Chapter 5

Summary and Conclusions
SUMMARY AND CONCLUSIONS

Homeopathic prescription is based on the law of similars, minimum dose, single remedy and drug proving on healthy human beings. A homoeopathic medicine is capable of healing those symptoms, which it was capable of producing during the process of drug proving. According to the method of preparation of the medicine from the drug substance, the end product contains only the dynamic healing and curative power of the drug devoid of any original crude substance. This is done by the method of potentisation. This method activates vital force to such a reactive level that the body becomes capable of eliminating the disease.

The concept of multi factorial involvement in the disease production causation and the development of chronicity is the key point in the homoeopathic case taking and make Homoeopathy an inevitable choice of therapy. Besides, homoeopathic medicines have even in this era proved astoundingly its prophylactic capability in taming the rampant epidemics.

The popularity of Homoeopathy has brought not only recognition but also envy from other disciplines of medicine. The most outstanding
criticism is that Homoeopathy is nothing more than a placebo. Lancet, an English allopathic medical journal came up with a result of meta analysis conducted by Shang et al. (2005), the findings of which were unfavourable for homoeopathy in spite of its growing popularity.

Scientific basis is not just a collection of facts but it is result oriented. Criticism and accusations from various quarters in medical field and scientists and even beneficiaries of homoeopathy are however rampant, especially after the publication in Lancet. This has created confusion not only among the common people, but also among the homoeopathic clinicians. A strong viewpoint has emerged from among homoeopathic professionals to question the irrational prejudices and criticisms levelled against the system. The investigator takes it as a challenge to scientifically study the rationality and scientific efficacy of homoeopathic medicines. The present study intends to either prove or disprove the accusations that the homoeopathic medicines are nothing but placebo. For this purpose the investigator focuses her study on patients suffering from low back pain, the most common musculoskeletal disorder ever reported.
Low back pain is a major public health problem all over the world. Most people suffer from incapacitating low back pain at some stage in their lives. It is estimated that, 6.5 million people in the United States are bed-ridden because of low back pain. Approximately 1.5 million new cases of low back pain are seen by physicians in each month. There has been growing concern about the low back disability in western society. Occurrence of low back pain is alarming in India also; nearly 60 per cent of the people in India have significant low back pain at some time or the other during their life span.

Emotions cause intense changes in physiological functioning. A patient with somatoform disorder may experience a similar back pain in a stressful situation without organic changes.

Chronic low back pain as a leading symptom of a somatoform pain disorder is a remnant diagnostic category for many physicians, general practitioners and orthopaedic surgeons.

Pain & functional disability are the characteristic features in both somatoform back pain disorder and low back pain disorder. Depression, anxiety and well being are major co morbid conditions generally found reported along with pain among patients with low back
pain. Hence assessment of pain & disability, anxiety, depression and well being are considered important in the evaluation of treatment effectiveness of both these disorders. Hence anxiety, depression and well being are selected along with pain and disability as variables for the present study.

The investigator had taken up the present study with the intention to find an answer to the allegations that the homoeopathic medicines are not in any way better than placebo.

The study was designed in such a way as to differentiate the effects of homoeopathic medicines, placebo and homoeopathic medicines in combination with placebo on patients with pathological low back pain and patients with somatoform low back pain.

**Need and significance of study**

Homoeopathy has been facing criticisms from health professionals all over the world. These criticisms could not be explained with evidence by the homoeopathic practitioners due to the paucity of scientific research in the field of homoeopathy. A well documented research on the action of homoeopathic medicines is inevitable to help the practitioners to face the challenges created by other medical systems.
Homoeopathy is a cost effective system which touches the core of the disease and heals gently the disease symptomatology along with improvement in the overall health. Therefore the growth of homoeopathy as a complimentary system of therapeutics is imperative. High quality researches are needed to bring homoeopathy into the main stream of therapeutics.

Homoeopathy being a simple, gentle and cost effective therapy this should be accessible to individuals and families in the community at a cost that people can afford to maintain. The effectiveness of the therapy also should be validated before the public. Hence studies which might prove or disprove the allegations that homoeopathic effect is just placebo are highly necessary.

The findings of the study in either way will help the homoeopathic practitioners to explain the effect of homoeopathic medicine and also the effect of placebo based on scientific evidence.

The sample of the study was patients with low back pain. Low back pain is a major public health problem all over the world. There has been growing concern over the large number of disabled working population, the cause of which is reported to be low back pain. Nearly
60% of people in India seem to suffer from low back pain at some time or the other in their life span. Though patients with low back pain rank second in the total number of cases attending the primary health care, no serious studies have been found reported in the field of homoeopathy. Appropriate management has the potential to reduce the number of people with disabling long-term back pain and so reduce the personal, social, and economic impact of low back pain to society. A study on the effectiveness of an eco friendly treatment like homoeopathy might be of great help to hundreds of patients suffering from low back pain.

An alarming number of patients with low back pain with somatoform symptoms visit primary health care centres seeking treatment. Homoeopathic treatment is found to provide relief to their somatoform pain. A study to differentiate the effects of homoeopathic medicines and placebo on patients with pathological low back pain and patients with somatoform pain is of high relevance.

Co morbid conditions like anxiety and depression are found reported along with pain in almost all the cases. It would be a significant contribution if the present study succeeds in pinpointing the effects of
homoeopathic medicines, placebos and medicine in combination with placebos in the management of co morbid conditions also.

The study is entitled- “Medicinal & placebo effects of homoeopathic remedies-a study on patients with somatoform low back pain and patients with pathological low back pain”.

Objectives

1. To study whether there was difference in the effect of homoeopathic medicines on pain & functional disability, anxiety, depression and well being in patients with pathological low back pain and patients with somatoform low back pain.

2. To study whether there was difference in the effect of placebo on pain & functional disability, anxiety, depression and well being in patients with pathological low back pain and patients with somatoform low back pain.

3. To study whether there was difference in the effect of homoeopathic medicines in combination with placebo on pain & functional disability, anxiety, depression and well being in patients with pathological low back pain and patients with somatoform low back pain.
4. To study whether there was difference in the effect of homoeopathic medicines, placebo, homoeopathic medicines in combination with placebo on anxiety, depression, well being and physical signs of patients with pathological low back pain.

5. To study whether there was difference in the effect homoeopathic medicines, placebo, and homoeopathic medicines in combination with placebo on anxiety, depression and well being of patients with somatoform low back pain.

6. To study the correlation between pain and anxiety, pain and depression and pain and well being in patients with somatoform low back pain and patients with pathological low back pain.

**Hypotheses**

1. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in pain & functional disability when treated with homoeopathic medicines.

2. There will not be any significant difference between patients with pathological low back pain and patients with somatoform
low back pain in pain & functional disability when treated with placebo.

3. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in pain & functional disability when treated with homoeopathic medicines in combination with placebo.

4. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in anxiety when treated with homoeopathic medicines.

5. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in anxiety when treated with placebo.

6. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in anxiety when treated with homoeopathic medicines in combination with placebo.
7. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in depression when treated with homoeopathic medicines.

8. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in depression when treated with placebo.

9. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in depression when treated with homoeopathic medicines and placebo in combination.

10. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in well-being when treated with homoeopathic medicines.

11. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in well-being when treated with placebo.
12. There will not be any significant difference between patients with pathological low back pain and patients with somatoform low back pain in well-being when treated with homoeopathic medicines in combination with placebo.

13. There will not be any significant difference in pain & functional disability among patients with pathological low back pain when treated with homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.

14. There will not be any significant difference in pain & functional disability among patients with somatoform low back pain when treated with homoeopathic medicines, when treated with placebo and when treated with homoeopathic medicines in combination with placebo.

15. There will not be any significant difference in anxiety among patients with pathological low back pain when treated with homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.
16. There will not be any significant difference in anxiety among patients with somatoform low back pain when treated with homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.

17. There will not be any significant difference in depression among patients with pathological low back pain when treated with homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.

18. There will not be any significant difference in depression among patients with somatoform low back pain when treated with homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.

19. There will not be any significant difference in well-being among patients with pathological low back pain when treated with homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.

20. There will not be any significant difference in well-being among patients with somatoform low back pain when treated with
homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.

21. There will not be any significant correlation between pain and anxiety in patients with pathological low back pain.

22. There will not be any significant correlation between pain and depression in patients with pathological low back pain.

23. There will not be any significant correlation between pain and well-being in patients with pathological low back pain.

24. There will not be any significant correlation between pain and anxiety in patients with somatoform low back pain.

25. There will not be any significant correlation between pain and depression in patients with somatoform low back pain.

26. There will not be any significant correlation between pain and well-being in patients with somatoform low back pain.

27. There will not be any significant reduction in the physical signs in patients with pathological low back pain after treated with homoeopathic medicines, treated with placebo and treated with homoeopathic medicines in combination with placebo.
Methodology

Research design: The research design was pre post experimental design with control group.

Sample: Sample for the study was selected using systematic random sampling method.

The sample for the study was selected through the camps organised exclusively for patients with low back pain. The camps were organised by Back Pain Research Clinic of Dr. Padiar Memorial Homoeopathic Medical College, Chottanikkara. Out of the total number of 1142 patients, 673 patients met with the inclusion criteria. From among the 673 patients sample was selected randomly. 225 patients who reported at least one of the signs positive based on the physical examination checklist were randomly selected and included under the group of pathological low back pain (Group I). 225 patients who did not have even a single sign positive based on the physical examination checklist were randomly selected and were included under the group of somatoform low back pain. The inclusion of the somatoform low back patients was based on the DSM IV (APA 2000) classification for somatoform diagnostic criteria.
The patients in the Group I were further classified into three categories based on the type of intervention used. The category I (medicine) consisted of 75 patients who received homoeopathic medicines alone. Category II (placebo) consisted of 75 patients who received placebo alone. Category III consisted of 75 patients who received both medicine and placebo (combination).

The patients in the group II (somatoform low back pain) were also grouped into three based on the type of interventions used. The first group who were given homoeopathic medicine consisted of 75 patients category I (medicine). Category II consisted of 75 patients who received placebo alone. Category III consisted of 75 patients who received both medicine and placebo in combination.

Seven patients from Group I and 4 patients from Group II were dropped out from the follow up. Thus the final sample consisted of 439 patients with low back pain.

**Tools used:**

1. Hamilton anxiety rating scale (Hamilton1959)
2. Beck depression inventory (Beck 1961)
3. PGI General well being measure (Verma &Verma 1989)
4. Oswestry low back pain scale (Fairbank 1980)


6. Personal information data sheet (developed by investigator).

**Procedure**

A fully informed written consent was obtained from each and every patient before the beginning of intervention. The tools were administered to the patients individually. The instructions were read out and explained. Doubts were cleared and clarifications were given to the patients. The inventories were collected and checked for their completeness. The completed inventories were scored as per the manuals. The scored data were coded and subjected to statistical analyses.

**Statistical techniques**

1. ANCOVA,

2. Pearson correlation analysis

3. Wilcoxon signed rank test.
Findings

1. Patients with pathological low back pain had higher reduction in Pain & functional disability when compared to patients with somatoform low back pain when treated with homoeopathic medicines.

2. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Pain & functional disability when treated with placebo.

3. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Pain & functional disability when treated with homoeopathic medicines in combination with placebo.

4. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Anxiety after treatment with homoeopathic medicines in combination with placebo.

5. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Anxiety after treatment with placebo.
6. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Anxiety when treated with homoeopathic medicines in combination with placebo.

7. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Depression after treatment with homoeopathic medicines.

8. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Depression after treatment with placebo.

9. Patients with pathological low back pain and patients with somatoform low back pain did not differ in Depression after treatment with homoeopathic medicines in combination with placebo.

10. Patients with pathological low back pain and patients with somatoform low back pain did not differ in well being after treatment with homoeopathic medicines.
11. Patients with somatoform low back pain had better enhancement of Well being when treated with placebo when compared to patients with pathological low back pain.

12. Patients with pathological low back pain had better enhancement of Well being when treated with homoeopathic medicine in combination with placebo when compared to patients with somatoform low back pain.

13. Patients with pathological low back pain who received homoeopathic medicines had higher reduction in Pain & functional disability followed by the patients who received homoeopathic medicine in combination with placebo. Patients who received placebo had least relief.

14. Patients with somatoform low back pain had higher reduction in Pain & functional disability when treated with homoeopathic medicines followed by patients who received homoeopathic medicine in combination with placebo. Patients who received placebo did not show any reduction in Pain & functional disability.
15. Patients with pathological low back pain had higher reduction in Anxiety when treated with homoeopathic medicines followed by patients who received homoeopathic medicine in combination with placebo. Patients who were treated with placebo did not show a significant reduction in Anxiety.

16. Patients with somatoform low back pain had higher reduction in Anxiety when treated with homoeopathic medicines followed by patients who received homoeopathic medicine in combination with placebo. Patients did not show significant reduction in Anxiety when treated with placebo.

17. Patients with pathological low back pain had higher reduction in Depression when treated with homoeopathic medicines in combination with placebo followed by patients who received homoeopathic medicine in. Patients who were treated with placebo did not show a significant reduction in Depression.

18. Patients with somatoform low back pain had higher reduction in Depression when treated with homoeopathic medicines followed by patients who received homoeopathic medicine in
combination with placebo. Patients did not show significant reduction in Depression when treated with placebo.

19. Patients with pathological low back pain had better enhancement of Well being when treated with homoeopathic medicines in combination with placebo followed by patients who received homoeopathic medicines. Patients who were treated with placebo did not show a significant enhancement of well being.

20. Patients with somatoform low back pain had shown similar reduction in well being after treatment with homoeopathic medicine, after treatment with placebo and after treatment with homoeopathic medicine in combination with placebo.

21. A positive relationship was obtained between Pain and Anxiety of patients with pathological low back pain. Anxiety of pathological low back pain increased with increase in pain and decreased with decrease in pain.

22. A positive relationship was obtained between Pain and Depression of patients with pathological low back pain.
Depression of pathological low back pain increased with increase in pain and decreased with decrease in pain.

23. A negative relationship was obtained between pain and well being of pathological low back pain. The feeling of well being of patients with pathological low back pain improved with the decrease in pain and worsened with increase in pain.

24. A positive relationship was obtained between Pain and Anxiety of patients with somatoform low back pain. Anxiety of somatoform low back pain increased with increase in pain and decreased with decrease in pain.

25. A positive relationship was obtained between Pain and Depression of patients with somatoform low back pain. Depression of somatoform low back pain increased with increase in pain and decreased with decrease in pain.

26. A negative relationship was obtained between Pain and Well being of somatoform low back pain. The feeling of well being of patients with somatoform low back pain improved with the decrease in pain and worsened with increase in pain.
27. The patients with pathological low back pain who received homoeopathic medicines had a higher reduction in physical signs followed by the patients who received homoeopathic medicines in combination with placebo. The patients who received placebo had shown the least reduction of the three groups of patients with pathological low back pain.

**Implications**

Low back pain is a very common condition which is very difficult to be managed. Pain and associated co morbid conditions (anxiety and depression) of low back pain were found to be significantly reduced when treated with homoeopathic medicines alone. Feeling of well being also was found to be enhanced. The findings imply that homoeopathic medicine given alone is an effective therapy in managing pain of patients with pathological low back pain where there is a clear medical indication.

A similar finding was observed in the case of patients with somatoform low back pain also. Though not to the same extent as in the case of patients with pathological pain, the patients with somatoform low back pain also reported a reduction in pain as well as co morbid conditions-
Anxiety and Depression. The reduction was reported when treated with medicine alone and also with medicine and placebo in combination. The findings imply the effectiveness of homoeopathic medicines and also the use of medicines in combination with placebo in managing the pain of patients with somatoform low back pain. The well being of patients with somatoform pain disorder was found to be enhanced with homoeopathic medicines, medicines in combination with placebo and placebo alone. This implies that placebo can be effectively used to enhance the well being of patients with somatoform disorders.

Homoeopathy has considered management of co morbid conditions along with presenting complaints. The holistic approach both in theory and practical has been found emphasized through the findings of the present study.

An interesting finding of the study was that patients with pathological low back pain had no enhancement in well being or reduction in pain, anxiety or depression when treated with placebo. The general practice to use placebo with the intention to enhance trust and well being of patients is rejected through the findings of the study. This implies that
unnecessary and frequent use of placebo can be avoided, especially in
the case of patients with pathological indications.

The findings of the study help in boosting the confidence of
practitioners in managing pain and co morbid conditions of patients
with low back pain. The findings has shown that homoeopathic
medicines either alone or given in combination with placebo are
effective in managing pain, anxiety and depression among patients
with pathological low back pain and also among patients with
somatoform low back pain. The findings indicate that homoeopathy
which is cost effective with minimum side effects can be
recommended as a strong alternative treatment in low back pain
disorders. This may also help the patients to get relieved from the
burden of other expensive therapies.

The findings of the study has been successful in providing a scientific
basis for an eco friendly treatment which will be of great help to
thousands of patients suffering from low back pain – both pathological
and somatoform.

The findings of the study have been able to disprove the allegation that
‘homoeopathy is nothing but placebo’. Hereafter, homoeopathic
practitioners will be able to explain the effect of homoeopathic medicines based on scientific evidence.

**Limitations**

Difficulty in getting high quality research studies especially on low back pain disorders was a limitation while designing the study and formulating objectives & hypotheses of the study. The study could not be double blind. It was a study with the investigator having knowledge about the type of intervention being given to the patients. Making the study double blind will help to improve the quality of the study.

The follow up period was too short for a disorder like low back pain which is chronic in nature.

**Scope for further research**

The present study alone will not serve the purpose of generalizing or drawing conclusions regarding the effectiveness of homoeopathic medicine on low back pain. More studies are to be taken up by other researchers.

The study can be replicated with larger sample of patients with low back pain.
Studies can be carried out in other types of disorders where pain is involved.

Double blind studies can be done for more reliable results.

The study can be replicated with longer period of interventions between pre and post test.

As the present study is first of its kind, further studies can be conducted in similar lines across the country to revalidate the findings of the study.

The finding of the present study has found that placebo when used without medicine has no effect in managing pain or its associated conditions. The use of placebo by homoeopathic practitioners is as old as the history of homoeopathy. The investigator herself feels it unsafe to question the integrity of placebo based on the findings of a study conducted with certain limitations of a doctoral research. However the issue of placebo has to be definitely researched with great concern.