervical flexor strengthening exercise, Isometric neck exercise, Self -Stretching of trapezius muscle (upper fiber), Self-Stretching of pectoral muscle, Shoulder retraction exercise, Self-Stretching of long flexors of forearm, Self -Stretching of small muscles of hand and fingers (Appendix 12).

Following instruction were given to the participant regarding the exercise

• Subjects complaining of severe pain were advised to take hot fomentation prior to exercise

• Frequency- all the subjects were advised to perform exercise once a day at their preferred time and on all working days (5 days in a week)

• Duration 10-15 minutes, for 12 weeks
- **Termination of the exercise** - Subjects were advised to stop doing the exercise if they experience any severe increase in symptoms and immediately contact the investigator.

All the participants in the intervention group were provided with the log book in which exercises were mentioned by the investigator. They were asked to document the date if they have not done the exercise.

**Table 3.3 Ergonomic Intervention summary**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Methods</th>
<th>Time Duration</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>Using power points, verbal explanations and live demonstration</td>
<td>15 minutes</td>
<td></td>
</tr>
<tr>
<td>Workstation /work style readjustment</td>
<td>Live demonstration</td>
<td>5-10 minutes</td>
<td>Once in every 2 weeks</td>
</tr>
<tr>
<td>Structured Exercise</td>
<td>Live demonstration and pictures</td>
<td>10-15 min</td>
<td></td>
</tr>
</tbody>
</table>

During the follow-up visits, compliance of the participants to the intervention program was assessed. The participants were considered to be adherent if ergonomic intervention was being followed for 4 or more days in a week. Participants were labeled as being non adherent if they were following intervention less than 4 days for 2 consecutive weeks. Three components of ergonomic intervention was checked separately for the adherence.
a) Adherence to exercise program

b) Adherence to injury prevention program (proper posture, use of foot rest, rest break, back support)

c) Adherence to work re-adjustment guidelines

3.3 Figures showing few workstation modification

Figure 3.3.1 Clearance of leg space

Figure 3.3.2. Introduction of Footrest
Before

After

Figure 3.3.3 Change in seating

Figure 3.3.4 Raise in height of the stool after adjustment
3.2.11 Data Analysis

- Frequency and percentage was used to summarize all categorical variables.
- All scores were summarized using mean (SD) except when the standard deviation exceeded mean, median (IQR) was the preferred summary measure.
- To compare across the duration and between the groups both parametric and non-parametric test were used.
- Baseline characteristic comparison was done using t-test and Mann Whitney test.
- Two way Friedman test was used to compare the skewed continuous data.
- Repeated measure ANOVA was used for comparing normally distributed continuous data.