A Guide in Securing the Quality of Research Projects for Alternative Therapists

Lone Mørch and Leila Eriksen

The Council Concerning Alternative Treatment
The National Board of Health
Denmark
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Prepared by the Danish Reflexologists Association's (FDZ) Research Committee
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Preface

In 1993 the Research Committee of the Danish Reflexologists Association (FDZ) got the idea to write "Research Guide", which could be used by reflexologists who wished to research in reflexology. Since then, thanks to experiences from completed projects, we have compiled a great deal of new information, which is why this material has been revised considerably in 1996 by reflexologists Lone Mørch and Leila Eriksen.

As the interest for alternative health methods grows, so does the interest for well-documented research projects. It has, therefore, been one of our greatest wishes to publish this "Guide in Securing the Quality of Research Projects for Alternative Therapists" through The National Board of Health's Council Concerning Alternative Treatment, so that alternative therapists wishing to enter the world of research, would have an effective tool to complete research and projects concerning alternative health methods.

The Council's Research and Project Committee has read and commented the material.

The Council Concerning Alternative Treatment
The National Board of Health Michael von Magnus

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Introduction

Working with “A Guide in Securing the Quality of Research Projects for Alternative Therapists” has been an exciting and educating process, making it possible to assist those, who in the future may wish to try the effectiveness of the many alternative therapy offers available today.

Securing quality in future projects will strengthen a factual and interdisciplinary dialogue between the conventional and alternative healthcare systems, and give the users a real picture of existing therapy options.

Being fully aware, that demands and requirements used in Denmark for securing the quality of research projects are not necessarily the same in other countries, we have chosen to translate the full extent of this booklet. By doing so, we hope, the booklet will be a source of inspiration for finding out which guidelines are applicable in your country.

We hope, this booklet will help to prepare the way towards developing new research models.

We wish to extend our appreciation to all of those who, each in their own way, have contributed with knowledge and expertise in this field.

Lone Mørch and Leila Eriksen.

Description of a Project

The basis for the work involved in a research study is formed by describing the project, and it is important to take the time necessary to carefully formulate the project description, even though this step may take a long time to complete. As a general rule it takes about one year from the conception of an idea until the clients can start receiving treatment – depending of course on the size of the project.

The description of a project is very often used as the basis for an application for financial support for the project. As the competition for funding among researchers is very intense, only well-considered and well-formulated projects are likely to receive any funds. It is therefore important the description of the project is presentable, that it meets the basic requirements for a research project, and that it can be easily read by anyone. It is a good idea to ask a couple of outsiders to read through the project description in order to find out if it can be understood by pople without any knowledge of the alternative treatment form being investigated.

The project description should contain the following:

1. Introduction
2. Purpose/target group/formulation of problems
3. Participants, including criteria for inclusion and exclusion
4. Procedure: What methods will be used to investigate the problems
5. Time schedule
6. Methods used to collect data and methods used for analysis
7. Conclusion
8. Publication
9. Ethical considerations
10. Economy – resources – sponsors
11. List of literature

In the following each of the items above will be discussed.

1. Introduction

The background for the project is drawn up. How did the idea of the project arise?, and why is it relevant to undertake a study of this particular subject?

You should also be able to describe experiences made with the particular alternative form of treatment in connection with investigating a particular health problem. An explanation of the principles this form of therapy is built on can be given as well.

Will the outcome of the study have any consequences for clients or therapists?

Will the outcome of the study lead to the initiation of other research projects?

Can the result lead to socio-economic savings in the form of reduced sick leave or fewer hospitalizations?

Conclusion.

The project description should contain references to other studies on the subject and

the results of these. It is also possible to conduct a literature search in one or more databases.

2. Purpose/target group/formulation of problems

This part shows the main idea of the project. Here it is described **what** the purpose of the study is? You should pay attention to the fact, that it has a greater impact when you write, that the purpose of the study is **not** to prove whether this particular therapy form work or not, but rather that the therapy work on the health problem being investigated.

3. Participants, including criteria for inclusion and exclusion

This describes:

- The client group to be selected. The group should be carefully specified
- The nature of the health problem. In case of a specific disease, it should be clearly defined
- The number of clients
- If working with a control group, the selection criteria for the group should be explained

Inclusion criteria (requirements for being allowed in the study)

- Sex
- Age
- Possible minimum or maximum limits of the health problem (duration of disease, seriousness or specific symptoms)
- Medical doctor's diagnosis
- Insight and consent of the client to participate in the project
- Readiness to complete questionnaires before, during and after the treatment period
- Other issues found to be of considerable significance for the particular category of clients, including education, social status, network, environmental influence. Furthermore, whether any other treatment is taking place and the phase this may have reached.
- Drop-outs (follows bellow).

Exclusion criteria (the sorting out of unqualified participants)

- Lacking diagnosis of the illness by the clients GP
- Severe psychiatric or somatic illness
- Established pregnancy at project start – unless the study deals with pregnancy
- Other issues relevant for the particular health problem, which could mislead investigation

The above points are examples of in- and exclusion criteria used in research studies. This does not imply, that alternative therapists should normally abstain from treating clients not meeting these criteria, in their daily work.

4. Procedure

The procedure of the project is described from start to end:

1. Recruitment of the clients
2. The selection of a possible control group (what treatment should they receive?)

3. Number, duration and frequency of treatment sessions
4. Recording before, during and after the treatment period

The actual treatment: Can be exactly the same as the therapist would usually perform in her clinic. All sessions should be recorded in the clients file to ensure that the therapy is documented 100%.

Placebo control: It is considered extremely difficult, not to say impossible, to carry out placebo controlled experiments with alternative treatment methods. The reason being, that the treatment systems are based on theories in which it is believed to be impossible to give the placebo clients a real "ineffective" treatment, that is a "fake" treatment. Furthermore, the therapist will always know which clients are treated "right" and which are treated "wrong", thus blurring the picture of the treatments effectiveness and influencing the result.

Control group: Often it is appropriate to include a control group in the project. In order to facilitate the comparison between the experimental and the control groups, the two groups should have an equal number of persons, equal distribution of age, etc. The control group can consist of persons, who are not being treated or who receives a different form of treatment. For the treatment group the same questionnaires should be completed and the same records kept as for the treatment group.

Through cooperation with local hospitals, doctors, mid-wives, health-nurses and others in the health care system, it is possible to establish a control group (perhaps receiving conventional therapy) and obtain assistance in the evaluation of the treatments in the project. Such a control group is recorded simultaneously with the course of the experiment.

Drop-outs: are clients who for some reason drop out of the project.
Anyone dropping out of the investigation should be accounted for. If for example a client wishes to stop treatments after half the agreed number of sessions, because no effect is felt, then the client should be counted in the group, where no effect is registered.

The clients who quit before the end of the study, could be registered in the therapist's file, possibly with a note of the causes for the drop-out. It should be pointed out though, that according to the Declaration of Consent the clients have no obligation to explain why they wish to leave the project.

Payment: The question of free versus paid treatments should be clarified. As a principle treatment should be free for clients participating in a research project. Instead various types of funding can be applied for to pay the therapist's work. Sometimes the nature of the study can imply that user payment be desirable. In these cases the reasons should be stated in the project description.

Advertising: If the project needs advertising, a press release is worked out and enclosed with the project. For ethical reasons the press release should be kept as neutral as possible, but still be able to catch the attention of the readers. Absolutely

nothing should be promised in the press release, nor should it contain any figures or presumptions unless you posses documented facts. If in doubt, you should contact an alternative research council and get help in drawing up the add or press release. The names of those responsible for the project and the participating therapists should always be stated.

The procedure related to the use of questionnaires and registration forms will be discussed later.

5. Time schedule

In order to keep track of the project from one end to the other, it is recommended to make a plan of the tasks involved and a time frame, which is adjusted to fit the treatment form in question.

Here is an example of a time schedule:

Week	Task
0	Preparation of the project description (optional contact to a research council). A press release is written and enclosed with the project description. Optional recommendation from The Council Concerning Alternative Treatment, The National Board of Health. The Ethics of Science Committee and The Inspection Office for Registrations are informed. Applications for funding.
1	Media exposure and recruitment of clients. Start-questionnaire, informational letter, and Declaration of Consent are sent out.
2	Start-questionnaire and Declaration of Consent returned.
3	Selection of participants meeting in- and exclusion criteria following contact by telephone or mail.
4	Registration forms are sent out (including instructions).
5	Initiation of project record.
6	Treatments begin.
7	Treatment sessions for example twice a week.
8	
9	
10	
11	Treatment sessions for example once a week.
12	
13	
14	Final questionnaires are handed out.
15	
16	Final questionnaires are returned.
17	Evaluation 1-3 months after the final treatment follow-up questionnaires are sent out and returned.
18	Data analysis.
19	The Ethics of Science Committee and The Inspection Office for Registrations are notified about the termination of the project.
20	Publication.

6. Methods used to collect data and methods used in analysis

To ensure the investigation is designed according to the purpose of the project, it is advised, that a statistician is involved in preparing the project description and questionnaires. This eliminates the risk of the project group finding themselves at the end of the project with a pile of questionnaires, which are filled in but useless for their purpose. A research council can help establish the contact to a statistician.
Also included in the project description should be the statistical methods to be used, who will be in charge of the calculations, the cost involved and how it is financed.

7. Publication

How to publish the project should be carefully considered. Should the results be published in a professional journal, in a foreign journal, in the news media or in popular magazines?
Publication in a medical journal requires that the results have not previously been published and that the project has been approved by the Ethics of Science Committee. (When applying for approval by the Ethics of Science Committee the text of any advertisements should be included with the project file).

Before sending the manuscript to a publisher it is a good idea to get the manuscript guide for the particular journal. By using the manuscript guide you can avoid having the manuscript returned, even before it has been read by the editor, just because some formalities have not been met.

The project group also has to decide, who should be credited as authors and in which order they should appear.

8. Ethical considerations

In order to obtain approval by an Ethics of Science Committee the project description must contain a chapter with "ethical considerations". As a minimum this chapter should estimate the risks and inconveniences for the project participants compared to the possible benefits. This discussion should end by concluding, that the expected beneficial effects of participation will reasonably exceed the inconveniences.

If the project contains a possible conflict between the expected outcome of the study and the risks involved, the project description should hold a description of how to limit this conflict as much as possible.

In the ethical considerations chapter a discussion of the choice of scientific method should also be included, as this can influence the quality of the investigation results obtained. Even though the project group might be able to show, that the subject of the study is important, argumentation for the chosen research design is needed, because an insufficient or poorly organized research plan is unethical.

Concerning the clients rights as participants in a research study: See the chapter “Information for Clients about the Research Project” (page 15) and appendix D “Ethical Guidelines for Clinical Research” (page 25).

9. Economy – resources – sponsors

Relevant foundations can be applied for funding of the project. In "The Handbook of

Foundations" (see your local library) you can get an overview of the possibilities for financial support. From counties having a "Prevention Council", it is possible to receive aid for projects falling outside the conventional healthcare system.

In applications for funding most foundations require one person to be nominated as head of the project. In case a grant is given, this person is responsible for the project following the guidelines laid out in the project description. The "head" person is also responsible for the budget.

A detailed budget should be enclosed with the application.

10. List of literature

The project description **must** contain a list of the literature forming the basis for the project. By numbering the titles it is possible to make references from the text by using the relevant number in brackets.
Example:

Reflexology is the mostly used alternative treatment form in Denmark (1).

In the literature list:

1. Rasmussen, N.Kr., Groth, M.V., Bredkjær, S.R., Madsen, M. & Kamper-Jørgensen, F.
   Sundhed og sygelighed i Danmark i 1994. En rapport fra DIKE´s undersøgelse.
   Dansk Institut for Klinisk Epidemiologi, København 1995.
2. .....
3. .....

About literature: See page 31.

Registration Forms and Questionnaires

1.
If possible, the client should fill out a **registration form daily** for 2-4 weeks **before** the treatments start, **during** the treatment course and perhaps for 2-4 weeks **after** completing the course of treatment.

The registration form should in detail show the degree and extent of the health problem: How much does it take up of the clients daily life? Does it influence the quality of life? This information could be noted in the file. The registration form design depends on the actual health problem being investigated. If you intend to publish the study, it is recommended, that you use an already established investigation method. (page 8, item 4).

2.
The **questionnaire** is filled out **before** or at the **first** treatment session and is also intended to uncover health problems, the case history of the client and any medical treatment and diagnoses. The questionnaire could be completed **again** at the final treatment session and for the **last** time maybe three months later. The purpose of the final questionnaire is to show whether the treatments had any effects and whether the effects are lasting.

Possible side-effects should be asked for at every treatment session. Example: Have you noticed any unwanted effects of the treatment since the last session? If the answer is yes, the extend and duration are noted.

In order to assess the treatment's effects on secondary health problems, it is important, that these are described and noted in the questionnaire. Possibly this effect could be investigated in a later project.

Statisticians, Anthropologists, Sociologists and Physicians

At the Danish Technical University, Roskilde University Centre and University of Copenhagen so called "Science Shops" have been established. Here you can get in touch with students offering to make certain studies as part of their education. It is a good idea to make sure the students do not finish their degree before your project is completed however. The services of the Science Shops are free, but on certain conditions: The project must have no commercial interests; The subject must be of general public interest; the project results must be publicly accessible and the project group should actively cooperate. The Science Shops distribute the project applications to various parts of the universities according to their subjects and you do not know in advance, if any students will be interested in your project. (See Science Shops addresses on page 30).

A Statistical Research Unit is available at Panum Instituttet (The Medical Faculty, University of Copenhagen). Here you can obtain two hours of free statistical help. (See page 30).

The Council Concerning Alternative Treatment

In 1985 the Danish National Board of Health established The Council Concerning Alternative Treatment. The council consists of representatives from the alternative field, a sociologist, and experienced medical researchers.

The task of the council is to forward a dialogue between the conventional health care system and alternative therapists, but also:

- to collect information and knowledge about alternative treatment
- to pass information and knowledge on about alternative treatment to the established health care system and the general public
- to pass information and knowledge on about legal initiatives and results concerning the alternative health sector
- to participate in the initiation of studies, where health effects of alternative treatment are being scientifically evaluated.

The procedure for obtaining a recommendation of your project from The Council Concerning Alternative Treatment is as follows: Send the completed project description to the council's Research and Project Committee (address page 28). If the committee finds the project relevant and accomplishable, they present it to the council who then decides whether the project can be recommended.
If the council does not recommend the project, you will receive a written

justification. This does not imply, you should stop the project. After receiving a rejection from the council you should not loose your courage, but instead use the justification constructively in the further moulding of the project, thus making it justifiable and well-documented.

The Ethics of Science Committee

All research projects categorized as "bio-medical research" should be submitted to the local Ethics of Science Committee.

The primary task of the Ethics of Science Committee is: To carry out an ethical assessment of research projects. To see to that the project is carried out according to the given permission. To monitor the development of the bio-medical field and disseminate knowledge about the ethical questions involved.

All researchers, planning to carry out bio-medical research, are affected by the law concerning the system of Ethics of Science Committees, and must submit a research protocol/project description and notification before the committee. The study cannot be invoked, until approval from the committee has been obtained. Handling of the case usually takes 2-3 months.

It has not been clarified whether or not research into alternative therapies should be classified as bio-medical research. A project may very well be "an alternative project" and still belong to the bio-medical research group. It all depends on the research design. For updated information you can contact your professional association or an Ethics of Science Committee. Addresses of the Ethics of Science Committees see page 29.

The local Ethics of Science Committee will be happy to send you a "Guide to Notification of a Bio-medical Research Project".

The fee for submission of a project is 2,500 DKK + 500 DKK for each additional committee involved (1997).

The Inspection Office for Registrations

For statistical purposes all projects make use of a record. According to §2, point 3 of Law of Private Registers, all private registers must be reported to The Inspection Office for Registrations. From this office, you can order an application form which contains information on:

- who can access the record
- who is responsible for the the collection data
- what information is recorded
- what happens to the records later on, etc.

Even though this office has laid down certain limitations in order to protect the privacy of those registered, this law is not applicable to private research and statistical registers, because this would restrict free scientific research and because

such scientific data is usually published anonymously.

Paragraph 4 of the law deals with the passing on of information. As a main rule information about an individuals health condition must not be passed on without the consent of the registree. Under certain conditions The Inspection Office for Registrations can allow such information to be passed on for statistical or scientific use.

Information to the Clients about the Research Project

For ethical reasons, a **written** consent must **always** be given from clients and healthy participants in a scientific investigation. The declaration of consent should be based on written as well as verbal information given about the project.

The information and declaration of consent should be in two copies. One copy is handed to the client, while the other signed copy is kept by the therapist.

The participants should be informed about the following (According to Danish Law no. 503 of 24 June 1992 about the Ethics of Science Committee's system and the handling of bio-medical research studies and The National Board of Health's circular: "Doctor's duties and patients rights" about information and consent (22 September 1992)):

1. The purpose of the research project
2. The methods applied (form of treatment and extent)
3. Implications for the participants: completion of registration forms and questionnaires, inconveniences or side effects following treatment
4. That anyone can withdraw from the project at any time without problems or obligations (including financial obligation)
5. Who has access to the information gathered in the study
6. Contact person for the project (name, address, telephone).

Examples of information letters to participants are available from the Ethics of Science Committee.

Declaration of Consent

Below is an example of a Declaration of Consent.

Declaration of Consent

The project group recommend, that you read Information about the Project (name of project). At the end of the study all personal data will be deleted. Results from the study will be published in an anonymous form.

If you decide to participate, you must sign this declaration and hand it to your therapist.

Participation is voluntary, and you can withdraw from the treatments at any time without any further obligations.

I hereby declare, that I have read Information about the Project (name of project), and that I wish to enter the project on the terms given.

Date Signature

Five Pieces of Good Advice

-before starting a research project in an alternative therapy.

1. Read through "Guidelines for Constructing a Research Project for Alternative Therapists" before you start out.
2. Brainstorm on the following subjects:
   -**Purpose:** What is the idea of the study? Why is it necessary to do this investigation?
   -**Target group:** Who and how many should participate?
   -**Course of action:** How is the study carried out. Is it in a way, that satisfy the purpose?
3. Contact your professional association. By doing so at an early stage, you can avoid entering into a project that may already be running somewhere else.
4. Carefully work out a project description according to the guidelines.
5. If your association has a research council, then make use of it in the process, also with regard to press releases and applications for financial aid.

Appendix A: Basic Requirements for a Research Project

By Helle Johannesen, Mag.Scient.,Ph.D., Institute of Anthropology, University of Copenhagen, January 1995

Before starting any research project a project description/protocol should be formulated. The protocol serves as the basis for applications for financial support, and also functions as the working schedule of the project. Both ways, it is an advantage to have a protocol as clear and unambiguous as possible. Beginners, starting out with their first research project often find, that they spend too much time working out the protocol. But it is well worth the effort spending a fair amount of time on this stage of the project. The fight for research funding is intense, and only the very best formulated projects are granted support. During the process of applying for funds the project description alone represents your abilities and visions. For the research group it is also advantageous to have the whole project course well thought out and written down. This way you can avoid running off the track and ending up investigating something quite different from what you intended.
If you want the project classified as RESEARCH and if you want financial support from public or private research foundations, then the project protocol should meet certain requirements. These will be briefly outlined below:

1. The project background is outlined. Existing research, on which your hypotheses are built, are accounted for, and the relevance of the current research subject is discussed.
   To clarify this item, it is important to check existing research on the subject and find out what results this research has yielded. It is a good idea to search for literature references in one or more databases.

2. The project's problems are clearly presented. This can be in the form of a hypothesis you want to validate.

3. If a specific disease or symptom is involved, it should be clearly defined. Furthermore, in- and exclusion criteria for participating patients are stated.

4. The applied research method is defined and described in detail. The description includes:
   -a presentation of the theories you start out with (which facts are taken for granted?)
   -a presentation of data collection methods (video recordings, blood samples, objective measurements, questionnaires, interviews, etc.) Note: Certain standard questionnaires exist (from medical research) to examine, for example, the therapeutic effect on pain
   -a presentation of the parameters you are going to assess (blood pressure, pain, quality of life, social mobility, etc. – when studying treatment effects remember parameters for possible side effects)
   -a presentation of methods for data analysis (statistical account of specific parameters (which), qualitative interpretation of interviews, etc.)
   -if the project involves a control group, possible randomisation methods, blinding and quantitative basis of statistical significans are accounted for.
   -if the project involves assessment of a therapy, the treatments in the therapy

as well as control groups are accounted for.

5. A demonstration of how these theories, parameters and methods are relevant for the problem/hypothesis you want to examine.

6. A discussion of how theories and methods influence the outcome of the study (what can and what can not be studied with these methods?).

7. A presentation of the written information to participating patients, stating:
-the purpose of the study
-the methods applied
-implications for the individual participant
-that anyone can withdraw at any time.

8. A discussion of ethical implications for participants.

9. A list of researchers and therapists taking part in the project.
For the researchers a curriculum vitae with information of past research experience and publications is enclosed.

10. A description of how it is planned to publish the project results.

11. Detailed time schedule.

12. Detailed budget.

Some tips:
Most foundations require one person to be elected as responsible for the project and formal applicant. The responsibility of this person is to make sure, the project (in case of a grant) follows the guidelines laid out in the protocol.

It is not wise to state, that the purpose of a project is, to prove that treatment X works. Instead you can write, that the purpose is to study whether it works according to specific chosen parameters, which will be assessed during the course.

It is always a good idea to show a critical, investigative attitude towards the subject. An application with a sense of knowing "the one and only truth" will never be supported by the large foundations, nor will the project be taken seriously by other researchers.

There are many academically trained persons, who are out of jobs. Try to find one, who will assist you in writing the project description and carrying out the study, in case funds are granted.

Several faculties at the University of Copenhagen have established so called "Science Shops". Here you can get in touch with students, who are willing to undertake certain studies as part of their training. The service is free, but you can not be certain, that your project will wake anyone’s interest.

The National Research Councils have pamphlets available, directing you on how to

apply for National Research Council funding, what can be supported, and what information is required in the project description.

Appendix B: Karl F. Popper and Falsification

By Palle Gad, Consulting Specialist in Surgery, Psychotherapist

In the 1920's the Austrian-English philosopher Karl F. Popper developed his theory of falsification, being a way of thinking as well as a procedure for clinical medical research.

The idea is, that even though it is very difficult to definitely prove that factor X (which is the component being investigated in the clinical situation, for example a drug or a therapy) is important for the outcome of the course, then it is astoundingly easy to prove the opposite: That factor X has no significance for the outcome of the course.

As usual the entities of the study, for example a group of people, are divided into two equal groups, which are matched with regard to known relevant parameters such as: Diagnosis, gender, age, etc.
Now a so called zero-hypothesis (H-0) is established. The zero-hypothesis implies, that in the minds of the researchers zero significance is attributed to the clinically interesting factor X, and therefore, still in the minds of the researchers, the result of the treatment/medication is expected to be the same for the two groups. The result of the therapy will be the same for both groups, even though factor X is added to (respectively removed from) one of the two groups, which is the only known difference in the treatment they receive.
All the rest of the experimental procedure is carried out as described in "A Guide in Securing the Quality of Research Projects for Alternative Therapists".

Now the point is, that in the progress of the study it will become clear, whether the two groups will come out of the project with similar results. If it turns out, in reality, that there is no difference, i.e. (H-0) is sustained, then you can carry on examining other interesting things than factor X. If indeed, a difference between the groups appears, then you must reject (H-0): Your original suspicion that factor X is significant has been strengthened. To the positivists displeasure it is still not proven, that factor X is responsible, for the joy of others it seems likely, that factor X has some significans, and enough to justify further experiments.

Appendix C: Documentation of Knowledge

By Carsten Vagn-Hansen, M.D. (Zoneterapeuten (Journal of the Danish Reflexologists Association), no. 1, Jan. 1996)

Over the years much so called knowledge has appeared to be built on mistaken prejudices. Today natural sciences require allegations to be documented. The method of natural science presumes, that assumptions are built on measurable, i.e. objective, quantities. Valuable scientific results must also be able to explain and predict the course of events. A theory about high blood cholesterol levels leading to coronary thrombosis, can be tested by assessment of cholesterol and heart attack cases. On the other hand it is impossible to test theories about the number of stars being infinite or the existence of God.

Knowing your limitations

In this respect many unauthorised, as well as, many medical therapists lack a scientific basis for their work, and therefore they can make mistakes! All therapists should know their limitations and refer patients to, for example, a doctor – for reasons of liability, if nothing else.

Opposite the method of natural science stands the hermeneutic method used in fields such as psychiatry and the science of literature. This builds not only on objective facts, but also includes identification and interpretation, which is accepted or rejected by others – depending on just their sense of identification.

The first step towards documentation

The first step is keeping a file. The pages in the file should be numbered, to prevent later removal of bad results. Carefully kept files can give valuable retrospective information.

The most simple validation consists of letting the patient be his own control. How is the condition before and after treatment? This is referred to as the casuistic method. Case reports of for instance new effects/side effects of a therapy are often valuable.

Before doing an investigation, of course, you will have to formulate the problems and the way of investigating. Is vitamin-C effective on hay fever? How are improvements measured? (fewer sneezing attacks, reduced use of other medication).

Reliable studies

Studies can be retrospective: From an occurred effect you look back and assess the causes, for example that almost everyone suffering from lung cancer have been smoking for many years.
Another method is the prospective: After dividing everybody into smokers and non-smokers you look ahead and note who gets lung cancer and who does not.

The prospective study has the greatest credibility, because you are tied to examining one specific cause and therefore unable to manipulate the explanations. When on the contrary you are looking back, you may be able to find many explanations, some of which can be accidental.

Controlled or uncontrolled
The preferred study is controlled. That is, the effect of a therapy is studied by comparing a group of treated patients with a group of untreated. The two groups should be as similar as possible with respect to everything except the treatment.

In an uncontrolled experiment you only assess the condition of the treated patients before and after the therapy. An accurate file is important. Often it will be impossible to evaluate a therapy by means of an uncontrolled study, because many diseases have spontaneous recovery or a varying degree of intensity (for example multiple sclerosis). This type of study can be useful as a pilot study, rising the suspicion of what takes place during a therapy. Later you should continue your research in a controlled experiment. Was it all just coincidental?

Double-blind studies
A double-blind study is a controlled, prospective investigation, in which neither the researcher nor the patients know who receives what kind of treatment. Even though you have a control group (controlled experiment), and from the start have defined what to examine (prospective study), you can still be deceived by the fact, that both the therapist and the patient know, who receive active treatment. Therapist as well as patient can be so enthusiastic, that a placebo effect arises – or unconsciously the therapist may only treat the healthiest patients.

Randomisation of patients is important
For the latter reason randomisation of the patients is important. The patients are separated into two groups by lot. It is preferable if the control patients match the treated in all relevant areas, for example age, gender, smoking habits, disease pattern etc. Identical twins are ideal but in short supply. This is called matched controls. Very often an alternative can be the use of cross-over. With this technique a patient group alternately and without knowing when receives active and placebo treatment. In this way the patients act as their own control and the control and therapy groups are identical.

Less preferred are single-blinded studies. Only the patients are "blinded" and therefore unaware of the kind of treatment they receive. The attitude of the therapist may therefore influence the result.

Not at any price
When the result is summized, some degree of uncertainty usually still exists despite all precautions. The result needs to go through statistical analysis in order to assess the validity. Often the result is given as a p-value, showing the probability of the result having occurred by chance. When p is less than 0.5, there is 5% probability that the result is accidental. Usually this is the limit below which a result is accepted as valid. The result is said to be significant and the p-value is stated. Therefore, even though the result may be true, you will by chance get a different result 5 out of every 100 times you undertake the investigation. Even though a result may be statistically significant it is not necessarily relevant. A method may be effective against pain, but still irrelevant if the relief is very limited or the method too expensive. Similarly, reduction of a common cold by one hour is totally irrelevant.

The Helsinki Declaration
In 1964, with the latest revision in 1983, the World Medical Association adopted the Helsinki Declaration, stating ethical rules for scientific experiments involving human beings. Among other things, it is pointed out, that the therapist must observe common scientific principles, and must be acquainted with the scientific literature on the subject. Any risks involved in the experiment should measure up to the possible benefits. It is assumed, that a research protocol is used, describing the course of the project, the presumptions, etc. Following full verbal and written information about the project and possible risks involved, the patient should give a written consent. This does not relieve the researcher from full responsibility, nor does it impose an obligation on the patient to finish the experiment.

In Denmark all medical research must be approved by regional Science of Ethics Committees, who decide whether the projects are reasonable and justifiable.

Appendix D: Ethical Guidelines for Clinical Research

By Chr. F. Borchgrevink, Professor, Dr.Med., Institute of General Medicine, Oslo, Norway, 1994
(Mainly based on the World Medical Association's Helsinki Declaration from 1964, revised in Tokyo in 1975)

1. Bad research is unethical. It is a waste of resources, abuse of the patients and may lead to false conclusions.

2. In all research involving human beings, a voluntarily given and fully informed consent should be obtained from the participants, preferably in writing. If this is impossible or if it is regarded as essential not to obtain the informed consent, then the reasons should be explained in the research protocol and evaluated by an independent committee.

3. The information should be adequate and relevant in proportion to the project and should be written in a comprehensible language.

4. The patients should be informed, that participation is voluntary and that the consent can be withdrawn at any time.

5. Refusal of participation must not influence the therapist-patient relationship.

6. A system where consent can be bought is unacceptable.

7. The potential benefits, dangers and inconveniences of the new method (treatment) should be measured against the benefits of the best current diagnosis and treatment procedure.

8. All patients in a clinical trial, including those in a control group, should be ensured the best possible diagnosis and treatment.

9. Experiments involving children should not be carried out, if the same information can be obtained by using adults.

10. Experiments involving patients should not be carried out, if the same information can be obtained by using healthy persons.

11. Experiments involving humans should not be carried out, if the same information can be obtained by using animals.

12. Experiments involving living objects should not be carried out, if the same information can be obtained in a laboratory by the use of tissue samples, etc.

13. Research protocols for studies involving living research objects should be submitted to a special independent committee for consideration, comments and counselling.

14. In research involving humans the interests of science and society must never overrule considerations regarding the health of the participants.

15. Experimental research of any kind should only be executed if it is necessary, useful and has a sound foundation.

16. Research not meeting these guidelines should not be published.

Appendix E: Starting Procedures for Research Projects Including Financing

1. Contact your local Ethics of Science Committee and obtain informational material for research projects: General information, guidelines for making a research protocol and participants information, reporting forms, etc. Consider whether you want the committees approval - or just want to inform the committee before starting the project.

2. Projects can be submitted to and approved by The Council Concerning Alternative Treatment, The National Board of Health. (This is important if the project is done under public patronage).

3. The Inspection Office for Registrations is contacted for forms and information about compulsory notification of the project.

4. The therapist(s) initiating the project also has the financial responsibilities. Public as well as private research foundations can be applied for funding.

Appendix F: Addresses

The Research and Project Committee of The Council Concerning Alternative Treatment, The National Board of Health
(updated 1 June 1997)

Sundhedsstyrelsens Råd vedr. Alternativ Behandling
Amaliegade 13
Postboks 2020
1012 København K, Denmark
Att.: Helle Bihlet
Tel.: (+45) 3391 1601, #3303

Chairperson
Jesper Norup
Lægehuset
Dommervænget 27
4000 Roskilde, Denmark
Tel.: (+45) 4635 0185

Vice-chairperson
Leila Eriksen
Syvhøjvænge 268
2625 Vallensbæk, Denmark
Tel./fax: (+45) 4364 8139

Kate Hallquist
Minkemarkvej 22, Udby
4300 Holbæk, Denmark
Tel.: (+45) 5946 5606
Fax: (+45) 5946 5505

Bjarne Hjelmsted Pedersen
Konggårdsvej 11, Nordenhuse
5800 Nyborg, Denmark
Tel.: (+45) 6536 1285

Anne Dall
Søgårdsvej 84
5270 Odense N, Denmark
Tel.: (+45) 6618 3011

Ethics of Science Committees in Denmark

Den Videnskabsetiske Komité for Københavns Amt
Secretariat:
Amtsgården, Stationsparken 27, 2600 Glostrup, Denmark, Tel.: (+45) 4322 2308/2309.

Den Videnskabsetiske Komité for Københavns og Frederiksberg kommuner
Secretariat:
Københavns Sundhedsdirektorat, Postboks 620, Sjællandsgade 40, 2200 København N, Denmark,
Tel.: (+45) 3530 3530.

Den Videnskabsetiske Komité for Bornholms, Frederiksborg, Roskilde, Storstrøms og Vestsjællands amter
Secretariat:
Sygehusdirektoratet, Amtsgården, Kongens Vænge, 3400 Hillerød, Denmark,
Tel.: (+45) 4226 6600.

Den Videnskabsetiske Komité for Vejle og Fyns Amter
Secretariat:
Odense Sygehus, Administrationen, 5000 Odense C, Denmark, Tel.: (+45) 661 3333.

Den Videnskabsetiske Komité for Århus Amt
Secretariat:
Sygehusforvaltningen, Lyseng Allé 1, 8270 Højbjerg, Denmark, Tel.: (+45) 8944 6666.

Den Videnskabsetiske Komité for Viborg og Nordjyllands amter
Secretariat:
Nordjyllands Amtskommunes sygehusforvaltning, Amtsgården,
Niels Bohrs Vej 30, Postboks 8300, 9220 Aalborg Øst, Denmark, Tel.: (+45) 9635 1000.

Den Videnskabsetiske Komité for Ringkøbing, Ribe og Sønderjyllands amter
Secretariat:
Centralsygehuset i Esbjerg, Østergade 80, 6700 Esbjerg, Denmark, Tel.: (+45) 7518 1900.

Den Centrale Videnskabsetiske Komité
Secretariat:
Fuldmægtig, cand. jur. Hanne Koktvedgaard, Forskningsrådene, Bredgade 43,
1260 København K, Denmark, Tel.: (+45) 3392 9700.

Science Shops

Videnskabsbutikken på Danmarks Tekniske Universitet, bygn. 208, Anker Engelundsvej, 2800 Lyngby, Denmark, Tel.: (+45) 4525 2525 (direct 4525 5940).

Videnskabsbutikken på Roskilde Universitetscenter (RUC), Postboks 260, 4000 Roskilde, Denmark, Tel.: (+45) 4675 7711, #2129.

Videnskabsbutikken på Samfundsvidenskab/Jura, Københavns Universitet, Jagtvej 155 D. 1. sal, 2200 København N, Denmark, Tel.: (+45) 3532 3099.

Videnskabsbutikken på Naturvidenskab, Københavns Universitet, Studiestræde 6, st. tv., 1455 København K, Denmark, Tel.: (+45) 3532 0090.

Panum Instituttet
Blegdamsvej 3B, 2100 København Ø, København, Denmark, Tel.: (+45) 3532 7054

National Research Councils

The National Research Council for the Humanities
The National Research Council for the Social Sciences
The National Research Council for the Medical Sciences

Through the National Research Council's folders there are directions available on how to apply for funding by the councils, what kind of projects can be supported, and information required in the project protocol. Tel.: (+45) 3392 9700.

The Inspection Office for Registrations

Registertilsynet
Christians Brygge 28
1559 København V, Denmark
Tel.: (+45) 3314 3844.

Appendix G: Research Literature

Andersen, J.C. **Overtro eller nytænkning. Befolkningens brug af og holdning til alternative behandlingsformer.** Center for Kulturforskning v/Århus Universitet, Århus 1990.

Brendstrup, E., Launsø, L. **Holistisk integreret behandlingsmodel - brugt af cancerpatienter og forskningsevalueret.** Institut for Samfundsfarmaci, Danmarks Farmaceutiske Højskole. Januar 1994.

Brendstrup, E,. **Hovedpine og zoneterapeutisk behandling.** 1995. Sundhedsstyrelsens råd *Launsø, L.* vedr. alternativ behandling. Rekvireres hos Sundhedsstyrelsen.

COST B4 **Complementary medicine research: An international perspective.** A conference co-sponsored by The Research Council for Complementary Medicine and The European Commission June 1994.

COST B4 **Unconventional medicine in Europe.** Responses to the COST B4 Questionnaire. Directorate-General XII, Science, Research and Development. 1994.

Eriksen, L. **Zoneterapi - forskning og effekt evaluering.** Forenede Danske Zoneterapeuter. 1995.

Eriksen, L. **Appendiks til hovedpinerapporten - indeholdende spørgeskema, projektbeskrivelse samt publicerede artikler.** Forenede Danske Zoneterapeuter (FDZ) 1996.

FDZ's statistikmappe. Materiale der er samlet for at give et billede af udførte undersøgelser. FDZ 1997.

Geil, K.O. **Basisviden om patienter, der søger zoneterapi.** Handelshøjskolen i Århus, Institut for Erhvervs- og Samfundsbeskrivelse. 1989.

Hofmeister, E., Launsø, L., Brendstrup, E. **Centre for integreret medicin - alternativ behandling i udvikling.** Institut for Samfundsfarmaci. 1994.

Johannessen, H. **Alternativ behandling i Europa: Udbredelse, brug og effekt - et litteraturstudie**. Sundhedsstyrelsens Råd vedrørende alternativ behandling. Marts 1995.

Johannessen, H.S. **Studies in Alternative Therapies.** Vol. I-IV. Odense University Press.

Launsø, L., Gosvig Olesen, Staugård, F. Jan. 1995, Nov. 1995, Aug. 1996, Marts 1997.

Kjørup, S. **Forskning og samfund.** En grundbog i videnskabsteori. Gyldendal 1985.

Launsø, L. **På vej mod integreret medicin - en kamp på paradigmer i behandlings- og forebyggelsesarbejdet. Kvinders krop og sundhed - en samfundssag?** Samkvind Skriftserie nr. 7, København 1991.

Launsø, L. **En beskrivelse af zoneterapeuters klienter og zoneterapeuters praksis i Danmark.** Sundhedsstyrelsens råd vedr. alternativ behandling. 1993. Rekvireres hos Sundhedsstyrelsen. (English version available through FDZ, Danish Reflexologists Association).

Launsø, L., Brendstrup, E. **Forskning i alternativ behandling i Danmark - et litteraturstudie.** Sundhedsstyrelsens Råd vedrørende alternativ behandling. Marts 1994.

Launsø, L. **Brug og brugererfarede virkninger af alternativ behandling - en sammenfatning.** Sundhedsstyrelsens Råd vedrørende alternativ behandling 1995.

Launsø, L., Rieper O. **Forskning om og med mennesker**. NNF 1995.

Launsø, L. **Det alternative behandlingsområde - brug og udvikling, rationalitet og paradigmer.** Akademisk forlag 1996

Lund, A.B. (red.) **Sundhedsvæsenet i det 21. Århundrede - hvad får brugerne brug for?** Komiteen for Sundhedsoplysning 1994.

Rasmussen, N.Kr., Groth, M.V., Bredkjær, S.R.., Madsen, M., Kamper-Jørgensen, F. **Sundhed og sygelighed i Danmark 1994.** En rapport fra DIKE´s undersøgelse. Dansk Institut for Klinisk Epidemiologi, Købehavn 1995.

Schjelderup, V. **Nytt lys på medisinen.** Cappelens Forlag, Drammen 1989.