Chapter 1

Introduction
INTRODUCTION

Homoeopathy is a system of therapeutics, which is based on the nature’s law of cure, similia similibus curentur - let likes be treated by likes. This law though was mentioned as the only possible way for cure by Hippocrates himself, it was first experimented and put into actual practice by a German physician Dr. Christian Friedrich Samuel Hahnemann in 1796. Homoeopathy has thereon evolved as a revolutionary natural medical science, which is gentle, simple but effective and works by stimulating the body’s own healing power.

The concept of disease in homoeopathy is that disease is the total affection of the mind, body and soul, ie the disturbance of the whole organism. Disease is not something which is coming from outside but it is coming from within. The disease is due to an internal derangement and is manifested externally in the form of signs and symptoms. When the vital force, which keeps the body in the healthy state, is deranged, there is external manifestation of the same in the form of abnormal physiology or the symptoms. The vital force is susceptible to factors like life style, mental attitude, intelligence, environment etc. and therefore when so deranged it affects the equilibrium of health, which manifests as disease.
The Homoeopaths consider both the pathognomonic (diagnostic) as well as the individual peculiarities, which make the person sick and prescribe medicines based on both. The Homoeopaths never confines themselves to the general pathology alone, but consider the mental, physical, social as well as the spiritual factors in disease, which is very much in compliance with the WHO definition of Health. Homoeopathy is holistic, totalistic and individualistic in its approach. As individualization of each and every patient is vital, his mental and physical peculiarities become important.

Primary health care is essential health care based on scientifically sound and socially acceptable and practical methods made universal. This should be accessible to individuals and the families in the community through their full participation, at a cost that community and country can afford to maintain. Homoeopathy is simple, gentle and cost effective.

Early in the 20th Century, Sigmund Freud applied psychoanalytic concepts to the physical symptoms and thus the psychosomatic hypothesis became popular. At present most researchers and clinicians believe that for any given individual, a host of variables-physical, psychological and social- contribute to the phenomena of disease, and that illness is not simply due to the influence of external agents. The
biopsychosocial point of view is not limited to the cause of illness but also to the prevention and treatment. Thus a multifactorial individualistic approach is inevitable in today’s lifestyle disorders and newer diseases.

This biological predisposition to disease is of prime importance for a Homoeopath who considers the disease from a Holistic viewpoint that is based on the susceptibility of the person to get influenced by extrinsic and intrinsic factors. This affection may be manifested in the mental and physical plane. The objective of science is not just collecting evidence but finding out cause effect relationship in health care.

Allopathy, at the time of Hahnemann was not based on strict principles and henceforth Hahnemann felt a need for a therapeutic system based on sound principles. Hahnemann, a renowned Allopathic physician of the time was dissatisfied with the then existing mode of therapy. This led to intense experimentations and subsequently to the evolution of Homoeopathy.

The disease concept changed from unifactorial to multifactorial where everything including life style, way of thinking, environment, hygiene, food, etc. supplemented as causations or intensifying factors. This was
prophesied by Dr. Hahnemann 200 years earlier and hence Homoeopathy is considered by many to be the most advanced system of therapeutics. 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 drug quantity is very minimal because of the fact that the body is already sensitized with the disease and the remedy used is having the property of producing similar affection to that of the disease. This also minimizes the unnecessary side effects.

At the time of introduction of homoeopathy, this concept of disease and treatment was quite novel. But with the invention of antibiotics, the unifactorial cause of the disease gained importance and the
Homeopathic concept received a setback. The diagnosis of diseases thus became more important and treatment was centered around those causative agents wherever it could be found. In situations not possible to be diagnosed, the symptoms were considered and remedies administered to suppress the same but only to re-appear sooner or later and that too in a more aggravated form.

The present era however beholds many a new disease especially the viral disease that began to get a strong hold on the humanity, consequent on the depreciation of vitality, by the current life style. In situations like these, homoeopathy alone can efficaciously cure, as it is not necessary to obtain a diagnosis to commence the treatment. But the diagnostic procedures help in analyzing the prognosis of the condition. Diseases like psychosomatic disorders, lifestyle disorders and chronic disorders are on the rise. 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 even in this era have proved astoundingly its prophylactic capability in taming the rampant epidemics.
The investigator being a clinician can claim the efficacy of homoeopathy based on the multitude of patients cured. Homoeopathy is the second most widely used system of medicine in the world after Allopathy. The WHO recognizes it as a form of traditional medicine.

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 (2005), the findings of which were unfavourable for homoeopathy in spite of the growing popularity. In this study they compared the effect of placebo controlled clinical trials of homoeopathy with that of Allopathy. The same journal contained an editorial named ‘The End of Homoeopathy’. In the editorial they urged doctors to be bold and honest with their patients about homoeopathy’s lack of benefits. The same however contained more thoughtful comment from the Dutch epidemiologist Ian Vandendroucke, reflecting on the growth of truth, including the relationship between bias, background knowledge and the concordance of clinical results with laboratory scientific findings. He therefore concluded that the ultimate proof of
the validity of a scientific or medical idea is in the extent to which it changes reality.

The findings of the study by Shang (2005) resulted in the presumptive failure of homoeopathy because the cases selected and treated were not based on homoeopathic principles. Moreover no homoeopathic consultants were included in the study. Among the selected cases only 16% were treated according to classical homoeopathy. 99% of conventional medicine cases were drug investigation studies. They sarcastically claimed that the remedies act only on the mind and hence the effect is of a placebo. The second criticism worth mentioning is that the system of homoeopathy has no scientific basis. This is because; one of the fundamental principles of homoeopathy is ultra high dilution by potentisation. The scientific community does not yet explain the ultra high dilutions. Homoeopaths all over the world in their everyday practice however claim to verify clinically the effect of the same.

Scientific basis is not just a collection of facts but it is result oriented. Criticisms 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 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.

The musculoskeletal disorders such as impairment of the back and spine are leading causes of health problems and cause severe disability, particularly in people during their employment years. The limitations imposed on patients are severe. The economic cost, in terms of loss of productivity, medical expenses, and other costs that are not compensated, is in the billions of dollars according to Pauline & Williams, 2004. Suffering from musculoskeletal pain can be seen as being on the spectrum from health to disease as there is a tendency for chronicity [Antonovsky, 1996].
Low back pain is one of the most common and incapacitating disorders in the modern society. Low back pain is a disease condition, which is statistically recorded to seek medical attention second only to upper respiratory tract infection. About 80-88% of people experience incapacitating low back pain during their adult lives according to Nachemson & Sahlstrand, 1977. Low back pain (LBP) is one of the most common musculoskeletal health problems in society and causes considerable disability, work absenteeism, and use of health services. It is said to affect 50% to 80% of people in their lifetime and 15% to 30% of people at any given time. During any 6-month period, 72% of adults in the general population report LBP and 11% report disabling LBP. Lower back pain is said to be very common with a life-time cumulative incidence approaching 70% by the age of 40 years, and a 1-year prevalence of 15% for 30 to 40 year old men and women (Leboeuf-Yde & Kyvic, 1998).

Low back pain is a major public health problem all over the world. Most people suffer incapacitating low back pain at some stages 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. In India, occurrence of low back pain is also alarming; nearly 60 per cent of the people in India have significant low back pain at some time or the other during their lifespan. Approximately 35% people suffer from chronic back pain, which significantly hampers their day-to-day routine (Suryapani, 1996) which can be considered as a matter of high significance.

Low back pain usually goes undiagnosed, thereby increasing the risk of musculo-skeletal disease. This can result in complications like decreased flexibility and movement and may cause a range of issues in lifestyle, sleep, work and other social problems. The 2010 Global Burden of Disease Study estimated that low back pain is among the top 10 diseases and injuries that account for the highest number of disability adjusted life years (DALY) worldwide (Mazroa & Mohammed 2012). It is estimated that as the world population ages, low back pain also increases.

The human spine holds the man on an upright position against defies gravity. It forms the infrastructure of a biological machine that anchors...
the kinetic chain and transfers biomechanical forces into coordinated functional activities. The spine acts as a channel for precious spinal cord and possesses the physiological capacity for lifting and walking.

The spine is subjected to aging, to the wear and tear of gravity and biomechanical loading through compensatory structural and neurochemical changes. Some of these changes can be maladaptive causing pain, functional disability, and altered neurophysiologic circuitry. Some compensatory reactions are benign; however, some are destructive and interfere with the organism’s capacity to function and cope. Spinal pain is multifaceted, involving structural, biomechanical, medical, and psychosocial influences.

Low back region is extremely complex; both anatomically and functionally. The term low back pain (LBP) is very broad and covers a large heterogeneous group of disorders. LBP may not only be characterized by pain, but also by discomfort and/or stiffness. “LBP” covers several sub-groups with differing aetiologies and prognoses, but current knowledge does not allow to determine the exact medical cause of LBP in most patients. In fact, it has been estimated by some that a somatic cause is found in 10-20% of cases with LBP, whereas others
find that as much as 97% of LBP is termed “non-specific” or “sprain/strain”. Thus, LBP refers to a set of symptoms or a syndrome rather than a diagnosis. Although low back trouble would be a more precise term, LBP (or non-specific LBP) is the most commonly used term for non-specific trouble relating to the lower back. Low back pain (LBP) is defined as chronic after 3 months because most normal connective tissues heal within 6-12 weeks, unless pathoanatomic instability persists. A slower rate of tissue repair in the relatively avascular intervertebral disc may impair the resolution of some persistent painful cases of chronic LBP.

The main causes of chronic low back pain can be listed as follows:

Mechanical syndromes like

- Discal and facet motion segment degeneration
- Muscular pain disorders (eg, myofascial pain syndrome)
- Discogenic pain with or without radicular symptoms
- Radiculopathy due to structural impingement
- Axial or radicular pain due to a biochemical or inflammatory reaction to spinal injury
- Motion segment or vertebral osseous fractures
- Spondylosis with or without central or lateral canal stenosis
• Macroinstability or microinstability of the spine with or without radiographic hypermobility or evidence of subluxation

Nonmechanical syndromes

• Neurologic syndromes
  
  o Myelopathy or myelitis from intrinsic/extrinsic structural or vascular processes
  
  o Lumbosacral plexopathy (eg, diabetes, vasculitis, malignancy)
  
  o Acute, subacute, or chronic polyneuropathy (eg, chronic inflammatory demyelinating polyneuropathy, Guillain-Barre syndrome, diabetes)
  
  o Mononeuropathy, including causalgia (eg, trauma, diabetes)
  
  o Myopathy, including myositis and various metabolic conditions
  
  o Spinal segmental, lumbopelvic, or generalized dystonia

• Systemic disorders
  
  o Primary or metastatic neoplasms
  
  o Osseous, discal, or epidural infections
  
  o Inflammatory spondyloarthropathy
  
  o Metabolic bone diseases, including osteoporosis
- Vascular disorders (e.g., atherosclerosis, vasculitis)
- Referred pain
  - Gastrointestinal disorders (e.g., pancreatitis, pancreatic cancer, cholecystitis)
  - Cardiorespiratory disorders (e.g., pericarditis, pleuritis, pneumonia)
  - Disorders of the ribs or sternum
  - Genitourinary disorders (e.g., nephrolithiasis, prostatitis, pyelonephritis)
  - Thoracic or abdominal aortic aneurysms
  - Hip disorders (e.g., injury, inflammation, or end-stage degeneration of the joint and associated soft tissues [tendons, bursae, ligaments])

Low back pain may be associated with pure organic disorder or may appear to be a condition where there is no identifiable organic pathology except for the symptom of low back pain which is equally disabling like that of the one with organic pathology. Chronic LBP (CLBP) is a condition where biological, psychological and social factors interact and mutually influence each other, both as causal factors and maintaining factors (Dersh, Gatchel, & Polatin 2001). Chronic back pain patients are regarded to be somatising patients who
express psychological and social distress through persistent subjective health complaints according to Ford, 1983. This is reflected in the extremely high prevalence of somatoform pain disorders often found in chronic back pain populations, and 99% goes undiagnosed (Kinney et al., 1993). Somatisation also leads to high rates and costs of health care utilization (Escobar, Burnam, Karno, Golding 1987., Swartz, 1991., Smith, Monson, Ray 1986) like the chronic low back pain.

Emotion and behaviour cause intense changes in physiological functioning. A patient with somatoform disorder may experience a similar back pain in a stressful situation without organic changes. According to the DSM IV somatoform disorders, musculoskeletal manifestation like low back pain can be a somatoform pain disorder (APA, 2000). These are patients who present with the clinical symptoms of low back pain, but even a thorough investigation never reveals background pathology. In some, psychological factors are aetiologically involved. In other cases the evidence may be to the pain permitting the person to avoid some activity that is noxious to him or to get support from others.
Both these two types of disorders present clinically in the same manner. The physical nature of the complaint in somatoform pain disorder patient never sends the patient to a psychiatrist. But the complaint may be so severe as to handicap the patient physically, mentally and socially. The symptom is neither factitious nor malingering. Pain is the focus of the disorder, but psychological factors are believed to play the primary role in the perception of pain. Patients with pain disorder use the health care system frequently, make substantial use of medication, and have relational problems in marriage, work, or family. Pain may lead to inactivity and social isolation, and it is often associated with co-morbid depression, anxiety, or a substance-related disorder.

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. Patients with somatoform pain disorder (ICD-10: F45.4, WHO 1994) are often not diagnosed until after several years and multiple diagnostic procedures, in some cases after iatrogenic impairment. A more precise knowledge of the disorder can prevent chronification. The limited efficacy of treatment for back
pain has been attributed to failure to appreciate the psychosocial setting of pain and its associated complaints. They may become socially isolated and experience problems with work and family life.

Homoeopathy never considers treatment based on the diagnosis but it gives importance to the totality of symptoms i.e., the logical totality of the whole symptom array. It takes into account the physical and the mental peculiarities of the patient along with the presenting complaints. This means, even if there is a physical diagnosis, after detailed case taking and evaluation of the symptomatology, the homoeopath considers all the mental as well as physical peculiarities in selecting a similimum. The same is true for low back pain disorders also, even if it has a physical diagnosis or a psychiatric diagnosis. The concept of multi factorial causation and the ability to commence immediate treatment on the basis of symptomatology are unique to the homoeopathic method of treatment.

Chronic low back pain like other chronic diseases is supposed to be due to a deep seated fundamental cause- the chronic miasm. According to Hahnemannian classification of diseases, chronic back pain is a local malady or one sided disease. This group of diseases present with only
one or few symptoms. The few symptoms may be obscuring other symptoms, because of its intensity. Lack of physician’s observation in eliciting other symptoms may be another factor. Hahnemann says such diseases are difficult to be managed.

The somatoform back pain disorders should be considered in the similar way as in any other chronic disease as far as case taking and treatment are considered. Though the person has physical symptoms, his mental symptoms are also given equal importance in homoeopathy. According to Hahnemann theses cases will not be improved by just friendly exhortations, consolatory arguments, serious representations and sensible advices as these will only aggravate the condition. The management is true like that of other chronic diseases.

In both, the somatoform back pain disorder and low back pain disorder, pain & functional disability are the characteristic features. Hence the assessment of pain & disability can be considered as important tools in the evaluation of treatment effectiveness of both these disorders. Somatoform back pain disorder as well as low back pain disorder show depression and anxiety as co-morbidity. These may be seen as triggering, aggravating or maintaining factor for the presenting
condition. These factors may also be seen aggravated with the aggravation of back pain. Hence an evaluation of these two factors, depression and anxiety, are considered important by the investigator for the effectiveness of treatment. As the chronic low back pain disorder is a disabling condition functionally and socially, general well being measure is also an important outcome measure to evaluate the effectiveness of treatment. In the low back pain of organic pathology a set of clinically validated check lists will help in validating the effectiveness of the treatment.

The ‘placebo effect’ can be described as a positive change seen after medical treatment --which is caused solely by the patient’s psychological response being given to the treatment (improvement occurs because the patient expects to get better). Placebo effects are associated with all medical interventions. Placebo-controlled trials – which directly compare an experimental treatment with an inactive ‘dummy’ treatment – have therefore become a routine part of medical research in order to discover whether new treatments have any ‘real’ clinical effects above and beyond placebo.
Placebo has become a burning issue in the pharmaceutical industry in recent years, as an increasing number of initially promising new drugs have had to be abandoned during development because they are found to be not more effective than placebo. The level of placebo effect can be surprisingly high and even bring accepted treatments into question.

Shang, 2005 claimed that Homoeopathic treatment was nothing but placebo. Results from numerous high quality randomised controlled trials (RCT) and several systematic reviews have shown that homeopathic medicines have a clinical effect above and beyond placebo. Homeopathic treatment will also have a placebo effect, but this should not be confused with its indirect effects such as the therapeutic effect of the homeopathic consultation.

Treatment by a homeopath gives patients the opportunity to explore their health problems thoroughly during one-to-one consultations with their practitioners. Some sceptics suggest that this process initiates a placebo effect responsible for much of the clinical results seen with homeopathic treatment, but a more accurate description would be that the homeopathic consultation has a ‘therapeutic effect’. If a patient treated by a psychologist improved, this would be correctly described
as a therapeutic effect of the treatment not a placebo effect. The homeopathic consultation is clearly different from a psychotherapy consultation, but it does appear to have a strong therapeutic effect of great value to patients. Homoeopaths strongly believe that the medicines heal not only the physical symptoms but also the psychological symptoms, as the system focuses on the mind-body dualism. For having a deeper scientific exploration the investigator has selected certain physical variables as well as psychological variables to be studied. The variables are pain & functional disability, anxiety, depression, wellbeing and physical signs related to low back pain. The investigator tries to explore the following through the present study.

1. The effect of homoeopathic medicines on patients with pathological low back pain and patients with somatoform low back pain.

2. The effect of placebo on patients with pathological low back pain and patients with somatoform low back pain.

3. The effect of homoeopathic remedies in combination with placebo on patients with pathological low back pain and patients with somatoform low back pain.
4. The effect of homoeopathic remedies, placebo, homoeopathic remedies in combination with placebo on anxiety, depression, well being and physical signs of patients with patients with pathological low back pain.

5. The effect of homoeopathic remedies, placebo, homoeopathic remedies in combination with placebo on anxiety, depression, well being and physical signs of patients with somatoform low back pain.

6. Relationship between pain & anxiety, pain & depression and pain & well being in patients with pathological low back pain and patients with somatoform low back pain.

For the purpose of study, low back pain was categorized into two- low back pain with positive physical signs (pathological low back pain) and low back pain without any recognizable physical signs (somatoform low back pain disorder). The two groups were again divided into three categories according to the type of intervention used – category I receiving homoeopathic medicines, category II receiving placebo and category III receiving homoeopathic medicines combined with placebo. Only chronic cases having at least 6 months of history were
selected for the study. The medicines were prescribed based on the homeopathic principles.

**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 remedies 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 should be made 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 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 hence reduce the personal, social, and economic impacts of low back pain. 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 centers seeking treatment. Homoeopathic treatment is found to provide relief to the pain reported by somatoform patients. A study to differentiate the effects of medicines and placebos on patients with pathological pain and 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 is any difference in the effect of homoeopathic medicines on pain & functional disability, anxiety, depression and well being between patients with pathological low back pain and patients with somatoform low back pain.
2. To study whether there is any difference in the effect of placebo on pain & functional disability, anxiety, depression and well being between patients with pathological low back pain and patients with somatoform low back pain.

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

4. To study whether there is any difference in the effect of homoeopathic medicines, placebo, homoeopathic medicines in combination with placebo on anxiety, depression, well being and physical signs among patients with pathological low back pain.

5. To study whether there is any difference in the effect homoeopathic medicines, placebo, and homoeopathic medicines in combination with placebo on anxiety, depression and well being among patients with somatoform low back pain.
6. To study the correlation between pain & anxiety, pain & depression and pain & well being among 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.