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Research Methodology in Naturopathy and Yoga

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Introduction:

My experience while doing M.D. in Physiology:

Most probably I was the first medical graduate to select a problem related with a yoga practice, “Kapalbhati” for M.D. thesis at the All India Institute of Medical Sciences during 1961-62 . Prof. A.S. Paintal was one of my guides.

During the course of my work, Prof. Paintal asked me the following questions:

- How the yoga teacher as well as the practitioner comes to know that Kapalbhati has taken place?
- How do you ensure that you are investigating the effects of Kapalbhati and not any other type of breathing such as voluntary hyperventilation, panting, tachypnoea etc.?

I was unable to answer his questions as I was educated in the modern medical science and I had no background of traditional yoga whatsoever. I enquired from the yoga teachers imparting training to students on whom I was conducting my work. They could not satisfy me on this subject.

Similar questions could be asked in respect of each and every yoga practice and technique selected for investigation, treatment etc.

This is just one example to highlight the need and importance of undertaking research in yoga and to develop suitable methodologies.

My experience in France:

During my seminars in France in 1971-72 many participants said that “they did not get any experiences mentioned in yoga books inspite of practicing yoga techniques for 8 to 10 years”.

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Therefore either (1) their practice was wrong, (2) they were taught wrongly and/or (3) the claims given in the yoga books were false.

Again, I was unable to answer their questions. But I got some guidelines to plan my research activities in yoga.

What did I learn from these experiences in respect of laboratory research in the field of yoga?

- Yoga is a Subjective Experiential Science.
- Therefore we should enquire about and get guided by the sensations, feelings and experiences of the individual during different yoga techniques and practices.
- The same terms indicate a concept, a technique or a practice, effect of the technique/practice and a resulting state of consciousness.
- Sanskrit terms require to be properly understood for a good practice.

Various Areas of Research:

1. Philosophico-Literary Research

- Critical Editions of Yoga Texts.
- Critical study of Yogic concepts and their interpretation and understanding in various technical languages and disciplines.
- Study of the Philosophical foundations of different schools and disciplines of Yoga.
- Interpretations of Yogic terms, concepts and techniques in the language of modern medical sciences.

2. Educational Research

- To highlight the important features of Yoga education.
- To study the effects and outcomes of these education programs.

3. Experimental Research

- To study the “Modus Operandi” of different Yoga techniques through suitable available laboratory procedures belonging to different scientific disciplines and otherwise.

4. Clinical and Applied Research

- To study the clinical and other kinds of applications of Yoga philosophy, concepts and techniques in suitable populations.
- To understand the therapeutic applications and importance of Yoga techniques on lines similar to any medical pharmacopia.
- To study the indications and contra-indications of various Yoga techniques.
- To develop suitable ways to establish Yogic diagnosis for therapeutic work.

5. Experiential Research

- To understand the nature of subjective experiences related with different groups of Yoga techniques and practices.
- To understand the logic of giving personal guidance for reaching higher states of consciousness in Yoga.

Need for Developing Research Methodology in Yoga:

- Western basic medical sciences dealing with human beings are Anatomy, Physiology, Biochemistry, Biophysics, Psychology, Psychiatry, Embryology, Genetics, Food, Diet and Nutrition etc.
- Most of these sciences are essentially Objective and Experimental in nature. They are used to develop various kinds of treatment protocols and therapies.
- Yogic sciences, on the other hand, are essentially Subjective and Experiential in nature. We can talk of Experiential Anatomy, Physiology, Psychology, Dietology etc. as found in different Yogic texts and traditions.
- One can not think of using highly objective modern investigative techniques to investigate, analyze and understand highly subjective Yogic approaches without making suitable modifications and changes.

Some examples for Laboratory studies:

1. There is a need to standardize Yoga techniques for research work.

- The same term indicates a concept, technique, effect and the resulting state of consciousness in Yoga. For example-Kapalbhati, Uddiyana, Asana, Pranayama, Pratyahara, Dharana, Dhyana, Meditation, etc.
- One must know and be able to highlight the particular aspect that is being studied for research.

2. Need to develop some kind of Yogic Pharmacopia for Yoga Therapy.
3. Need to differentiate between Yoga Treatment and Yoga Therapy.
4. Need to develop proper tools to establish “Diagnosis in Yogic Language” or “Yogic Diagnosis” for Yoga therapy.
5. Need to switch over from the well accepted “Double Blind Studies” used in modern medicine to “Double Cited Studies” in the field of Yoga.

Some examples for Literary studies:

- Differentiating between the terms Svasa (Breath) and Svasana (Breathing).
- Understanding the terms Svasa, Vayu, Pranashakti and Pranayama, Ghrana, Nasika, Nasanala, Surya-Chandra, Ida-Pingala, Savya-Daksha Nadis, Vayu marg and Prana Marg, Lotuses and Chakras.

Some examples for Experiential studies:

- Working with Vayus and Prana.

Need to develop “Working Definitions” of various yogic terms and concepts for research work :

Established methodology for research:

1. Review of Literature
 2. Recognizing the gaps in the existing knowledge and the need to know more
 3. Problem selection and problem definition
 4. Recognizing the tools, apparatuses and equipments required for work
 5. Setting-up of equipment, methods and techniques
 6. Standardization of materials and methods
 7. To work out the Experimental Design based on statistical methods
 8. Trial run and finalization of methods and materials
 9. Collection of data
 10. Analysis of data
 11. Conclusions
 12. Presentation of the results
 13. To indicate further lines of study and research
- In Yogic Research, do we standardize the techniques and methods?
 - What kind of Review of Literature is there? Of traditional Yogic texts or of the modern medical researches only?

Conclusion:

At present, medical world is more keen on doing clinical research in Yoga. This amounts to applied research in Yoga. There is a big scope for fundamental research in Yoga for which different methodology requires to be developed by Yoga experts in consultation with people from scientific side. We are lacking proper knowledge and understanding about the “modus operandi” of different Yoga techniques and concepts.



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Planning Holistic Health Research

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ABSTRACT

Research is a determined and disciplined activity aimed at answering questions. Research generally originates as a vague idea. To start with, the idea is narrowed down to a research problem. Once the problem has been identified, the next step is to formulate one or more clear questions amenable to a systematic attack by the existing tools of science. The questions are then elaborated into a project. Since research may need money, the project is then written up in the form of a research grant application. There are six basic points addressed in a research grant application. First, *why* is the proposed research necessary? This question is answered by reviewing existing knowledge, and bringing out the lacunae that still remain. Further justification may be provided by highlighting the academic or applied significance of filling up the lacunae. Second, *what* is it exactly that the investigator wants to do? This is usually given in the form of objectives of the project which should be concise, enumerated and prioritized. Third, *how* does the investigator propose to fulfill the objectives? This section outlines the experimental design, the inclusion and exclusion criteria of the subjects to be used, the minimum number of subjects to be studied, the end points selected, and the techniques to be used for measuring the end points. It is also desirable to name the statistical tools that will be used for evaluating the results. Fourth, *is the project important? It is not enough that the investigator wishes to study something that has not been studied earlier; what he wishes to study should also be important.* Fifth, the investigator has to answer *whether he can* carry out the project. This question has two aspects. First, the qualifications, training, experience, and preferably previous work, of the investigator should be appropriate to the proposed work. Secondly, the investigator should be working in an institution where the basic facilities and infrastructure required for the project are available. Sixth and last, the investigator has to tell *what he wants* from the funding agency to carry out the project. The budget should mention not only how much money the investigator wants, but also reasonable detail of how it will be used in terms of personnel, equipment and consumables, and the justification for each item asked for.

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Holistic health research has some special features which need attention while planning the project. One important category of such research is that which examines whether an intervention such as yoga or naturopathy really works. The ideal experimental design for testing the efficacy of an intervention is the randomized controlled trial (RCT). However, for an intervention like yoga, neither a suitable placebo can be designed, nor can the patient be 'blinded'. Therefore, generally the best control group is that on conventional treatment only, whereas the experimental group receives the conventional treatment as well as the test intervention. For ethical reasons, the test intervention should not be denied to the control group. Therefore, it is common to have a wait-listed control group. The end points should be carefully selected because in many cases, the conventional treatment may be quite effective. Therefore, it is also valuable if it can be demonstrated that the holistic test intervention can achieve similar efficacy with less side effects, less medication and at a lower cost.

Assuming that the project is carried out, and the holistic intervention is effective, two questions are often raised. First, which component of the intervention is responsible for its efficacy, and second, the mechanism by which the intervention works. Planning projects which answer these questions needs greater skill, and general guidelines are difficult to formulate.

Planning holistic health research using the methods of modern scientific medicine is riddled with unique problems and pitfalls. But for these very reasons, good quality research in holistic health systems is more challenging, and in view of the satisfaction it brings to the investigator and the benefit it brings to mankind, it is worth taking up the challenge.

Research is a determined and disciplined activity aimed at answering questions. All questions do not lead to research; in fact the fate of most questions is to get consigned to oblivion. It is only when the question occurs to the right person at the right time under the right circumstances, and the person puts in the necessary time and effort, that we get a piece of research. Much of research today is systematic research in the sense that it involves a uniform sequence of steps. Here we shall first briefly outline the steps involved in planning research, and then discuss a few issues specially relevant to holistic research.

IDEA

Every piece of research is born as an idea. The idea may occur as an intuitive flash, or may emanate logically from a previous study. The intuitive flash may occur

in bed or in the bathroom, or while reading a book. The idea on which a research study is based is of capital importance because the impact of the study depends on the quality of the idea behind it. Since research is time-consuming, and the time required for working on a poor idea is just as much as that required for working on a good idea, it is extremely important to select the idea with great care. The tragedy of life is that the best of ideas do not occur when needed the most. The way to solve this problem is to store ideas for opportune moments. All good research workers collect ideas the way children collect stamps or coins. Whether you are actually engaged in research, or intend getting into it later in life, it is a good idea to keep a paper and pen handy all the time, and jot down the idea as soon as it occurs. It is futile to depend on memory: in spite of best intentions most ideas are lost unless recorded immediately. Just as important as recording ideas is to build up a system for storing them. Otherwise, instead of the ideas getting lost, the scraps of paper on which they have been noted will get lost! The old fashioned way of storing ideas is to use either index cards or a file; now there are electronic options available. But seeing the frequency with which accidents wipe out stuff stored electronically, there is still something to be said for the old fashioned storage systems. At the first available opportunity, transfer the idea from the scrap of paper to an index card or an A4 sheet (only one idea per card or sheet). Elaborate upon the idea a bit as you copy it, and add the card or sheet to your collection. You may also add the date to the idea: it may give you some nostalgic pleasure when you flip through several virgin ideas a quarter century later.

Let us assume that the great day has finally arrived when you have an opportunity for research, and you have taken out your collection of ideas to select one gem. As you go through your collection, you may find that many of your own ideas do not appeal to you any more for one reason or the other. Among the ideas which deserve a second look, some may be fascinating but impractical; some others may be feasible but you may not have the facilities to pursue them. Finally, you may be left with very few ideas worth considering in your present circumstances. To narrow down your choice further, search the literature for work already available on the idea. This search has been made very easy by the internet. You should consider yourself lucky if nobody has done anything *similar to* what you have in mind. At the same time, it is quite likely that nobody has done *exactly* what you have in mind. After considering how significant your study would be in view of the work already available, select one or two most promising ideas. Now discuss these ideas with a few friendly colleagues. This process would further help you make a good choice, and will also sharpen the focus of your ideas. Now that you have selected your idea, it will have to be followed up with a lot of work. Without that work, the idea will just remain an idea; it will never get translated into a real study. Do not wait endlessly for

that dream idea which is sure to change the world. While selecting a good idea is important, waiting indefinitely for the best idea to arrive is unwise: one can spend the whole life rejecting one idea after another in the hope of getting the perfect idea one fine day.

THE PROBLEM

Once the idea has been selected, the next step is to identify the problem. Searching the literature has already revealed areas of ignorance, commonly called the lacunae. Based on the lacunae, the problem may belong to one out of three broad categories. *First*, it may be an area of total ignorance. Nobody did anything on the subject ever before. Here is an opportunity to be a pioneer, and fortunately such problems still exist in the area of holistic health. *Second*, it may be an area of controversy. Although there are several studies available on the subject, their results are conflicting. Now you can dream of designing that decisive study which will resolve the issue once and for all. However, do not be disappointed if your study succeeds in only adding to the controversy. *Third*, the literature search might open up an ocean of knowledge. However, you will find that for each question that has been answered by the studies available, several new questions have been raised. In short, in spite of all what is known, there is scope for more studies which would extend the limits of knowledge. Most of the problems tackled by research today fall in this category.

THE QUESTIONS

Once the problem has been identified, the next step is to formulate one or more clear questions which the research will seek to answer. Let us assume the problem belongs to the third category, i.e. there is scope for extending existing studies. Although a variety of extensions in different directions may be desirable, we have to choose the direction which is relevant, exciting, and feasible in terms of available expertise and facilities. Depending on the direction selected, a few clear questions should now be formulated. The questions are then elaborated into a project. Since research may need money, the project is then written up in the form of a research grant application.

THE RESEARCH GRANT APPLICATION

Every funding agency has a prescribed format in which the application has to be made. Irrespective of the format, every research grant application asks six basic questions. The first three questions are the why, what and how of the project. These are questions which one should answer while planning any research even if no grant is required. The next three questions ask whether the project is important, whether

the investigator will be able to do the research, and what the investigator wants for doing the research. Now we shall discuss these six questions one by one.

Why?

In order to spell out why an investigator wants to do something, he should give the present state of knowledge as well as ignorance regarding the topic. This section is important, but the commonest pitfall here is that most applicants make the *review of literature* very long. The aim of the literature survey in a research grant application is not to educate the referee: the aim is only to bring out the rationale for the proposed research. Therefore, the review should begin very close to the point where the known meets the unknown so that the write-up can quickly reach the limits of what is known, and hence the need for further exploration. If the proposed research is an extension of previous work done by the applicant, the previous studies could be the starting point. However, enough of related work by other investigators should also be cited in order to place the work in a broader context. Then the review should quickly move to the work being proposed, and point out that such work has not been attempted by other investigators in the field, and that the work is important. In some research projects, the work may not be directed at finding out something unknown but rather at resolving a controversy. In that case both sides of the controversy should be briefly stated with adequate references, and a clear need for resolving the controversy.

Bringing out the lacuna which has prompted the research proposal is so important that it may be summarized under the subheading 'rationale of the study' at the end of the review of literature, even if the format of the funding agency does not include such a subheading. In addition, the lacuna(e) also invariably get woven into the 'objectives of the project', and must also form the first one or two sentences of the 'summary of the project'.

What?

This section tells the reader exactly what the investigator proposes to do. Although brief, this section is of vital importance. It should be clear, concise and realistic. The backbone of this section are the *aims and objectives* of the project, which should be enumerated and prioritized.

How?

This is the *methods* section of the project and describes how the project will be carried out. This section has, broadly speaking, four parts. The first part gives details of the subjects to be used and the sample size. The second part gives the experimental

design, including the outcome measures. This is a crucial part, which should receive the maximum possible thought and attention. The design should be that which is most appropriate for the project under consideration. A statistician should be consulted, and the issue discussed with colleagues to arrive at the best design. These two parts of the 'methods' are always read carefully by the reviewers, and are strong determinants of the decision regarding funding of the project. The next two parts should also be written in detail, although they may be only glanced through rather than read. The paradox is that if they have been given in detail, they are not read; but if they are sketchy, the defect is pointed out and may become one of the reasons for rejection! This paradox is particularly true of the third part which deals with the techniques that will be used for making the measurements. These may run into several pages, and the reviewer does not gain much by reading them, but it is only by their presence in the project that the reviewer knows that the investigator knows the techniques (hopefully!). The fourth part deals with the statistical methods and software that will be used for analysis of data. A statistician must be consulted for writing this part too. Advances in statistics have made this part beyond the competence of most scientists to handle entirely on their own.

Is it important?

It is not enough that the investigator wishes to study something that has not been studied earlier; what he wishes to study should also be important. This question has several aspects. First is the likely outcome of the project scientifically important, i.e. does it have academic merit? In other words, will the new information gained from the project add something significant to the existing scientific knowledge on the subject? Secondly, in medical research, it is desirable to know whether the project is clinically important? Is the outcome of the project likely to influence clinical practice? Will it help prevent a disease? Will it provide a new diagnostic tool? Will it provide or validate a new modality of treatment? In short, is the outcome of the project likely to find application in scientific medicine? Thirdly, is the project relevant to national problems? In developing countries, it is considered especially important that the limited resources available should be spent preferably on solving local problems. Finally, does the subject fit into the priority areas earmarked by the funding agency for support? The funding agencies frequently identify a few areas for preferential support: the selection consists of problems perceived by a group of top scientists to be pressing for urgent solution.

While writing the section on importance of the project, calculated optimism and a little exaggeration are quite an accepted norm. Having said that, it is important to realize that hardly any project would be important from every angle. Therefore,

even the section on importance of the project should be basically honest. There is no need to bend over backwards to justify the project as scientifically significant, clinically important as well as nationally relevant.

Can he do it?

The project may be good, but the funding agency also wants to judge, as far as possible, whether the investigator will be able to deliver the goods. This question has two aspects. *First*, does the investigator have the necessary expertise and training for carrying out the project? This can be assessed from the biodata of the investigator, which is generally one of the items asked as a part of the application. It is not essential that the principal investigator should be an expert in all the techniques to be used for the research. Nobody knows everything. That is one reason why there are co-investigators. If all the investigators put together can do everything required, that is quite enough. *Second*, does the institution where the work will be done have the necessary facilities? The investigator may have the expertise, but if he does not have the equipment available, he will still be unable to do the research. The funding agencies generally do not give money for all the equipment required for the project. If most of the equipment is already available with the investigators, one or two missing pieces may be sanctioned for the project under consideration. The research grant application generally includes an item on 'facilities available'. Under this heading one should describe the space, equipment, patients, healthy subjects etc. to which the investigators have easy access.

What does he want?

This question is answered in the section customarily called the 'Budget'. The budget generally has four or five parts. The first item usually asks for the personnel to be employed in the project, and the expenditure likely to be incurred on them. In order to arrive at a good estimate, it is important to find out the latest scales of emolument for different categories of research staff. The next item of the budget consists of the equipment required from the research grant. The next item lists the glassware and chemicals ('consumables') required for the project and their cost. Some agencies might ask for the foreign exchange component (FEC) in the expenditure on equipment or consumables. Next, one may list miscellaneous items not covered under the previous heads, such as the expenditure on books, journals, stationery, software, photocopying, postage, transport and travel. Travel generally refers to the journeys that might be made to present the results of the research at professional meetings.

Finally, the budget also includes justification for the personnel and equipment, and also for other major items included in the budget.

Money is not the only resource a research worker needs: he also needs time. That is why funding agencies also ask for the duration of the project and sometimes also for a 'timeline' or Programme Evaluation and Review Technique (PERT) chart. This should be realistic: work generally takes longer than expected. Getting staff, equipment and chemicals may take a lot of time even if money is available. One should commit to only what can be actually done in the duration of the project (usually 3 years or less): there is no penalty for doing more than what one is committed to do. Sometimes projects received by funding agencies promise in 3 years work that might take a lifetime to complete. On the other hand, some projects promise very little work (e.g. a simple study on 20 patients having a common disease) and ask 3 years for it. Then the funding agency might increase the sample size and reduce the duration.

SPECIAL CONSIDERATIONS FOR HOLISTIC HEALTH RESEARCH

Holistic health research has some special features which need attention while planning the project. One important category of such research is that which examines whether an intervention such as Yoga or Naturopathy really works. The ideal experimental design for testing the efficacy of an intervention is the randomized controlled trial (RCT). However, conducting an RCT on the efficacy of Yoga poses some unique problems which have been discussed here.

Problems and limitations in conducting an RCT on Yoga

The first problem is to decide on the treatment that should be given to the control group. It is unethical to give no treatment at all to the control group because some conventional treatment is generally available for the disease for which the efficacy of yoga is being tested. For the same reason, the control group can not be given only a placebo. Moreover, it is virtually impossible to design a placebo for yoga practices. Therefore, the control is generally given the conventional treatment.

The second issue to be considered is what treatment should be given to the experimental group. For ethical reasons, even the experimental group can not be denied conventional treatment. Therefore, the experimental group receives not only yoga but also the conventional treatment.

A good RCT is usually double-blind. In an RCT on yoga, the investigators may be 'blinded' but it is impossible to 'blind' the patients. If a patient participates in a trial on the efficacy of yoga, he generally expects lessons on yoga. Therefore, even the control group can not be denied yoga; moreover, it would be unethical to do so. Therefore, the control group is only a wait-listed control. After the study is over, all willing participants in the control group are also taught yoga.

Finally, there should ideally be also a third group (an additional control group) which receives the conventional treatment plus a substitute for yogic practices as given in Table 1. But this group is generally omitted because it is extremely difficult to retain control patients for the entire study period in a study on yoga.

Table 1. Controls for yogic techniques

<i>Yogic techniques</i>	<i>Control</i>
Asanas	Aerobic exercise
Meditation	Sitting quietly with the eyes closed, or simply 'relaxing'
Pranayama	Slow and deep breathing

Designing an RCT on the efficacy of yoga

In view of the above discussion, a feasible and satisfactory design for an RCT on the efficacy of yoga is as follows.

After a lead-in period of one or two weeks, the volunteers who satisfy the inclusion criteria are divided randomly into two groups. The baseline parameters are recorded for both groups. The control group is put on conventional treatment. The experimental group is also put on conventional treatment but receives, in addition, training in yoga. The duration of treatment is variable, but generally varies from 2-12 weeks. When it is longer than 2 weeks, it may consist of supervised yoga training for 2 weeks followed by continuation of yoga at home for the remaining duration of the treatment. At the end of the period of treatment, the parameters are recorded again. Then, the control group is given training in yoga, except for those members of the group who do not want it.

Training in Yoga

Ideally, yoga is a 24 hour activity. It consists of a few hours of yogic practices which keep a person physically fit, mentally alert, emotionally stable and spiritually oriented. The remaining part of the day is spent in giving a new colour and motive to everyday

activities. At the other extreme, training in yoga may consist of a few yogic practices which the subjects practice mechanically. A compromise between the two is to teach the patients not only a wide variety of techniques such as asanas, pranayamas, kriyas and meditation, but also to give them a few talks on the philosophy of yoga, the place of yoga in daily life, the application of yoga in stress management, and to involve them in a few sessions of devotional music and socially useful work. Apart from giving the participants a truer picture of yoga, this type of comprehensive approach to yoga also gives better results because it takes into account the totality of man. Man consists of not just the body which breathes, but also the mind, intellect, and his divine essence (often called the soul). All these components or layers of man (the *panchakoshas*, in yogic terminology) are interrelated. Acting on anyone layer influences the other layers. An integrated and comprehensive training in yoga has various components which affect predominantly one or the other layer. For example, asanas and kriyas affect predominantly the body, pranayamas act as a bridge between the body and the mind, meditation and devotional music affect the mind, and lectures act at the level of the intellect. The whole package put together along with the socially useful work creates an opening towards the divine essence. Administering such an integrated package is not unpractical: it is being done at Swami Vivekananda Kendra (Prashanti Kuteeram), near Bangalore, as well as at the All India Institute of Medical Sciences, New Delhi, in the form of structured 2-week courses (Nagarathna & Nagendra 2004, Bijlani 2004).

End-points

The end-points should be carefully selected because the conventional treatment may be quite effective: nothing can bring down the blood glucose of a diabetic as predictably and dramatically as insulin. Therefore, in addition to efficacy *per se*, the end-points may also include the side-effects of treatment, subjective well-being, change in anxiety or stress levels, the variety and dose of medication required, effect on sequelae of the disease (e.g. complications of diabetes), effect on the basic pathology (e.g. degree of stenosis of coronary arteries), the cost of treatment, and the acceptability of treatment. Thus a holistic treatment like yoga may be considered better than the conventional treatment if it can achieve similar efficacy with less side effects, less medication, and at a lower cost.

Questions raised by an RCT on Yoga

Assuming that an RCT demonstrates clearly the efficacy of yoga, two questions are often raised: first, which component of the intervention is primarily responsible for its efficacy; and second, the mechanism by which the intervention works. The first

question is somewhat inappropriate because different components of a holistic treatment act synergistically. Each component may contribute to the effect of the treatment, but the effect of all the components may be greater than the arithmetic sum of their individual contributions. Part of the effect may come from the pleasant surroundings or smiling faces of the therapists, and may be considered a placebo effect. But from the practical standpoint, that does not matter. There is no harm if some therapeutic benefit can be obtained from such simple, harmless interventions, the side effects of which are also all desirable (e.g. reduction in anxiety, or growth of love and compassion).

The second question is of great academic interest. The general mechanisms are in terms of restoration of a healthy autonomic balance, and immunoenhancement through the psychoneuroimmune axis. But there may be other general mechanisms yet to be discovered. Further, there may also be some mechanisms specific to the disease in question (e.g. upregulation of insulin receptors in diabetes). These questions are very interesting and exciting, but general guidelines for experimental protocols designed to answer them are difficult to formulate. These questions invariably take us towards basic studies on physiological effects of yoga.

CLOSING THOUGHTS

Planning holistic health research using the methods of modern scientific medicine is riddled with unique problems and pitfalls. But for these very reasons, good quality research in holistic health systems is more challenging, and in view of the satisfaction it brings to the investigator and the benefit it brings to mankind, it is worth taking up the challenge.

References

1. Bijlani RL. Body-mind medicine in action: the Integral Health Clinic of All India Institute of Medical Sciences. *New Approaches to Medicine and Health (NAMA)* 2004; 12(2):37-48.
2. Nagarathna R, Nagendra HR. *Integrated Approach of Yoga Therapy for Positive Health*. Bangalore: Swami Vivekananda Yoga Prakashana, 2nd Edition, 2004.



3

Project Preparation for Clinical Research

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Continuing Research is an essential component of the development of organization and country. It is the basic requirement to achieve the progress and to quench the thirst of the ever increasing problems of mankind. The research is conducted by an individual or by a group of individual.

The research is serious activity and requires absolute dedication. The research requires sincere and planned efforts to increase knowledge of natural phenomena. The research provides the solution of problems in all spheres of human life. Research method is often an active, diligent, and systematic investigation process. The research involves observing, finding, analyzing and interpreting. This exercise of investigation produces a greater understanding of events, behaviors, or theories, and makes practical applications through laws and theories.

For the sake of convenience, the research can be divided into two types: basic and applied research.

Basic Research

Basic research aims mainly at increasing the understanding of a subject, a phenomenon or a process in a much detailed manner. It tries to answer “who, why, when and how” part of question in depth and have as its primary objective as the advancement of knowledge and the theoretical understanding of the relations among variables. The terms “basic” or “fundamental” indicate that, through theory generation, basic research provides the foundation for further, sometimes applied research. In basic research there may not be short term or immediate gain which will have value in current situation; probably therefore, researchers often find it difficult to obtain funding for basic research.

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Applied Research

Applied research is done to solve specific, practical questions; its primary aim is not to gain knowledge for its own sake. It tries to answer “ what and how” part of question in depth. It can be *exploratory*, but is usually *descriptive*. It is almost always done on the basis of basic research. Applied research can be carried out by academic or industrial institutions. Often, an academic institution such as a university will have a specific applied research program funded by an industrial partner interested in that program.

Many a times there can be a research proposal which involves both of the above aspects of research. Thus, the clinical research can be both the basic and applied type.

What is status of research requirement in our country?

As stated above, the research in any country is absolutely essential for the development of the country. It requires methodical documentation of the national needs and proper guiding forces to conduct research. The research may also be focused on purely basic issues, however in developing countries it was largely believed that the research should be directed to the needs of the country. In other terms it should be application oriented. Thus it's important for government to provide guidelines for the research in terms of well defined thrust areas and adequate funds allocated for the cause. While various funding agencies under Govt. of India have formulated policies for promoting the research, it becomes the duty of the researchers in Academia to properly utilize such opportunities.

Requirements of conducting research

The first step to move in the scientific research is to formulate a good research proposal for submission to the funding agency. Good research proposal is a guide for others as an example of ideal way to do research and also many outcomes, like a new technique, can serve a stimulus for future research. A research proposal make it possible for us to provide scientific manpower training which will increase further chance of propagating the research activities. The ultimate outcome of any good research proposal is its outcome in terms of enrichment of scientific development and having the indigenous technologies.

Thus for the cause of developing of academics, each one of us should write good research proposals and submit them to the appropriate funding agency. The quality

of your research proposal is determined by both the method of presentation and the significance of idea.

How to write a good research proposal?

Following brief description may help you to prepare a research proposal.

Requirements for a research proposal:

1. A specific title
2. A precise summary/abstract
3. A proper introduction
4. A comprehensive Literature Review/background
5. Clearly written objectives
6. Detailed methodology conforming to scientific principle
7. If required by funding agency : Expected Results and Discussion
8. Information about facilities available in your centre/organization
9. A practical justification for the equipment/supplies/other cost
10. A Realistic budget proposal

How to write a specific title?

The title is single line representation of your project proposal. The title should briefly represent the project. It should be free from verbosity. The title should indicate the functional relationship describing “what is being studied with what”. Such title will tell about independent (intervention or treatment) and dependent variables (on patients’ response in terms of physiology or clinical advantage). The title should be clear and unambiguous. The title should not be too catchy or flowery. It should be an exact scientific statement. Be careful to select words for your title. Place the most important words should first, then the less important words.

If it is difficult to make title then I find it useful to generate 4-5 titles and then weighing the merit and selecting the most appropriate one. A good title reflects the exact focus of your proposal. At times an independent view is very valuable.

If the funding agency requires title in a particular given form, then it should be done so. It is good style to put the title on cover page and also include designation of chief investigator, phone numbers, email id(s), and website address of the organization. The proposal should include one or two collaborators, their details should be included

on the first page. The cover should give a look of professional touch. You should chose simple colors (avoid gaudy/jazzy colors). Avoid wasting too much time using costly covers, expensive binding. Here simple presentation appeals best.

How to write precise summary/abstract?

A lot of success of project approval depends on good summary. You can understand the constraints of the reviewer(s), who is invariably a senior and busy person. You can leave best impression by introducing him by giving the best piece of the proposal. By good summary you can form a strong impression in the mind of the reviewer.

The summary should be brief, of approximately the word length mentioned in the guidelines of the funding agency. If the word limit is not mentioned then any thing between 250 to 350 words should be sufficient. The best abstract are those which are subtitled the subtitles could be:

1. One or two statements on background of research idea.
2. The relevance /the research question/hypothesis (if any).
3. The plan/the method (include the design, procedures, the sample size, instruments and place of study).
4. Expected outcome(s).
5. Expected application of the research.

The best time to prepare the summary is after completion the entire proposal. The summary should be last thing to be written.

Common problems associated with the summary are:

1. Lack of justification.
2. Use of vague ideas.
3. Uncertain projected expectations.
4. Inappropriate size.

How to write a proper Introduction?

This is the main body where you introduce the problem in detail and bridge to latest knowledge and finally justify your rationale. The important goal of the introduction is to provide the necessary background or context for the research problem. The proposal should be presented in the context of a absolutely focused. If proper steps are followed then the significance will be clear.

In introduction you should write previous research findings (others and/or self) pertinent to this proposal, national perspectives, write down your rationale, justify you rationale, and write down expected outcomes (real not inflated). Here is opportunity to let the funding agency know that you are aware of the preceding work and you can justify the proposal. You should be extremely careful in your use of language. At times a friend, outside of your area of expertise may give valuable suggestions. You should avoid the use of abbreviations, colloquial phrases, redundant phrases and vague language. All these make the proposal confusing. You may require revising the proposal several times (5-6 times) before you submit it.

You should justify as why the proposed project is certainly needed in the country and should be funded. Include relevant references. Justify why your centre/ hospital/ organization is uniquely suited to conduct this piece of research. (Availability of certain type of patients/facilities availability/geographic advantage/earlier involvements in similar research). In simple terms everything should be justifiable.

You get an edge over others if you have already done some pilot work or you are already engaged in the same line of work for some time (after getting ethical clearance from your own institute). If not, you have already taken some small steps to begin your project. An excellent small step that you can do prior to requesting funding is to assess the need for doing this research (i.e. survey, interviews, analysis of existing problem/data etc.).

You should try to present your research question in the context of either a current “hot” area, or an older area that is still viable. Secondly, you need to provide a brief but appropriate historical review. Thirdly, provide the contemporary context in which your proposed research question occupies the central stage. Finally, identify important key publications and refer to the most relevant and representative publications. In short, try to present your research question in broad background and at the same time bring focus out its significance pointedly.

The introduction typically begins with a general statement of the problem area, with a focus on a specific research problem, to be followed by the rational or justification for the proposed study.

Thus, the introduction generally covers the following elements:

1. Describe the context for research in question. This should show the necessity and importance of conducting the research.

2. Define the research problem, or the purpose of the study.
3. Describe the rationale of the study and clearly indicate why it should be done. Mention the hypothesis (if any). The hypothesis is a statement which may in all good probability predicts the outcome or explains the mechanism.
4. In short describe the main issues and sub-problems to be addressed by your research.
5. State and clearly define the independent and dependent variables of your study as defined before.
6. State and clearly define the dependent and dependent variables of your study as defined before.

How to write Literature Review/background?

At times the background material or the review of literature is written in the introduction section itself. If the guidelines insist on a separate section, then the two should be justifiably separated.

The literature review should include:

1. Describe the knowledge of the background research.
2. Critically evaluate relevant information available in the Literature.
3. Make sincere attempt to integrate and corroborate the existing literature with the research in question.
4. Prove that the proposed research will make a significant and substantial contribution to the advancement of the field of research. This may be new finding, complementary finding(s) to solve bigger issue, resolving an important theoretical issue or provide a link to a missing information.
5. Adequate and properly written bibliography (the reference should be written in a standard format).

Some commonly observed drawbacks are:

1. Lots of repetitions and verbosity.
2. Failing to cite recent research developments in the area.
3. Failing to justify the cited research work.
4. Failing to cite important research findings/ papers carried by local researchers.
5. Inclusion of useless citations.
6. Poorly written bibliography.

It is also observed that the style lacks structure, coherence, continuity and clarity of the thought.

It is advisable to use subheadings to bring structure in the review of literature. This will bring coherence to the review in question. The simple formula I follow is to write the review as if you are narrating story to people of mediocre intelligence. To make effective the story should be told in an exciting and stimulating manner. This will ensure inclusion of necessary details and avoid bringing unnecessary details automatically.

How to write clear Objectives?

This portion is heart of the project. This should be written very carefully.

Objectives are measurable entities and they tell specific things which will be accomplished in your project. The objectives form the basis for the activities of the project and also serve as the basis for the evaluation of your project.

Avoid mentioning the abstract ideas in the objectives. The success of the funding of your proposal depends on how funding organization perceives your objectives. You should clearly outline the outcomes. If you write your objectives in measurable ways, there are chances that the project will seek approval.

How to write methods?

Proper documentation of methods is important because it describes the way the research problem will be solved. It should include the work plan and describe the activities needed for the smooth running of your project and taking its final concluding stage.

The Method section should include sufficient and necessary description of what all will be done.

The Methods should describe design (its justification), number and selection of subjects (volunteers or participants), selection and rejection criteria, what will be done (the plan to carry out your study, activities which will be involved, and the duration of the study). Use of a diagrammatic representation of the study plan makes presentation effective.

You should briefly describe the equipment/instruments. Their reliability and validity should be mentioned.

It is a common error to forget to mention the role of collaborators. The best way to justify the role of collaboration is to describe their contribution in the methods. Justify how the methods used by you will be able to fulfill the objectives laid by you. You may use a table to justify the same.

If possible one should obtain ethical clearance from your own institute. This helps the reviewer to take quick decision.

What about the results?

The research proposal does not have results section. If at all, this heading may be used to give little idea about expected results, data structure, statistical procedures to be followed, and how this result will meet objectives.

What about Discussion?

At times the discussion is not required. If it is written than it is important to write convincing statements about the potential impact of the proposed research. This should reflect a sense of enthusiasm and confidence. This should be done without exaggerating the merits of proposal. It is good idea to mention the limitations and weaknesses of the proposed research.

How to write about facilities available in your centre/organization?

Several funding agencies provide a readymade table to describe the facilities available and to be utilized in the research proposal in the question. Even if this is not provided it is good idea to give a brief description of the facilities that will be used for the project.

How to write justification for the equipment/supplies/other cost?

Writing this is time consuming exercise and at times very demanding. You should be extremely careful in making a list the equipment that will be needed for your project. Several funding agencies are usually much more willing to provide funds for the support of manpower than they are to support the purchase of equipment. You should check this thing before you write project. It will help if you do some background search on the actual cost of the equipment you specify. Visiting

laboratories and searching internet is very useful. One should avoid guessing and approximation.

It requires lot of thinking to calculate the cost of supplies. It is easy to overlook many of the lab and office supplies that will be needed for your project. The best way is to create a long list and then to reduce it justifiably. Eatable are usually not included in the proposal. These are personal (not project) expenses.

If permissible, you may consider including in your proposal additional funds for organizing some form of workshop/symposium to promote the cause of science in which both you and the funding agency are interested in. Some organization support travel cost for attending scientific meetings/conferences/workshops.

How to make a realistic budget proposal?

You should carefully plan exactly what you will require from the funding agency to carry out the project and establish your budget around this amount. You must always remember that it is public money and all funding agencies receive lots of research proposals for funding. There is always a tough competition. The reviewers are really experts (they have already completed several projects themselves) and for them it is easy to detect when someone has inflated a budget in order to procure funds for other purposes. Avoid such situation and entering your name in the list of at times untold “debarred ones”. Request someone else to review your budget to see how realistic you are. If you write a realistic budget, the very fact increases your chances of approval not only this time but also next time automatically.

Several funding agencies have pre-defined categories for funding, use these guidelines. Normal categories are manpower or personnel (salaries), equipment, supplies, travel, contingencies, institutional overheads (costs that your organization requires that you include), and unexpected expenditures. You must obtain these guidelines before your plan your budget.

Some common errors and mistakes in writing Proposal:

1. Project based on old idea.
2. No provision of proper context to justify the research.
3. Incomplete review of literature. Undermining contributions by our own researchers.
4. Losing focus on the research question.

5. Failure to provide a coherent and persuasive argument for the proposed research.
6. Not focusing major issues.
7. Too much repetitions.
8. Too long or too short project write up.
9. Not conforming to the confirmed guidelines of the funding agency.
10. Inflated budget.

Usual causes of rejection: poor presentation or because of worthless idea.

A research proposal should be written in proper scientific manner and presented in way so that one should be able to convey to the funding agency the research idea as well as your preparedness to do the scientific research. Thus you should present your project clearly, concisely, with adequate and necessary information. The contents of the project should be coherent and must present the research idea forcefully. It is important to visit the funding agency personally and gather information about priorities and guidelines of the particular agency. Currently most of the funding agencies are maintaining websites, making things lot more easier. You should be religiously sticking to guidelines if there are any.



4

Bioethics

Dr. Nalin Mehta*

The presentation covers:

- a) Ethics of clinical trials involving Yoga & Naturopathy as intervention modalities
- b) Bioethics in Yoga & Naturopathy practice
- c) Priority setting in Yoga & Naturopathy
- d) Grant proposals: the essential aspects

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this standard provides public assurance that rights, safety and well-being of trial subjects are protected and consistent with the principles that have their origin in the declaration of Helsinki, and that the clinical trial data are credible.

These involve the responsibilities of researchers, institutions, institutional ethics committees and the sponsors towards carrying out scientifically valid and ethically sound research/trial to ensure that the research subjects are exposed to minimal identifiable risk. Also, there are a host of criteria that should be met by the parties mentioned above to ascertain their competence, accountability, capability and maintenance of confidentiality regarding the research subject's data and personal information.

In the context of Yoga and Naturopathy, globally accepted as alternative systems of medicine, it is very important to have a set of guidelines governing both clinical practice and research, including clinical trials.

While conventional western or modern medicine and health care is still thought by many to be the primary option for treating an illness, particularly in the developed world, many people throughout the world seek alternative medical solutions to their physical ailments. In fact, alternative medicine is slowly becoming a widely accepted

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form of health care. Much of this acceptance has been prompted by a worldwide crisis in terms of quality health care, a crisis that has taken hold of the developed as well as the Third World and developing nations. Prohibitively expensive conventional medical care has prompted many people to seek alternative means to cure their ailments. Often times, this decision is motivated by more than a lack of health insurance or resources. People suffering from chronic conditions or life-threatening diseases will often seek out alternative treatment when they have exhausted all the possibilities that conventional care has to offer and have found those possibilities to be inadequate.

What is interesting about the growing acceptance of alternative medicine is that practices now deemed “alternative” were for thousands of years considered standard medical practices. However, as world population continues to expand and health care concerns grow, it is likely that alternative treatments will continue to expand in popularity and acceptance by lay (non-medical) persons and medical professionals alike.

Yoga and Naturopathy are traditional Indian systems of medicine and have established health and longevity benefits. They are slowly becoming popular in the western world as well. Lack of specific ethical guidelines for the practice and research involving these traditional systems of medicine, however, have rendered them ‘unscientific’ in the eyes of the scientific fraternity. Efforts are afoot to establish their place as an alternative to modern western medicine but a lot needs to be done before this can be achieved.

Priority setting, also known as rationing, in health care is inevitable. In market based systems, the rationing of access to care is based on the people’s ability to pay for healthcare. In regulated healthcare systems, the responsibility of rationing or priority setting is shared by politicians, policy makers, administrators and healthcare providers. Traditionally the decisions regarding the provision of access to healthcare and specific therapies were made by the doctors. In the face of rising patient expectations, awareness and resource constraints, however, most nations have resorted to address this challenge by setting up committees of experts to deal with Priority setting in healthcare delivery systems to ensure adequate, equitable, need based and easily accessible healthcare.

Yoga and Naturopathy are very cost-effective, easy to administer, acceptable and absolutely safe practices which can benefit vast numbers, especially the economically underprivileged, who may not be able to afford expensive allopathic medicine. The popularization of traditional systems of medicine in a country like ours would be a

boon from the health status and health economics point of view. In this context, from purely a Priority setting angle, it is obvious that Yoga and Naturopathy can actually provide a very valid and tangible answer to the health woes of India, a nation with a huge population burden and limited resources.

As systems of Medicine, Yoga and Naturopathy require a set of Ethical guidelines to ensure that they are practiced by certified, qualified and trained experts and not used to misguide, even though unintentionally, patients. Only the professionally qualified expert can actually ascertain whether a patient is physically capable and mentally prepared to undertake Yoga and Naturopathy. Lack of supervision on masses undergoing treatment, have increased possibilities of injuries, adverse fallouts, morbidity and mortality. Guidelines will also ensure that these practices are performed properly, under supervision of professionals where accountability and institutional responsibility exists and records are scrupulously maintained.

Today, research proposals involving traditional Indian Systems of Medicine are being entertained for funding by a host of National and International agencies. It is imperative that scientists, practitioners and healthcare professionals involved in the study of Yoga and Naturopathy (and other traditional systems) understand the process of 'grant writing' to avail of these opportunities. The essential components of the grant proposals are based on processes that provide scientific validity and principles of bioethics and they shall be elaborated upon.



5

Ethical Issues in Clinical trials

Dr. Nandini K. Kumar*

*A solitary Orchid, stands, adorning the side of a mountain,
perfumes the air even in the absence of appreciation
A true scholar, learned in morality and philosophy,
is always a gentleman, even in the absence of wealth.*

Confucius 500 BC

India has a rich heritage of tradition, custom, culture and philosophy handed down from Vedic ages. The Hindu philosophy originated from the *Vedas* much earlier to the Western one which was shaped by the Greeks and interestingly there were many similarities between the Greek and Hindu thoughts. The ethical principles involving health care was traditionally handed down as our heritage from Vedic times through ancient scriptures, namely *Athrava Veda* and *Caraka Samhita*, *Susruta Samhita*, *Ashtanga Hridaya* and so on through our traditional systems of Medicine like *Ayurveda*. However, these pertained to practice termed today as clinical ethics.

Ethics is a generic term referring to the moral code of conduct which is correct behaviour dictated internally by one's own moral integrity which comes from within and is related to the culture and approved customs of a society. Later in life the rules, which control our social behaviour, could be general in nature or special pertaining to aspects or some sects of society. However these are only guidelines, which are not enforceable. Correct behaviour, which is governed externally through law is enforced by the State which does so for the general good of that society.

Why do we need ethical guidelines for research on human participants?

There are evidences shown historically and in modern times that ethical guidelines should be implemented to protect the participants involved in research. As mentioned earlier the ancient Indian code of medical ethics was documented by *Caraka*, *Susruta* and others from 1-2nd century onwards. In the West during the Greco-Roman period, the most well known code of ethics is the 'Hippocratic Oath'. All these codes state

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the norm of 'non-maleficence' *i.e.* 'Do No Harm'. This was the mainstay of physician – patient relationship. Philosophically, two main concepts based on circumstances leading to consequence prevail, that of bringing greatest good for the greatest number where means justify the end and that of doing right dictated by duty, which is not governed by consequences, where means do not justify ends. In 1846, the American Association of America had laid down the first national code of ethics for physicians.

The ethical guidelines for research in modern times resulted mainly from the shock generated by the human rights violation of the Nazi experiments during the Second World War. The Nuremberg Trial led to the formulation of the Nuremberg Code in 1947, which stated that basic principles must be observed in order to satisfy moral, ethical and legal concepts in research. The longest principle highlighted in this code is that “the voluntary consent of the human subject is absolutely essential.” Later Helsinki Declaration in 1964 awakened the Western world about adherence to some norms which were based on moral and ethical principles. In the coming years this served as a guide to every physician in biomedical research involving human subjects.

In 1966, Henry K. Beecher, a professor of anesthesiology at Harvard Medical School published the land mark article in the New England Journal of Medicine on 22 clinical studies carried out unethically by reputed physicians and in some reputed institutions. The unethical and racist Tuskegee study on natural history of Syphilis in Blacks of Alabama, USA from 1932-72 led to outrage from public and the subsequent publication of the Belmont Report of USA in 1979. This report described three cardinal ethical principles that every researcher should follow, namely, autonomy, beneficence and justice. Doing no harm, non-maleficence, is part of beneficence principle. However, autonomy as applied to the Indian culture will have to take into consideration the harmony of the environment of the research participant. In 1980, the Indian Council of Medical Research brought out its first guidelines as “*Policy Statement on Ethical Considerations involved in research on Human Subjects*” which described guidelines for Ethics Committee, informed consent, clinical trials, research on children, mentally disadvantaged, those with diminished autonomy, traditional Medicine and publications. Keeping in mind the science and technical advancements that have spanned in the following years these guidelines were revised in 2000 as “*Ethical Guidelines for Biomedical Research in Human Subjects*”. Thereafter, momentum gathered globally to revise guidelines with relevance to the present trends in research.

More than 400 national guidelines have been brought out since then, prominent among them being guidelines from WHO/ CIOMS, Geneva, Nuffield Council, UK, and NBAC Report, USA. The latter revised the Guidelines with special emphasis on

requirements of developing countries. In India the code of ethics in Medical Council of India (MCI) Act was described in 1956. In its amendment of 2002, and in the amendment of Drugs & Cosmetics Act, 1940, ICMR's ethical guidelines were incorporated. The amendment of Schedule Y of Drugs & Cosmetics Act, 1940 is the latest to be added to the list for clinical trials. Although mandated indirectly in the MCI and Drugs & Cosmetics Act, "The Biomedical Research on Human Subjects (Promotion and Regulation) Bill, 2006 will necessitate the researchers to abide by it, including those from the Indian Traditional Systems of Medicine. These guidelines are considered to offer equal protection to human participants when compared to those required by USA.

The General Statement on medical and related research using human beings as subjects must ensure that the purpose of the research proposal should be to gain knowledge, and for the betterment of humans. It should be conducted in fair manner causing no greater risk and should be evaluated at all stages. The General Principles of the ICMR code elaborate on essentiality of the proposal; voluntariness, informed consent, community agreement; non-exploitation; privacy and confidentiality; precaution and risk minimization; professional competence; accountability and transparency; maximisation of public interest and distributive justice; institutional arrangements; public domain; totality of responsibility and compliance. Specific Principles include research for Clinical Evaluation of Drugs, Vaccines, Devices, Diagnostics and Herbal Remedies.

Good Clinical Practices (GCP) provide a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials assuring that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. The Indian GCP has been released in 2001. The twin pillars of human protection are informed consent process and ethical review procedure. The latter is required to ensure sound ethical and scientific decision making, promote ethically viable priority research to provide public assurance and to safeguard welfare and rights of participants. There should be no conflict of interest and regular monitoring should be there.

The general ethical issues described in the ethical guidelines include informed consent process, compensation for participation, special groups as research subjects, essential information on confidentiality, compensation for accidental injury, international collaboration, and relations with media and publication practices.

While taking informed consent (IC) all information should be communicated. There should be no deception. The investigator should not influence decision-making. A

relative or unrelated witness should sign written informed consent. Thumb impression can be accepted but witness should not be one who cannot write. In some circumstances oral, audio-video consent can be taken with ethics committee's approval. The research participant can withdraw from the trial without assigning reasons but it should not affect her/his treatment to routine care. Whenever necessary community consent should be taken. The language of the IC should be simple, understandable and in short sentences avoiding technical jargon. The IC should describe study purpose, aims, procedures, risks and discomforts, benefits, payment for participation, mention voluntary participation, consent withdrawal, compensation for injury, confidentiality, alternatives available, details about sample storage if any, and contact information about investigator and Chairman of ethics committee. IC should be translated in local language and back translated whenever required. Compensation for participation should be for inconvenience/time lost in earning wages. S/he should get full benefit if reason is related to study. Proportion of benefit could be decided if other reasons are there. There should not be any undue inducement in terms of monetary benefits, academic credits, medication, travel vouchers etc. Compensation in case of injury should be a total responsibility of investigator, institution and sponsor and should be decided *a priori*. The sponsor should provide insurance coverage for an unforeseen injury.

Special and vulnerable groups have reduced autonomy. They include persons affected by diseased condition, mentally ill, elderly, uneducated, poor, employee, students, defense personnel, prisoners, institutionalized persons, and tribals. Pregnant or nursing women and children can be subjected to research only in special instances relevant to them.

Maintaining confidentiality is important. Who accesses the information and what type of information can be communicated should be clearly stated in the proposal. There could be direct /indirect identifiers (coded)/ anonymised. Storage of data/ records is equally important. Only the investigator, ethics committee, institution and sponsors can access these. Disclosure is allowed only when required by court, or danger to society/ public health (homicidal tendency, HIV/AIDS) Information is sensitive when it concerns genetic diagnosis, DNA banking, assisted reproductive technology, and epidemiological studies when it concerns a particular community.

The trial protocol should include justification for the trial, the trial design procedures and phases, clearly define the question for which the trial is designed to provide the answer, primary and secondary end points, describe study population indicating inclusion and exclusion criteria and allocation of participants to various treatment protocol.

In collaborative international health research the developing countries should strive to build expertise and capacity. The proposal should have social value, scientific validity, resort to fair selection of subjects and communities, should have favorable risk-benefit ratio, be subjected to independent review, obtain individual informed consent, respect enrolled subjects and communities and be a collaborative partnership. The Indian investigator should have necessary expertise and submit application for approval from Health Ministry's Screening Committee through appropriate agencies before initiating the research.

In India the patients/ study participants are not aware of their rights to information and have full faith in doctor as in God. Different religious groups with sub-caste systems, tribal groups and many languages complicate issues. There is general lack of comprehension about informed consent and people are culturally dependent on the decision of head of the family or village/community. As regards the researcher the doctor/ scientist are mostly unaware of ethical conduct during the study involving animal or human subjects. There is no separate curriculum for ethics except in few medical colleges mostly as part of religious teaching of good conduct. Except in few no ethics committees exist in many medical colleges / research institutions and if they do they are mostly non functional or improperly constituted. There is no mechanism to monitor the activities of Ethics Committees. The researcher's lack of awareness or feigned ignorance of country's rules and regulations regarding transfer of biological material, data transfer, intellectual property rights (IPR) and social and political sensitivities in collaborative research with different countries complicate matters further. Co-existence of different system of medicines *viz.* Allopathy, Ayurveda, Siddha, Homeopathy and Unani require different ethical guidelines.

WHO definition of Traditional Medicine includes diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness. Traditional Medicine is that which is indigenous to the region either recognised or ethnic as in Chinese medicine, Indian *Ayurveda*, Arabic Unani medicine, African & Latin American practices.

It is essential that clinical trials on traditional medicine should be carried out only when a competent practitioner/ physician from the system concerned is one of the investigators.

Conclusion

Bioethics has emerged as a topic to reckon with since last four decades in Western world. Gradually awareness is growing about it in India regarding application of its principles in biomedical research. It has developed as a multidisciplinary specialty and in many nations it has become mandatory to abide by the ethical principles. In the health care and research institutions this requirement is overseen by institutional research ethics committees, which safeguard the welfare and rights of the research participants. Enabling policies to facilitate implementation of ethical guidelines and including ethics in curriculum of teaching institutions will make clinical trials in India a safer bet. This also applies to institutions teaching traditional medicine.



6

An Introduction to Research

R.L. Bijlani*

Professor N.K. Bhide, Former Professor of Pharmacology at All India Institute of Medical Sciences, defines research as 'original and critical intellectual activity'. This definition is extremely broad, and would cover almost all types of research, including that in subjects such as language, literature, history, geography or mathematics. Scientific research involves investigating a question or testing a hypothesis through a systematic carefully designed study.

Why Research?

It is often asked whether developing countries like India can afford an expensive luxury like research. There is an intimate relationship between teaching and research. Teachers who are engaged in research make better teachers for a variety of reasons. First, they are better informed about the latest advances in their subject. Secondly, they encourage the students to ask questions. Finally, they are less dogmatic in their approach because they know that what they are teaching today may be obsolete tomorrow. Research also helps in generating a climate of science in society. The scientific temper, characterized by commitment to truth, a rational attitude, spirit of enquiry, and the urge to experiment, is desirable for its own sake; in addition, it also prepares the soil where technology can strike roots. One reason why our country has been able to adapt to the age of computers and mobile phones so well today is because of the encouragement scientific research has received since independence. In short, there are very powerful and valid reasons why developing countries should invest in research. Research is expensive; in the long run, not doing research is even more expensive.

There may be good reasons why even poor countries should invest in research, but why should an individual get into research? Certainly everybody does not have to get into research: a few will do. Research is difficult, research is tedious, research is painful, but when observations collected assiduously over a long period of time fall into an unforeseen meaningful pattern, the thrill generated is no less than that experienced by a child when he completes a jigsaw puzzle.

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Steps in Systematic Research

Much of research today is systematic research in the sense that it involves a uniform sequence of steps from conception through publication.

Idea

Every piece of research is born as an idea. All good research workers collect ideas the way children collect stamps or coins. Let us assume that the great day has finally arrived when you have an opportunity for research, and you have taken out your collection of ideas to select one gem. It is indeed important to give a good thought to selection of the idea before going any further because time and other resources are limited, and the time and effort required for working on a poor idea is just as much as on a good one.

The Problem

Once the idea has been selected, the next step is to identify the problem. The problem may belong to one out of three broad categories. *First*, it may be an area of total ignorance. Nobody ever did anything on the subject ever before. Here is an opportunity to be a pioneer, but such problems are extremely rare today. *Second*, it may be an area of controversy. Although there are several studies available on the subject, their results are conflicting. *Third*, the literature search might open up an ocean of knowledge. However, for each question that has been answered by the studies available, several new questions have been raised. In short, in spite of all what is known, there is scope for more studies which would extend the limits of knowledge. Most of the problems tackled by current research fall in this category.

The Question

Once the problem has been identified, the next step is to formulate one or more clear questions which the research will seek to answer. Let us assume the problem belongs to the third category, i.e. there is scope for extending existing studies. Although a variety of extensions in different directions may be desirable, we have to choose the direction which is relevant, exciting, and feasible in terms of available expertise and facilities. Depending on the direction selected, a few clear questions should now be formulated.

Experimental Design

Experimental design is the first step in translating a question into an actual study. It includes a consideration of the subjects that will be used, the groups into which they will be divided, the treatment each group will receive and for how long, and the variables that will be studied. The principal outcome measures are identified, and how much effect on the outcome measures would be considered significant is also decided. Based on these considerations, the minimum number of subjects is also determined.

Statistics

The role of a statistician begins when a research problem is conceived, and continues till the work has been published. Statisticians are experts in advising on the best experimental design, the minimum number of subjects required, and the most appropriate tests for analysis of data. Therefore the right time to consult a statistician is when the study is being designed.

Methods

After the experimental design is ready, one has to get serious about the techniques to be used for the various measurements involved. Some of these might be already established in the lab, or in a friend's lab. The rest have to be either established, or one has to find a reliable place from where one can get the measurement done on payment. Once most of the techniques to be used are in place, it is always a good idea to perform a few pilot experiments. The experience gained from these experiments is very useful in improving the study before it is too late.

The Study

The next step is to begin the study. Utmost attention should be paid to the conditions of the experiment because the observations depend on that. Next, maximum possible care should be taken to record the observations correctly. Besides what was planned, any unplanned and unexpected observations should also be recorded. The recording should be immediate, and in a notebook or register. Leaving things to memory is unreliable, and noting down observations on scraps of paper is unsafe. Considering the effort it takes to reach this stage, it would be a pity to lose observations through avoidable negligence.

Analysis and Interpretation of Results

Raw data is often too voluminous and not much can be made of it. The first step is to organize it into appropriate tables, charts and graphs, etc. Multiple observations are condensed by calculation of measures of central tendency (e.g. mean) and dispersion (e.g. standard deviation). Condensation of data is always a compromise. It needs fine judgment to decide how much detail may be sacrificed in the interest of clarity and convenience while still leaving the essentials intact. Looking at the raw data again and again may require repeated analysis from different angles. This is an effort which is enjoyable as well as immensely rewarding.

Tentative interpretation of the data is generally possible after the analysis. But truly objective interpretation needs application of appropriate statistical tests. Science does not prove or disprove anything with absolute certainty. Scientific evidence is in terms of probability. If the probability of something being true is greater than 95% it is tentatively accepted as a scientifically proven truth. It is because of the doubt up to the tune of 5% that we keep our mind open to a revision if observations made anytime in the future indicate that a revision is necessary. Being always open to revision is both a weakness and a strength of science. It is a weakness because scientific knowledge is always tentative; it is a strength because it enables scientific knowledge to improve and grow constantly without being obstructed by tradition or authority.

Writing up the work

Writing up the research is a necessity as well as a responsibility. It is a necessity for getting jobs, promotions, and further research grants. It is also a responsibility because the benefits of research, which is largely funded by the tax-payer, should reach the society. The benefits cannot reach the society unless the findings of the research become authentic public knowledge, which happens best through scientific publications.

Publication is not the end of research. Each publication raises a few new questions, which require further research. Thus research is an endless process.



7

Issues in designing a study to assess a therapeutic intervention

Dr. Kameshwar Prasad*

Introduction

Health practitioners are rightly interested to know whether a new treatment works? Whether it makes any difference? Difference in what? In the outcome of his case or the prognosis of his patient. But there is a problem. The problem is that there are many factors which influence the outcome in a given patient. Some such factors are called prognostic factors, like age, sex, nature of the disease, disease severity, comorbidities, etc. The other factors are biases and chance. If we can eliminate these factors and other treatments as the possible cause of a particular outcome, then we can be sure that the new treatment given to the patient has caused the outcome – whether beneficial or adverse. But it is impossible to eliminate the role of these factors. Hence it is difficult, if not impossible, to know for sure whether a given treatment makes a difference in the outcome. Researchers use several strategies to control these extraneous factors; one of which is to use a control group.

Need for a control group

Give the treatment to a group of patients and observe the outcome. This strategy is the one most commonly used. But it has its own problems. **First**, the disease may be self-remitting in some or all patients. Thus, whether the patients recovered due to the treatment or on their own, you cannot say. **Second**, there is something called Hawthorne effect – that is, there is a change in response or behaviours of people when they are kept under observation. **Third**, there is placebo effect – that is, patients feel improvement even if something inactive (placebo) is given. For example studies in early eighties with a single group of patients reported moderate to marked improvement with thyrotrophin releasing hormone in motor neurone disease. A control group who receives the same attention as the experimental one and also receive a placebo, then the Hawthorne and placebo effects cancel out in the comparison for routine check up of their blood pressure. But subsequent controlled

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trials did not find any significant improvement. **Fourth**, there is something called 'regression to the mean'. To understand this, let us consider a group of health subjects with a true mean systolic blood pressure (SBP) of 135 mmHg. They were attending your out-patient department (OPD). As you know there is physiological fluctuation in SBP and it rises particularly when the patients are being examined by a health care worker (so called 'white-coat hypertension'). If you did not know this and you wanted to test the effects of a new anti-hypertensive drug you picked up some of the above patients with SBP above 140 mmHg in the OPD. You administered the drug to all such patients. After one hour you checked their SBP again. Prior to treatment, mean of their SBP was 142 mm but it came down to 137 after one hour, and the difference turned out to be statistically significant. Does it mean the drug is effective? The answer is we don't know. The SBP may have come down in normal course without treatment. The reason is that you picked up those with the upswing in their SBP. Such upswings are known to be normal. What happens after the upswings – SBP will come down towards its mean. This phenomenon is called 'regression to the mean'. This happens spontaneously. So, you won't know whether the drug did something or SBP came down because of 'regression to the mean' phenomenon. Patients selected because of high value if any characteristic can be expected to have lower value on subsequent measurements, purely because of phenomenon regression to the mean.

Randomisation

Randomisation is a method to allocate individual patients or persons who have been accepted for a study into one of the groups (called arms) of a study. Usually, there are two arms: one arm is called experimental or treatment arm and the other is called control arm. Another term for randomisation is random allocation. This should not be confused with random selection, in which the investigator uses a process to recruit sample for the study. This is usually used to select a representative sample from the study population, usually in a survey.

Randomisation process is like tossing a coin to allocate the patients into the different arms of the study. Let us say there are two arms in a study. Mr X is a patient who is eligible and has given consent. Now a decision has to be made to put him into either experimental or control arm of the study. You first set a rule that each time a patient is accepted into the study, you will toss a coin – if it comes head, he will go to (say) experimental arm; however, if it comes tail, he will go to control arm. Accordingly, Mr X comes, you toss a coin – it comes tail, therefore, Mr X will go to control arm. Likewise, whenever a patient comes, the same steps and rule is followed. Finally,

you will have two groups totally created by tossing a coin. As you can imagine, if there are two hundred subjects – approximately 100 will be in experimental arm and another approximately 100 in control arm. Thus you will have two groups created through randomisation.

The question is why do we randomise? We randomise to create two prognostically similar groups. In the two hundred subjects we had, if there were 50 females, you will find roughly (not exactly) half in each group; if there were forty old people, you will find roughly half in each group; if you had 80 diabetics, you will find roughly half of them in each group. It happens because each patient has equal (50-50) probability of going into one of the two arms. This divides all the characteristics, measured or non-measured, visible or invisible, known or unknown approximately equally into the two arms, provided you have enough number (say hundreds) of patients. When is the number enough? The exact number depends on how many factors you want to balance. Of course, it will be roughly half and half, not exactly. In fact, if you are very unlucky and have small numbers, you might find one third in one group and two-thirds in another group. This is why you need to check whether the randomisation worked well in your study or not.

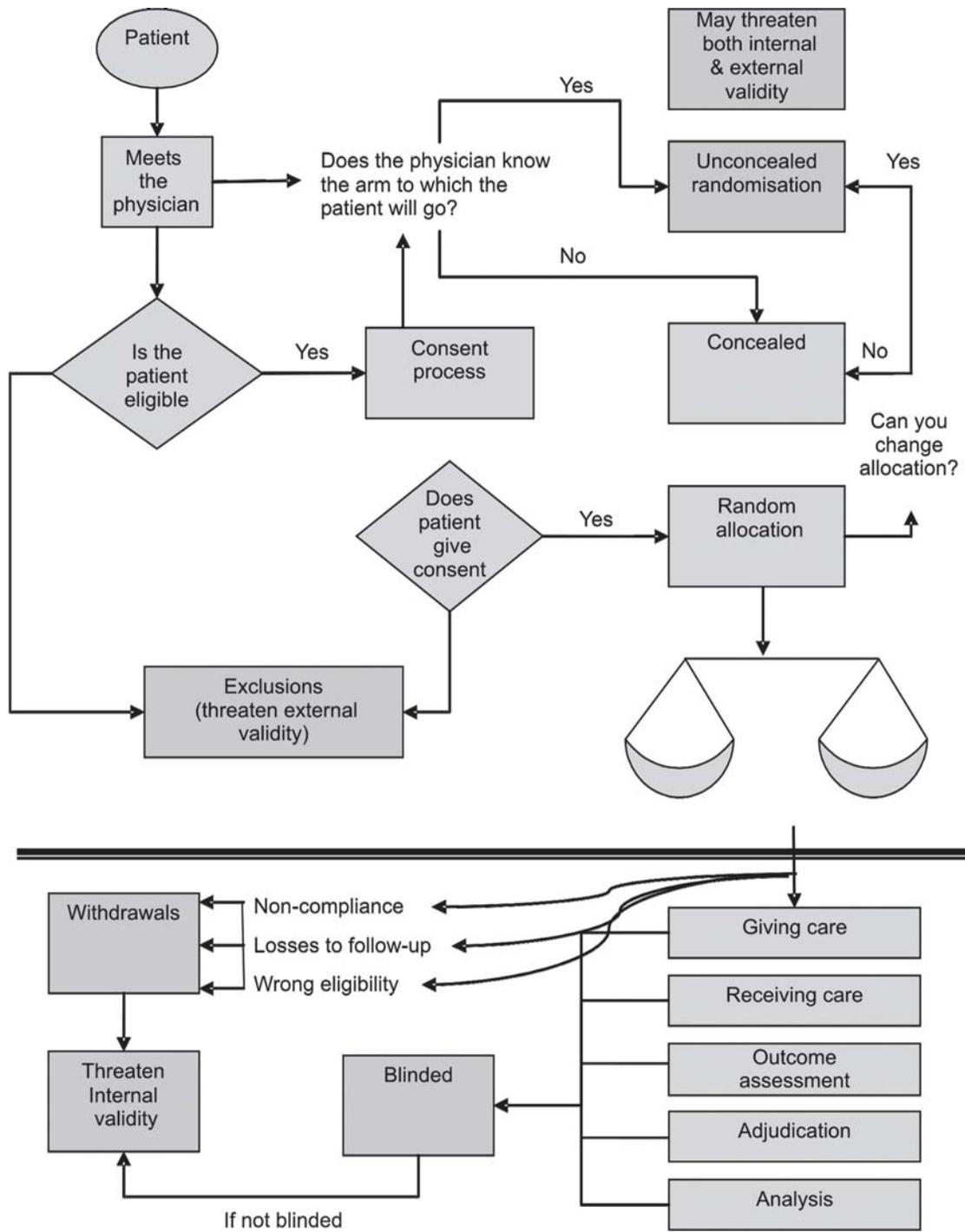
There are two more advantages of randomisation – one, you cannot consciously or subconsciously introduce bias in selection of the patients. If you were relying on alternate patients going to one or the other arm – say, medical versus surgical – you may select only the low risk patients into surgical and the high risk cases into medical. This is possible if you are deciding the eligibility and taking consent from the patients, and you also know that next patient goes to one particular arm (more details on this in Chapter 4). Second advantage of randomisation is that it meets the assumption of all the statistical tests used to compare the two groups.

The process of randomised controlled trial

An RCT, like any other research, starts with writing a protocol, that defines the objectives research question hypothesis, eligibility criteria, recruitment procedure, consent outcomes and their measurement and methods of analysis to be used. The actual conduct of the trial goes through the following steps.

1. **Eligibility assessment:** As soon as a potential subject appears, the investigators assess whether he (the subject) fulfils the eligibility criteria (Inclusion and exclusion) of the trial.

2. **Consent:** If the patient is eligible, he is given all the relevant information in a consent form with opportunity to seek clarification. An informed consent is then taken for participating in the RCT, though the patient has right to withdraw consent anytime.
3. **Randomisation:** A patient who is eligible and consenting is then randomised to one of the arms of the RCT.
4. **Baseline assessment:** All patients are assessed at baseline (before initiating intervention) according to the protocol. Sometimes, it may already be complete at step 1 (eligibility assessment).
5. **Initiation of Interventions:** Patients receive the intervention according to the random allocation; either experimental intervention or control.
6. **Standard case:** All patients receive the standard care.
7. **Follow-up:** Patients are followed-up as per the protocol.
8. **Outcome assessment** is performed by blinded assessors whenever possible and desirable.
9. **Adjudication:** A group of experts judge whether the outcome measurement are correct and acceptable.
10. **Analysis:** The data is analysed usually by statisticians.



Intention-to-treat analysis

In our hospital in India, serious patients with spontaneous supratentorial intracerebral haemorrhage (SSIH) were all admitted in neurology and treated medically with hyperventilation, mannitol, control of hypertension etc. Our policy was to treat such patients medically. Our chief of neurosciences, a neurosurgeon, returned after visiting some neurocenters in UK and USA and convened a meeting of neurologists. The discussion was on the following lines:

Neurosurgeon (NS): I found in all the centres I visited that their policy is to admit all serious patients with SSIH to neurosurgery, particularly those with altered consciousness. Right from the emergency, neurosurgery is involved. Most, but not all, patients are operated upon. My impression is that this approach yields better outcome.

Neurologist (N): I do not believe that surgery has a role in SSIH. I have looked at the available evidence from randomised studies. It does not favour a policy to treat such patients in neurosurgery.

NS: OK, I understand your point. See, your intention is to continue the present policy – that is, all patients are admitted and cared for by neurology service – some of them may require surgery at a later date. My intention is to treat all patients with altered consciousness in neurosurgery such patients get early surgery. Let us compare the two policies in a randomised study, particularly for patients with altered consciousness: intention to treat medically with later surgery if required versus intention-to-treat with surgery early.

N: What will you do with the conclusions?

NS: If the policy of intention to do early surgery is associated with decreased mortality, we will adopt this policy so that right from emergency, patients will go to neurosurgery. Otherwise, the present policy will continue. My impression is that early surgery policy will reduce mortality rate of such patients in our hospital and this will have national or even international impact as regards treatment of such patients.

A randomised study was carried out with 200 patients. 100 patients of SSIH with altered consciousness were randomised to enter neurology and 100 to enter neurosurgery right from emergency. It turns out that 10 patients in the surgery arm died before surgery could be arranged, and 10 died after surgery. In the medical arm, 20 patients died in total.

The question is how to analyse the data – mainly how to analyse the deaths prior to surgery in the neurosurgery arm? If we ignore them, surgery looks better because 20% died in medical and 10% in surgical. If we include them in medical arm, surgery looks much better – 30/110 deaths in medical and 10/90 in surgical. If we count them as death in surgical arm, both medical and surgical arm looks similar – 20% death in each arm.

The answer has to do with what will happen with the conclusions. If we conclude surgery is better, then all such patients will go to neurosurgery right from emergency (a new policy). If the study represents what normally happens, 10% (or more) are likely to die before surgery whereas 10% will die after surgery. The mortality will be 20%. Even with the present policy, the mortality is the same. Thus the outcome for the hospital will remain the same but with a costly approach of surgery in at least 90% of patients. In other words, the conclusion was falsely positive in favour of surgery. If we want to know what results to expect with change of policy from medical to surgical, then everything, which happens after randomisation to an arm, must be counted on that arm. The deaths occurring before surgery have to be counted in the surgical arm because this is what is likely to happen in real settings. Thus, the medical arm will have 20% mortality and so will the surgical arm.

An analysis which counts all outcomes pertaining to an arm in a randomised trial in that arm only irrespective of whether the patients receive the intervention or not is called an ‘analysis based on intention-to-treat principle’.

What does it tell us?

It tells us what outcomes to expect with one policy vs. another. It tells us what happens with a policy under real (usual) circumstances. In other words, what does happen/or what does an intervention do? This is often different from what can an intervention do.

Another example

A new drug to reduce cholesterol came into being. A study to assess the effectiveness and safety of the new drug randomised 1103 patients to the treatment arm and 2789 to placebo arm.[1] In the treatment arm, 746 patients complied to the protocol (treatment), of which 112 (15%) died, whereas in the placebo group 585 (20.9%) died, a statistically significant difference (P value = 0.0003). Analysed in this way,

you may conclude that the treatment is effective in reducing mortality. However, this is a biased analysis. You have taken all patients in the placebo arm and only compliant ones in the treatment arm. In placebo arm also, there were compliants and non-compliants. The compliants in the placebo arm also had only 15.1% mortality, practically no difference from those in the treatment arm. If you compare compliant patients only in both the treatment vs. placebo arm, there is no difference. If you compare all patients in the treatment (mortality 20%) vs. all patients in the placebo arm (mortality 20.9%), there is practically no difference (P value = 0.55). This last analysis is called “intention-to-treat” analysis.

The question is which of the above analysis is likely to be unbiased. Here you have to remember why, in the first place, you chose a randomised design. You did so because randomisation tends to balance the prognostic factors between the two arms on an average. Having done it, you must take its advantage. The only analysis which allows you to take the full advantage of randomisation is intention-to-treat analysis, that is, *attributing all patients (and their outcomes) to the arm to which they were randomised, irrespective of whether they actually received their assigned treatment or not.*

Why intention-to-treat analysis?

If you analyse only the compliant patients, you are likely to get biased results. Why? The reason is that the compliant patients in the two arms may not be prognostically balanced.

You would mix up the effects of treatment and bias introduced by prognostic imbalance. Even if you show balance in known prognostic factors, there is no guarantee that unknown prognostic factors will be balanced. Therefore, the only analysis, which takes full advantage of a successful randomisation, is the one based on intention-to-treat principle. If you don't, you may lose the benefits of randomisation and also the strength of a randomised design. Some experts say, you convert a randomised study to a cohort one.

Principle of Intention-to-Treat (True ITT Analysis) vs Intention To Treat Analysis. (Quasi-ITT)

Guyatt and his group distinguish between the principle of intention-to-treat and the common usage of the term intention-to-treat analysis.[2,3] The principle of ITT

requires that all patients randomised must be included in the analysis in their respective arms. On the other hand, the common usage of the term 'ITT' includes violations of the principle, which means withdrawing patients, after randomisation. There are three usual reasons for withdrawal: mistaken eligibility, non-compliance, losses to follow-up.

(i) **Mistaken eligibility:** Consider a trial of steroids in acute bacterial meningitis, in which some cases of viral (aseptic) meningitis are also included inadvertently. Withdrawing the latter may not threaten validity greatly, except if they had adverse effects of steroids. As such outcome of aseptic meningitis is universally good, and hence prognostically the withdrawn groups are likely to be balanced. No major threat to validity arises as the prognostic balance is not disturbed.

(ii) **Non-compliance:** Non-compliance to the treatment to which the patients are randomised arises usually due to the following reasons:

- adverse effects: more often in experimental treatment group than placebo
 - perceived lack of efficacy: if the treatment is ineffective and patient is deteriorating
- negligent behaviour of the patients: this is likely to be distributed equally in both the groups. It is evident that the non-compliance due to (a) and (b) reflects on the risk-benefit profile of the new treatment and hence should not be neglected. In fact, this in itself can be one of the important outcomes to be analysed. Removing the non-compliant patients may in fact paint a rather unduly favourable picture of the new treatment.

(iii) **Losses to follow-up:** This will be discussed under adequate follow up in the next.

From the above it is clear that non-compliant patients need to be included in the analysis and there should (ideally) be no losses to follow-up. All patients need to be included in the respective arms in the final analysis.

Limitation of ITT

You might have noticed that there are some problems in the concept of ITT. The benefit (and adverse effects) of the treatment can be experienced only by those who take it. If only 50% of the patients comply with the treatment and all patients are counted in the analysis, then there is bound to be dilution of the effects, both beneficial

and adverse, of the treatment. This will result in underestimation of the effects (sometimes, with two active treatments under comparison, there can be overestimation of the effects). Yes, this is right. ITT commonly results in underestimation of effects.

Is there a way to resolve this problem? Some experts think that analysing only the compliers (per-protocol analysis) can solve this problem. This is not right. Compliers in the two groups may not be similar. In the control group, moderately sick may leave the study; to seek other treatments while in the treatment group, such patients may benefit and therefore remain compliant while some may develop adverse effects and leave. Thus, kind of patients in the two groups remaining compliant would differ in prognosis. Thus, per-protocol analysis will give biased results. Experts are still working on methods, which will give the estimate of effects of treatment with 100% compliance.

Note: Most drug controlling agencies (like FDA of USA) insist on ITT analysis for approving new drugs. The reason must be obvious to you. ITT protects against biased results. This is also the reason why editors insist on ITT for publishing a paper.

To summarise, the questions to be addressed while planning a therapy study are related to 3 x 3 Cs as shown in the Box.

Start well: 3 Cs

- Control group
- Concealed randomisation
- Comparability of groups at baseline

Run well: 3 Cs

- Co-intervention minimal or nil
- Contamination minimal or nil
- Compliance maximal or adequate

Finish well: 3 Cs

- Complete follow-up
- Correct outcome measurement
- Credible analysis

References

1. Coronary Drug Project Research Group. Influence of adherence treatment and response of cholesterol on mortality in the Coronary Drug Project. *N Engl J Med.* 1980; 303:1038-1041.
 2. Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA.* 1993;270:2598-601.
 3. Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA.* 1993;270:2598-601.
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8

Research in Yoga - Some random thoughts

Dr. M.V. Bhole, M.D., Ph.D*

Introduction:

The term “research” has of two components, ‘re-search’ i.e. to seek again. As per standard dictionaries, ‘research’ denotes “careful, patient, systematic, diligent enquiry or examination or investigation in some field of knowledge undertaken to establish facts or principles. Laborious or continued search after truth¹.” This meaning of the term also gives us the broad guidelines for its methodology.

Research could be done for oneself, our family, organization, business, society and/ or a nation in any field such as science, technology, fine arts, biology, medicine, philosophy, literature etc. There is some difference between discovery, invention and research.

Various steps involved in carrying out research greatly depend on the objectives of the ‘research’. However, certain norms have been established and protocols have been developed for preparing research proposals, selection of items, collection and analysis of data, report writing and its presentation.

We are more concerned with research in the fields of Naturopathy and Yoga. In our country, CCRYN, NIN and MDNIY are apex bodies entrusted with Yoga and Naturopathy. They are connected with the Department of AYUSH, Ministry of Health. Guidelines for applying for grants-in-aid for research projects are available from this Department. Other funding agencies have their own guidelines and formats for submitting research projects.

Research in Yoga:

Swami Kuvalayananda was the pioneer in the field of laboratory research in yoga. He started his experiments around 1922. Later on, he established Kaivalyadhama Samiti at Lonavla near Pune to carry out full time research, training and therapy in yoga. Since then and till to-day, many individuals and institutions, in and outside India, have developed interest in yoga research, training and therapy.

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Today sVYASA, Bangalore is most active in these areas related with yoga and it is having collaboration with institutions outside India. Bihar School of Yoga, Munger is another institution totally devoted to yoga. DIPAS, AIIMS and JIPMER are basically working in psycho-physiology and medical fields and they are also carrying out research in yoga. We can get lot of important guidance from these institutions.

Areas of Research in Yoga:

At Kaivalyadhama Institute, Swami Kuvalayananda instituted yoga research and related training activities in the following areas:

1. Scientific research in Yoga

- Effects of individual yoga practices such as Uddiyana, Kapalbhathi, Basti etc. using modern laboratory equipments.
- Special subjects of scientific and general interest such as pit burial, heart stoppage etc.

2. Philosophical and Literary research in Yoga-comprising of the following:

- Procurement, compilation, editing, translation and publication of critical editions of old works on yoga from manuscripts and published sources such as Goraksha Shataka, Bruhad-yogi-yajnavalkya, Hathapradipika etc.
- Evolution of yogic concepts and practices such as pranayama.
- Interpretation of yoga sutras.

3. Developing courses in yogic physical culture for people with average health.

4. Education of yoga teachers, and

5. Yoga therapy

6. Spiritual guidance to aspirants

The list given above looks very comprehensive. However, we can extend and expand this list in the light of our requirements e.g. developing yoga programs for specialized professions such as executives, computer workers, house-wives, school children, people working in high altitudes, space travelers; patients suffering from different ailments; spiritual aspirants with different ambitions and motivations etc.

Present trends in Yoga Research:

We can recognize the following trends in yoga research in India and outside.

In respect of laboratory experimental work:

- Study of the short term effects of short and long term yoga training programs on various psycho-physiological parameters.
- Study of selected yoga practices such as well established Buddhist meditation on brain activity with special reference to consciousness. Some of the topmost neuron-scientists are working in collaboration with His Holiness Dalai Lama in this area.
- Study of yoga techniques in relation to therapy, especially in relation to heart.

In respect of literary studies:

- Preparation and publication of critical editions of old yoga texts with translations.
- Study of the living traditions in yoga.
- Preparation of catalogues of yoga related manuscripts.
- Research in relation to specific yogic concepts such as 'prana'.

There are highly specialized books and literature on this subject and we should consult them according to our personal interest and requirement from time to time. However, here are some broad generalized guidelines in the interest of producing good research in yoga:

If you want to carry out Experimental Work in Yoga:

1. Interest in doing research:

- Ascertain that you are having a genuine interest in yoga research i.e. you have a searching attitude.
- Just do not think of undertaking a research project because some funds are going to be available or there is pressure from somewhere to take up such a work.

2. Proper technical persons, equipment and place to carry out work:

- Ascertain that you will have a full time technical person to work on the instruments and people knowing the upkeep and maintenance of the equipment.

- Ascertain that you will have a separate room with proper atmosphere to carry out experimental work.
- In case, you do not have the background of science and biology, then ascertain that you have properly qualified people in science, biology, medicine and statistics to help you from time to time right from the project planning phase till the publication of your work.
- If you are from science side, then try to have the services of Sanskrit knowing people available to you. You may be required to refer to the classical texts from time to time.
- It is highly advisable to have medical person taking interest in your work and who is ready to guide you in respect of the modern medical sciences from time to time.

3. Subjects and their training:

- Ascertain that subjects will be easily available for your experiments and there will be proper facilities for their training in yoga.

4. Objectives of training in Yoga and its assessment:

- Spell out the objectives of yoga training as per the living tradition and the yogic scriptures i.e. what do you want to achieve through yoga training.
- Usually they are going to be “first person subjective experiences”. These may be related with the yoga training as a whole and/or with the individual yoga practice.
- Spell out as to how you will proceed to assess and evaluate the achievements in respect of these “first person subjective experiential objectives” in the participants.
- This point is usually missing in most of the research protocols. Parameters studied by us (third person) become the side-effects of the main first person achievements.

5. Experimental observations:

- Observations made with the help of any kind of instrument become “third person objective measurements” which is different from the “first person subjective experiences”.
- We will have to find ways and means to develop proper integration and synthesis of these two approaches.
- This point is missing from our experimental studies and it requires to be emphasized.

If you want to carry out Literary Research in Yoga:

1. Present trend in Literary Research:

- To edit critical editions of yoga texts based on manuscripts and published works.
- To prepare Catalogues of MSS, Concordances and Encyclopedias.
- This is the classical approach. It is important and should be continued.

2. Some suggestions:

Background for making these suggestions:

- Yogashastra is “first person subjective experiential science” while the modern science is essentially “third person objective observational” in nature.
- Yogic terms are usually related with human consciousness while terms in modern science are related with material substances.
- Authoritative yoga texts are in Sanskrit language which is not the language of education, even in India. Some yoga texts are written in other Indian languages.
- Most people getting interested in yoga to-day do not have the right type of exposure to Sanskrit and these other languages of yoga texts.
- The modern language of education, being mostly objective in nature, incapacitates a person to grasp and understand the highly subjective language of yoga.
- Usually people attend yoga courses from two weeks to six weeks and start their own yoga classes. Under the name of yoga, they are seen to learn and practice some body positions, breathing manipulation techniques, recitation of bhajans and mantras. Their subjective experiences are not assessed nor evaluated.
- Some of them go into more details and get introduced to yoga philosophy in a proper manner. Others continue adding more body positions to their armory. In due course of time they write books in their own languages. This becomes the yoga literature for other people in that country.

The suggestions:

- We will have to differentiate between games, sports, physical exercises, dance movements from asanas. This requires properly planned research work.
- We find various concepts such as vayus, pranas, lotuses, chakras, nadis, and mahabhutas. These concepts require to be properly highlighted in modern

languages to convey their meanings, understandings and subjective experiential aspects.

- We have practical approaches like vayu-sadhana, pranayama, purifications of various kinds. All these require proper presentation for which suitable research work is a must.
- As yoga is an experiential science, some of us will have to undertake research projects to develop protocols to assess and evaluate the subjective nature of yoga practices and yoga sadhana.

Conclusion:

At present, we are following the guidelines for objective research. We will have to think of developing ways and means of integrating “first person subjective experiential aspect of yoga” with the existing “third person objective observational scientific methods”.



9

Efficacy of Naturopathy and Yoga in bronchial asthma-a self controlled matched scientific study

**T. N. Sathyaprabha*,
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Abstract : Asthma is one of the common psychosomatic illness influenced by many factors. Bronchodilators give temporary relief and have side effects. The present study is aimed at finding the efficacy of a non-pharmacological approach of naturopathy and Yoga in bronchial asthma. A total no of 37 patients (19 men, 18 women) with mean age 35.06 yrs (men), 40.74 yrs (women) admitted to INYS, Bangalore, for the period of 21 days.

The treatment included 1. Diet therapy 2. Nature cure treatment and 3. Yoga therapy. The various parameters including lung function test were measured on admission and once a week. Results showed the significant improvement in PEF, VC, FVC, FEV₁, FEV₁/FEC %, MVV, ESR and absolute eosinophil count. The patients reported a feeling of well being, freshness and comfortable breathing. Naturopathy and yoga helps in inducing positive health, alleviating the symptoms of disease by acting at physical and mental levels.

Key words : asthma yoga naturopathy

INTRODUCTION

Bronchial Asthma has been recognized for more than 30 centuries (1). It affects about 5% of general population with female being affected more than males (2, 3, 4). Bronchial asthma is not a specific disease, but a syndrome that derives multiple precipitating mechanism and results in

airway hyperresponsiveness and airway obstruction (5). The important clinical feature of this syndrome includes episodic occurrence of dyspnea and wheezing. The morbidity and mortality from asthma appears to be increasing and it has been suggested that medications used to treat asthma are contributing to this trend (6, 7, 8, 9, 10). Hence the main aim of this study

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is to find out the efficacy of non-pharmacological treatment of bronchial asthma by naturopathy and yoga.

METHODS

In this study 37 patients with established bronchial asthma as per clinical criteria of Crofton and Douglas (11) were included. Eighteen women and 19 men with mean age of 35.06 ± 2.10 yrs and 40.74 ± 3.56 yrs respectively were admitted to Institute of Naturopathy and Yogic Sciences (INYS), Bangalore. Patients suffering from associated ailments or those who had history of chronic infection like Tuberculosis, Cystic disease of the lung, Abscess, severe emphysema etc were excluded from the study after appropriate investigation.

The study has been conducted in two phases, control period and treatment period. The patients were studied on the first day and after 21 days of stay at home with drugs which they were taking, which was termed as control period. On 22nd day they were admitted to Institute of Naturopathy and Yogic Sciences for 21 days of treatment which was termed as treatment period. Hence each patient acts as a control for himself.

All the medications for the Asthma patients were stopped gradually within 2-3 days of admission. During 21 days of treatment, all the patients were given diet therapy, nature cure treatment and yoga therapy.

Diet therapy: Diet therapy (12) consists of 3 phases, eliminative phase, soothing phase, and constructive phase. During eliminative phase which is about 3 to 5 days. Patients were given lime juice with honey, tender coconut water and plenty of water. During soothing phase the fast is broken with seasonal fruit juice and fruits, salads and sprouts for 8 to 12 days depending upon patients. During constructive phase the patients were brought back to normal diet with few modification like avoiding milk and milk products.

Nature cure treatment (13): Patients were given nature cure treatment like chest pack for 45 min, hot foot and arm bath for 10-12 min, back message steam, and sauna bath for 30 min at regular intervals.

Yoga therapy: Yoga therapy (14) compromising of kriyas (Vastra dhauthi, Vamana dhauthi, Sutra nethi & Jalanethi) which is a traditional voluntary nose and stomach wash technique, done once daily, Pranayama which is a breath slowing technique performed about 20 min daily, Asanas (Bhujangasana, Matyasana, Dhanurasana, Ustrasana, Suryanamaskara and Shavasana) which is a modified physical posture, performed for 45 min daily.

For all the Bronchial Asthma patients lung function tests were assessed at 8 A.M at weekly intervals by using Fukuda Sangyo (Japan) Spiro analyser Model No ST-460. The following parameters were studied. Vital capacity (VC), Forced expiratory volume (FEV1), Maximum voluntary ventilation (MVV).

Peak expiratory flow rate (PEFR) recorded daily morning at 8' O Clock with a mini Wright's peak flow meter. The best of three readings were considered. Haematological investigation which includes WBC, Differential Count, absolute Eosinophil Count, Hb%, RBC Count, ESR, and biochemical investigation which includes glucose and lipid Profile were done on admission and on discharge.

Data analysis

Mean and Standard Deviation values were evaluated for all measured parameters. The significance of mean difference in the value was analysed using students paired 't' test.

RESULTS

The results presented in Table I which shows the general Vital data of Bronchial asthma patients. The male patients were

TABLE I: Physical characteristics and duration of illness of patients.

Parameter	Male (n = 19)	Female (n = 18)
AGE (yrs)	40.7±13.5	35.0±12.1
Duration of illness (yrs)	14.3±11.7	9.5±5.4
Height (cms)	167.0±6.3	154.0±6.1
Weight (kgs)		
On admission	61.3±14.4	57.4±13.8
On discharge	56.8±12.8*	53.4±12.1*

*P<0.001

older than female patients and they had longer duration of illness. There was significant reduction in body weight in both male and female patients. The results of Lung function tests in patients have been presented in Table II and III respectively. There was no significant change between base line values (control value) and on admission values. There was significant improvement (P<0.001) in vital capacity, Forced vital capacity, FEV/FVC (%), maximum voluntary ventilation at the time of discharge.

TABLE II: Lung function test (male = 19).

Parameter	Base line (A)	On admission (B)	On discharge (C)	P value (A&B)	P value (B & C)
VC (L)	2.97±0.52	3.00±0.52	4.03±0.47	NS	P<0.001
FVC (L)	3.06±0.46	3.07±0.55	4.16±0.48	NS	P<0.001
FEV1(L)	2.31±0.42	2.37±0.41	3.71±0.49	NS	P<0.001
FEV1/FVC (%)	75.27±5.64	76.78±5.20	89.29±7.72	NS	P<0.001
MV V (L/min)	57.10±11.17	57.89±11.04	75.30±9.08	NS	P<0.001
TV(L)	0.45±0.08	0.45±0.09	0.63±0.09	NS	P<0.001

VC - Vital Capacity;
FEV1 - Forced expiratory volume in 1st sec;
TV - Tidal volume.

FVC - Forced vital capacity;
MVV - Maximal voluntary ventilation;

TABLE III: Lung function test female (n=18)

Parameter	Base line (A)	On admission (B)	On discharge (C)	P value (A&B)	P value (B & C)
VC (L)	2.78±0.84	2.75±0.85	3.50±1.15	NS	P<0.001
FVC (L)	2.84±0.89	2.85±0.88	3.65±1.08	NS	P<0.001
FEV1 (L)	2.04±0.58	2.08±0.59	3.14±1.00	NS	P<0.001
FEV1/FVC (%)	72.87±16.43	73.65±6.67	85.91±9.89	NS	P<0.001
MV V (L/min)	59.68±8.45	59.56±8.77	71.15±10.56	NS	P<0.001
TV (L)	0.43±0.07	0.42±0.07	0.56±0.07	NS	P<0.001

VC - Vital Capacity;
FEV1 - Forced expiratory volume in 1st sec;
TV - Tidal volume.

FVC - Forced vital capacity;
MVV - Maximal voluntary ventilation;

PEFR was measured on base line and at weekly interval during their 21 days stay. The measured mean values are presented in Table IV. There was no significant change in PEFR values between baseline and on admission value, and on admission to first week value in female patients. There was

significant (P<0.05) change in PEFR values in 2nd week and highly significant (P<0.001) change in 3rd week values in female patients. There was no significant change in PEFR values between base line and admission values in male patients, whereas there was highly significant (P<0.001) increase in PEFR values between on admission to 1st week and week 2nd to week 3rd in male patients.

TABLE IV: Peak expiratory flow rate (L/min).

Parameter	Male (n = 19)	Female (n = 18)
Base line	254.1±96.3	197.0±87.5
On admission	258.7±97.7	199.8±90.1
Week1	316.6±48.8**	206.0±104.5
Week2	341.1±160.2**	227.5±106.1*
Week3	371.4±152.4**	238.1±108.6***

*P<0.05; **P<0.01; ***P<0.001.

The results of hematological profile presented in Table V show the significant reduction in ESR and absolute eosinophil count at the time of discharge (P<0.001).

TABLE V: Haematological profile.

Parameter	Male (n=19)		Female (n=18)	
	on adm	on dis	on adm	on dis
Hb	14.6±1.7	14.0±1.7	12.9±0.	12.6±0.8
WBC	7563±1400	7647±628	7838±544	7422±564
RBC	4.95±0.7	4.74±0.6	4.28±0.32	4.19±0.28
ESR	8.05±3.9	3.63±1.6**	9.22±9.03	4.33±1.46**
AEC	563±291	328±67**	469±138	305±87**

**P<0.01

Hb - Haemoglobin gm %;
RBC - Red blood cell/ cu.mm;
AEC Absolute Eosinophil count / cu.mm.

WBC - White blood cell/cu mm;
ESR - Erythrocyte sedimentation rate (mm/hr);

DISCUSSION

Bronchial asthma is a psychosomatic disorder which is characterized by airway hyper responsiveness (5, 15) associated with bronchospasm, oedema of mucous membrane and bronchial obstruction. As the pharmacological treatment to asthma has got its own disadvantage (6, 7, 8), an effort is made to explore an alternative non-pharmacological treatment of bronchial asthma by Nature cure and Yoga.

In our study there were 19 males and 18 females. All patients were using bronchodilator at the time of admission. Three males and two females were on oral steroids at the time of admission. All medication was gradually stopped within 2 to 3 days of admission. All subjects were given 3 modalities of treatment namely diet therapy, nature cure treatment and yoga therapy. The diet therapy eliminates toxins and clears digestive tract. It is believed most of the diseases are caused due to accumulation of toxins and morbid matter in the body.

Nature cure is a complete revolution in the art and science of living. It is a practical realisation and application of all that is good in natural science. The treatment approach is basically holistic rather than compartmental. Nature cure treatment includes chest pack, hot foot and arm bath, massage and fomentation to back. It relieves congestion of lungs, decreases pulmonary mucus membrane irritation and increases the depth of respiration.

Goyeche et al claimed that the psychosomatic imbalance is present in most of the patients suffering from asthma (16).

Yoga therapy gives relaxation to mind and body. Many studies have confirmed evidence of the beneficial effect of yoga in bronchial asthma (17, 18, 19). Practice of Yoga reduces the emotional disturbances there by modifying the airway resistance (20) resulting in easy breathing and well being of the patients.

Pranayama (21), which is a part of yoga therapy is a yogic exercise in respiration. It is defined in the yoga sutras of patanjali as the sciences of cleansing, balancing and gaining control over the prana in the human systems. It has been documented in etiology of asthma emotional stress could increase the levels of vagal tone (22) there by increasing efferent vagal discharge and broncho constriction. Khanan (23) have demonstrated increased sympathetic activity in bronchial asthma. Crisan have showed a significant reduction in anxiety after practice of pranayama (24). Pranayama, with its calming effects on mind, can reduce and release emotional stresses.

The Yogic kriya, which is an important aspect of yoga therapy, brings about cleansing of inner tracts, and desensitization of the nerve ending. It has been documented that inflammatory mediators such as air pollution activate sensory nerve endings in the airways causing cough, chest tightness and broncho constriction (25, 26).

We have documented that with the practice of nature cure treatment and yoga therapy there was improvement in both subjective and objective scores. There was significant improvement in all parameters of lung function tests. In female asthmatic,

there was no significant change PEFR in first week's value. The important physiological reason for this could be that, five patients had menstrual cycle during first week of their 21 days treatment and they were not allowed to perform the pranayama and also to have some of water treatments. In animals, estradiol has been shown to increase acetylcholine concentration, cholinesterase activity (27), mucus secretion (28) and prostaglandin production (29).

Rubio et al (30) evaluated the concentration of progesterone and estradiol in asthmatic and normal females. They reported that at least one of the hormone level was out of the normal range in 80% of asthmatic females. They concluded that 'bronchial asthma is associated in a high proportion with abnormalities in production or metabolisms of sex steroid hormones in women during reproductive life'. In our study all female patients were in reproductive age. Hence this could be another physiological basis for difference in response between male and female patient's PEFR values.

It is well documented that eosinophil plays an important role in pathogenesis of asthma (31) our results have shown highly significant reduction in absolute eosinophil count there by decreasing pathogenesis of asthma.

In conclusion, we have documented significant improvement in both objective and subjective sense of well being in asthma patients with drug less therapy of naturopathy and yoga.

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REFERENCES

1. Elluc-Micallef R. Asthma: A look at the past. *Br J Dis Chest* 1976; 70: 112-116.
2. Emil, Skobeliff MD, Willam H et al. Influence of age and sex on asthma admission. *JAMA* 1992; vol 268, No 24: 3437-3440.
3. ER Mc Fadden JR. Asthma. *New Eng J Med* 1992; 327: 1928-1937.
4. Moawad AH, RiverCP et al. The effect of estrogen & Progesterone on beta adrengic receptor activity in rabbit lung tissue. *Am J Obstet Gynecol.* 1982; 144: 608-613
5. Snapper JR. Inflammation and airway function: the Asthma syndrome. *Am Rev Respir Dis* 1990; 141: 531-533.
6. Crane J, Pearce N, Flatt A, et al. Prescribe fenoterol and death from asthma in Newzealand. *Lancet* 1989; vol 1: 917-922.
7. Barenes PJ, Chung KF Page CP. Inflammatory mediators and asthma. *Pharmac Rev* 1988; 40: 49-84.
8. Sears MR, Taylor DR, Printch, et al. Regular inhaled beta agonists treatment in Br. asthma. *Lancet* 1990; 336: 1391-1396.
9. Page CP. et al. One explanation of asthma

- paradox: Inhibition of natural anti-inflammatory mechanisms by beta-agonists. *Lancet* 1991; 675-678.
10. Spitzer WO, Shina et al. The use of beta-agonists & the risk of death and near death from asthma. *New Eng J Med* 1992; 326: 501-506.
 11. Crofton J, Douglas et al. Crofton & Douglas Respiratory disease. 4th edition, Blackwell Publication pp 660-714.
 12. Murthy BTC et al. INYS Medical Research Society's Annual Report 1998; pp 12-13.
 13. Singh SJ. Baths-encyclopedia of treatment by water. 1978: 13-15 & 42-45.
 14. Iyengar BSK. Light on Yoga. 11th edition Harper Collin Publisher 1997, pp 1-53.
 15. Mc Fadden ER. Pathogenesis of asthma. *J Allergy Clin Immunol* 1984; 73: 413-422.
 16. Gogeche JRM, Abo Y, Ikemi Y. The Yoga perspective part II: Yoga therapy in treatment of Asthma. *J Asthma* 1982; 19: 189-201.
 17. Nagarathna R, Nagendra H.R. Yoga for Bronchial asthma: a controlled study. *Br Med J* 1985; 291: 1077-1079.
 18. Kulkarni VA et al. Effect of short term Yoga training programme on PEF. *Yoga Mimansa* 1997; 32: 14-20.
 19. Bhole MV. Treatment of Br.Asthma by Yogic methods-A report. *Yoga Mimansa* 1982; 15: 43-50.
 20. Gore MM. Effect of Yogic treatment on some pulmonary function asthmatics. *Yoga Mimansa* 1982; 120: 51-54.
 21. Nagendra HR. Pranayama - The art of science. *Vivekanda Yoga Kendra Prakashana* 1997: 54-85.
 22. Barennes PJ. Mechanisms in Asthma. *British Medical Bulletin* 1992, vol 48 no. 1, 149-168.
 23. Khanam et al. Study of pulmonary and autonomic function of asthma. *Indian J Physio Pharmacol* 1996; 40(4): 318-324.
 24. Crisan HG. Pranayama in anxiety neurosis-a pilot study. Heidelberg: *University of Heidelberg* 1984 (PhD Dissertation).
 25. Barnes PJ. Neural control of human airways in health & disease. *Am Rev Resp Dis* 1986; 134: 1289-1314.
 26. Barnes PJ, Chung KI, Page CP. Inflammatory mediators & asthma. *Pharmac Rev* 1988; 40: 49-84.
 27. Abdul-karim RW, Drucker M, Jacobs RD. The influence of estradiol on cholinesterase activity in the lung. *Am J Obstet Gynecol* 1970; 108: 1098-1101.
 28. Vidic B, Kapur SP, Jenkim DP. Estrogen on tracheal secretion : the effect of estrogen on the epithelial secretory cells of the rat trachea. *Cytobiology* 1978; 18: 10-12.
 29. Eliasson O, Densmore MJ, Scherzer HH, De-Graff AL. The effect of sodium meclofenamate in pre menstrual asthma: a controlled clinical trial. *J Allergy Clin Immunol*, 1987; 79: 909-918.
 30. Rubio RL, Rodriguez GB, Collazo JJ. Comparative study of progesterone, estradiol and cortisol concentration in asthmatics and non asthmatic women. *Allergol Immunopathol* 1988; 16: 263-266.
 31. Bousquet J, Chung P, Lactose JY. Eosinophilic inflammation in asthma. *New Eng J Med* 1990; 323: 1033-1039.
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10

Recent Research Update in Yoga

Sw. Mangalteertham*

ABSTRACT:

If we try to summaries the recent trends of Research in Yoga, we will have to give a bird's eye view to the research work done in last two decades in India & abroad. These researches are mainly centered round the following areas: Physiological research; Health & Management of diseases; Pranic Healing; Perception & Motor Co-ordination; Athletic performance; Yoga in Army, Yoga in prison, Yoga for women, Alcoholism, Smoking & Drug Addicts, Yoga as life style. In this way, slowly but surely, the ancient science of India is being integrated into the main stream of modern medicine & relevance of this science is well understood.

Introduction:

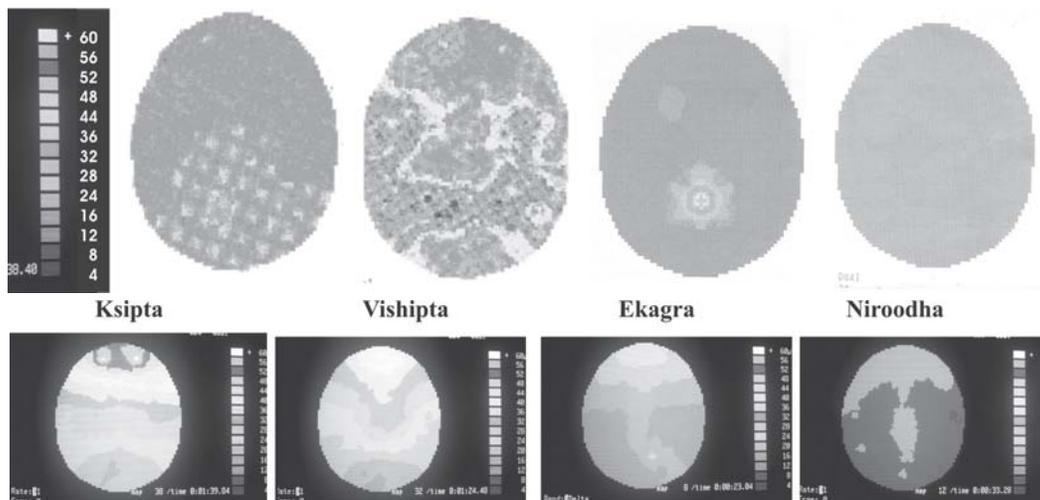
In the last few decades, much has been added to ours scientific knowledge of Yoga, a science that gives inside into the nature of mankind. For those wishing to explore the nature of the relationship between body & mind, the work carried out in India & other part of the world is quite inspiring. These investigations clearly indicate the Yoga is not only a health preserver & promoter, but it also helps to relieve many diseases, which are resistant to conventional therapy. In this way, slowly but surely, the ancient science of India is being integrated into the main stream of modern medicine, if we give bird's eye view to research carried out in Yoga, we reveal that they are centered round in following area: (1) Physiological Research (2) Health & Management of diseases (3) Pranic Healing & function computerized diagnostic tool by ARM PERSEVET (Dermetron), (4) Perception & Motor Co-ordination (5) Athletic performance (6) Yoga in Army (7) Yoga in prison (8) Yoga for Women (9) Alcoholism, Smoking & Drug Addiction (10) Yoga as Life Style.

(1) Physiological Research: The initial work which started in 1923 –1924 at Lonavala by Kovalynanda & his associates was begging of Yoga Research but this

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put a solid base to fundamental research on influence of Asanas, Pranayamas, Mudra Bandha, & Kriyas. They studied in detail about the influence of Hatha Yoga & Meditation on Human system i.e. circulatory & respiratory system responses. Bhole & his associates 1980 studied the influence of Dhauti & Nauli on Gastric, Constipation & Indigestion. They showed also a regulation of heart rate B.P. Prabha, 1987 showed in detail about reduction in sympathetic tone of ANS at Himalayan International Institute. They also studied neurochemical co-relates, neuro muscular activity, neuro physiological activity during TM.

Brain activity & Yoga- Bagchi & Wgner (1957) Anand Chinna, Singh (1961) Kasamatsu (1966), Banquet (1972) Davidson (1976) Wallace (1981) studied about alpha synchronization during Yoga. Mangalteertham (1986) at Charing Cross Medical School in London studied in detail showing the synchronized the alpha activity in Yoga Nidra practice. The author also reveal that Yoga Nidra bring simultaneous & relaxation in both the hemispheres of brain.



Sequence of changes in Yoganidra

Cell physiology & Metabolic efficiency- Udupa, Singh & Shettwar did a commendable job at BHU and studied the effect of Yogic Kriya & others on biochemical influences and found significant effect on physiological homeostatic state. Fenwick (1977) showed a significant influence of physiological, metabolic efficiency & general well being in human system. Mangalteertham (1985) working at Yoga-Bio-Medical Trust at Cambridge proved general deduction in stress related hormone and decline trend in stress reactions.

(1) Health & Management of diseases:

Arthritis – Yoga reduces pain & inflammation was first studied by Coudron (1987), Varni (1998). Further Hoslock, Monro, Nagaratna showed significant improvement in rheumatoid arthritis. Mangalkeertham (1998) proved the efficacy of dietary regulation & Yoga in Management of arthritis & gout.

Bronchial Asthma – Series of studies done at Lonavala (1963-2002, Nagaratna & Nagendra 1982-83) made significant contribution in Yogic management of Asthma, the work at Bihar School of Yoga (1964-2004) indicated that Bronchial Asthma is reversible disease if managed by Yoga.

Hypertension – Datey & Subramanyan (1970) showed significant decrease in B.P. & 68% decrease in drug intake in Yoga group. Benson (1977) Udappa & Singh showed the influence of Sheetli, Ujjayi & relaxation practices on systemic hypertension. Chandra Patel (1977) at London showed significant reduction in B.P. through Savasana. Dean Ornish (1978) studied in detail about the influences of Yogic life style in reversal of heart diseases.

Gastro-intestinal diseases- Series of studies at BSY, Munger, Lonavala, Vivekananda Kendra, Bangalore showed the influence of Yoga practices & Kriyas on IB Syndrome, Peptic Ulcer, Colitis, Constipation, Indigestion & obesity in last few decades.

Diabetes Mellitus – Boden (1985) Desai & Bhole (1985) Nagendra & Nagaratna, Vijlani showed in a series of study that NIDDM group of patient can managed their sugar level efficiently with yoga. Worked at BYB, Munger 2003 at applied yogic science proved that yogic life style could efficiently manage problems of diabetes mellitus.

Insomnia- Mangalkeertham & Rajesh (1999) showed that Tratak helps patients of insomnia.

Depression/ Anxiety/ Anger- H. Jelle (1974) Joseph (1976) studied influence of Hatha Yoga on self-actualization & anxiety. Rajiv Ranjan at BYB, Munger found significance change in anger after yoga practices.

Parkinson-Mangalkeertham (1999) studied the effect of Yoga Nidra asanas & pranayama on group of Parkinson patients & found that yoga helps in stabilizing the situation from further deterioration & relative reduction in dose of dopamine was recorded.

IQ/EQ-Fehr (1979) concluded through a study that yoga increases emotional stability. Sw. Niranjana (2001) studied the effect on IQ & EQ Applying principals of Swan Model.

Kim Seenkum (2002) showed the influence of Yoga in school children & concluded that it can bring about a change in their life by creating balance in physical, mental, emotional & spiritual growth. They are socially more acceptable & decline trend in anxiety level was noticed in children separated from families.

Vivekananda Kendra under the leadership of Dr. S. Telles studied in details about the influences of Asanas, Pranayamas on anxiety neurosis & showed a decline trend in nervousness & depression.

Kochar & Pratap (1972) showed the effect of Yoga Nidra in management of anxiety & hostility. Sushan & Sinha (2001) also recorded reduction in hostility in yoga group.

Management of Pain - D.Ornish (1978), Varni (1981) & Himalayan Institute scientist in (1982) showed importance of pain management in arthritis by Yoga techniques. Gitananda (1982) at I.I.T, Madras studied on the influence of Yoga in management of pain. Kabat Zinn (1987) claimed a significant reduction in chronic pain through Yoga.

Improved resistance to diseases-

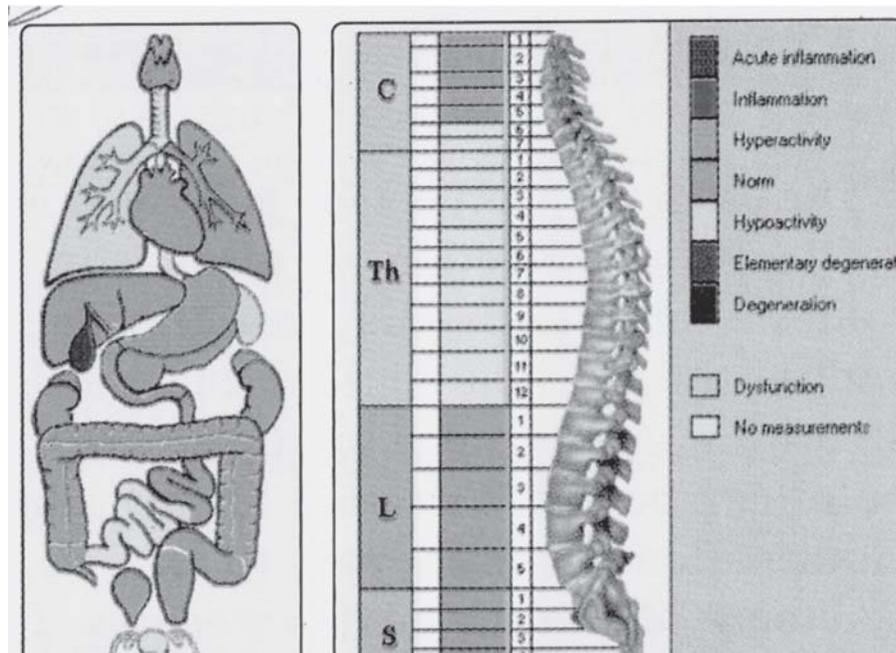
Cancer- Ancel Mears (1960) in Australia for the first time showed the influence of Yoga in management of Cancer. Black Wood Bolden studied the influence of yoga and Cancer. Monro (1985) said Yoga helps Cancer patients. Vivekananda Kendra, Bangalore also formulated the management of cancer through Yoga.

AIDS- Praamurthy (1994) at Satyananda Yoga Center, London studied the use of Yoga & Amroli in management of HIV patients. Out of ten, six still surviving while four died during treatment. M. Vega (2002) said that practice of Antar Mouna & Meditation made him HIV negative.

Rheology & Yoga- S.K. Pathak (2001) at I.I.T, Bombay studied a significant positive change in blood viscosity, rigidity & RBC cell aggregation.

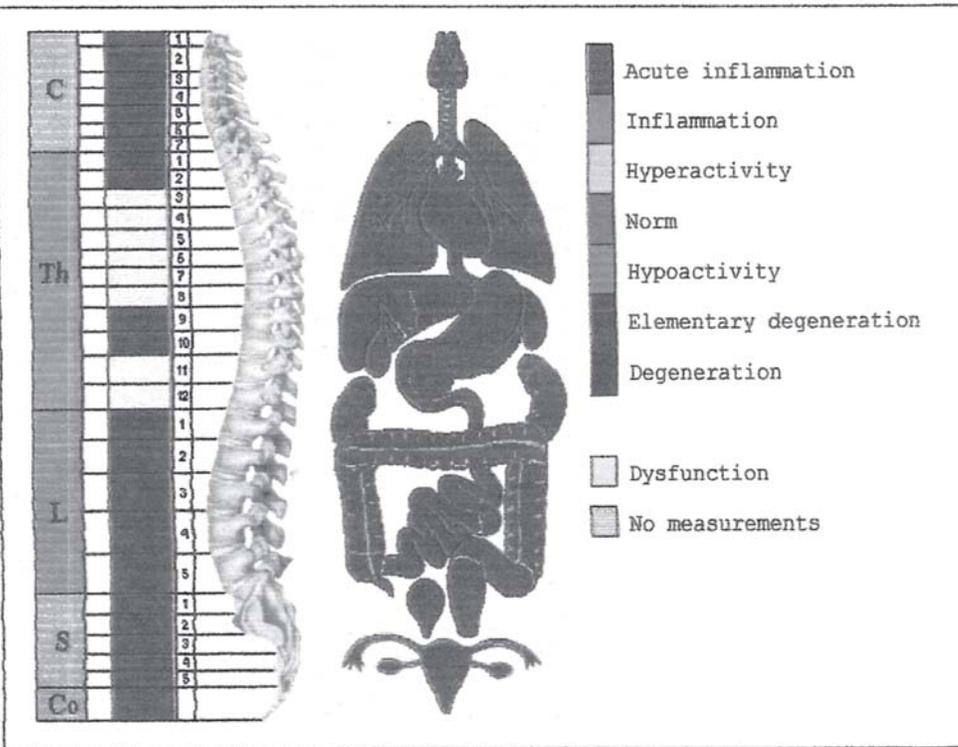
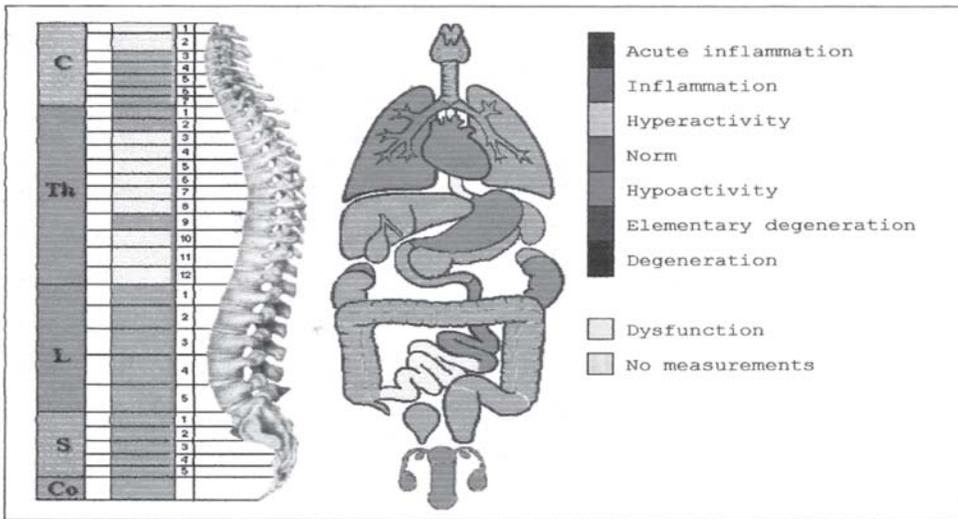
(2) **Pranic Healing & function computerized diagnostic tool ARM PERSVET (Dermetron):** C. Sundaram Vrunda (1999-2003) did

commendable job in assessing the human bio-energy field through GDV, where digital aura was registered and they indicated how this can be used in interpretation of the functioning of Chakra and different organ. Mangalteertham (2003-2004) made use of latest computerized diagnostic tool **ARM PERSVET** in diagnosis of the pathological, pathomorphological changes in organs and tissues. It was also studied latent or other pathological process to determine their pathogenic effects on separate organs and system. On the whole by means of topical it your logic, nosologic & differential diagnosis can be made through this apparatus. This can also be use to realize preventive diagnosis of pre clinical heath status, a new direction of preventive medicine, especially for Yoga & Naturopaths. This enables to Yoga therapist and Naturopaths to diaganose their patients quickly and effectively. It also opens up the possibility to evaluate efficacy of treatment at any phase of progress and to detect in proper time, a side effect of the therapeutics methods in use.



Diagnosis of Pathological Conditions

86 Year old Swami practicing Yoga with no Pathological symptom



Bed ridden patient with different pathological conditions

(4) Perception & Motor Co-ordination:

Intelligence, Learning, Memory & Attention:

Collar (1973), Tioa (1974), Orme-Johanson (1974), Abrams (1974) said Yoga improve academic performance, increases intelligence, learning ability and long term recall memory.

Plicter (1974) found that Yoga helps in development of full mental potential

Mangalteertham (2001) Vaivhare (2002) found Yoga increases both short & long term memory. Vikas (2002) found Yoga enhances memory creativity, self discipline, self confidence, self esteem. In department of yoga psychology, researcher found that yoga increases attention and awareness.

(5) **Athletic performance** : Gupta (1999), Sri Devi (1998) found yoga increase concentration, self confidence & peace. Further studied at BYB, Munger shows significant change in flexibility & stamina while there is reduction in anxiety & depression in sports man through the practice of yoga.

(6) **Yoga in Army:** Selvamurthy (1993) showed yoga improves body flexibility, concentration, memory, learning efficiency, Tivashree (2002) at BYB, Munger showed a marked change in psychomotor performance, emotional security, and emotional stability.

(7) **Yoga in Prison:** Bhushan (1998 a) of BYB, Munger found significant positive transformation in attitude, Behavior and future plans. Improvement in quality of sleep was noticed while significant decrease in interpersonal conflicts and anxiety, was recorded.

(8) **Yoga for women:** Seema, Mrinalini (2001) BYB, applied yogic science, BYB; Munger studies the significant role of yoga in normal childbirth. Prembhaw (2002) showed related to pre menstrual tension & menopause could be tackled better by practices of yoga.

(9) **Alcoholism, Smoking & Drug Addiction:** Benson (1969, 1974) showed a declining trend in alcohol intake, smoking and drugs in yoga group. Robin Monro (1986) through an epidemiological survey showed yoga helps reduction intake of drug, smoking habit and Alcoholism.

(10) **Yoga Life Style:** BYB, Munger (2003) at dept of yoga Psychology did a remarkable study showing, if yoga is added as life style, there is substantial reduction

in anxiety, depression, obsession, hostility, phobic anxiety, period ideation and psycholism.

Books for Further Reading :

1. Abstracts and Bibliography of Articles on Yoga (1983-2004); Kaivalyadhama S.M.Y.M. Samiti, Lonavla (INDIA).
2. Monro, Ghosh, and Kalish(1989) Yoga Research Bibliography; Yoga Biomedical Trust, Cambridge.
3. Dr. Mangalteertham Saraswati (1989) Management of Diabetes through Yoga; Nutan publication, Deoghar (Jharkhand) INDIA.
4. Dr. Mangalteertham Saraswati (1991) Effect of Yoga on Human System & Relevance of Yoga in Prevention & Care of Psychosomatic Disease; Nutan publication, Deoghar (Jharkhand) INDIA.
5. Dr. Mangalteertham Saraswati (2000) Psycho-physiological Change & Healing through Altered State of Consciousness; Nutan publication, Deoghar (Jharkhand) INDIA.
6. Dr. Mangalteertham Saraswati (2001) Yogic Principles of Healing; Nutan publication, Deoghar (Jharkhand) INDIA.
7. Dr. Mangalteertham Saraswati (2002) Science of Brain Breathing; Nutan publication, Deoghar (Jharkhand) INDIA.
8. Dr. Mangalteertham Saraswati (2002) Occupational Health Hazards & Related Disorders; Nutan publication, Deoghar (Jharkhand) INDIA.
9. Dr. Mangalteertham Saraswati (2004) New Rays of Hope in the management of Psychosomatic Diseases; Nutan publication, Deoghar (Jharkhand) INDIA.
10. Dr. Mangalteertham Saraswati (2005) Altered state of Consciousness & Prana in health & healing; Nutan publication, Deoghar (Jharkhand) INDIA.



11

Methodology to be followed in carrying out a Research Project

Dr. Krishna Dalal*

Introduction:

A well structured methodology is always to be followed to carry out any research project in any field to achieve the desired goal within a target time scale. The step-by-step procedure and the related responses must be documented in order to enable others to reproduce the same. It is always to be remembered that all the findings including any adverse result (if any), should be exposed with comments so that any one following the identical route is able to reproduce the identical result and avoid the situation(s) which introducing ill effects . The end result is to be utilized by the public. By this way only, one can authenticate a new method. The research conclusions may be made by a particular person but the beneficiaries may be quite a good in number. Keeping all these in view, one can easily realize the utility of a well planned methodology in carrying out a research project.

Aim of the research project planning:

The investigators must be specific about the aim and objectives of the research project before framing the proposal so that the answers of the following questions are readily available:

- (a) Is it a method of diagnosing any dysfunction/ailment?
- (b) Is it to prevent a disease?
- (c) Is it to treat the patients suffering from chronic/acute disorder?
- (d) Is it aiming at establishing efficacy of a health care system in relation to quarry no.(a) to (c)?
- (e) What should be the target results and accordingly how to frame the objective/ subjective parameters of the study group data records?

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Elements of a proposed trial design:

Any scientific study design can lead to conclude the efficacy of the proposed system only if there is a proper control group. Otherwise, it may be affected by the elements of the social or political environment, which a scientific community does not permit. The elements to be considered in a clinical trial design may be of either of the following:

- Active control
- Placebo control

The proposed trial must also mention the following:

- Place of study
- Whether multi-centered
- Patient population
- Process of randomization
- Levels of blinding
- Duration of treatment
- Protocol of study design

All these elements need attention before finalizing the proposal.

Step-by-step procedures to be followed:

Step-I: Selection Criteria and sample size calculation

The investigator(s) has to think the subjects of the proposed study and accordingly should be strict to select the patients for their study. Keeping this in mind the following type of criteria may be framed.

INCLUSION CRITERIA

- Type of disorders to be included should be specified.
- The maximum distance from the centre of study to the residences of the sample patients should be mentioned. This is required for monitoring the health of the samples.

- The contact address/ telephone number must be mentioned and strict to it so the response of the patients to the therapies (to be provided to them) could be monitored. This is a vital issue for keeping the data records to be used not only at the end of the study but also at least 5 years of the post therapy period. This is because any particular observer wants to monitor the samples at his/her desire, he/she will be able to do it by directly contacting the studied samples.
- A well framed consent proforma should prepared and will be distributed to all the sample patients before admitting them as the study samples. Written consent for offering the individual samples to the study should be collected so that in future there should not be any complaint from the sample patients. This will not only minimize the social/ professional harassment but also medical ethics will be followed.
- What type age group should be included will be mentioned.

EXCLUSION CRITERIA

In the proposal one must mention the following:

- What type of ailments should excluded from the study age group, and
- Any sample not willing to produce the written consent, will be excluded from the study group.
- Any other relevant desired constraints should be specified clearly under this head.

AGE GROUP:

The age group of the sample should be a matched one so that the result of the study would be consistent.

Sample size calculation:

In order to analyze the data statistically, to utilize the possible outcome of the study and hence to conclude research project successfully, the number of samples should be appreciably significant. And accordingly the number should be calculated for this purpose.

The investigator has to remember what type of the study is to be carried out. In the case of a study carrying an equivalent trial between two arms, (to establish the efficacy of a system on the established conventional one, it should always be two arms) the either of following structures may be cited for example:

Group I : Conventional treatment

Group II : Proposed one

OR

Group I : Conventional system

Group II : Conventional system + Proposed one

The response of both the groups should be noted during carrying out the research project. Depending on this, the sample size should be calculated on the basis of the assumed fact that the proposed system would produce the result similar to that of the standard conventional therapies or slightly less than it . These are many hypotheses, out of which the null hypothesis is a well accepted one which can be used for sample size calculation. In this respect one must take advice of a statistician before framing the proposal. One must keep an important characteristics of the public in mind that at least 20% of the samples will be withdrawn from the study. Hence after getting the number through calculation, one must add 20% extra for withdrawals.

Step-II: Initial stage of administering the patients

After selecting the patients for the study, one must be very indifferent in choosing the individuals for the group of patients to be included. One should be strictly unbiased at this stage, otherwise the outcome of the findings will not be a valid one. If the proposed research project Is a randomized clinical trial, one has to select the study subject by generating a set of random numbers by using the standard programme. Keep each of these randomly generated numbers in individual closed envelop which should be opened only by the samples at the time of admission to the therapy in the presence of the investigator/therapist whose signature must be put on the opened numbered sheet. The strict confidentiality should be maintained so that the sample patient and the therapist are not biased in picking up the number and this will lead to select the study samples randomly.

Step-III: Distribution of information sheet

Since the proposed system will be a new type, the sample patients should be aware of the following:

- What is the mode of the treatment?
- What is the duration of the therapy session/administering of oral drugs?
- What are the possible side effects (if any)?
- In case of emergency whom to contact.

It should also mention the following :

- if any item to be brought from home,
- if any precaution to be taken
- if any restriction of diet/any other parameters.

The patients information sheet must contain all the parameters viz., methods, procedure, duration of therapy etc., including the above and are to be illustrated carefully.

Step-IV: Method for prescribing the conventional drugs (if required)

The intended dose of the standard drugs, if it is proposed to be administered to the patients, should be prescribed by a registered practitioner and tailoring of doses, if required during the course of study, should also be done by the same person with proper data record and monitoring the patient's health during a predetermined time period.

Step-V: Recordings of case history

There must be a well-framed format for maintaining the case history of the patients, which may include the following:

- ***Subjective parameters*** (which includes the patients behavior, pain chat, diary for the relevant symptoms, urinary habit, bowel movement, menstrual period, sleep pattern etc.)
- ***Objective parameters***

Depending on the ailments concerned, the investigator has to decide on the objective parameters. The followings are the few examples to choose amongst the others.

The following are the few parameters (for example) to be recorded:

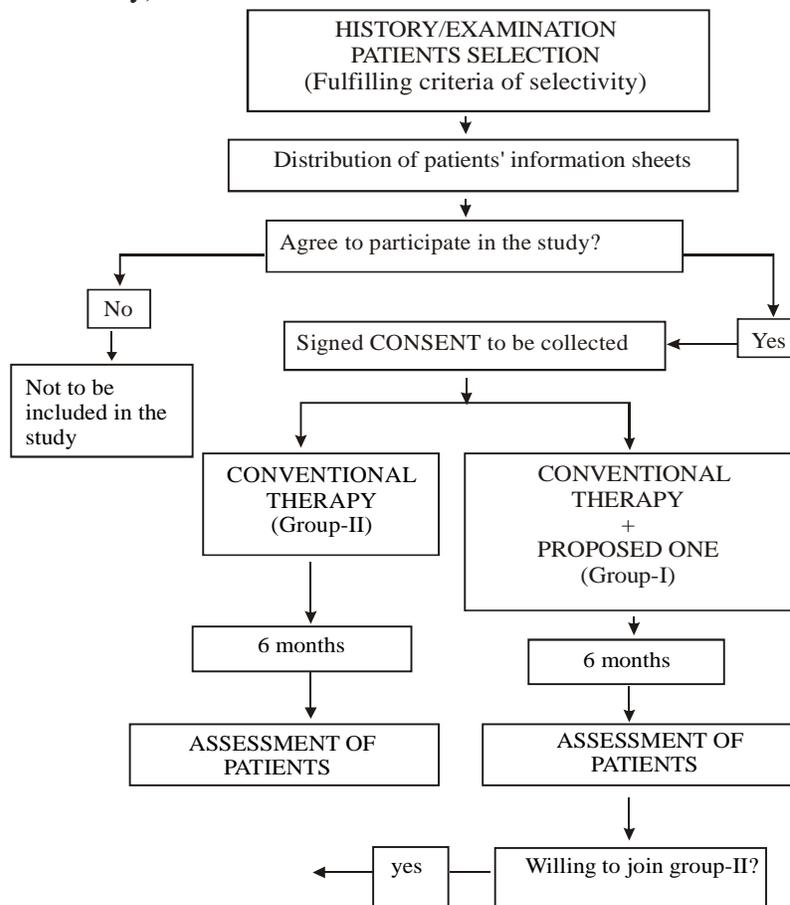
- (a) Pathological
- (b) Bio-chemical

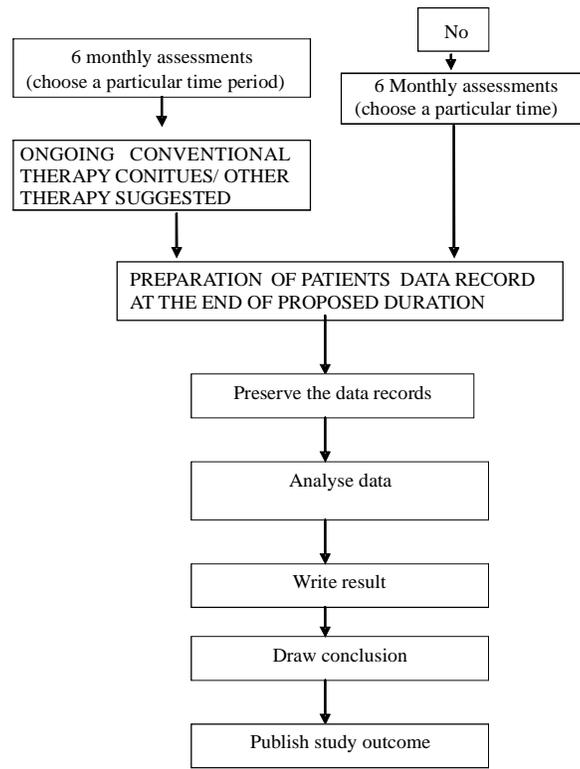
- (c) Physiological
- (d) Physical

The parameters relevant to the ailments should be recorded under different occasions in order to judge the prognosis of the ailments with respect to the proposed method over the conventional standard /any other. These are the very important recordings for judging the efficacy of the proposed system and hence each one of them should be preserved not only upto the study period but also at least 5 years from the date of completion of the study.

Step-VI: Protocol of the study design

Protocol of study design and the step-by-step procedure to be followed during execution of the study should be determined during framing the research proposal. One may proceed as an example in the following (in case of a randomized clinical trial of two arms study):





Block diagram (an example) for the step-by-step procedures

In this regard, it may be mentioned that this exemplified block diagram may be put in a bar chart for expediting one to have a timeframe activity of the research project.

Step-VII: Study Design

This may include the following:

- (1) How is the case history to be maintained?
- (2) How will the health condition of the individual sample be monitored?
- (3) What will be the step-by-step procedure for applying treatment?
- (4) How will the mode of therapy be changed if required?
- (5) What will be the decision criteria of the individual patient's response to the proposed system?

Step-VIII: Decision on the individual patients' response

It is desirable to monitor the samples with a predetermined scale. For this purpose, one must frame the scale according to the requirement. For measurement of pain, one may use visual analog scale having either 100 or 10 divisions and each time

patients themselves should mark their own status of pain by themselves only on this scale and it must be noted down. In the case of behavior there are different scales are availability of life in different age group different ailment group.

For depression in different diseased state or mental status there is also quite large number of scale available in the literature. For this purpose, it is advised to search in the internet or to discuss with the experts. Here id an example of a scale measuring the epilepsy seizure.

(response of epilepsy patients to the proposed therapy, an example)

S. No.	Category	Nos. of seizures occurred with therapy w.r.t. that of the baseline (N_{th}/N_0)*
1.	No improvement	100%
2.	Mild response	75%
3.	Moderate response	50%
4.	Excellent response	25%

* N_{th} = Nos. of seizure episodes with *reflexology therapy* + *Conventional drug therapy (group-I)*

N_{th} = Nos. of seizure episodes with conventional standard drug therapy (**group-II**)

N_0 = Nos. of seizure episodes on base line (i.e. **pre-study data**)

Likewise, one may design one's required scale to measure the response of the sample patients to the treatment.

Conclusion:

It may be remembered that poor planning at the initial stage of the project proposal may result not only in R&D losses but also in both budget and resources. Keeping this in view, there should not be any compromise with respect to any situation. The methodology to be followed in the course of carrying out the study should be standardized by following the same route to all the samples. If there is a change one must mention the case and repeat the same among all the sample patients. One must write in details of the standard methods to bring out the successful conclusion of the research project. This write up only puts an outline of what one has to propose while framing the project proposal and to be followed during the execution of the project. But one has to frame the proposal according to the requisites.



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Research Trends in Yoga Therapeutics: A Perspective

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Introduction:

Research has proved itself to be an essential tool in leading man towards progress, hence it is vital for every type of development to reduce man's areas of ignorance by discovering new truths, which in turn lead to better predictions, better methods of doing things and new and better products. Therefore, Research is diligent and systematic inquiry- an investigation to discover or revise facts, theories and applications.

Here, our main purpose is to review in some detail the types of researches in Yoga conducted so far, especially scientific studies and to suggest some avenues of further research in the field of science of Yoga. The review is no longer exhaustive, yet it takes the cognizance of important landmarks in the investigations of Yoga from different aspects. A glimpse of most facets of scientific research on Yoga given here suggests early and incomplete state of Yogic research and the need for further intensive collaboration between Scientists and Yogins.

Yoga has a great antiquity and long tradition and is a result of thousands of years of careful and systematic exploration by a long line of sages and Yogins on the basis of their meticulous observations and personal experiences. Yoga is a science of life, which helps man to attain his highest potential and highest state of consciousness. Yoga, in its technical sense is supposed to deal mainly with spiritual unfoldment of the individual. However, it has necessarily to do with health activities, which are essential for the success in different spheres of life. The ancient positive sciences of Indian medicine and Yoga consider success essential in all sorts of efforts, ranging from the materialistic gains (worldly pleasures) of lowest category to those of self realization- the highest in the field of spiritualism.

The word "Yoga" signifies functional integration at highest level of spirituo-
psychosomatic development ensuring not only the health of the body but also

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experiencing the positive sense of well being and therefore, laid down certain ways and means in the form of various physical and mental procedures to counteract the malicious environmental influences within and without the human organism. All such yogic practices including Yamas- the rules of social hygiene, Niyamas- the rules of personal hygiene, Shudhikriyas- the purificatory procedures, Asanas- the postural patterns, Pranayama- the breathing exercises, etc. are prescribed to prepare the aspirant for higher practices of yoga proper. These preparatory practices seem to be designed with the purpose of conditioning, deconditioning and /or reconditioning the body-mind machinery so as to extend its range of adaptability.

Beginning of Yogic Research:

Although Yoga has a long tradition, in course of time it was shrouded in mystery and until the beginning of the 20th century there were many misconceptions about Yoga, some of which still prevail in many quarters of the society both in India and abroad. The end of 19th century and beginning of the 20th century was marked with the period of great patriotism and increased awareness of the need for the revival of Indian values and traditions. Yoga was also looked upon as a great cultural heritage of India and attempts were made to revive the age-old discipline of Yoga and bring out its significance in the present day society in the light of modern scientific advancements. Such attempts were the beginning of research in Yoga.

In 1920s Swami Kuvalyananda established the first laboratory devoted to the study of Yoga in Kaivalyadhama at Lonavla. Along with the continuing systematic investigations of Yoga at Kaivalyadhama, there have been studies on Yoga and meditation since 1950s by various Universities and Research Laboratories throughout the world. At present we find a considerable interest in various aspects of Yoga among the research workers. Until now more than 5000 scientific papers have been published on various aspects of Yoga.

Types of Research in Yoga:

Yogic research may be considered in two parts:

1. Fundamental, and
2. Applied

Fundamental research concentrates mostly on obtaining knowledge of what is happening and how is it happening. It is meant for the observation of facts about the various Yogic techniques like Asanas, Pranayamas, Bandhas, Mudras, Kriyas and Meditation, investigated singly or collectively and to understand their working on

various psycho-physical mechanisms and to understand their effects on various psycho-physical levels during their performance or as a result of the performance. Applied research is based on the observed facts of fundamental research and attempt is made to investigate the suitability or otherwise of these principles and facts when applied to a given situation to derive desirable results. The main area of interest in applied research in Yoga is Health and Fitness, which has the following three aspects:

1. Promotive
2. Preventive, and
3. Curative and Rehabilitative

Progress in fundamental research in Yoga:

H.V.Gundu Rao et al.(1958), Ananda and Chhina(1961), Karmbelkar et al(1988) conducted experiments on pit burials. Although in general it was claimed that Yogis could voluntarily control their metabolic functions; it seems more probable what Karmbelkar has pointed out that rather than the control of the subjects on metabolic processes, the results are more related to the concentration of carbon dioxide in the pit. Heart and pulse control by Yogis was studied by Bhole et al (1960), Anand and Chinna (1961a). Wenger and Bagchi (1971) Kothari et al (1973), Green et al (1973), and Karmbelkar et al. (1988). However, these researches were under-taken out of general curiosity. These feats are not real Yoga or Yogic techniques.

Physiological studies may be considered under the following heads:

1. Muscular-Articular responses

Electromyographic studies have been conducted by Karambelkar et al.(1969) and Gopal and Lakshaman(1972) which showed that the performance of Asanas involves less muscular work. Studies by Rasch (1958; Lande, Gharote(1973); Dhanraj (1974); Mall and et al.(1976); Mall and et al (1978) and Gharote,(1990), showed considerable changes in flexibility as a result of Yogic training programme.

2. Circulatory responses

Ganguly and Gharote (1974) measured scores on Harvard Step Test on normal individuals before and after 8 months of Yoga training. There was found an increase of 7.6 in the test score, which was statistically significant. Plethysmographic studies by Bagchi and Wenger (1957) concerning finger blood flow in various practices of Hathayoga showed that the blood flow in the toe was less and blood flow in the finger was greater during the Head stand than during either the horizontal supine position or the erect standing position. They measured the forehead temperature and top of the foot temperature during head stand and found that the forehead skin

temperature increased and the skin temperature of the foot decreased during head stand as compared to other body positions.

3. Respiratory responses

A number of studies have found the basal respiratory rate to be lower in subjects who have practiced a Yogic routine for some time. Datey et al(1969) and Dhanraj(1974) reported breath rate decrease during and after Shavasana. Increase in Breath holding time has been reported by Chinna et al (1968, 1971 ,1974); Udupa(1971); Bhole et al (1973). Increase in tidal volume has been observed by Rao (1968) volume was also found greater than erect standing volume, which resulted in minute ventilation. The normal movement of air in basal state after a regimen of yoga practices or in non basal states in particular Yogasanas or Pranayamas have been studied by Bhole et al.,(1973,1978) respiratory efficiency was improved as a result of Yogic training. The oxygen consumption during and after various Yogic practices was found low.

4. Endocrinal responses:

Dhanraj (1974) reported Thyroxine increase after 6 weeks of Yogic training. Udupa et al (1971,1973) found increased catecholamines in urine and plasma, increase in blood Histaminase, increase in Plasma cortisol and decrease in acetylcholine and cholinesterase. Karambelkar et al.(1969) observed decrease in Uropepsin secretion after the training in Asnas. Autonomic balance studies by Bagchi and Wenger (1957) and Gharote(1971) showed increase in the direction of Para-sympathetic function after Yogic training. Increase in palmer conductance was found in the Yogic subjects, which was indicative of ability to relax voluntarily.

A large number of papers have been contributed on the bio-feed back mechanism and transcendental meditation. A separate publication has been brought out in the form of collected papers on transcendental meditation by Maharashi International University (1963), which indicates the utility of transcendental meditation. ECG patterns and other respiratory variables have been investigated after the practice of various other forms of meditation including Zen. This may be considered a pointer for trans-psychological research.

Progress in Applied Research:

The main interest in Yoga has been from the therapeutical or curative point of view. Although Swami Kuvalyananda started clinical work as an applied aspect of Yoga

in 1920s. No clinical research in Yoga seemed to have been undertaken until 1950s. When the occidental world came in contact with Yoga they looked at it if it could serve as a solution to their problems. An increasing number of people in the society are affected by physical discomforts, which have a psychological background. Gastric Ulcers hyperacidity, headaches, hypertension etc. are the forms of these psychosomatic diseases as they are called. Traditional medical scientists have been occupied with research to find medical remedies and this has been relatively successful. But unfortunately these medicines seem to have unwanted secondary effects. Further more, in most cases it is necessary for the patients to be on medication for the rest of his life. Therefore, lot of people are welcoming new therapeutical approaches and research. Yoga practices including meditation have been investigated mainly for its effects on one of the most ordinary psychosomatic disorder, namely hypertension. The results are promising. Benson and his co-workers (1972) have shown from a number of controlled studies lowering effect of transcendental Meditation on hypertension. Datey and et al.(1969) investigated the effects of Shavasana on the patients of hypertension and showed significant improvement. Effect of yogic practices on various disorders of various systems were also seen and found a remarkable positive response. Terrien(1968); Meti, (1985); Selvamurthy (1998); and Sherifian and Nazi (2006).

Research in Yoga Psychotherapy:

First attempt in this direction was made by Swami Kuvalyananda and Vinekar, (1973). Later on “The Evolution of Consciousness” of Swamy Rama, Ballantine and Swamy Ajay (1976) and Psychotherapy East and West: A Unifying Paradigm (1984) of Swamy Ajay, presented a full fledged system of yoga therapy based on smakhya yoga, hatha yoga, adavita vedanta and tantra. The system encompasses a wide variety of body, mind and behavior techniques. Swami Ajaya also pointed out in his book, striking similarities between current psychotherapies and classical practices. Those of us who are looking for a conceptual framework and a set of procedures, which are, not alien but close to the Indian mind, would certainly find yoga therapy as very handy. Krishna Rao (1995) reviewed the progress in area by his paper on Yoga: Its Scientific and Applied aspects. Vasudevan and et al (1972) on tension and headache; Punjwani on epilepsy and et al(1995); Mukhopadhyya (2005) on the concept of psyche; Chhabra (2006) on depression also conducted studies on the same lines. Kochar and Pratap (1971,1972) and Kochar (1972,1972a,1976 studied the effects of Yogic Practices on neuroticism, anxiety and hostility.

It is very interesting to note that historically it was the psychoanalytic writer Geraldine Coster who in the classic, *Yoga and Western Psychology* (1934) first appraised the therapeutic potential of yoga and presented an elaborate comparison of Freudian Psychoanalysis and Patanjali's yoga. In a sense she anticipated the contemporary interest in yoga as a psychotherapeutic system.

It would be refreshing for those of us who are interested in yoga or psychoanalysis to look at some of Coster's observations, especially in the context of an overwhelming contemporary interest in yoga. In the background of Freud's skeptical attitude towards the mystical experience, which he tended to regard as regressive and pathological in nature (e.g. Freud, 1961) it will be instructive to juxtapose yoga and psychoanalysis.

According to Coster, Yoga contains the clue needed by the West if the psychoanalytic method and theory is to reach its fullest scope as a regenerating and recreating factor in modern life. If salvation is understood as the security of genuine happiness, poise determined by one's own inner life, self-knowledge of the analytic kind and the Eastern kind might supplement each other. For some people it may even give an experimental proof of the reality of the world beyond the drop curtain.

Decreased level of anxiety is a main trend of number of experiments by Udupa (1972); Goleman (1976). A major finding is an increased ability to resolve conflicts. The report concluded significant difference with higher scores for self-esteem, self-identity, self-satisfaction, personal worth, behaviour and physical self. The emotional adjustment seemed to be more positive, less feeling of general mal-adjustment, less personality disorder and less neurosis.

So far as preventive aspect of applied research is concerned practically no work has been done. For example, any controlled group not practicing yogic exercises will have disease as compared to the group, which has long term practiced yoga and did not fall at all or had comparatively lesser frequency of illness during a definite period. The researchers are expected to undertake such studies. Promotive aspect deals with the maintenance or improvement of health and fitness. This is a very potential field and though limited research has been done, the work of Giri (1963); Ganguly (1974) and of Therrien (1968) have shown enough evidence about how Yoga could be gainfully employed in the promotion of physical fitness. Different factors of physical fitness and qualities required in the betterment of performance in various sports activities seem to be effectively developed by intelligent use of varieties of Yogic techniques. Books such as "Yoga and Athletics" *Yoga and Tennis*", *Inner Game of Tennis* have been written which indicate the directions of applying Yoga in different fields of Physical Education and Sports activities.

Literary Research:

Apart from fundamental scientific and applied research there is an area of philosophico-literary research, which has not been much attempted. Only indologists and oriental scholars sometimes publish research papers in the literary aspect of Yoga. But as yet, not much has been written by way of research on the various Yogic practices. Now people in India are engaged in such type of literary research as preparation of Yogic Encyclopedia, Dictionary of Yoga, Bibliography of articles on Scientific Yoga as well as philosophico-literary and exhaustive catalogue of Yogic literature in Manuscript form. But there is much to be done in this area of research. Only Kaivalyadhama, S.M.Y.M Samiti, Lonavla and Lonavla Institute of Yoga, Lonavla have done some pioneer work by publishing selected ancient yogic texts, glossaries, bibliography and encyclopaedia.

Problems, Limitations and suggestions for improvement in the research of Yoga:

The studies conducted to see the effects of yogic practices included a very small number of subjects. Further, no comparative study of two types of programme i.e. yoga and any other system of exercise has been made. Similarly no comparative study has been made on male and female subjects. More reliable instruments and techniques to evaluate components of physical fitness need to be used and better design and statistical procedures should be applied to enhance reliability and validity of our results.

Similar is the case with the studies conducted to gauge psychological and physiological effects but replication of studies in most of the investigations conducted by medicos and other scientists in India and abroad has proved beyond doubt that yogic practices help in the development and maintenance of better biological integration than any other conventional physical activity (Romancwaski and Pasek, 1970). However, it still needs further verification of results under controlled conditions. To achieve success in such efforts it is desirable that some schools and colleges should be run on the lines of yogic way of life in various parts of the world. So that long term as well as comparative studies on the two systems of activities may be easy.

Our methods of doing asanas or any other practice are different. Age and sex groups are similarly different; limitations of the duration of the individual practices have not been assessed by laboratory work. This needs immediate attention of the scientists. Besides, the asanas are practiced in variety of rhythms i.e. in slow and fast sequences. There is definite instructions in the yoga literature that yogic practices be done in slow and consistent rhythm.

The major problem in wide popularization of yogic practices is that the original yoga texts, which are in Sanskrit language, are neither being read nor interpreted properly. The task of translation and interpretation of such texts should immediately be taken up by the scholars from the field of yoga literature and philosophy.

Next, we badly need the use of sophisticated instruments to gauge the subtle psycho-physiological effects and also their expertise use. Research institutes should see that some suitable people are sent to distinguished laboratories abroad to be trained in monitoring and manipulation of such instruments and useful gadgets should be imported for the use of research in yoga.

For proper popularization we need inexpensive yoga literature to be available in all regional languages with elaborate illustrations and instructions for distribution among the masses. A number of magazines and generalists too are needed to be published regularly to keep abreast of the new developments, achievements and application of yoga practices.

The dearth of adequate competent personnel to man the research department/institute of yoga is only matched today by the lack of vision, back ground of language and literature, self practice of and experience in yoga, originality and even of elementary knowledge of latest research techniques displayed by quite a few who are trying to fill the void. What to say of private yoga institutions some of our Government training and research institutes/organizations are headed and subordinated by such personnel and hence the outcome, if it cannot be said nil, it is definitely below expectations. Therefore the controlling authorities should see that the heads of such institutions are highly qualified in the science of yoga. The director/head should be one who is most effective, stimulative and consciously active in research. He should be most prone to have thorough knowledge of and insight into his field. Workers from other allied disciplines like anatomy, physiology, physics, chemistry, anthropology, psychology, nutrition, sociology etc. should be incorporated as per requirement of an institution/organization. The research in yoga needs cooperation and mutual understanding between the various agencies like health, medicine, education, industry, defense etc. in conducting research. A better communication between such agencies can be developed by organizing seminars, symposia etc. In short the following are some important points to be considered for the improvement of Research in Yoga:

1. There is a dearth of devoted workers in the field of research in Yoga who have proper background of research and adequate knowledge of Yoga.
2. Although there is an interest in therapeutical application of yoga, the

progress of clinical research in Yoga is very slow. This is owing to the following reasons:

- a) People are not ready to receive Yogic Treatment or over a long period.
 - b) Research worker is unable to maintain a follow up because of the lack of cooperation from the patients.
 - c) There is no uniformity in the techniques.
3. Even when some research workers want to pursue Yogic researches, many a time financial and technical assistance is not adequate.

Therefore to remove the above hurdles and to promote Yogic research, the following steps would be useful.

1. To encourage devoted workers and induce them to take up research projects by providing some research scholarships.
2. To remove the difficulties of the institutions working in the field who have reputation for their research work by providing liberal technical and financial help.
3. Proper Design of Research Protocols. This will help-
 - a) to establish a cause and effect relationship and
 - b) more important mechanisms involved in bringing about the changes at different levels of cascade of the net results.
4. People are interested in curative aspect of Yoga. This situation can be exploited for conducting research projects, which should be liberally supported. Although Central Council for research in yoga and Naturopathy is helping this cause, the efforts are inadequate.
5. Frequent symposia and seminars should be held for the exchange of information gathered by various institutions and individuals.
6. International research projects should be encouraged under cultural exchange programme.

Much needs to be done by way of research on sound lines in the yogic research. The field is full of potentialities for research and we hope to see this field of research to develop at the global level in near future.

References:

Ajay, Swami (1984)

Psychotherapy East & West : A Unifying Paradigm, Honesdale: Himalayan International Institute of Yoga Science and Philosophy.

Ananda, B.K. and Chinna, G.S. (1961)

Investigations on Yogies Calaiming to Stop Their Heart Beats; Ind. J.Med. Res. 49,1,Jan. pp 82-94.

Ananda,B.K.,Chinna,G.S. and Singh,B(1961a)

Studies on Shri Ramananda Yogi during his stay in an air tight box. Ind J.Med. Res. Vol.49:82-89

Bagchi, B.K. and Wenger, M.A. (1957)

Electrophysiological Correlates of some Yogic Exercises, Electroencephaclin Neurophysiol, 7,132-149.

Bhole,M.V.(1960)

Studies on human subjects staying in an air tight pit. Ind Jour.Med. Res..Vol 56:1282-1287

Bower, J.E, Wooery, A , and Sterniebo, B (2005)

Yoga for Cancer patients and survivors. Cancer Control: July;12(3); 165-71.

Chhabra,V(2006)

The role of Yogic Processes in the management of depression. In Ganesh Shankar ed. Psychotherapy, Yoga and spirituality. New Delhi: Jagdamba Publishing Co.

Chinna,G.S.,Anand B.K. and Singh B.(1968)

Some further studies on physiological changes in Yogis. Ind jour. Physiol. Pharmacol, Vol 12: pp40-45.

Chinna,G.S.(1971)

Effect of yogic practices on some body functions. Proc. Int U. Physio. Sci.25th Int. Congr. Munich, Vol.9:p.110.

Chinna G.S (1974)

The voluntary control of autonomic responses in Yogis. Proc. Int. U. Physiol. Sci. Vol 10:pp.103

Coster, G. (1934)

Yoga and Western Psychology: A Comparison, Oxford University Press, London.

Datey, K.K., S.N. Desmukh, C.P. Dalvi and S.L. Vinekar (1969)

Shavasana-A Yogic Exercise in the management of hypertension. *Angiology* 10:325-333

Dhanraj, V.H. (1974)

The Effect of Yoga and the 5 BX Fitness Plan on Selected Physiological Parameters. Ph.D. Thesis, University of Alberta, Canada.

Ganguly, S.K. and Gharote, M.L. (1974)

Cardiovascular Efficiency Before and After Yogic Training, *Yoga Mimamsa*, Vol. XVII, No.1, 89-97.

Gharote, M.L. (1982)

Yoga Therapy- Its Scope and Limitations, *Jour. of Res. and Edu. in Indian Med.* 1:2:p.37.

Gharote, M.L. (1990)

Applied Yoga, Kaivalyadhama, S.M.Y.M. Samiti., Lonavla.

Giri, C. (1963)

Yoga and Physical Fitness with Special Reference to Athletics: A Research Report, Submitted to the Govt. of India through K.S.M.Y.M. Samiti, Lonavla.

Green E.L. and Green, A.M. (1973)

Volition as Metaforce in the Field of Mind Theory. Voluntary Controls Programme Research Deptt. The Menninger Foundation, U.S.A.

Goleman, D. (1971)

Meditation as Meta therapy: Hypothesis towards a Proposed 5th State of Consciousness, *Jour. of Transpersonal Psychology*, 31:1-26.

Gopal and Laksaman (1972)

Some Observations on Hatha yoga- The Bandha: A Study , *Indian Jour. of Medical Sciences* 9:564.

Gundu Rao, H., Krishnaswamy, N., Narasimhaiya, R., Hoening J and Govindaswamy, M. (1958)

Some experiments on a "Yogi" in controlled states. *J. All India Institute of Mental Health*, Vol.1:99-106.

Hiroki, K., Hisako, W., Keishin, K. (2006)

Yoga Therapy for management of liver dysfunction due to chronic Hepatitis B. A case study" in *Psychotherapy Yoga and Spirituality* –G.Shankar ed. New Delhi: Jagdamba publishers Co.

Karambelkar et al (1969)

Effect of Yogic Asanas on Uropepsin Excretion:. Ind. Jour. Med. Res. 57:5:944-947.

Karambelkar, P.V. Gharote, M.L., Ganguli, S.K. and Moorthy, A.M. (1977)

Effect of Short-term Yogic Training on Serum Cholestrol Level, Yoga Mimamsa, 19: 1:1-12.

Karambelkar, P.V., Vinekar, S.L. and Bhole, M.V. (1988)

Studies on Human Subjects Stayingin an Air tight Box, Indian Jour. of Med. Res. 56: 1282-1288.

Khanam,A.A.,Sachdeva,U. and et al (1966)

Study of pulmonary and autonomic functions of Asthma patients after Yoga Training, Indian Journal of Physiolo. Pharmacolo.40 (4) 318-324)

Kochar, H.C. (1972)

Yoga Practices as Variable in Neuroticism, Anxiety and Hostility, Yoga Mimamsa, Vol. XV, No2 :37-46.

Kochar, H.C. (1972)

Yoga Practices as Variable in Neuroticism, Anxiety and Hostility, Yoga Mimamsa, Vol. XVI, No.2: 37-46.

Kochar, H.C. (1976)

Anxiety, General Hostility and its Direction as Result of Yogic Practices, Yoga Mim., Vol. XVII No.4,73-82.

Kochar,H.C. (1979)

Effect of Yogic Practices on Immediate Memory:., SNIPES Jour. 2(2):36-38.

Kochar, H.C. and Pratap, V. (1971)

Neurotic Trend and Yogic Practices, Yoga Mimamsa, Vol. XIV.No.1 & 2

Kochar, H.C. and Pratap, V. (1972)

Anxiety Level and Yogic Practices, Yoga Mimamsa, Vol. XV, No.1 : 11-15.

Kothari, L.K. Bordia, A., and Gupta, O.P. (1973)

Studies on a Yogi During an Eight Day Confinement a Sealed Underground Pit:. Indian Jour. of Med. Res. 61:1645-1650.

Krishna Rao P.V. (1995)

Yoga : Its Scientific and Applied Aspects, Jour. of Indian Psychology, 13:2;pp1-11.

Kuvalyananda, Swami (1925, 1928)

Cited in Papers on Yoga, Swami Digambar ji(Ed), Kaivalyadhama, Yoga Institute, India.

Kuvalyananda, Swami and Vinekar, S.L. (1973)

“Yogic Therapy”, Central Health Education Bureau, Ministry of Health, Govt. of India, New Delhi.

Lanade, V.K. and Gharote, M.L. (1990)

Effects of Yogic Training on Physical Fitness and Selected Athletic Events, Yoga Mim., Vol. XXIX No.1,55-56.

Malhotra, J.C. (1963)

Yoga and Mental Hygiene, Amer. Jour. Psycho Therapy, 17:436-442.

Malhotra, V and Tandon,O.P.(2005)

A study of the effects of individual asanas on blood pressure, Indian Journal of Traditional Knowledge. Vol.4(4) 367-372.

Mall,N.N., Chaudhary,G.S. and Giri, C. (1976)

Effects of Relaxo- concentration Training on Two Psychomotor Tasks After Submaximal Exercise, Paper presented at the VI National Conference of Sports Medicine at Amarawati (Maharashtra).

Mall, N.N. Chaudhary G.S. and Giri,C. (1978)

Effect of Yogic Relaxo- Concentration Training on Two Psychomotor Skill after Submaximal Exercise, SNIPESJour. Vol. 1,2: 55-58.

Meti, B.L. (1985)

Study of Neurophysiology of Pranayamas, Ph.D. Thesis, Bangalore University, Bangalore.

Mukhopadhyaya, A.K. (2005)

Elements of Human Psyche:Crystallizing new rationality and objectivity in Psychotherapy, Paper presented in World Congress of Psychotherapy IV, at BuenosAires, Argentina.

Punjwani,U.,Gupta,H.L. et al(1995)

Effects of Sahaj Yoga practices on Stress management in Patients of Epilepsy. Indian Journal of Physiological Pharmacology.39(2):111-116.

Ram,Swami(1976)

Evolution of Consciousness.Honesdale:Himalayan International Institute of Yoga, Science and Philosophy.

Rao,S (1968)

Oxygen consumption during Yoga breathing at altitude of 520 m and 3800 m Ind. J. Med. Res. Vol. 56: 701-5

Rasch. C.J. (1958)

The Functional Capacities of a Yogi, Jour. of the American Osteopathic Assoc. 58; 520-523.

Romanovaski,W and Pasek,T (1970)

Tentative introduction of relaxation-concentration Gymnastics according to Yoga system as supplementary exercise in physical education of students". Scientific Conf. Medic. Faculty, Poznan 4:24-25.

Selvamurthy,W. (1998)

"Yoga in Army", Yoga, Vol. 9, No. 3, May, 1998.

Sharifian,S and Nazi.S.A (2006)

Effects of Yoga on Diabetes. In psychotherapy, yoga and spirituality: Ganesh Shankar Ed. New Delhi: Jagadamba Publishing Co.

Terrien,R. (1968)

Influence of a 5BX and a Hathayoga Training Programme on Selected Fitness Measures Completed Research in Health, Physical Education and Recreation, 11-25.

Udupa, K.N., Singh. R.H., Yadav, R.A. (1973)

Certain Studies as Psychological and Biochemical Responses to the Practices of Hatha Yoga in Young Normal Volunteers, Indian Jour. Med. Res., 61-62.

Udupa, K.N., R.H. Singh & Yadav (1973)

Certain studies on psychological and biochemical response to the practice of Hatha Yoga. Ind. Jour. Med. Res. Vol. 62:237

Udupa, K.N., R.H. Singh & Settiwar (1974)

Physiological and biochemical studies on certain yogic practices. Proc. Symp on yogic practices and physiological functions, M.L.B Medical College, Jhansi.

Udupa, K.N., R.H. Singh & Settiwar (1972)

Physiological, Endocrine and Metabolic Response to the Practice of Yoga in Young & Normal Volunteers, Jour. of Research in Indian Medicine, 61:345-353.

Vasudevan.A.,Kumaraih,V. and Balodhi,J.P.(1994)

Yogic meditation in tension headache. NIMHANS Journal, 12:69-73.

Wallace, R.K. (1970)

Physiological Effects of Transcendental Meditation, Students International Meditation Society, Los Angeles, California.

Wenger, M.A. and Bagehi, B.K. (1971)

Studies of Autonomic Functions in Practitioners of Yoga in India, Behavioural Science 6:312-323.



13

Psychological aspects in Yoga Research

Saraswathi V, *

ABSTRACT

This paper poses the fundamental question for researchers: “Does *yoga* need to be proved by science?” It explores the current trends in *yoga* research that have a strong leaning on physiological and biomedical aspects with minimal focus on psychological outcome measures. While the mind-body relationship is very well established and accepted by the scientific community, this concept has unfortunately not percolated deep enough to influence the research orientation in *yoga* that continues to follow the pure scientific model. An alternative model that is based on the *yoga* tradition encompassing every dimension of human existence is suggested and empirical evidence based on such a study is presented in this paper.

Introduction

Research in *yoga* is predominated by studies focused on physiological and bio-medical outcomes. Autonomic balance, cardiac and respiratory activity, biochemical changes, muscular flexibility etc., are researched in relation to *yoga* practice in normal volunteers as well as clinical groups. *Yoga* research has also focused on specific effects of postures singularly as well as in combination. An extension of this approach has demonstrated the therapeutic impact of *yoga* in disease management, prevention and health promotion.

A second line of research has emphasized on the cerebral or cortical functions in relation to breathing and meditative practices. Effect of concentration and meditation in influencing different states of consciousness is also being explored which has far reaching influence in changing the psycho-physiological status of an individual. Studies have also focused on stress reduction techniques in *yoga*, practices designed to reduce anxiety, depression etc., where again the emphasis has been on standardization and quantification with the outcome being measured through standard objective tests rather than the subjective feelings of improvement and well being experienced by the subjects.

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In this process, we have undermined the most fundamental and essential component: “the mind”. The mind is the object of concern based on which the entire philosophy of *yoga* was structured. This basic entity has now been eclipsed by the importance given to body postures and techniques, physiological functions and biochemical changes.

As a result of this orientation, *yoga* research is conducted in sophisticated laboratory settings with very little or no space for acknowledging or exploring the real meaning or impact of *yoga* on different dimensions of human existence namely, physical, psychological, social and spiritual.

Does *yoga* need to be proved by science?

To let science “evaluate” or “prove” *yoga*, that has survived thousands of years through generations of practitioners, would be undermining the strength of this wonderful system of knowledge and practice. At the same time, disregarding science would be tantamount to marginalising the system and taking a risk of it being understood as merely a “belief” model. *Yoga*, as any other holistic system, will benefit from a scientific approach to gain insight into its different dimensions without having to compromise on its basic structure and values. Placing and understanding *yoga* in the light of science in such a way that it reflects the entire spectrum of human life is the challenge of any meaningful research study.

Hence, the purpose of *yoga* research should ideally be:

1. To understand **how** *yoga* works: what are its different components, how do they function, what is their influence on different dimensions of our system, what factors impact their influence etc.
2. To **explore means to apply** this knowledge and develop meaningful models in therapy/healing.

Resolving the dichotomy: physiological vs. psychological studies

Scientific investigations in *yoga* have paid minimal attention to psychological parameters in therapeutic interventions. The relationship between mind and body has been very well established by holistic systems like *yoga* and also accepted by modern science. But the interrelationship between psychological and physiological aspects is yet to be thoroughly evaluated in these studies. The physiologists have ignored the psychological components and psychologists or others studying psychological effects have undermined the physical impact.

Research in *yoga* has therefore become piece meal with some groups focusing on body, some others emphasizing on specific mental functions and others trying to see the impact of *yoga* on social factors. This specialization has become so reductionistic that people have started believing Asana is for body, *Pranayama* is for *prana* and Meditation is for mind.

The obvious dichotomy that exists between physiological and psychological approaches needs to be resolved to arrive at a comprehensive and meaningful understanding of the process of healing or change through *yoga*.

Understanding the term *Yoga*

According to Sage Patanjali, *yoga* is for the mind. In his text *Yoga Sutra*, the earliest and most authoritative text on *yoga*, he defines *yoga* as a state of mind - “*Yogah Citta Vrtti Nirodhah*” (*Yoga Sutra*: 1.2) - a state where the mind is totally focused and stable. Mind and its functions, its problems and unimaginable possibilities are presented in this text. By dealing so exhaustively with the most versatile, elusive, enigmatic and all pervasive aspect of our existence, Patanjali takes the position of the foremost and greatest psychologist that ever existed.

The impact of *yoga* is predominantly on the mind or the psyche. *Vyadhi* (illness) is presented as an obstacle in the path of *yoga* along with other problems of the mind¹.

A disturbed state of mind manifests in four ways²:

- (1) *Duhkham*: emotional suffering
- (2) *Daurmanasya*: negative thinking
- (3) *Angamejayatva*: physical discomfort
- (4) *Svasaprasvasa*: disturbed breathing pattern

It can be seen that a disturbed mind influences the body, breath, emotions and attitudes, and therefore the whole being. Disturbance at the level of the body affects the breath and mind, disturbance of the breath affects the mind and body and disturbance of the mind affects the body and breath. This interrelationship between body, breath and mind can be exploited through appropriate practices in *yoga* (such as asana, *pranayama*, meditation, visualization etc.,) to bring about positive changes.

Understanding the human system and health

The fundamental premise on which *yoga* operates is that every individual is made

up of a complex whole comprising of several interdependent, interconnected dimensions. The essence of any approach in *yoga* is the seamless connection between these dimensions.

Several interesting models have been presented by the ancient Indian scientists to substantiate this view. One such model given in the *Taittiriya Upanisad* (Chapters 2 & 3) which forms the corner stone for healing is the ***Panca Maya* model**. This basic model of human health and well being interweaves five different dimensions: the physical body, energy (breath), intellect, personality and emotions. The dynamic balance of these dimensions forms the basis for good health and imbalance denotes ill-health.

Whether it has to do with understanding a symptom or its cause or the efficacy of a particular tool in *yoga*, it is difficult, rather impossible, to compartmentalize them as being purely physical, mental or emotional. The same model also reinforces the fact that every human being is unique and special, requiring individualized attention for the intervention to have any substantial influence.

The model for healing

Yoga presents the whole model of healing through a very practical and simple model³ :

1. ***Heyam***: Awareness or recognition of the problem that requires remedy. *Heyam* encompasses all those symptoms the person experiences that he/she wishes to overcome.
2. ***Hetu***: Enquiry into the cause(s) of the problem will provide the actual direction for therapy.
3. ***Hanam***: Defining realistic and workable goals will be the next step in the healing process.
4. ***Upayam***: The different possibilities and solutions offered in *yoga* to reach the desired goals, comprising of both conventional and unconventional tools.

This model implies that the *heyam*, *hetu*, *hanam* and *upayam* can be different for

Yoga Sutra: 1.30

Yoga Sutra: 1.31

Model drawn from the second chapter of Yoga Sutra of Patanjali; actively used in therapy and research work in the tradition of T Krishnamacharya.

different people and vary for the same individual from time to time. The approach in healing should hence be dynamic and comprehensive.

Approaches in *yoga* should be essentially individual-centric and not disease-centric.

Current Trends in *Yoga* Research

Research models used in *yoga* studies follow the basic clinical paradigm where a certain set of characteristics to be studied are defined in terms of physiological or psychological parameters, specific and standardized set of techniques are used as input, training in *yoga* follows the mode of “administration” of a drug with specific dosage/intensity and the output is measured through physiological/biomedical tests to prove or disprove a hypothesis. Hardly any importance is given to the process except ensuring standardized practices and “clinically managed” dosages of intervention. The individual who receives the training and is the actual focus for healing has no place in this paradigm.

Also, with reference to psychological factors, following the pattern of clinical studies, only negative attributes/variables are studied.

This model stands in stark contrast to the models of healing presented in the yogic tradition. *Yoga* is a positive science. Most of the immediate benefits of *yoga* practice are expressed as positive attributes: better energy levels, positive frame of mind, relaxation, peace, better focus and attention in activities, positive attitude towards self and others, improved relationships etc. Hence there is also a need to evolve positive measures specifically for measuring the outcome of *yoga* training rather than using the existing standard measures to evaluate psychological changes.

Need for a paradigm shift

“... while modern scientists have looked ‘outward’ for measurable observations for the basis of their knowledge, yogis have looked ‘inward’ to their own bodies and minds. There is nothing unscientific about it. There is no reason from a scientific point of view why such internal information should not be utilized as an observational basis for scientific knowledge. ... Our preoccupation with quantification and standardization needs to be tempered with ‘disciplined subjectivity’”.

- Robin Monroe

In the fourth chapter of *Yoga Sutra*⁴, the yogi is presented as a farmer who knows everything about the crop, the field, the climate and appropriate conditions for growth and change. This is a very interesting allegory for a *yoga* teacher/therapist who should know everything about the student and apply his knowledge in choosing the appropriate tools to effect healing/transformation. The process of healing itself is one that requires intensive study.

Input: *Yoga Upayam*

Yoga offers a variety of tools that are often used in combination to bring about the desired change in the individual:

- Social attitudes (*Yama*)
- Personal attitudes (*Niyama*)
- Physical postures (*Asana*)
- Breathing practices (*Pranayama*)
- Meditation (*Dhyanam*)
- Visualisation techniques (*Bhavana*)
- Food disciplines (*Ahara Niyama*)
- Life style modifications (*Vihara Niyama*)
- Gestures (*Mudra*)
- Spiritual practices (prayer, rituals etc.)

Patanjali says “*Yatha Abhimata Dhyanadva*⁵” – choose anything that will help the person.

Solutions offered in *yoga* are hence not restricted to *asana* or *pranayama*, it uses a whole range of tools – whatever is appropriate for that individual at that point of time. Rather than looking at *yoga* techniques as external agents of change, the different tools offered in *yoga* have to be accepted as means to tap the inner healing potentials and initiate change from within.

How *yoga* works: the process

Several important factors mediate the healing process:

The characteristics of the student: attitude, faith (in the process and the teacher), focus, ability to assume responsibility for one’s own healing, perseverance and continuous effort through sustained practice. Many of these factors are deeper personality traits (*svabhava*) that are often ignored in research. Whether a person

will continue with the training or drop out will depend on these qualities of the subject.

Qualities of the teacher: The competence and experience of the teacher, his/her level of motivation, whether they can motivate the student, their attitude and above all, their ability to establish a strong connection with the student decides the healing outcome.

“Yoga is a relationship – the relationship between a teacher and student. The nature and quality of this relationship results in transformation, which takes place in the mind (teacher/taught) which in turn influences many aspects of the individual’s life.”

- T K V Desikachar

Intelligent application of the tools (yukti) is vital to the healing process. This should be oriented to the individual, his/her capacities, needs and the specific context. Individual differences need to be taken into account, especially in an intervention where a person’s physical, emotional, spiritual resources are harnessed to facilitate healing.

Qualities of practice: Unlike any other kind of intervention, in *yoga* the subject/student is an active participant in the healing process and a well established practice is a very important aspect. Long term practice, without interruption, with a positive attitude and enthusiasm are the qualities presented by Patanjali⁶.

Hence the effectiveness of a *yoga* training program will depend on all these factors:

- Who teaches? (teacher’s knowledge, experience, care, motivation)
- Who is taught (student’s attitude, faith, motivation, effort and perseverance)
- Compliance with practice
- What is taught (techniques/tools)
- How is it taught (intelligent application of tools)

Output

There is hence a need to include qualitative measures that can study all the key

Yoga Sutra 4.3
Yoga Sutra 1.39

variables, study all the factors that impact the change and help integrate the physical and psychological aspects rather than compartmentalizing them. There is also a need to focus on positive attributes in *yoga* like better energy levels, well-being, calmness, focus and quality of life. The tools used for *yoga* studies must be sensitive enough to capture the different dimensions of healing, and hence should be comprehensive and customized based on the principles of *yoga*.

From the perspective of scientific research, many of these factors discussed above may not be accepted, may even be considered as the placebo effect. The teacher factor, faith and attitudes are inherent aspects of the process that cannot be distilled out as placebo because healing employs the mind and healing happens from within. Faith and relationship with teacher are, in fact, as important, if not more, than the techniques employed.

Impact on psychological factors through empirical studies:

Research efforts at Krishnamacharya *Yoga* Mandiram are based on the new paradigm that utilizes quantitative and qualitative measures and employs a comprehensive individual-centric approach in training and evaluation. The current study on the therapeutic effect of *yoga* on persons with epileptic seizures offers the following empirical evidence:

- Reduced anxiety and anger levels
- Reduced levels of Depression
- Improved energy and motivation in life activities
- Better quality of life
- Improved psychological well being

Several critical changes have been observed and documented in individual cases:

- from anxiety to confidence
- from feelings of dependence to freedom
- positive outlook towards life
- ability to assume responsibility for one's health
- acceptance of the condition
- better relationships
- compassion and sharing

Yoga Sutra 1.12

Conclusion

With more advancement in science, rigorous attempts are made to ‘fit’ *yoga* into a pure scientific model, and also substantiate such a stance using complex scientific procedures and measurements. But the bottom line is that **ultimately human beings have to benefit**. While *yoga* as a system of knowledge and practice has the mind as its central focus, much of the research activity in this area undermines the mind – its faculties, problems and all pervasive influence on every other dimension of life. There is a need for a paradigm shift from a disease oriented compartmentalized approach to an individual oriented comprehensive approach in *yoga* research.

“Yoga is not a technology that can be generalized. It should respect and honour the individual, encourage and facilitate the individual to make use of the resources available to heal (himself/herself). Consistent effort on the part of the individual and the teacher are also important.”

- T K V Desikachar

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Research Treatment for Leprosy with the aid of Naturopathy and Yoga

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Leprosy or Hansen's disease is one of the many communicable diseases and it is widely spread all over the world. The problem of leprosy is not only of medical, but also social in serious. In the year 1873 a Norwegian physician Gerhard Hernrik Armaner Hansen discovered a rod shaped bacillus as the causative organism for leprosy and it grows strongly in the skin, superficial parts and nerves. The transmission of infection is direct from person to person contact. Generally the bacillus penetrates through small wounds on skin. The persons with lowered resistance are afflicted depending on the percentage of resistance. It affects first skin then superficial nerves, leading to deformities of hands, feet and disfigurement of face.

The leprosy bacilli grow and multiply at a low rate and of this reason it takes 2 to 5 years and often 10-20 years to appear the first symptom of the disease. Therefore, somebody may be contagious to others before any symptom appears in him/her. It is divided into two groups: poly bacillus and paucibacillus depending on its B.I. and M.I. In cases of leprosy the involvement of nervous system causes loss of sensory perception in hands and feet. And above the added infection to the deeper tissue and bones causes irreversible damage, leading to deformity. Early treatment can prevent serious damage and disfigurement.

Chaulmoogra oil extracted from the seed of the fruit was the first remedy to be applied externally before the discovery of DDS (diamino diphenyl sulphone, a sulphur derivative drug) the first Anti Leprosy Drug.

Naturopathic intervention in each of the specific condition:

Immunity:

Much of the suffering in leprosy is due to immunological reactions against the invading microbe. For this in Naturopathy fasting, eliminative raw-diet, cleaning up the bowel, and external treatments like cold hip baths and mud baths helped the system to have the pathogenic matter demobilized and eliminated from the system which enable the system to develop the immunity. The bacteriological index and

general feeling well being are two cardinal indications found among all the cases in assessing the immunological development of the individual. The major problem, in infectious poly bacillus (lepromatous) leprosy is a deficiency of cellular immunity, leading to excessive bacterial multiplication and in non-infectious leprosy (poly bacillus), a heightened cell mediated immunity leading to hypersensitive inflammatory damage of nerves leading to deformities. In our study it has been found for this diet regulation, external treatment-applications as and when required, Remedial Exercises of Physiotherapy and Yogic were found very much useful for considerable management.

Reaction in Leprosy:

It has been established during the research treatment done in the control of leper Reaction cause lot of suffering, with the effect of naturopathic diet and treatments as observed, the patients were relived of the symptom, their appetite improved, felt a general feeling of well-being. Three days fast followed by raw alkaline diet (details given under the heading Diet in Leprosy) along with daily enemas, mud baths, and full wet packs. The other patients whose bacteriological smears are strongly positive and prone to develop such reaction did not have it during the course of treatment.

Infectivity and other symptoms:

As will be evident almost all the cases of Leprosy had symptomatic improvement, especially good improvement showed of reduction in the degree of infectivity. Subsidence of neuritis observed in almost all the cases in a period of six months to two years depending the degree of involvement. The skin smear and Bacteriological Index (B.I.) in each case shows the good prognosis of the disease, and it is conceded that the dietary modification and the external treatments and required physical exercises could be the correct remedy. Symptoms like reactive neuritis, Erythema Nodosum Leprosum (ENL) iritic, ulcers and deformities resulting from damaged nerves etc. are well managed. It has been our experience that simpler Naturopathic applications like mud-packs, tub-baths, hot and cold applications, leaf-bath, (the patient is wrapped in Banana or Lotus leaves tight and allowed in the Sun to the condition of perspiration),Mud bath, full wet sheet pack, steam bath, enemas, washing up the ulcers with neem boiled water, neem oil (Margo oil) application to the ulcers, Infra-red irradiation followed by Ultra-violet irradiation are more effective. It is also observed not only the relief of the symptoms and improvement in the general condition, but also the reduction of the bacteriological load as well. As it is observed in one case, the eczematous condition associated with this disease was also cleared during the treatment period.

Healing up of the ulcers:

It has been found in the patients with ulcers, showed good improvement in getting the ulcers healed up more quickly by fasting and alkaline raw diet, with the aid of external treatment like cold-hip baths, mud-packs, and infra-red irradiation, washing-up the ulcers with Margo leaves boiled water and application of Margo-oil (Neem Oil) over the ulcers.

Resistance of mycobacterium lepre:

It has been observed in the research study these acid fast bacilli are rapidly destroyed by the hot treatments as they are susceptible to heat. Treatments given with the aid of Sun, hot & cold friction baths, Infrared followed Ultraviolet irradiation are affective. At the same time the Naturopathic applications are so.

Diet in leprosy:

It is very simple and cheap; the patients can follow themselves with a little training, As described in each specific condition fasting, periodical raw-diet and regulated cereal diet found effective. In our study of the research work the alkaline diet showed good role. It included Carrot, Spinach, Radish, Garlic, Onions, Cabbage, Cucumber, Sweet Potatoes, Tomatoes, Apple, Pomegranate, Cauliflower, sweet oranges, Grapes, Figs, Dates, Water melon, Papaya, Coconut, etc. along with germinated seeds of green gram, gram, wheat and Fenugreek, depending the seasonal availability.

External treatments in Leprosy:

The effective curative parameters were enemas, cold-hip bath, cold-Spinal bath, dry and wet friction bath, leaf bath, cold full wet pack, Sun-bath, mud-bath. The application of Margo oil, Chaulmoogra oil and washing up the ulcers with Neem-boiled water and irradiation of Infra red followed by Ultra violet rays over the ulceration area found very effective.

Use of water is very important in daily care:

1. The skin loses its ability to sweat and becomes dry. Soaking the limbs in water gives back moisture to the skin covering the limbs. After soaking, Margo Oil to be applied to reduce the rate of water loss through evaporation.
2. Cleaning the sores with Neem boiled water help to prevent infection and heal quickly.

3. Water helps to reduce the rigidity of the skin and enable to improve the blood circulation thereby its movement is improved.

Exercises:

Remedial Exercises of Physiotherapy and Yogic were found very much useful in the management of Deformities, Nerve damage, and Peripheral neuritis.

Further Plan of Study:

1. Further study to be made in various conditions like primary polyneuritic leprosy,
2. Prevention of deformity and reactions in Leprosy etc., on the basis of above study and establishment,
3. There is a problem faced in Allopathic treatment with multi drug regimen programme for this disease regarding elimination of the Debris of the dead bacilli from the body, as it is a protein. In such condition declaring cure is difficult. The theory of Naturopathy is based on elimination of the pathogenic matter from the body thereby the immunity is developed to fight against invading microbe. Naturopathy comes as a boon so that the period of time to declare cure of the patients both clinically and bacteriologically can be cut short. For that a Research study to be made on the patients who have taken full dose of Multi-drugs, by Naturopathy and Yogic Therapies on modern scientific lines & Methods.



15

Status of Research in India on Naturopathy

Dr.S.N.Murthy*

While treating a patient, every physician will plan to:

1. Understand the symptoms, identify the cause and diagnose the case.
2. Give relief from the suffering as immediately as possible.
3. To establish normal function of the vital organs.
4. To re-strengthen the immune system.

Since Naturopathy recognizes the basic cause of all the diseases is accumulated morbid matter in the system, the practitioner tries to detoxify the system and establishes “health” on adopting various Natural therapies.

Background:

The 19th century is the period of global revolution in all the aspects, viz. engineering, science and technology and medicine. The orthodox medicine which was in practice in Europe at that period of time, was more superstitious and unscientific and not acceptable to some of the intellectuals. They came out of their practice and inducted a new wave of different medical sciences which are presently recognized as alternative therapeutics.

Emergence of alternative therapies:

Homoeopathy	- Hanehman
Osteopathy	- Andrew taylor
Naturopathy	- Louis kuhne
	- Kneipp
	- J.H. Kellogg
	- Lindlahar

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	- Tilden
	- Adolf Just
Zonal Therapy	- William fitzerald
Reflexology	- Unice ingham

These stalwarts advocated the above branches of medical sciences basing upon their experience, study and Research.

Indian Medical Sciences:

The scenario of medicine in India is quiet different from European methodology at that time. Ayurveda, Unani, Siddha, Marma Chikitsa etc., were all patronized and established sciences in all respects. When Louis kuhne’s theory of the “**origin of the disease**” was explained to Dronamraju Venkata chalapati sarma and others, they readily accepted as this basic principle is similar to the basics of Indian Medical Sciences. A naturally beautiful amalgamation of this science took place with them and the science was perfectly got indianised and developed by other stalwarts like Krishnam Raju, Acharya Pucha Venkata Ramaiah, Vital Das Modi, Dr B. Venkat Rao and others, giving a different shape from the European presentation of the science as on to-day. We can see the visible difference in practice of these sciences.

The accepted basic principles of Modern Naturopathy:

The modern naturopathy system accepts the following points as its basic principals:

1. The cause of all diseases is one, i.e. accumulation of toxins in the body, (both endogenous & exogenous)
2. The cure is also one i.e. elimination of toxins.
3. The human body is a living machine and contains elaborate healing system, if given a chance; it has the power to bounce back to normal status of health.
4. There is no place for any kind of medication in the form of pills, potions etc., While treating a case even food supplements in the form of medicine are not acceptable. The therapeutics involves the “pancha bhootas” only to achieve the goal.

Some of the modern Naturopaths are also using manipulative therapies such as therapeutic massage, aroma therapy, acupuncture, acupressure, reflexology,

osteopathy & chiropractic for crisis management in different acute and chronic conditions.

Thus we have seen a dramatic advancement of the naturopathic profession in all areas-education, quality of practice, license, public acceptance and therapeutics during the last 120 years. Naturopaths are presently valued in policy as a legitimate part of an overall system of health care in the country. But it is sad that we are logging behind in the research field unlike our European and U.S. counter parts.

Some of the research Institutes in Canada, U.S. & U.K.:

1. Canadian College of Naturopathic Medicine, Toronto
2. Bastyr University Research Institute, Kenmore, Washington, U.S.A.
3. Bastyr University Cancer Research Center
4. National Institute of Health Services, (NIH) Bethesda, U.S.A.
5. National Center for Bio-technology Information & National Library of Medicine, U.K.

There are more than 25 centers involved in research in U.S. Australia is also not lagging behind and the growth of Naturopathy during the last two decades is quiet exemplary.

Nature Cure Research Centers in India:

The inception of CCRYN in 1960's ignited the enthusiasm to conduct research in naturopathy in our country. Naturopaths started learning modern medical subjects. viz. Anatomy, Physiology, Pathology etc., and nature cure colleges started teaching these subjects. The GNC & NCH, Hyderabad and Bharatiya Prakriti Chikitsa Vidya Peeth, Calcutta were in forefront to adopt these subjects initially.

At present very few centers are being given grant in aid for conducting Research in our country by CCRYN. The Research Department of INYS, Bangalore established in the year 80-81, is presently engaged in Research on Nature cure management of diseases such as Bronchial Asthma, Coronary risk factors such as Obesity, Diabetes mellitus, Hypertension, Hypercholesterolaemia, Osteoarthritis and showing significant results. There may be other institutes, as well conducting Research with the patronize of CCRYN.

The present question:

Can rigorous research in Nature cure developed? Can it be held to the same standards of evidence as modern medicine? Should it be held to those standards? Are there additional standards and better integration strategies for Naturopathy that are of value to all medicine, complementary or conventional?

These challenges include, quality standards of research - the evolving nature of science, accommodating pluralism, addressing underlying assumptions and managing controversial topics in Naturopathy Research. These challenges are formidable and will require attaining a sufficient level of science to move it out of the margins of health care and more careful approach to Research integration that can keep its focus on public benefit and the public's health.

The scope: There is a wide scope to develop the science further by Promoting Research on therapeutics, management of complicated diseases including Cancer and Aids. Also to high light the side effects of various therapies such as plasters, poulties, hot & cold baths, diets & their combinations.

Research Methodology:

To conduct Research a standard protocol may be developed on the following points and implemented in all the Research Institutions.

- 1. Selection of the subject, Needs and opportunities etc.:** at this stage the Research team identifies the subject and justifies the subject from various angles.
- 2. Determine Research objectives:** The Research team determines the Research objectives, parameters etc., that must be implemented to address the subject identified.
- 3. Create optimal Research team:** Each Research projects success is based on a well developed, experts team.
- 4. Data collection:** The experts of Research team design and implement the data collection process.
- 5. Test survey design:** The Research team tests and reviews the data, time to time, extensively for clarity and accuracy before finalization & tabulation.
- 6. Results:** The Research team with the help of statistician finalizes and tabulates the data and prepare the periodical reports and at the end of the project prepares the a final reports.

7. Presentations: Basing up on the data collected, the Research team presents scientific papers for publication and presentation in the scientific conferences.

In this context it is quiet natural to expect the CCRYN to play the role of **National Guardian** for the promotion of the science by implementing Research projects on acceptable standards at various competent centers, collect the data, process and publish. Necessary planning is required on these lines.



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Multiple Coronary Risk Factors and their Modification by Naturopathy & Yoga

Prof. Dr. B.T. Chidananda Murthy*

Mortality and Morbidity due to Coronary Heart Disease (CHD) is increasing day-by-day, more so in developing countries like India, whereas in USA and in other developed countries though controlled due to public awareness of Coronary Risk Factors (CRF) and their modification, still it is serious concern all over the globe and needs great attention.

The well recognized coronary risk factors are –

1. Smoking,
2. Hypertension,
3. Hypercholesterolemia,
4. Diabetes,
5. Obesity and
6. Psychosocial factors

There are number of improved drugs to control hypertension, diabetes and hypercholesterolemia, but drugs alone cannot control for longer period or prevent the damage to the vital organs and they have their own side-effects. These days smoking, obesity and psychosocial factors are creating an increased menace in India and bringing an increased incidence of coronary heart diseases.

Coronary artery disease and CRF are the life-style disease/disorder and needs to be corrected. The general social or family atmosphere does not help to correct the faulty life-style. A centre, where scientifically body and mind are helped to rehabilitate are very much essential. In many naturopathy and yoga hospitals, we find such atmosphere is available and many people spontaneously are being helped to change their life-style and modify their coronary risk factors. When we say to correct their life-style there is only slight impact on their mind but when they do or involve in the activity they are pro-active and benefit more. Doing is believing. Every aspect of change is visible and subjects themselves are actively involved in doing, along with

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naturopaths, who just initiate and guide them in this regard. Treatment with five great elements – the Mother Nature has such potent capacity to draw towards her and rehabilitate, as rightly put by the great poet Wordsworth – “Mother Nature never betrays those who believe her”.

One such study was conducted in the Institute of Naturopathy and Yogic Sciences, Bangalore and poster presentation was done in the conference held by Cardiology Society of India. 92 patients with one or more CRF were studied with the objective to simultaneously modify CRF without drugs by Naturopathy & Yoga. Out of 92 patients 46 were male and 46 female and their mean age between 48-35 years and range between 17-70 years.

The table shows the risk factors of smoking, hypertension, hypercholesterolemia, diabetes and obesity and among 46 males there were 11 patients who had the risk factor of smoking.

TABLE SHOWING INDIVIDUAL RISK FACTORS		TABLE SHOWING SINGLE / MULTIPLE C.R.F.				
NUMBER	PERCENTAGE	NUMBER OF C.R.F.	MALE		FEMALE	
			No.	%	No.	%
11*	23.8	ONE	17	57	5	11
80	87	TWO	19	41	33	72
20	22	THREE	5	11	7	15
9	97	FOUR	5	11	1	2
55	60					

The management of CRF with diet, nature cure treatments, yogasanas, yogic kriyas, yoganidra and pranayama for the duration of three weeks was conducted.

Diet: Diet Therapy was based on individual needs depending upon their risk factors. It was divided into three phases viz. eliminative, soothing and constructive phase. In the eliminative phase they were given fasting therapy with lemon juice, wheat grass juice, vegetable or fruit juices for 3-5 days. In the soothing phase, fasting was slowly broken with vegetable soups, fruit juices, raw salads or fruits in lunch and dinner which lasts for another 8-10 days. In the constructive stage for rest of the days fruits and vegetable juices in breakfast and chapattis, boiled vegetables, curd/

buttermilk/soups in lunch and in dinner, raw diet consisting of fruits, raw salads, sprouts, soups are provided. The calories in the constructive stage depend on individual needs which help them to maintain their condition during the follow-up after their discharge. Certain foods which had medicinal values were also given during the smoothening and constructive stages like garlic, fenugreek soaked in curds, wheat grass juices, vegetable juices, knolkol in salads, whole wheat chapattis, hand pound brown rice which were rich in fibre and micro-nutrients.

Nature Cure Treatments: were also given in three phases. Hydrotherapy, mud therapy, reflexology walking, massage therapy were the main therapies and in hydrotherapy enema, hip bath, spinal bath, steam bath, immersion baths, packs – gastrohepatic pack and kidney pack were given. Partial and full body massage were given depending upon the day-to-day condition of the patient.

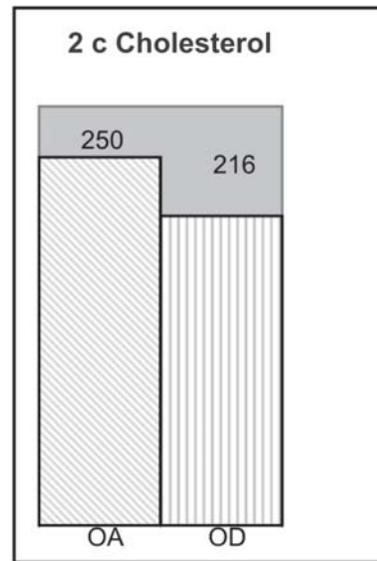
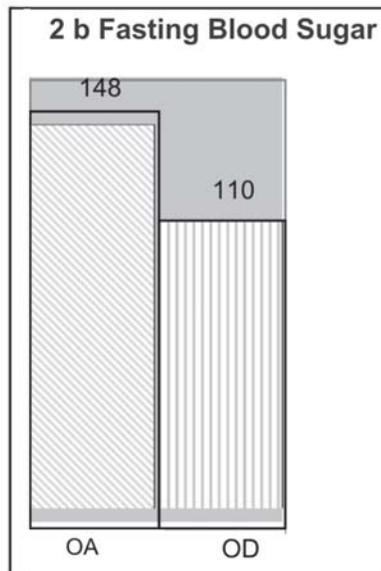
Yoga Therapy: Breathing exercises, yogasanas, yogic kriyas, pranayama and yoga nidra were the integral part of the treatment. Asanas adopted helped the patients to experience stability, calmness and improve their flexibility gradually. In yogic kriyas – which were again individually tailored, depending upon the risk factors and condition. Vaman dhouti, shankhprakashana, jalneti mainly helped in obesity and diabetes cases, whereas yoganidra session were emphasized for hypertensive, though all of them underwent pranayama and yoga nidra session.

In each and every phase, the day-to-day signs and symptoms were monitored through modern diagnostic methods like monitoring blood pressure, blood sugar levels, cholesterol and other needed vital and bio-chemical investigations to ensure the safety of the treatment modality. The following tables show the changes in important risk factors.

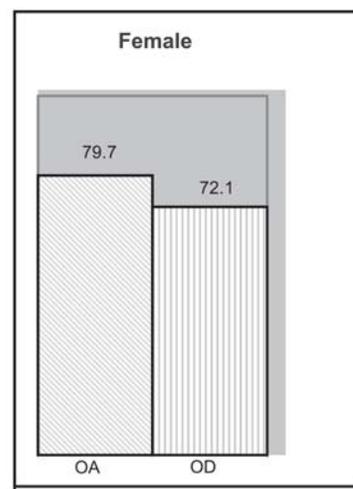
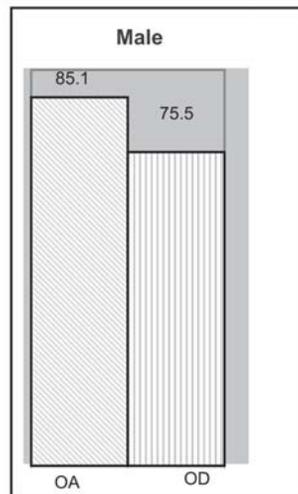
**2a BLOOD PRESSURE:
TABLE SHOWING FALL IN B.P.**

SYSTOLIC B.P.			DIASTOLIC B.P.		
On Admission	On Discharge	Mean Difference	On Admission	On Discharge	Mean Difference
MALE 151.5	1296	217***	97.5	85.1	12.4***
FEMALE 153.7	1292	245***	96.3	84.2	12.1***
POOLED 152.5	1294	251***	96.9	84.7	12.2***

***P<0.001



2d Body Weight (in Kg.)



C.R.F. REDUCTION ACHIEVED

C.R.F.	ADMISSION		DISCHARGE	
	No.	%	No.	%
SMOKING	11	25.8	0	0
HYPERTENSION	80	87	14	15.2
HYPERCHOLESTEROLEMIA	20	22	0	0
DIABETES	9	97	1	1.1
OBESITY	55	60	14	15.2

SINGLE/MULTIPLE C.R.F.

	ADMISSION	DISCHARGE
C.R.F.	No.	No.
FOUR	6	0
THREE	15	0
TWO	52	1
ONE	22	27

There was considerably positive changes in all the coronary risk factors, simultaneous reduction of multiple CRF, change in life style, relief of stress and due to simultaneously monitoring of the individual conditions on day-to-day basis with well facilitated modern diagnostic methods has helped to check any adverse effects which is most important aspect in rehabilitation of CRF.

In conclusion we can say that Naturopathy & Yoga has a useful role in the long term modification of CRF. Thus contributing to prevent coronary heart disease. However, comprehensive studies with gold standard investigations further enhances and establishes the efficacy of Naturopathy & Yoga. In other Naturopathy & Yoga Centres also patients are routinely treated for one and more CRF but they lack proper scientific documentation and monitoring which would be helpful in publishing the scientific papers and popularise this non-invasive and non-pharmacological, cost effective and safe treatment modality to the world, which is the need of the hour, so that patients can opt for their treatments and also referrals can be made by the scientific community. In many well established allopathy hospitals Naturopathy & Yoga wing can be opened, so that simultaneous treatments as an adjuvant therapy can bring quicker and better healing effect. The specialized OPD of Yoga & Naturopathy wing in Dr. Ram Manohar Lohia Hospital, New Delhi is one such effort, since November, 2004.

