RESEARCH IN
OSTEOPATHIC MEDICINE

- Scientific Philosophy
- Purposes and Goals for Osteopathic Research
- Scientific Methodology within Osteopathic Medicine
- Literature Search
- Kinds of Osteopathic Research
- Designing and Conducting Osteopathic Research
- Structure of a Scientific Research Study
- Don’t fear the “Stats”
SCIENTIFIC
PHILOSOPHY
Osteopathy and Science

Reductionism

~

Holism

Evidence

~

philosophical Concept

Clinical evidence

~

Research
Classification of Sciences

- **positive sciences**: mathematics, logic
- **empirical sciences**: nature sciences, humanities
- **philosophy**
Osteopathy and Scientific Philosophy

Scientific Philosophy

- Osteopathic Medicine
- Osteopathic Research
What is Science?

**Definition:** an objective, logical and systematic method to analyse phenomena = **INDUCTIVISM**

**Purpose:** collecting reliable knowledge in order to enable the making of predictions

*(Lastrucci, 1966)*
What is Science?

Logical thinking

- Truth
- Validity
- Correctness
The Problem of the Concept ‘Truth’

- Being in accordance with ‘facts’
- Being deductable from the theory
- Offering the possibility of exact predictions

(Koningsveld, 2000)
Function of Science

The function of science is to offer a description of phenomena, sensorially perceived.

This description should be as reliable, as accurate and as unambiguous as possible.
The concept ‘truth’ is being weakened to inductive ‘probability’

= 

POSITIVISM
Critical Rationalism

(‘Logik der Forschung’, 1934 – Karl Raimund Popper)

the phenomena have to be proven empirically and critically

by means of falsification

verification is the method of inductivism
Critical Rationalism

Purpose: “to find satisfactory explanations of whatever strikes us as being in need of explanation”

‘satisfactory’ implies ‘being testable and rejectable’

(Popper, 1983)
Demarcation
Science / Non-Science

“I certainly do not believe in anything like a sharp demarcation.”

(Popper, 1983)
Demarcation
Science / Non-Science

**SCIENCE**

- Being testable
- Accumulation of knowledge
Characteristic Features of the Scientific Method

- classic sciences
  ~ comprehension of nature

- modern sciences
  ~ mathematical method
  ~ experimental method
“The scientific approach can be defined as a systematic, empirical, controlled and critical examination of hypothetical propositions about the associations among natural phenomena.”

(Kerlinger 1973, in Portney and Watkins, 2000)
Scientific Method

- systematic
- empirical
- controlled
- critical
- objective
- logical
Scientific Method

- **Deductive reasoning**: is characterized by the acceptance of a general proposition, that can be drawn in specific cases.

- **Inductive reasoning**: is characterized by the developing of generalizations from specific observations.
Research Process

(basiert auf Zeidler 2000, in Sommerfeld, 2004)
Relativity of Science

- Science redefines itself in conventional medicine every 30, 40 years
  (pathological anatomy ~ laboratory science and bacteriology ~ propabilistics statistics with randomized controlled science)
- Only a small percentage of our knowledge in conventional medicine is verified by the newest scientific methods
- Orthodox medicine is based on reductionism (a strong need to simplify the situation)

(EU Cost B4, 1998)
Relativity of Science

“The scientific method is by no means perfect,
especially when it is applied to the study of human behavior and performance.”

(Portney and Watkins, 2000)
Relativity of Science

NO PROVE IN EMPIRICAL SCIENCES

INDUCTIVE CONCLUSIONS SUPPORTED BY STATISTICS

TENDENCIES

“Statistical analysis allows us to put limits on our uncertainty, but not to prove anything.”

(Altman, 1999)
Relativity of Science

“Science is not a collection of absolute truths. Science is the gathering of a number of falsifiable statements that try to explain the world around us. This statements should be scrutinized over and over again for inconsistencies and if needed changed or improved.”

= attitude of self - criticism

(Schulze-Pillot, EU Cost B4, 1998)
Relativity of Science

“If truth were a necessary condition for technical development, then we would probably still be on the level of the caveman.”

concept of ‘truth’ ~ concept of ‘usefulness’

(Nordin, 1999)
Relativity of Science

“Medicine today, to deserve the name, must incorporate medical theory, science and research as well as empirical knowledge, explanation as well as understanding. It is either holistic or it is not medicine.”

(Lewinsohn, State University of Caminas, Brazil, 1998)
HOLISTIC IDEAS ~ SYSTEM THEORY

‘the whole is bigger than the sum of its parts’

= QUALITATIVE PARADIGM

the *qualitative paradigm* portrays reality as a multiple, constructed, interdependent whole that cannot be broken down into measurable segments
qualitative paradigm

~

the quantitative paradigm holds the mechanistic view that knowledge is concerned with ‘facts’
Qualitative ~ Quantitative Paradigm

**Quantitative paradigm**

Truth can be found by applying the proposition that measurable influences affect measurable outcomes in a cause-effect manner. These variables can be expressed numerically and processed by statistical analysis to determine relationships between phenomena.

**Qualitative paradigm**

Truth lies in gaining an understanding of the action, beliefs and values of others, from within the participant’s frame of reference.

(Grbich, 1999)
Is there a Dichotomy between Osteopathic and Scientific Ideas?

In this age of Evidence-Based Medicine the relationship between medicine and science seems uncontroversial.

“Research and clinical practice should be one in spirit, method and object.”

(Flexner, 1910)
Is there a Dichotomy between Osteopathic and Scientific Ideas?

There are 3 good reasons for science underlying osteopathic practice:

- “Scientific approaches use doubt and questioning, which are the driving forces behind ideas and discovery.

- Scientific verification is preferable to simple belief, no matter how comforting a belief may be.

- Scientific proof can justify expenditure.”

(Welsby, 1999)
Osteopathic Medicine

= 

SCIENCE ?

• Facts are objective and testable ?
• Theory leads to predictions ?
• Accumulation of knowledge ?
Osteopathic Medicine

= 

SCIENCE ?

• Facts (structures) are objective
• Mobility and dysfunction of mobility are often not testable
• Effects and effectiveness/efficacy are testable

~

Predictions and accumulation of knowledge
Osteopathic Medicine

= 

SCIENCE?

There is no pure “scientific method”

- making clinical decisions ‘is part of the ‘art’ of clinical practice

- however, we cannot dissociate the art from the science that supports it

= 

THE SCIENTIST PRACTITIONER

(Portney and Watkins, 2000)
PURPOSES AND GOALS FOR OSTEOPATHIC RESEARCH
What is Osteopathic Research?

- Any research that attempts to determine efficacy or value of osteopathic treatment?
- Any research into biologic mechanisms?
- Any research in fields that belong to the osteopathic curriculum?
What is Osteopathic Research?

“To require the investigator to explain how the hypothesis and expected findings of their research would be relevant to the theory, mechanisms, or practice of osteopathic medicine.”

(Patterson, 2003)
What is Osteopathic Research?

“No research is osteopathic by itself, the investigator must make it osteopathic by interpreting it in the light of osteopathic philosophy and practice”

(Patterson, 2005)

The data are then much more likely to be correctly used in understanding the profession’s basic questions.
What is Osteopathic Research?

Two misperceptions:

1. Osteopathic research is limited to investigation of OMT (the most distinctive modality of osteopathic medicine).
2. The general impression that osteopathic principles are so self-evident, axiomatic, implicit, and pervasive in biomedical research as to be too platitudinous to raise new questions for research

(Korr, 1991)
Why Osteopathic Research?

ULTIMATE QUESTIONS

• Effectiveness
• Truth
• The nature of reality
Why Osteopathic Research?

OSTEOPATHS QUESTIONS

What it is they do in their practice and how they might do it better?
Why Osteopathic Research?

OSTEOPATHS QUESTIONS

• Knowing what patients believe about their health and illness.
• Knowing how they value your treatment or other aspects of the care you give.
• Establishing which patients and conditions you seem to manage most successfully.
Why Osteopathic Research?

OSTEOPATHS QUESTIONS

• All of the osteopaths have a natural desire to know ...

• Part of the duty and professional responsibility held by osteopaths is to evaluate and improve the care they are offering to their patients.
Why Osteopathic Research?

PATIENTS QUESTIONS

- They want to understand more about the treatment they are receiving.
- “Will this treatment you are suggesting work?”
- “How long will it take?”
- “What sort of changes should I expect from having this treatment?”
- The more inquiring may ask: “How does it work?”
Why Osteopathic Research?

HEALTH PROFESSIONALS QUESTIONS

• “Could osteopathy help my patients and how would I be able to refer appropriately to osteopathic practitioners?”

• “Are the treatments safe?”

• “How does it work?”
Why Osteopathic Research?

• Those responsible for increasing access to osteopathic medicine, whether they be legislators or purchasers of healthcare services, need to know that osteopathy is safe, effective and cost beneficial.

• To make such decisions on behalf of the public, a body of research is required.
SCIENTIFIC METHODOLOGY WITHIN OSTEOPATHIC MEDICINE
Purpose of Research

- Description
- Explanation
- Evidence-gathering
- Generalisation

“Many studies do not fall neatly into only one category.”

(Kane, 2004)
Types of Research

- Basic ~ Applied Research
- Experimental ~ Nonexperimental Research
- Quantitative ~ Qualitative Research
**Kinds of Research**

**BASIC RESEARCH**

*Basic research* is performed to assess the effect(s) of a given ‘factor’ under study, on a number of defined variables related to the hypothetical effect of the factor under study.

How does it work?

*(Schulze-Pillot, EU Cost B4, 1998)*
Kinds of Research

BASIC RESEARCH

*Basic research* is done to obtain empirical data that can be used to develop, refine or test theory.

Basic research is directed toward the acquisition of new knowledge for its own sake.

*(Portney and Watkins, 2000)*
Kinds of Research

APPLIED RESEARCH

Applied research is directed toward solving immediate practical problems with functional applications and testing the theories that direct practice.

Most clinical research falls into this category.

(Portney and Watkins, 2000)
Kinds of Research

**CLINICAL RESEARCH**

*Clinical research* is performed to assess the efficacy and effectiveness of different therapeutic measures and other influences on the changes in the state of health or its maintenance.

Does it work?

*(Schulze-Pillot, EU Cost B4, 1998)*
EXPERIMENTAL RESEARCH

Experimental research refers to investigations in which the researcher manipulates and controls one or more variables and observes the resultant variation in other variables. The major purpose is to suggest cause-and-effect relationships.

(Portney and Watkins, 2000)
Nonexperimental research refers to investigations that are generally more descriptive or exploratory in nature. This type of research is often referred to as observational research, to reflect the idea that phenomena are observed rather than manipulated.

(Portney and Watkins, 2000)
Kinds of Research

QUANTITATIVE RESEARCH

Quantitative research involves measurement of outcomes using numerical data under standardized conditions.

Quantitative information may be obtained using formal instruments which address physical or physiological parameters, or by putting subjective information into an objective numerical scale.

(Portney and Watkins, 2000)
Kinds of Research

QUALITATIVE RESEARCH

*Qualitative research* is more concerned with subjective, narrative information, which typically is obtained under less structured conditions.

The purpose of the research may be to simply describe the state of conditions, or it may be to explore associations, formulate theory, or generate hypotheses.

*(Portney and Watkins, 2000)*
Kinds of Research

QUALITATIVE RESEARCH
appropriate to assess prevalence, attitudes, demand, time trends or belief systems to provide a proper basis to formulate a hypothesis

QUANTITATIVE RESEARCH
aims at hypothesis testing and at evaluating the efficacy, safety and (cost-)effectiveness of diagnosis

(Resch and Ernst, 1996)
Continuum of Research

Research methods are classified as

- DESCRIPTIVE
- EXPLORATORY
- EXPERIMENTAL

However, different types of research can overlap in their purpose and may incorporate elements of more than one classification.
DESCRIPTIVE EXPERIMENTAL

Describe populations

Find relationships

Cause and Effect

Case Study

Developmental Research

Quasi-Experimental Designs

Qualitative Research

Predictive Research

Survey Research

Cohort/Case-Control Studies

Methodological Research

Literature Review

Basic Research

(Randomized Controlled Trial

(Based on Portney and Watkins, 2000)
Case studies involve the in-depth description of an individual’s condition or response to treatment.

Case studies are necessary to build a foundation for clinical science and as a means of sharing special information among professional colleagues.

Case studies are an intensive investigation designed to analyze and understand those factors important to the etiology, care, and outcome of the subject’s problems.
Case Study

• A case study begins with *a full history, delineating problems, symptoms, and prior treatments, as well as demographic and social factors that are relevant to the subject’s care and prognosis.*

• *Documentation of all interventions, the subject’s responses, and any follow-up should be complete.*

• *Data may be qualitative or quantitative, and may be obtained using both objective and subjective methods of observation.*
The major contribution of the case study to research is its ability to provide information that can be used to generate inductive hypotheses.

The case study is the least rigorous approach because of its inherent lack of control and limited generalizability.

The validity can be enhanced (repeated measurements, multiple dependent variables, outcome measures that show large and immediate changes, follow-up).
<table>
<thead>
<tr>
<th>DESCRIPTIVE</th>
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<th>EXPERIMENTAL</th>
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<td>Describe populations</td>
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<tr>
<td>Case Study</td>
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<tr>
<td>Basic Research</td>
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</table>
Survey Research

- A survey is composed of a series of questions and may be conducted as an oral interview or a written questionnaire.

- The data are intended for generalization to a larger population or as a description of a particular group.

- Interviews can be structured oder unstructured.

- Questionnaires are structured surveys. The process of developing a survey instrument involves several stages.
DESCRIPTIVE

Describe populations

EXPLORATORY

Find relationships

EXPERIMENTAL

Cause and Effect

Case Study

Randomized Controlled Trial

Developmental Research

Quasi-Experimental Designs

Methodological Research

literature Review without or with Secondary Analysis or Meta-Analysis

Basic Research

DEVELOPMENTAL RESEARCH
Developmental Research

- Developmental research involves the description of developmental change and the sequencing of behaviors in people over time.

- Two methods:
  - Longitudinal study
  - Cross-sectional study
Developmental Research

• In a longitudinal study the researcher follows a cohort of subjects over time, performing repeated measurements at prescribed intervals. This research can be retrospective or prospective.

• In a cross-sectional study the researcher studies a stratified group of subjects at one point in time and draws conclusions about development within a population by comparing the characteristics of those strata.
DESCRIPTIVE EXPLOREATORY EXPERIMENTAL

Describe populations

Find relationships

Cause and Effect

Randomized Controlled Trial

Case Study

Quasi-Experimental Designs

Developmental Research

Cohort/Case-Control Studies

Methodological Research

Literature Review without or with Secondary Analysis or Meta-Analysis

Basic Research

Cohort Studies
Cohort Studies

• In a cohort study (also called a follow-up study) the researcher selects a group of subjects who do not yet have the outcome of interest and follows them to see if they develop the disorder.

• Cohort studies may be pureley descriptive or more analytic.
CASE-CONTROL STUDIES
Case-Control Studies

- A case-control study is a method of epidemiologic investigation.

- **Cases** are those classified as having the disorder, and **controls** are chosen as a comparison group without the disorder.

- The investigator then looks backward in time, via interview, questionnaire, ... to determine specific characteristics.
DESCRIPTIVE

Describe populations

EXPLORATORY

Find relationships

EXPERIMENTAL

Cause and Effect

Case Study

Randomized Controlled Trial

Developmental Research

Quasi-Experimental Designs

METHODOLOGICAL RESEARCH

Methodological Research

Literature Review without or with Secondary Analysis or Meta-Analysis

Historical Research
Methodological Research

- Methodological research involves the development and testing of measuring instruments for use in research or clinical practice.

- The purposes are related to the reliability and validity of a measurement tool.
Methodological Research

- **Reliability** is the extent to which a measurement is consistent and free from error = reproducibility.

- **Validity** ensures that a test is measuring what it is intended to measure.
Methodological Research

- Two types of measurement errors:
  - **systematic errors**: predictable, constant
  - **random errors**: unpredictable, due to chance

- Measurement errors can be attributed to:
  - the tester
  - the measuring instrument
  - the variability of the characteristic being measured
    (unpredictability of the environment and the human response)
Methodological Research

- **Test-retest reliability**: an instrument is capable of measuring a variable with consistency

- **Intrarater reliability**: refers to the stability of data recorded by one individual across two or more trials

- **Interrater reliability**: concerns variation between two or more raters who measure the same group of subjects
Methodological Research

- **Validity:**
  - a valid test is also reliable
  - an invalid test can be reliable

- **Specificity of validity:**
  How valid is an instrument for a given purpose?
The validity of a diagnostic test is evaluated in terms of its ability to accurately assess the presence of the target condition.

A diagnostic test can have four possible outcomes: true positive, true negative, false positive and false negative.
Methodological Research

presence or absence of target condition

<table>
<thead>
<tr>
<th>Screening Test Results</th>
<th>+</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>a (true positive)</td>
<td>b (false positive)</td>
</tr>
<tr>
<td>Negative</td>
<td>c (false negative)</td>
<td>d (true negative)</td>
</tr>
</tbody>
</table>

sensitivity = \[
\frac{a}{a + c}
\]

specificity = \[
\frac{d}{b + d}
\]
DESCRIPTIVE

EXPLORATORY

EXPERIMENTAL

Describe populations

Find relationships

Cause and Effect

Case Study

Randomized Controlled Trial

Developmental Research

Quasi-Experimental Designs

LITERATURE REVIEW

Methodological Research

Literature Review without or with Secondary Analysis or Meta-Analysis

Basic Research
Literature Review

- Literature review
  - narrative and historical literature review
  - systematic literature review with meta-analysis

- Literature review
  - basis for every study
  - study in itself
The scope of the review depends on
– the researcher’s familiarity with the topic
– how many relevant references are available.

The important consideration is the relevancy of the literature, not the quantity.
Literature Review

- **Primary sources:** a report of document provided directly by the person who authored it.

- **Secondary sources:** a description or review of one or more studies (presented by someone other than the original authors).

- Secondary sources are most useful for providing bibliographical information on relevant primary sources.
Organizing the review of literature:

- research question
- hypothesis
- research design
- criteria for diagnosis and for including or excluding subjects
- input and outcome variables
- measurements
- statistical analysis
- data reporting
- conclusions
Problems with literature review:

- publication bias
- heterogenity
- quality differences
Publication bias is a serious threat to the validity of literature search:

- **material not published**
- **still no ‘journal of negative results’**
- **studies not identified ~ selection bias**
Differences between studies manifest themselves in:

- sampling
- in- and exclusion criteria
- measurement technique
- reference group
- intervention
- follow-up
- …
Literature Review

Quality differences

One has to consider the methodological qualities of the study.
Basic Research

“It is no longer adequate for osteopathic physicians to do, and to do well, but it is necessary to explain the why and how. The intention is to discover how and why it functions as it does.”

(Greenman in Beal 1994)
Purposes of basic research in osteopathic medicine:

• truth and/or usefullness of the osteopathic concept
• knowledge about human functioning
Basic Research

“What we need as a profession,

- are physiological laboratories where we can prove or disprove the theories of osteopathy,

- a more profound study of bacteriology and pathology in their applications to osteopathy,

- a greater prominence given to the study and application of dietetics and hygiene,

- and finally a more common sense view of the extraneous causes of disease.”

(Cole in Northup 1987)
Basic Research

“The research in osteopathic medicine have to emphasize the mainenance and restoration of the body’s ability to cope with illness and stress.”

(Research Manual, AAO 2001)
Basic Research

“The main purpose of research in osteopathic medicine is not to prove that osteopathic medicine is at least as good as other medical treatments,

but is ‘to investigate problems that will lead to a better understanding and a more effective application of the philosophy and concepts of osteopathic medicine.’”

(Osteopathic Research Handbook, AOA 2003)
Basic Research

The research projects in osteopathic medicine have to stress on the reciprocal relationship between
- basic research and
- clinical research
Randomized Controlled Trial

- The Randomized Controlled Trial is the most common type of experimental design in epidemiology.

- The RCT presents the strongest evidence for causality.

- The RCT is a prospective study comparing the effect of an intervention against a control.
“Clinical decisions should be based on the best available scientific evidence.”

(Koes and Hoving, 1998)

“The best available external clinical evidence comes from systematic research.”

(Sackett et al, 1996)

EVIDENCE BASED MEDICINE
Randomized Controlled Trial

**EFFICACY**

Does treatment result in patient improvement in an ideal setting?

**EFFECTIVENESS**

Does treatment result in patient improvement in an average practice setting under usual treatment circumstances?
Randomized Controlled Trial

Scientific research aims at determining the relation between two variables:

- **Independent variable** ~ treatment, technique, way of life, ...

- **Dependent variable** ~ symptom, status of health, disease, ...
Randomized Controlled Trial

The relation between two variables:

- A is the cause of B
- B is the cause of A
- A and B have the same cause
- A and B are only related by chance
Randomized Controlled Trial

“It is crucial that the researcher is able to prespecify what the key variables are.”

(Kane, 2004)

Experience

~

Knowledge about every influencing factor

~

Control
Randomized Controlled Trial

“Researchers need to be able to control the intervention and circumstances surrounding their experiments to ensure that results are not being influenced by other interfering variables.”

(Kane, 2004)
Randomized Controlled Trial

PERCEIVED EFFECTS = INTERVENTION SPECIFIC EFFECTS + placebo effects, natural course, bias, regression to the mean, unknown factors and chance
Randomized Controlled Trial

- Intervention specific effects
- Placebo effects
- Natural course
- Other factors

(Based on Resch and Ernst, 1996)
Randomized Controlled Trial

- Intervention specific effects
- Placebo effects
- Natural course
- Other factors

Another treatment
Randomized Controlled Trial

- Intervention specific effects
- Placebo effects
- Natural course
- Other factors

SHAM TREATMENT
Randomized Controlled Trial

Intervention specific effects

Placebo effects

Natural course

Other factors

NO TREATMENT
Randomized Controlled Trial

Intervention specific effects

Placebo effects

Natural course

Other factors

(Based on Wallach, 2001)
Randomized Controlled Trial

- Intervention specific effects: A > B
- Placebo effects: B > A
- PERCEIVED EFFECTS: B > A
Randomized Controlled Trial

PLACEBO EFFECTS

- 0 – 100%

- Insufficient knowledge about the direct or indirect influence on illness, disease and health
PLACEBO EFFECTS

“Placebo as the control intervention is ethically acceptable only if there is no ‘gold standard’ intervention available which causally interferes with the underlying condition.”

(Resch and Ernst, 1996)
Randomized Controlled Trial

PLACEBO EFFECTS

Placebo effects can partially be prevented by BLINDING ~ patient, practitioner, observer, analyst
Randomized Controlled Trial

BLINDING

• **In general:** observer and analyst

• **In basic research:** patient, practitioner, observer and analyst ~ control techniques are ‘real’ osteopathic techniques
Randomized Controlled Trial

REGRESSION TO THE MEAN

“Patients are likely to present with their complaint at a ‘relative maximum’ which could consequently be expected to regress in due course due to its natural fluctuation around an individual mean.”

(Resch and Ernst, 1996)
Randomized Controlled Trial

RANDOMIZATION

Randomization is a formal requirement technically relatively easy to be realized

~

Unbiased assessment of therapeutic effectiveness
Randomized Controlled Trial

RANDOMIZATION

- Randomization ~ aselective
- Matching ~ selective
- Stratification ~ subgroups after the study is done

Sample size

“No magic number can be given.”
Randomized Controlled Trial

CONTROL GROUP

- No treatment
- Sham treatment
- Another treatment
Randomized Controlled Trial

CONTROL GROUP

- **No treatment** ~ gives information about the natural course
- **Sham treatment, another treatment, placebo** ~
  - Effect/efficacy studies ~ sham TECHNIQUE
  - Effectiveness studies ~ standard or another TREATMENT ~ determining placebo is not the purpose of the study!
Randomized Controlled Trial

TREATMENT

“It is essential that assessments of effectiveness of osteopathic treatment be of osteopathic treatment as it is practiced, as an integral part of the total interaction between physician and patient, and not as an isolated, contrived, and standardized procedure which, though nicely amenable to statistical analysis, is totally unrelated to clinical reality.”

(Korr, 1991)
“As it is practiced’’ means that experimental designs must be such as to accept as given that

- Osteopathic treatment cannot be made standard and uniform.
- The placebo response is an integral, inseparable part of the patient’s total response to osteopathic medical care.”

(Korr, 1991)

= PRAGMATIC RCT
“The pragmatic RCT evaluates treatments as they are delivered in the real world.”

“The practitioners are at liberty to adjust the treatment regimes as they saw fit for individual patients and to give the number of treatments they thought were necessary.”

(Kane, 2004)

IT COMPARES TREATMENTS AS THEY ARE GIVEN IN DAY-TO-DAY PRACTICE
Randomized Controlled Trial

PRAGMATIC RCT

“The disadvantage of the pragmatic approach is that it is impossible to identify the precise components of the intervention that are responsible for the observed difference.”

“This is sometimes less important than knowing that a particular therapeutic approach is the most effective strategy for a particular problem – whatever the precise mechanisms of action.”

(Cardini and Weixin, 1998)
Randomized Controlled Trial

PRAGMATIC RCT

~

BLACK-BOX DESIGN

- Osteopathic treatment must be done according to the osteopathic concept.
- Comparison by means of a acceptable outcome for both treatments (osteopathic and standard treatment)
- List of somatic structures: in dysfunction – treated
Randomized Controlled Trial

BLACK-BOX DESIGN

~

In medicine and in osteopathic medicine MULTICAUSALITY is the most accepted hypothesis

“It is in this incompleteness that the reductionist paradigm does not meet the requirements of osteopathic research. From the osteopathic viewpoint, nothing can be understood except in relation to something else, and especially to the totality of which it is a part and which it serves.”

(Korr, 1991)
Randomized Controlled Trial

BLACK-BOX DESIGN

OUTCOME DATA

“You cannot separate the specific effects from the nonspecific ones. Therefore, you can only look at the total outcome effect.”

(Edwards, 1998)
Randomized Controlled Trial

OUTCOME RESEARCH

Studies which examine the full range of outcomes from human disease and illness:

- pain
- functional status
- satisfaction with care
- costs of care
- impact of illness on society

(Carey and Motyka, 1999)
Randomized Controlled Trial

OUTCOME RESEARCH

- Validated measuring-instruments and questionnaires: VAS (Visual Analog Scale), NRS (Numeric Rating Scale), SF36 Questionnaire, …
- Enough participants: influence of prognostic variables
- Long-term evaluations
Randomized Controlled Trial

RESEARCH DESIGN

~

Waiting-list design

= 

Half of the sample first receives the treatment followed by a period without treatment.
The other half receives the treatment after a period without treatment.
Or, the whole sample receives the treatment (or another treatment) after a period without treatment.
Randomized Controlled Trial

WAITING-LIST DESIGN

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<tr>
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<tr>
<td>Treatment</td>
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<tr>
<td>Measurement X3</td>
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Randomized Controlled Trial

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<tr>
<td>Treatment</td>
<td>A</td>
<td>B / NO</td>
</tr>
<tr>
<td>Measurement X3</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Randomized Controlled Trial

RESEARCH DESIGN

~

Crossover design

= Half of the sample first receives treatment A
followed by treatment B.
The other half first receives treatment B
followed by treatment A.
## Randomized Controlled Trial

### CROSSOVER DESIGN

<table>
<thead>
<tr>
<th></th>
<th>GROUP 1</th>
<th>GROUP 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement X1</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Treatment A-B</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Measurement X2</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Treatment A-B</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Measurement X3</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Consensus on Quality Criteria

(EU Cost B4 Study, 1998)

• The experiment should have the approval of an official ethical committee before the start.

• The hypothesis to be tested must be stated before the start.

• The target group, persons or objects to be studied must be well defined before the start of the study.

• The intervention should be clearly defined at the start of the study.

• Methods for measuring the results of the intervention must be well defined before the start of the study.
Consensus on Quality Criteria

(EU Cost B4 Study, 1998)

- The study must be so designed as to minimise possible bias.
- The assignment into groups should be randomised and blinded.
- All data should be used.
- Only prospective trials can have convincing power.
- Sample size and power should be sufficient.
- Care should be taken when formulating general conclusions.
- Reproducibility is considered to be an absolute requirement of the experimental method.
LITERATURE SEARCH
Literature Search

Purpose of the literature search

- Gathering scientific information about the subject
- Information about the methodology
Literature Search

- Experts
- Books
- Medical dictionaries
  (www.nlm.nih.gov/medlineplus/dictionaries.html)
- References in publications
- Databases

What is currently being investigated in the field of interest?
Literature Search

Following questions are of value

(Research Manual of the Louisa Burns Osteopathic Research Committee of the American Academy of Osteopathy)

• What was the research question addressed?
• What was the hypothesis?
• What was the research design?
• What were the criteria for a confirmed diagnosis?
• What were the criteria for including or excluding subjects?
Following questions are of value

(Research Manual of the Louisa Burns Osteopathic Research Committee of the American Academy of Osteopathy)

- How are the dependent (outcome) and independent (input) variables defined and measured?
- What measurements were made to quantify the independent from the dependent variables?
- What statistical analyses were conducted?
- How are the data reported?
- Were the conclusions supported?
Databases

MEDLINE


MeSH Database (Medical Subject Headings)

- Searching with the MeSH Database
- Combining MeSH terms
- Applying subheadings and other features of the MeSH Database
The Cochrane Collaboration is an international not-for-profit organisation. It produces and disseminates systematic reviews of healthcare interventions and promotes the search of evidence in the form of clinical trials and other studies of interventions.

www.york.ac.uk/inst/crd/crddatabases.htm
Databases

Other databases

www.freemedicaljournals.com

www.pubmedcentral.com

www.biomedcentral.com
Databases

Databases in osteopathic medicine

www.osteopathicresearch.com (org)
Osteopathicresearch is a collaboration of the Wiener Schule für Osteopathie and schools in Europe, especially the Britisch School of Osteopathy and the Britisch College of Osteopathic Medicine

http://ostmed.hsc.unt.edu/
OstMed is a database from the American Osteopathic Association and the American Academy of Colleges of Osteopathic Medicine

www.corpp.org

www.osteopathie-akademie.de
Databases

Osteopathic Journals

Journal of the American Osteopathic Association (www.jaoa.org)

Osteopathische Medizin (www.osteopathische-medizin.de)

DO Deutsche Zeitschrift für Osteopathie (www.thieme-connect.de)
KINDS OF OSTEOPATHIC RESEARCH
Types of Research in Osteopathic Medicine

- Basic Research
- Integrative Model Building
- Synthesis and Meta-Analysis Research
- Qualitative Studies in Osteopathy
- Epidemiology and Outcome Studies
- Research on Manipulation

(Patterson, 2003)
Types of Research in Osteopathic Medicine

1. Manipulative techniques

Buerger A.A.,

Mayer M.,
Kontrollierte, randomisierte, einfach blinde klinische Effektstudie der Tuba auditiva Technik bei akuten Tinnituspatienten mit oder ohne Hörstörungen im Vergleich zur allgemeinen physikalischen Therapie
Types of Research in Osteopathic Medicine

1. Manipulative techniques

2. Studies of manipulative treatment

Black-box-design

The manipulation cannot be predetermined or “prescribed” by the research protocol, but must “go with the flow”.

Andersson G.B.J.; Lucente T.; Davis A. et al.,

### Types of Research in Osteopathic Medicine

**1. Manipulative techniques**

**2. Studies of manipulative treatment**

#### Subtypes of manipulative treatment

<table>
<thead>
<tr>
<th>Subtype</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1 Nonspecific design</strong></td>
<td>the effect of manipulative treatment in general; to improve body function</td>
</tr>
<tr>
<td><strong>2.2 Specific treatment design</strong></td>
<td>manipulative treatment applied to specific somatic dysfunction (diagnosed by TART)</td>
</tr>
</tbody>
</table>
**Types of Research in Osteopathic Medicine**

1. **Manipulative techniques**

2. **Studies of manipulative treatment**

3. **Effectiveness studies**

Manipulative treatment is given to alleviate a specific presenting complaint.

The patient is selected for low back pain; the osteopath gives appropriate manipulative treatment; the effect of the treatment on the complaint is measured.
## Types of Research in Osteopathic Medicine

1. **Manipulative techniques**

2. **Studies of manipulative treatment**

3. **Effectiveness studies**

4. **Functional outcome design**

   The effect of manipulative treatment on general physiological function is assessed. Conceptually sound!

   Measures of outcome: tolerance to stress, immune system function, general activities of daily live assessments, ...
### Types of Research in Osteopathic Medicine

<table>
<thead>
<tr>
<th>1. Manipulative techniques</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Studies of manipulative treatment</td>
</tr>
<tr>
<td><strong>Subtypes of manipulative treatment</strong></td>
</tr>
<tr>
<td>3. Effectiveness studies</td>
</tr>
<tr>
<td>4. Functional outcome design</td>
</tr>
<tr>
<td>5. <em>Total osteopathic care studies</em></td>
</tr>
</tbody>
</table>

*Manipulative treatment + . . . ?*

*Europe >< USA*
Four Forms of Research

- Basic Research in osteopathic medicine
- Clinical research in osteopathic medicine
- Research on the philosophical aspects of osteopathic medicine
- Socio-economical research in osteopathic medicine
Kinds of Research

- Basic Research in osteopathic medicine
  - Research in osteopathic teaching techniques
  - Research in methodology for osteopathic scientific research
  - Research in inter- and intraexaminer reliability studies
  - Research in fundamental sciences
  - Research in osteopathic diagnosis
Kinds of Research

• Basic Research in osteopathic medicine
  - Research in osteopathic teaching techniques
  - Research in methodology for osteopathic scientific research
  - Research in inter- and intraexaminer reliability studies
  - Research in fundamental sciences
  - Research in osteopathic diagnosis
Kinds of Research

- Basic Research in osteopathic medicine

Mann D.D.; Eland D.C.; Patriquin D.A.; Johnson D.F.;

2000, Increasing osteopathic manipulative treatment skills and confidence through mastery learning, JAOA, vol 100, 5: 310-309
Kinds of Research

- Basic Research in osteopathic medicine
  - Research in osteopathic teaching techniques
  - Research in methodology for osteopathic scientific research
  - Research in inter- and intraexaminer reliability studies
  - Research in fundamental sciences
  - Research in osteopathic diagnosis
Kinds of Research

• Basic Research in osteopathic medicine

Sommer K.; Mathys K.,

Kinds of Research

• Basic Research in osteopathic medicine

  o Research in osteopathic teaching techniques
  o Research in methodology for osteopathic scientific research
  o Research in inter- and intraexaminer reliability studies
  o Research in fundamental sciences
  o Research in osteopathic diagnosis
Kinds of Research

- Basic Research in osteopathic medicine

Kinds of Research

• Basic Research in osteopathic medicine
  o Research in osteopathic teaching techniques
  o Research in methodology for osteopathic scientific research
  o Research in inter- and intraexaminer reliability studies
  o Research in fundamental sciences
  o Research in osteopathic diagnosis
Kinds of Research

- Basic Research in osteopathic medicine

Roncada G.,

2004, HaMo-study: Investigation of the effect of breathing on the position of the heart, thesis to obtain the title of DO
Kinds of Research

- **Basic Research in osteopathic medicine**
  - Research in osteopathic teaching techniques
  - Research in methodology for osteopathic scientific research
  - Research in inter- and intraexaminer reliability studies
  - Research in fundamental sciences
  - Research in osteopathic diagnosis
Kinds of Research

• Basic Research in osteopathic medicine

Haas M.; Johansen R.; Krein R.; Panzer D.; Peterson D.; Rothman E.H.; Solomon S.,

1993, Reactivity of leg alignment to articular pressure testing: evaluation of a diagnostic test using a randomized crossover clinical trial approach, J. Manipulative Physiol. Ther.
Kinds of Research

- Clinical Research in osteopathic medicine
  - Research in outcomes studies on different modalities of osteopathic treatment techniques
  - Research in outcomes studies of osteopathic medicine
  - Research in osteopathic diagnosis
Important Questions in Osteopathic Research

- Efficacy
- Interrater and intrarater reliability
- Fundamental processes
  - Physiological effects of manipulation
  - Psychological effects of manipulation

(Patterson, 2005)
DESIGNING AND
CONDUCTING
OSTEOPATHIC
RESEARCH
**PHASE I**  
*Identify the Research Question*

- Identify the research problem
- Review of literature: Theoretical framework
- Identify variables
- State hypotheses
- Specify purpose

**PHASE II**  
*Design the Study*

- Design the protocol
- Choose a sample
- Collect data: Reduce data

**PHASE III**  
*Methods*

- Collect data: Reduce data

**PHASE IV**  
*Data Analysis*

- Interpret findings
- Analyze data

**PHASE V**  
*Communication*

- Report findings
- Suggestions for further study
Virtually all biomedical research stems from **clinical observation**:

- Valuable but rarely conclusive
- Usually subject to too many uncertainties (biases)
- However, it is the beginning point for investigation
Design and Conduct

1. Explore an area of interest
2. Think about the aims of the study
3. Define the research question
4. Define the study design
5. Write a study proposal
Explore an Area of Interest

Identify an area of your work in which there is a problem or puzzle you would like to solve:

- It could be the treatment of children;
- or patients presenting with complex problems;
- or ...
Aims of the Study

What do you want to achieve by conducting this study?

- It might have a personal aspect
- It will certainly have a professional aspect
Define the Research Question

The hypothesis (or the research question) is the statement of the question being asked by the study.

- It must be clear and concise
- It must state exactly what the research is to investigate
Define the Research Question

For example:

“Osteopathic treatment is good for headaches”

= not a good hypothesis

Although we would like to think that the statement is true.

- Can we test it? The answer is no!
- What is "osteopathic treatment"?
- What does "good" mean?
- What type of headache is to be studied?
Define the Research Question

Most beginning researchers:

- try to make the hypothesis too complex
- or design a hypothesis that is simply not testable.
Define the Research Question

Better:

“There is a significant difference in outcome of tension-type headaches in postmenopausal women treated with osteopathy, opposite to the control group.”

A good experimental hypothesis is:

- Simple
- Precise
- and well defined
Define the Study Design

The hypothesis will dictate the study design

“There is a significant difference in outcome of tension-type headaches in postmenopausal women treated with osteopathy, opposite to the control group.”

This hypothesis defined the study as an outcome study on a well-defined problem.
Define the Study Design

The hypothesis will dictate the study design. "There is a significant difference in outcome of tension-type headaches in postmenopausal women treated with osteopathy, opposite to the control group." This hypothesis defined the study as an outcome study on a well-defined problem. The study design might very well be a Randomized Clinical Trial.
Write a Study Proposal

Develop a workable plan for the project:

- Mapping out all the crucial steps you will need to take
  - Refining research question
  - Define research strategy
  - Define population
  - Sampling strategy
  - Collect data
  - Analyse data
  - Report...

- Create a project timetable
Mapping out the Protocol

**Fig. 1.1 Onderzoekschronologie**

**Legende:**
- T\(^1\) = meetmoment 1 bij groep 1 (geen behandeling)
- T\(^2\) = meetmoment 1 bij groep 2 (placebo)
- T\(^3\) = meetmoment 1 bij groep 3 (Weischenck)
- T\(^4\) = meetmoment 1 bij groep 4 (Barra/Mercier)
- I.1 = Interventie 1 (geen behandeling)
- I.2 = Interventie 2 (placebo)
- I.3 = Interventie 3 (Weischenck)
- I.4 = Interventie 4 (Barra/Mercier)
- T\(^1\) = meetmoment 2 bij groep 1
- T\(^2\) = meetmoment 2 bij groep 2
- T\(^3\) = meetmoment 2 bij groep 3
- T\(^4\) = meetmoment 2 bij groep 4

**Informed consent**

**Medische vragenlijst**

**Mogelijke factoren**

**Inclusie**

**Fysische diagnostiek op positie en mobiliteit van de lever**

**Exclusief factoren**

**247 proefpersonen**

Statistiek: Windows Excel → SPSS MS WINDOWS Release 8.0
<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
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<td>Literature review</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Write a Study Proposal

When research is to be part of a dissertation project

- Present a proposal for approval by the research coordinator of an osteopathic college.
- Approval of a research ethics committee is required if patient care is to be altered (hospitals?).

Each committee will have its own format for the presentation of the proposal.
STRUCTURE OF A SCIENTIFIC RESEARCH STUDY
Basic Structure of a Scientific Research Paper

IMRAD

• Abstract
• **Introduction**  (What question was asked?)
• **Methods**   (How was it studied?)
• **Results**    (What was found?)

And

• **Discussion**   (What do the findings mean?)
• Conclusions
• References
Abstract

- It should contain the essence of the whole study and should stand alone
- It should consist of 4 basic parts:
  - Why the study was done
  - What was done
  - What was found
  - What was concluded
- Be clear and concise and avoid unnecessary detail
Introduction

Introductions should be:

- Short
- Arresting
- Tell the reader why you have undertaken the study
Before beginning, answer the basic questions:

- What do I have to say?
- Is it worth saying?
- What is the right format for the message?
- What is the audience for the message?
Introduction

- Tell readers why you have undertaken the study.
- Clarify what your work adds.
- Keep it short.
- Make sure that you are aware of earlier studies.
- Be sure your readers are convinced of the importance of your question, but don't overdo it.
- Don't baffle your readers.
- Give the study's design but not the conclusion.
Introduction

Tell readers why you have undertaken the study

Questions may arise directly from clinical practice:

“We noticed that several patients with variations in blood pressure showed a normalisation after visceral manipulation, especially after manipulation of the liver-region..., we wondered if those two features were interrelated”
Tell readers why you have undertaken the study

Or, questions may arise after theoretical considerations:

“We learned that visceral normalization has physiological consequences within the viscus. We were unable to find a scientific explanation in medical literature and so designed a study to support this hypothesis by questioning if a mobilization of the mesentery has an influence upon the capacity of the portal vein.”
The introduction should not read:

“Several studies have shown the diameter of an uterusmyoma lessened with osteopathic treatment 1-7 and several others have shown that it does not 8-14. We report two further patients, one of whom the diameter had lessened and one of whom it had not, and review the literature.”
Rather it should read something like:

“Two previous studies have reported that the diameter of an uterus myoma lessened with osteopathic treatment. These studies were small and uncontrolled, used only crude measurements, and did not follow up the patients. We report a large controlled study, with detailed measurements and two year follow up.”
Introduction

Keep it short

Do not want to impress readers by summarising everything that has gone before!

“Many studies have addressed the influence of mechanical stress on bone density 1-9. Archaeologists have hypothesised… and the ancient Greek …”

With such a sentence you say almost nothing useful and you've promptly filled a whole page with references.
Keep it short

You should choose references that are apposite, not simply to demonstrate that you’ve done a lot of reading.

You must convince readers that your study is better!
Keep it short

Rather it should read something like:

We cannot be sure whether mechanical stress has a beneficial effect on bone density. Several studies have described such implications \(^{1-9}\). Three experimental studies have been published, two of which found a significant influence. One of these studies was uncontrolled \(^1\) and in the other patients were poorly matched for age and medication \(^4\). The study that did not find an influence included 6 patients which did not perform their training program regularly and the chance of an important effect being missed was high \(^6\). We have undertaken a study of 50 patients with controls matched for age, medication and training program.
Introduction

Make sure that you are aware of earlier studies

It is in nobody's interest to expend time and money exploring a question that has already been well answered.
Make sure that you are aware of earlier studies

- Authors should seek the help of librarians in finding any earlier studies.
- Make personal contact with people who are experts in the subject.
- Find the latest possible review on the subject.
- Many good studies remain unpublished (perhaps because they reach negative conclusions).
- Studies take years to conduct and sometimes years to get into published reports.
Introduction

Be sure your readers are convinced of the importance of your question, but don't overdo it.

You do not need to give (study of uterus/myoma):

An extensive text about the embryology and anatomy of the uterus. And do not elaborate on what a myoma is.

Your readers already know!
Be sure your readers are convinced of the importance of your question, but don't overdo it.

You might, however, want to give them a sense of the scale of the problem:

Prevalence figures of uterus myoma.
Figures on the cost to the nation of the problem.
Standard care procedure and its effects ...
Don't baffle your readers

Although you don't want to patronise and bore your readers by telling them things that they already know,

you certainly don’t want to baffle them by introducing, without explanation, material that is wholly unfamiliar.
Don't baffle your readers

Introduction

L'ultrasonographie en mode Doppler, appelée duplex, permet d’estimer le débit sanguin dans une artère donnée, ou, du moins, leur décours temporel. Le couplage écho-Doppler, par la visualisation, sur l'image échotomographique, de la «ligne de tir» du Doppler, renseigne sur l'angle d'incidence en mode Doppler, permettant ainsi de résoudre entièrement l'équation fondamentale de l'effet Doppler: \( V = \frac{\delta F \cdot C}{2F \cdot \cos \theta} \)

\( \delta F \) = Fréquence Doppler
\( F \) = Fréquence d’émission de la sonde
\( V \) = Vitesse circulatoire sanguine
\( C \) = Vitesse de propagation des US dans les tissus mous, ±1540 ms\(^{-1}\)

\( \cos \theta \) = cos de l’angle formé par la direction du faisceau ultrasonore et la direction de l’écoulement sanguin (figure 16)
Introduction

Give the study's design but not the conclusion

The last line might read:

“We therefore conducted a multicentric, randomized, operator- and evaluator-blinded, experimental study to determine whether a mobilization of the mesentery has an influence upon the capacity of the portal vein.”
Introduction

Give the study's design but not the conclusion

We don't like it, however, when the introduction also gives the final conclusion:

“Mobilization of the mesentery shows a higher capacity of the portal vein.”

Other editors may think differently.
Methods

“Methods” should describe:

- How your study was designed
- How the study was carried out
- How the data were analysed
Methods

How your study was designed

• Keep the description brief
• Say how randomization was done
• Use names to identify parts of a study sequence
Methods

How the study was carried out

• Describe how the subjects were recruited and chosen.
• Give reasons for excluding subjects.
• Consider mentioning ethical features.
• Give accurate details of materials used.
• Give the exact form of treatment and accessible details of unusual apparatus.
Methods

How the data were analysed

- Use a p value to disprove the null hypothesis.
- Give an estimate of the power of the study (the likelihood of a false negative - the $\beta$ error).
- Give the exact tests used for statistical analysis (chosen a priori).
Methods

A good methods section can answer these questions:

• Does the text describe what question was being asked, what was being tested, and how trustworthy the measurements of the variable under consideration would be?

• Were these trustworthy measurements recorded, analysed, and interpreted correctly?

• Would a suitably qualified reader be able to repeat the experiment in the same way?
Methods

- Studiendesign
- Kriterien zur Studienteilnahme
- Zielfaktoren
- Studiendurchführung
  - Rekrutierung
  - Informierung + informed consent
  - Studienablauf
  - Randomisierung
  - Messverfahren
  - Statistik
Results

The results section provides the answers to the questions you, as the author, pose in the introduction.

You must lead your readers into following your thoughts, usually by using a mixture of text, tables and illustrations.
Results

- Describe the subjects of your study.
- Present the answers; start with some text.
  - The text should tell the story
  - The tables will summarise the evidence
  - The illustrations will show the highlight
  - Both the tables and the illustrations should be capable of standing alone!
- Remember the reader.
Results

Table 4.1 Cardiovascular response to intubation

<table>
<thead>
<tr>
<th>Event</th>
<th>Heart rate</th>
<th>Systolic BP</th>
<th>Diastolic BP</th>
<th>Cardiac output</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premedication</td>
<td>75 ± 12</td>
<td>135 ± 14</td>
<td>87 ± 10</td>
<td>4.408 ± 0.714</td>
</tr>
<tr>
<td>Induction</td>
<td>72 ± 5</td>
<td>115 ± 12</td>
<td>71 ± 13</td>
<td>3.728 ± 1.135</td>
</tr>
<tr>
<td>Intubation</td>
<td>95 ± 10</td>
<td>179 ± 19</td>
<td>110 ± 32</td>
<td>4.693 ± 1.948</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>82 ± 8</td>
<td>130 ± 14</td>
<td>78 ± 12</td>
<td>4.296 ± 1.547</td>
</tr>
</tbody>
</table>

- What is intubated?
- Most of the grid lines are superfluous
- The columns have no indication of the units used
- No definition of ± (SD or standard error?)
- No indication of any statistically significant change, ...
The values for 10 subjects are the means, standard deviations, and ranges for the variables measured after premedication, after induction of anaesthesia, immediately after tracheal intubation, and five minutes after establishing anaesthesia. Statistically significant differences (p<0.05) from the initial values are shown by *. The significant changes were the increases in heart rate and systolic and diastolic blood pressures following tracheal intubation.

### Table 4.2: Cardiovascular changes during establishment of anaesthesia

<table>
<thead>
<tr>
<th>Variable</th>
<th>Premedication</th>
<th>Post-induction</th>
<th>Post-intubation</th>
<th>Anaesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate (beats/min)</td>
<td>75 ± 12 (62–104)</td>
<td>72 ± 5 (54–94)</td>
<td>95 ± 10* (72–124)</td>
<td>82 ± 8 (65–104)</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>135 ± 14 (105–155)</td>
<td>115 ± 12 (87–152)</td>
<td>179 ± 19* (125–219)</td>
<td>130 ± 14 (94–155)</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>87 ± 10 (67–107)</td>
<td>71 ± 13 (53–92)</td>
<td>110 ± 32* (92–145)</td>
<td>78 ± 12 (55–102)</td>
</tr>
<tr>
<td>Cardiac output (l/min)</td>
<td>4.4 ± 0.7 (3.2–6.0)</td>
<td>3.7 ± 1.1 (2.4–5.2)</td>
<td>4.7 ± 1.9 (2.9–6.8)</td>
<td>4.3 ± 1.5 (2.4–6.5)</td>
</tr>
</tbody>
</table>
Results

Figure 4.1 Heart rate measurements after premedication (P), induction of anaesthesia (I), tracheal intubation (T), and five minutes later (A). The data are taken from table 4.1 and show the mean values as the heights of the bars plus the T bar showing one standard deviation.

This figure uses too much ink.
The ordinate doesn’t give the units.
The horizontal grid is probably not needed.
Heart rate does not need repeating.
There are no marks to show the significant faster rate after tracheal intubation.
Results

This may be a more appealing picture:

- It gives more information
- The eye easily follows the flow of the changes seen

Figure 4.2 Heart rate measurements after premedication (Pm), induction of anaesthesia (Ind), tracheal intubation (Int), and after stabilisation of anaesthesia (An). The data are from 10 patients; the central dot represents the mean values and the surrounding bars identify the range (outer end) and 95% confidence limits of the mean (inner ends). The rate after tracheal intubation is statistically significantly ($p<0.05$) greater than at the other times.
Discussion

Aims of discussion

- To state the main findings
- To highlight any shortcomings of the methods
- To compare the results with other published findings
- To discuss the implications of the findings
Discussion

The main findings

Two sentences with the main conclusion of the study, without repeating the data:
**Discussion**

The main findings

“In this study patients who received a preoperative osteopathic treatment were half as likely to complain of nausea postoperative as there controls (17% vs. 36%)…”
Discussion

Previous work

• Confine your attention to the major players
• The work of a few reputable research groups active in a particular area must be discussed
“In 1986 Matsuda reported no improvement in the cortical thickness of metacarpal II, as a parameter for bone density, after a physical training program. Their assessment, however, was based on X-ray changes, which is obviously less specific than the fotonabsorbtometry method we have used. On the other hand, the difference between treatment groups is very similar to that reported by Montoye (1992) in patients with mild osteoporosis: their training program had a positive effect on bone density ...”
Discussion

Discussion of method

• The methods you used are most unlikely perfect
• Hopefully, you will have improved on the methods used previously:
  o = an opportunity to show your work in a good light
  o even gently chide rivals on the deficit of their work
Discussion

Discussion of method

“A recognised difficulty in studies of this type is the Doppler angle of isonation (Sabba, 1990). We believe that by limiting this angle (< 60° and > 50°) we have minimised the flow standard error.”
Discussion

What it means for practice

• Any clinical practice implications and
• Any basic scientific implications

should be discussed.

How did our scientific understanding progress ?!
Discussion

What it means for practice

“Our findings confirm the value of the long sitting test amongst people with a dysfunction of the iliosacral joint. In our large series of 120 patients the long sitting test proves to be the most reliable. As a result, the use of this test has become part of our clinic practice guidelines and teaching methods”
The need for further study

“Although we are much encouraged by the fact that the diameter of an uterusmyoma lessened with osteopathic treatment, further study of the longer term effects on uterusmyoma will be needed to see if the effect is sustained and/or if the possibility exists that continued osteopathic treatment lessens its diameter even more.”
References

- **Vancouver system**
  References are numbered consecutively in the order in which they are first mentioned in the text.

- **Harvard system**
  The order of references is strictly alphabetical.
Acknowledgments

- The source of research funding
  Conflict of interest may arise if commercially supported

- Anyone whose work enabled the study to proceed

Anyone who has contributed to the originality of the work, must be considered as a co-author
Exercise in Designing and Conducting an Osteopathic Research

1. Explore an area of interest
2. Think about the aims of the study
3. Define the research question
4. Define the study design
5. Write a study proposal
Exercise in Designing and Conducting an Osteopathic Research

Explore an area of interest

Theoretical consideration:
Is there an interaction between the visceral and the parietal system?

Practical considerations:
Practice experience presumed an interrelation between abdominal viscera and the cervical spine.
Exercise in Designing and Conducting an Osteopathic Research

- Explore an area of interest
- Think about the aims of the study
- Define the research question
- Define the study design
- Write a study proposal
Your aim is:

- To look for an interaction between the visceral and the parietal system.
- Practice tells you that linking the abdominal viscera with the cervical spine might be a good way to do it.
- Conducting this study might improve your professional insights.
Exercise in Designing and Conducting an Osteopathic Research

1. Explore an area of interest
2. Think about the aims of the study
3. Define the research question
4. Define the study design
5. Write a study proposal
Exercise in Designing and Conducting an Osteopathic Research

Preconditions:

- Define the abdominal viscus.
- Define the somatic dysfunction.
- Specify the parietal structure.
Exercise in Designing and Conducting an Osteopathic Research

Possible question or hypothesis:

Mobilizing a liver in ptosis towards elevation changes the mobility of C3

Possible problems:

- Is this liver ptosis mobile or not?
- How do we measure the mobility of C3, specifically?
Exercise in Designing and Conducting an Osteopathic Research

- Literature reveals much research has been done with a CROM – meter (Cervical Range of Motion).
- Preliminary diagnostics in practice give enough patients with a liver ptosis with restricted mobility.

Refined hypothesis:

Mobilizing a liver ptosis with restricted mobility towards elevation, changes the mobility of the cervical entity.
Exercise in Designing and Conducting an Osteopathic Research

Null hypothesis 1

There is no significant difference in mobility of the cervical entity in the six main directions between the two moments of measurement, in the Weischenk- and the Barral/Mercier group, opposite to the control and placebo group.

Null hypothesis 2

There is no significant difference in mobility of the cervical entity in the six main directions between the two moments of measurement, between the experimental group treated with the Weischenk normalization technique and the one treated with the Barral/Mercier normalization technique.
Exercise in Designing and Conducting an Osteopathic Research

Explore an area of interest

Think about the aims of the study

Define the research question

Define the study design

Write a study proposal
Exercise in Designing and Conducting an Osteopathic Research

Randomized controlled trial

- Inclusion and exclusion criteria
- Randomized
- Evaluator-blinded measurements
- 2 treatment groups (Weischenck and Barral-Mercier technique) and 2 control groups (placebo and no treatment)
Exercise in Designing and Conducting an Osteopathic Research

1. Explore an area of interest
2. Think about the aims of the study
3. Define the research question
4. Define the study design
5. Write a study proposal
Don't fear the Stats

Population Mean:

Sample Mean:

Sample Variance:

Population Standard Deviation:

Sample Standard Deviation:
Basis principles of a clinical study I

Definition of a research topic and generation of the hypotheses

Research topics: Effectiveness of a crisis resolution team or effectiveness of an osteopathic treatment

Typical hypothesis: Does a certain treatment have an effect?
Basis principles of a clinical study II

Random selection of a sample of subjects and measurement of a few important variables at certain time points

The basic idea is to compare two groups - an unexposed *control* group and an exposed *treatment* group
Basis principles of a clinical study

For the data being measured in the sample, statistical techniques are used to make inferences about the effect of the treatment.
Types of Statistics

There are two branches of statistics:

1.) **Descriptive** statistics: Numerical, graphical, and tabular methods for organizing and summarizing data

2.) **Inferential** statistics: Methods for generalizing from a sample to the population from which the sample was selected
• Human beings cannot cope with more than a few numbers at once

• Descriptive statistics are concise summaries. They report what characterizes a sample
Using graphs to summarize the data

Popular types of graphs are:

• Barchart
• Histogram
• Box plot
Bar Chart - example

![Bar Chart Image]

- Prostata_links
- Prostata_rechts
- Prostata_oben
- Prostata_unten

**Mittelwert**
Bar Chart

• Summarizes categorical data
• Horizontal axis represents categories, while vertical axis represents either counts (frequencies) or percentages (relative frequencies)
• Used to illustrate the differences in percentages (or counts) between categories
Analogy

Bar chart is to categorical data as

*histogram is to measurement data*
Histogram

- Measurements are (artificially) divided up into equal-sized categories
- A bar is drawn for each category - the height represents the number (or percent) falling into this category
Box plot(s) - example

STANDARD.
KOERPERLICHE SUMMENSKALA t1
KOERPERLICHE SUMMENSKALA t2

Osteopathie  KG  Medikamente

Behandlung
Box plot

- Summarizes measurement data
- Vertical (or horizontal) axis represents measurement scale
- Box plot gives information about minimum, maximum, median and middle fifty percent of the data
When to use which graph

• Box plots are good for comparing groups
• Box plots are good for identifying extreme values
• Histograms and box plots are good for identifying the shape of the data
• Bar charts allow for visualization of nominal data
Using statistics to summarize the data

Very frequently used statistics include:

• Average/mean (measures the central tendency)
• Median (measures the central tendency)
• Standard deviation (measures the heterogeneity)
The Average

Average = Mean = \frac{\text{Sum of Observations}}{\text{Number of Observations}}

The Median

The middlemost number in the list
What’s the Average Salary?
The Median Salary?

125,000 €
60,000 €
24,000 €
15,000 €
12,000 €
10,000 €
Average Salary

125,000
+ 60,000
+ 2 \times 24,000
+ 3 \times 15,000
+ 12,000
+ 7 \times 10,000

\[\text{\underline{= 360,000}}\]

\[\frac{360,000 \text{ €}}{15} = 24,000 \text{ €}\]

Median Salary

125,000 €
60,000 €
24,000 €
15,000 €
12,000 €
10,000 €

15 people, so 8th is middlemost

\[\text{12,000 €}\]
Using averages to compare groups

Table 1 Characteristics of experimental and control groups. Figures are numbers (percentages) of participants unless stated otherwise.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Experimental group (n=135)</th>
<th>Control group (n=125)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>65 (48)</td>
<td>67 (54)</td>
</tr>
<tr>
<td>Mean (SD) age (years)</td>
<td>38.0 (11.9)</td>
<td>37.8 (11.7)</td>
</tr>
<tr>
<td>Ethnic group:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>73 (54)</td>
<td>59 (47)</td>
</tr>
<tr>
<td>White Irish</td>
<td>20 (15)</td>
<td>12 (10)</td>
</tr>
<tr>
<td>Other white</td>
<td>9 (7)</td>
<td>19 (15)</td>
</tr>
<tr>
<td>Black Caribbean</td>
<td>10 (7)</td>
<td>10 (8)</td>
</tr>
<tr>
<td>Black African</td>
<td>8 (6)</td>
<td>11 (9)</td>
</tr>
<tr>
<td>Other black</td>
<td>7 (5)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (2)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Other or mixed</td>
<td>5 (4)</td>
<td>9 (7)</td>
</tr>
</tbody>
</table>

from Johnson & al. (2005)
Using averages to compare groups II
The standard deviation (SD)

• The SD is a measure of how spread out numbers are around their average
• It is, thus, a measure of heterogeneity of the sample. (A high SD indicates a pronounced heterogeneity)
Using SD to compare groups

Table 3  Patients’ satisfaction and clinical and social outcomes. Figures are mean (SD) score

<table>
<thead>
<tr>
<th></th>
<th>Experimental group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes measured at interview 8 weeks after crisis (118 interviewed in intervention; 108 in control)†</td>
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<td></td>
</tr>
<tr>
<td>Patient satisfaction: CSQ-8</td>
<td>22.8 (6.6)</td>
<td>21.2 (7.3)</td>
</tr>
<tr>
<td>Symptom severity: total BPRS</td>
<td>36.1 (9.0)</td>
<td>39.0 (10.8)</td>
</tr>
<tr>
<td>Quality of life: total MANSA</td>
<td>45.6 (13.2)</td>
<td>47.1 (14.7)</td>
</tr>
</tbody>
</table>

from Johnson & al. (2005)
Using SD to compare groups II
The confidence interval (CI)

Recall the results from Johnson & al. (2005):

| Table 3 Patients’ satisfaction and clinical and social outcomes. Figures are mean (SD) score unless stated otherwise |
|---|---|---|
| | Experimental group | Control group | Unadjusted |
| | | | Mean difference (95% CI) | P value |
| Outcomes measured at interview 8 weeks after crisis (118 interviewed in intervention; 108 in control)† | | | |
| Patient satisfaction: CSQ-8 | 22.8 (6.6) | 21.2 (7.3) | 1.7 (−0.1 to 3.5) | 0.074 |
| Symptom severity: total BPRS | 36.1 (9.0) | 39.0 (10.8) | −2.9 (−5.6 to −0.1) | 0.041 |
| Quality of life: total MANS | 45.6 (13.2) | 47.1 (14.7) | −1.5 (−5.2 to 2.2) | 0.43 |

**Interpretation:** A 95% CI is the interval that you are 95% certain contains the true population value
Statistical Inference

Statistical inference is the process of using data obtained from a small group of elements (the sample) to make estimates and test hypotheses about the characteristics of a larger group of elements (the population).
Process of Statistical Inference

1. The **Population** consists of all prostate patients. Effect of Osteopathy is unknown

2. A **sample** of patients is treated and controlled, respectively

3. The **sample** data provide two average sample effects

4. The values of the sample averages are used to make an estimate of the **population** average effect
Are these groups different?

Table 3 Patients’ satisfaction and clinical and social outcomes. Figures are mean (SD) score unless stated otherwise

| Outcomes measured at interview 8 weeks after crisis (118 interviewed in intervention; 108 in control)† | Experimental group | Control group | Unadjusted
| Mean difference (95% CI) | P value |
|---|---|---|---|---|---|
| Patient satisfaction: CSQ-8 | 22.8 (6.6) | 21.2 (7.3) | 1.7 (−0.1 to 3.5) | 0.074 |
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from Johnson & al. (2005)
The logic of significance testing

- A *significance test* is aimed at determining whether a result is *real* or could possibly be *due to chance*
- The *null hypothesis* says that there is no effect *other than chance*
- The *alternative hypothesis* says that there is an effect *other than chance*
The logic of significance testing II

• In order to prove that there is some kind of effect, you have to **disprove the possibility that the results could be due to chance.** Disprove the null hypothesis in order to establish the alternative hypothesis.

• The *test statistic* measures the difference between the data and what would be expected under the null hypothesis (e.g. z-statistic, t-statistic, …)
The logic of significance testing III

• A high test-statistic indicates that the observed data is *hardly compatible* with the null hypothesis

• The *p*-value, is the chance of getting a test statistic as or more extreme than the one observed if the null hypothesis were true

• Small p-values are evidence *against the null hypothesis*
The p-value and tradition

• A result with a p-value less than 5% is often called *statistically significant* or *significant at the .05 level*

• A result with a p-value less than 1% is often called *highly significant* or *significant at the .01 level*
Help on the internet

- Clinical trials Glossary:
  http://www.centerwatch.com/patient/glossary.html

- Wikipedia encyclopedia:
  http://en.wikipedia.org/wiki/Main_Page and
  http://de.wikipedia.org/wiki/Hauptseite (German version)

- Data collection, description and general statistics
  http://www.statcan.ca/english/edu/power/toc/contents.htm
Randomised controlled trial of acute mental health care by a crisis resolution team: the north Islington crisis study

Sonia Johnson, Fiona Nolan, Stephen Pilling, Andrew Sandor, John Hoult, Nigel McKenzie, Ian R White, Marie Thompson and Paul Bebbington

*BMJ* 2005;331;599-; originally published online 15 Aug 2005; doi:10.1136/bmj.38519.678148.8F
Abstract

Objective To evaluate the effectiveness of a crisis resolution team.
Design Randomised controlled trial.
Participants 260 residents of the inner London Borough of Islington who were experiencing crises severe enough for hospital admission to be considered.
Interventions Acute care including a 24 hour crisis resolution team (experimental group), compared with standard care from inpatient services and community mental health teams (control group).
Main outcome measures Hospital admission and patients’ satisfaction.
Results Patients in the experimental group were less likely to be admitted to hospital in the eight weeks after the crisis (odds ratio 0.19, 95% confidence interval 0.11 to 0.32), though compulsory admission was not significantly reduced. A difference of 1.6 points in the mean score on the client satisfaction questionnaire (CSQ-8) was not quite significant (P = 0.07), although it became so after adjustment for baseline characteristics (P = 0.002).
Conclusion Crisis resolution teams can reduce hospital admissions in mental health crises. They may also increase satisfaction in patients, but this was an equivocal finding.
Study participants

Sample characteristics
Table 1 shows the baseline characteristics of the experimental and control groups. Random allocation resulted in largely similar groups, though total scores on the Health of the Nation outcome scales were significantly higher in the control group, reflecting higher symptom subscores.
Admissions

Patients in the experimental group were less likely than those in the control group to be admitted during the eight weeks after the crisis (table 2). This effect persisted six months after baseline and when we included admissions to crisis houses. It was reflected in fewer bed days. Over the initial eight weeks, the number needed to treat to prevent one admission was 2.65. However, there was no significant difference in compulsory detentions.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Use of mental health services in eight weeks and six months after psychiatric crisis according to treatment. Figures are numbers (percentages) of participants unless stated otherwise</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em><em>Experimental group (n=135</em>)</em>*</td>
</tr>
<tr>
<td>Admitted to:</td>
<td></td>
</tr>
<tr>
<td>Psychiatric ward</td>
<td>29 (22)</td>
</tr>
<tr>
<td>Crisis house</td>
<td>25 (19)</td>
</tr>
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<td>Hospital/crisis house</td>
<td>49 (36)</td>
</tr>
<tr>
<td>Admission in six months after crisis:</td>
<td></td>
</tr>
<tr>
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<td>33 (24)</td>
</tr>
<tr>
<td>Hospital/crisis house</td>
<td>63 (47)</td>
</tr>
<tr>
<td>Compulsory detention under Mental Health Act after crisis:</td>
<td></td>
</tr>
<tr>
<td>In eight weeks after crisis</td>
<td>16 (12)</td>
</tr>
<tr>
<td>In six months after crisis</td>
<td>24 (18)</td>
</tr>
</tbody>
</table>
Results

Satisfaction
Patients in the experimental group were slightly more satisfied with their care (P = 0.07, table 3). After we adjusted for baseline characteristics the difference became significant (P = 0.002). However, baseline characteristics should be treated with caution as they were reported by staff after randomisation had occurred; thus adjusted results are not necessarily more valid than unadjusted.

<table>
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<tr>
<th>Outcomes measured at interview 8 weeks after crisis (118 interviewed in intervention; 108 in control)</th>
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<td>−1.5 (−5.2 to 2.2)</td>
<td>0.43</td>
</tr>
</tbody>
</table>

| Outcomes rated by staff eight weeks after crisis (133 in intervention; 124 in control) |
|---|---|---|---|---|
| Severity of clinical and social problems: total HoNOS | 9.9 (4.5) | 11.8 (6.0) | −1.9 (−3.3 to −0.6) | 0.004 |
| Social functioning: total LSP | 132.0 (13.2) | 129.0 (17.0) | 3.0 (−0.8 to 6.9) | 0.12 |

| Outcomes rated by staff six months after crisis (133 in intervention; 122 in control) |
|---|---|---|---|---|
| Severity of clinical and social problems: total HoNOS | 9.8 (5.5) | 10.4 (6.4) | −0.6 (−2.2 to 0.9) | 0.43 |
| Social functioning: total LSP | 133.2 (14.7) | 132.2 (16.1) | 1.1 (−3.0 to 5.1) | 0.61 |
If you don’t know by now…

What is already known on this topic

Crisis resolution teams are currently being introduced throughout England as part of national mental health policy

No randomised evaluation of this service model has been carried out in a modern community mental health system

What this study adds

Crisis resolution teams can prevent some psychiatric hospital admissions, especially voluntary ones

In this group of patients with acute mental health emergencies, people who received care from a crisis resolution team tended to be more satisfied with their care
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