

## **IMPROVING THE QUALITY OF PHYSICAL THERAPY**

### **Invited lectures**

**J. Dekker and R.A.B. Oostendorp (editors)**

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## PREFACE

Quality of care is the major issue in physical therapy. New approaches towards qualitative improvement are rapidly expanding. Research and research findings give a major impetus to these developments.

Because of the rapid developments, it was thought vital to have a platform for discussion. The international conference *Improving the Quality of Physical Therapy* was organized in order to provide such a platform for discussion. The conference took place 2-3 June 1994, in 's-Hertogenbosch, the Netherlands. The conference was organized jointly by the Netherlands Institute of Primary Health Care and the Dutch National Institute for Research and Postgraduate Education in Physical Therapy (as of July 1995: the Dutch Institute for Professions Allied to Medicine).

The conference was a great success. It was well attended, with participants from more than 20 countries from all over the world. As intended, there were many lively and stimulating discussions on research, quality of care and physical therapy.

The program of the conference consisted of invited lectures, paper sessions and a poster session. The present volume contains a selection of the invited lectures. These were very stimulating lectures. Therefore, it was decided to publish them: this is expected to reinforce the effect of these lectures.

We want to thank the contributors to this volume. After having already significantly contributed to the conference, they took the trouble to write down their thoughts. In our view, their effort is surely worthwhile reading.

J. Dekker and R.A.B. Oostendorp



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## 1. OPENING SPEECH

J. Verhoeff

Today I have the honour of delivering the opening speech. And I am pleased to do so in this beautiful town of 's-Hertogenbosch, with its age-old traditions and culture, it being the capital of the Province of Noord-Brabant. A suitable setting for this international conference, where in the next two days a great deal of expertise on 'quality and physical therapy' from all over the world will be concentrated.

I wish to start with to congratulate the organizers: the Netherlands Institute of Primary Health Care, and the National Institute for Research and Postgraduate Education in Physical Therapy on having realized this conference. It proves that your profession has become fully-fledged and that nowadays health care can no longer be imagined without it.

As the Chief Inspector of Health Care, responsible for health care quality control, I would like to draw your attention to the quality policy as pursued by the Dutch government over the last few years. The quality policy now being developed gained impetus by two quality conferences organized by and for the health care field in 1989 and 1990, in which the association of physiotherapists was involved. During these conferences, relevant involved parties (care providers, care insurers, consumers and government) reached agreement on both the various roles each had to play with regard to the quality policy and the execution of specific tasks and subjects.

Views and principles with respect to quality policy have been laid down in a 'white paper'. This 'Policy Document on the Quality of Care' was submitted to parliament in 1991 already. On the basis of this document, and in full compliance with the wishes of parliament, a Quality of Care (Institutions) Bill, the Quality Act, was designed. This bill is now under debate in parliament. If a reasonable period of time is taken to process this bill, it may be passed next year.

In anticipation of the implementation of this coming quality act, people everywhere in the health care field, the physiotherapists included, are working hard to arrive at a quality policy covering the many sectors of health care. Standards are being set and protocols drawn up by the various professional groups, while in many care institutions quality systems are being introduced.

In developing a quality policy for the care field, the responsibility lies with the care providers themselves first of all. Also the initiative to e.g. set up and carry out a quality policy should be taken by the care providers. The government is clearly convinced that a top-down policy, with the authorities issuing detailed instructions to the field, does not work. This is caused, on the one hand, by the developments in the field being so complex and taking place at such high speed that the authorities will never be able to react adequately to the local situations and should, therefore, not harbor the illusion that they can prescribe everything with regard to the micro-level. And, on the other hand, the level of professionization and self-confidence on the part of the providers is such that they can accept and shoulder this responsibility.

The Quality Act will also apply to the physiotherapists' practices. This will be the case when two or more physiotherapists work together. Physiotherapists who work single-handedly will be subject to the quality norms of an other but likely Act, namely the Individual Health Care Professions Act.

A major conclusion of the quality conferences I just mentioned and the Policy Document on the Quality of Care was that the parties in the field and the government cannot do without each other in developing a quality policy for the health care sector. The coming Quality Act is based on this conclusion.

However - and to make it quite clear I repeat - ideas about the delivery of health care in practice, and about the way the quality of health care should be assured, will have to be put forward particularly by the members of the various professional groups themselves. The central theme in this Quality Act is: responsible care. An institution should provide responsible care. Responsible care is a dynamic norm, the practical implementation of which should be taken care of by the health care field. Health care can be qualified as responsible care when it is effective, efficient and patient-orientated.

This dynamic norm refers to scientific developments and to the standards adhered to in the world of professionals. This implies that international conferences such as the one starting today can be of significance for establishing a norm that should be met by physiotherapists. Responsible care refers to an international view on the essence of quality: health care systems and the way they are financed are national issues, but quality of care is an international matter!

Yet another interesting aspect of the 'responsible care' norm is that it means an adaptation to and harmonization with the criteria of disciplinary law. The statement that this norm would be too vague and that it would fall short in serving as a tool for adequate control is, therefore, belied by the fact that the medical disciplinary law has successfully applied this norm for a hundred and fifty years.

In this context I would like to draw the attention of this international audience to a special aspect of disciplinary law in the Netherlands which is also of importance to physiotherapists. Here, other than in other countries, disciplinary law is not a set of rules drawn up by the association of professionals. On the contrary, it has come about by legislative procedures. This somewhat quells the ever recurring criticism that the disciplinary law were to be some sort of professional 'closed shop', where professionals reach out to each other in order to escape other forms of judicial inquiry. I would hazard to suggest that following the Dutch example would help enhance international professional credibility.

Back to the norm of 'responsible care'. This norm implicitly prescribes the conditions to be met in care provision: for example there should be sufficient staff. And this staff's training and education should conform certain requirements. In addition, accommodation and equipment should be up to standard. Unless this kind of quality requirements are met it will be impossible for institutions to provide responsible care. Furthermore the law prescribes that care institutions must assure quality in the process of care provision by systematically monitoring, evaluating and improving the quality of care. The Dutch legislature have so to speak translated the so-called Deming cycle, or quality cycle, into law sections. To make this all clear, every institution has to report yearly on the quality situation by means of an annual quality report. This is a public report.

While the government is withdrawing with respect to legislating, more emphasis will be placed on the control function. This is the responsibility of the government. When it becomes clear that an institution does not provide care of sufficient quality level, then the state may impose sanctions. The ultimate sanction is closing down an institution.

With respect to developing a quality policy, and taking into account the conclusions and agreements of the quality conferences, and the Quality Act, the physiotherapists as a professional group deserve to be complimented. Not so long ago it was the doctors in particular who strongly advocated 'quality of care', but in recent years the paramedical professionals, and especially the physiotherapists, have made their way to the forefront. Within the world of physical therapy norms have been set and protocols drawn up, and this process is still going on. Peer review has gained ground. In the end, all of this is to result in standards that will have been set by the physiotherapists themselves, about which they have reached consensus and to which they are obliged to adhere. This quality rules are by no means to be taken lightly, for our Health Inspection will go by the established norms when checking whether responsible care is being provided in the field of physical therapy. Also research of a more fundamental nature, such as the project on International Classification of Impairments, Disabilities and Handicaps of the National Institute, is important in the way of lending support. This cannot but further facilitate research into efficiency, as the results of this project contribute to physiotherapeutic treatment becoming more transparent.

Summarizingly we may say that, in the Netherlands, 'quality of care' is primarily the responsibility of the care field, which establishes the quality norms itself. The government provides the legal framework and is responsible for the superintendence. The care field lays down the quality rules.

The physiotherapists in the Netherlands are on the right track by having an impressive set of quality rules ready by the time the Quality Act will become operational. This is clear from the examples I have mentioned. And this can also be said of organizing this conference, one of its main objectives being to enhance the expertise and you may call it quality, of the participants.

I hope that this conference will be of benefit to you. I hope that scientific discussion on the international level will intensify, and that it will contribute to the development of international networks. Going by my own experiences with 's-Hertogenbosch I am sure that this will certainly be facilitated by the many opportunities this charming Burgundian town offers with respect to the social programme. I wish you a pleasant day.



## **2. ORGANIZATION OF PHYSICAL THERAPY**

**J.B. van Duljn-van der Pol**

It is a great pleasure for me as president of the Royal Dutch Association of Physical Therapy (KNGF) to tell you a little about the quality policy for physical therapy and physical therapists in the Netherlands, as it has been developed and initiated over the last few years, by this professional organisation.

Since 1989, the Dutch government has placed responsibility for the quality of professional competence in the hands of the professional organisations of the care providers. And although this responsibility represents a major challenge, its implementation does mean that we are faced with a number of dilemmas. Because what is the actual situation?

Over the last twenty-five years, the profession of physical therapists has acquired a fixed position in the field of health care. The task of the professional organization is to ensure that, from the point of view of society at large, this position is maintained and strengthened for its members.

On the other hand, government and the providers of financing are increasingly demanding scientific research and effectiveness studies, with a view to highlighting the effectiveness and efficiency of treatment by physical therapists. Through its very increase, this can be experienced as a threatening development for the practice of physiotherapy as it has developed over the years.

The task of the organization is on the one hand to take its own responsibility, and on the other hand to encourage participation by its members in a process of developing awareness, such that tools for quaranteeing quality once developed, together with any results of scientific research in the professional field, receive broad acceptance, and can then be more easily implemented.

A second bottleneck has arisen as a result of the fact that there are insufficient tools for achieving our intended goal, namely the development of a quality system or part system. Our first move was to introduce some order, whereby we broke down the quality of professional competence into a number of fields:

- quality of treatment techniques and methods
- attitude of the physical therapist
- organization of the profession.

Based on this skeleton framework we went on to divide up any already existing tools. As it was noticed during the development phase that a range of activities and projects comprised a combination of the three aspects outlined above, the most recent framework according to professional activity is as follows:

- the professional activity of the individual physical therapist
- the professional activities of physical therapists in general (as a profession)
- the definition of the professional activities.

Our next move was to prioritise matters, and we opted for the following structure:

1. classification and registration
2. development of central directives
3. definition
4. peer review, further training and in-service training.

I would now like to briefly discuss the current state of affairs in relation to these subjects.

In 1992, the directives for physical therapy reports were concluded, and they are currently being implemented.

In 1994, a three-year project was initiated with the objective of developing a tool for preparing directives, simultaneously with the development of the first two central directives.

In 1990, the Stichting Wetenschap en Scholing Fysiotherapie, co-organizer of this conference, started on a project entitled 'Classifications and definitions of terms for the paramedical professions dealing with movement therapy'. A number of components of these classifications and definitions have now been completed, such as the updating of the ICIDH and the draft standard on treatments.

Finally, I should mention the project for quality promotion through registration in physical therapy within primary health care.

It has been noted that a number of ideas, already long in existence, can be ranked under the heading definition: job description, description of expertise, ethics and code of conduct, model regulation for physical therapist-patient relations, and internal disciplinary rules.

All these matters relate to the attitude of the professional. Of course, it is vital that regular checks be made to determine whether in the light of developments, any of these matters require updating.

If we look in greater detail at the last-mentioned priority, we immediately come across a major problem for the organization. One of the most difficult things is translating an abstract quality policy and its related tools to the level of the individual physical therapist. After all, our eventual and indeed most important goal is actually to improve professional practice, to clarify the tasks of the physical therapist, to outline how these tasks are carried out; in short, to achieve a clear and measurable system of physical therapy.

Although the study by NIVEL indicated that 93% of the workers in our profession follow some form of further or in-service training, it is vital that guidance be given on training matters, by first determining whether the course followed is geared towards an aspect relating to the field of physical therapy, and subsequently, through a process of accreditation, to determine whether this course does meet the criteria imposed by the organization.

After this stage, an analysis tool which is still to be developed should assist the individual physical therapist in determining his or her own training needs, according to his or her own level of knowledge and work situation.

The final point I would like to deal with, is peer review. For quite some time, this was a term which elicited considerable resistance from within our profession. People had the impression that their colleagues would be looking over their shoulder; an uncomfortable and sometimes threatening feeling. In fact, the purpose of peer review is to determine whether the care provided meets the care requirements imposed.

In 1991, the Central Supervising Body for Peer Review (CBO) started a project targeted at the physical therapy departments of hospitals. In 1993, a similar project was implemented for physical therapists working in private practice.

As the quality policy begins to take an even greater form, the need and indeed the impossibility of avoiding using the policy and integrating it in daily professional practice, increases.

The executive committee of the KNGF (Royal Dutch Association of Physical Therapy) has consciously opted for a combination of a top down and a bottom up approach. After all, from the top down you can only act in a controlling and initiating manner, for example ensuring that tools are developed and made available, which are actually of some use to the profession; in other words, creating a framework, and facilitating its implementation.

It is therefore highly satisfying to note that in a number of regions our members are progressing rapidly in the further development and implementation of components of the quality policy.

In addition, professional member associations affiliated to the KNGF are concentrating on the development of specific areas of physical therapy. Many of them have their own training policies with related registration systems, the target of which is to raise the particular section of physical therapy in question to the desired quality level, and to keep it there.

I have attempted briefly to give an outline sketch of quality assurance and concern for quality in the Netherlands. I have also indicated how we are tackling the dilemma of bearing responsibility for quality policy in the Netherlands, with its resultant consequences, and the social position of the physical therapist.

We are fully aware of the fact, that we have now started on a path of development to which there is no real end. But at the same time, this very fact is a challenge: presenting this continuing process time and again to our members, in such a way that individual involvement remains at an optimum level, so that a true exchange does take place between the organization and its members, aimed at perfecting the level of professional practice in the Netherlands.





### 3. SCIENCE AND PRACTICE: EXAMINING OUTCOMES

J.M. Rothstein

Recently there has been considerable discussion about assessing the outcomes of physical therapy practice. Outcomes has become the fashionable byword of the 90s as therapists struggle to find assessment tools and evidence for the efficacy of their treatments. Ironically outcomes research is not new, but rather a new way of looking at two simple questions that have long concerned therapists. The questions are:

- 1) What is the nature of physical therapy practice?
- 2) What are the benefits of such practice?

Outcomes research and understanding outcomes means nothing more than understanding physical therapy practice. In order to do so, however, we must abandon previously held assumptions about the efficacy of our treatments and the needs for our services. We must be willing to examine with credible data what we achieve and whether we achieve clinically meaningful goals using appropriate societal resources. We can no longer rest on personal testimonials and assertions of 'it works!'.

Physical therapists offer a variety of treatments some of which are aimed at remediation of disabilities, some of which are preventative, and some of which focus on the elimination of pathologies. Given the diversity of our treatment approaches and our goals a consistent logic must be applied to the assessment of outcomes. In the past physical therapy effectiveness was often determined using goals that were predicated on specific treatment approaches. These goals were frequently not meaningful to the patient or relevant based on why the patient sought therapy. For example, manual therapists may have considered their efforts successful if they restored what they considered the proper amount of joint play, while some neuro-developmental therapists would have seen alteration of tone (reflex activity) as a worthwhile achievement.

Undoubtedly the manual therapist would have argued that the joint function restoration meant the patient would have less pain and be able to engage in more activities, and the neurological therapist would have made a similar case about the carryover from tone to function. Neither, however, was likely to have tested the relationships as they assessed outcomes. The prevailing, though unstated, assumption was that we knew what had to be treated and that as a natural consequence of that focus patients would get better. The oft repeated assertion of some manual therapists that "you take care of the joint and everything else takes care of itself" epitomizes this mode of thinking. Assumed relationships and treatment specific goals have hindered our ability to meaningfully assess outcomes. As a result our credibility is now in question and some question whether many of our treatments can be justified in a time of limited resources.

#### **The disability framework**

A common basis for the evaluation of outcomes is needed, one that can be used to examine all physical therapy interventions. Fortunately, a framework from which we can view our activities and examine at what level we are intervening with our patients and at what levels are we having effects is provided by contemporary models of disability. These models have recently been reviewed by Jette<sup>1</sup> and are variants on the original work of Nagi<sup>2</sup> and the World Health Organization<sup>3</sup>.

These models offer a view of disability as lying across a continuum of organization. According to Nagi there is active pathology which leads to impairments which in turn lead to functional limitations and then disability. Active pathology is any interference with normal processes while the organism attempts to regain a 'normal state'. This concept has been criticized because it presumes an 'active process' and many times there is no ongoing disease. A patient with cerebral palsy does not really have an 'active pathology'. The National Center for Medical Rehabilitation Research of the U.S. National Institutes of Health has suggested instead of the term active pathology that we use the term 'pathophysiology'.

According to Nagi an impairment is an anatomical, physiological, mental, or emotional abnormality or loss. In terms of physical disability this represents a loss of function within an organ system. This is in contrast to what Nagi calls a "functional limitation" which refers to a loss of performance at the level of the organism. A fracture would represent an active pathology that could limit motion (an impairment). This loss of motion could result in an inability of a person to do a task such as reaching for clothing and this would be a functional limitation. Nagi contends that disability occurs when we are limited in our abilities to perform our socially defined roles within our sociocultural and physical environments.

At what level should we examine the effectiveness of the therapist's treatments? The answer depends on the patient and the goals that have been set for the patient. Effectiveness of therapy for a worker disabled and unable to earn a living should be judged at the disability level, because the patient is seeking therapy in an effort to alter his disability status. Effectiveness of therapy for someone thought to be at risk for repetitive stress injury could be judged by determining whether an impairment was eliminated, an impairment that based on current knowledge, would have been expected to lead to a functional limitation and possible disability in the future. Outcome can only be judged in the context of expectations and patient needs. Outcomes assessment, therefore, should appeal to the humanistic nature of physical therapists because it offers them a chance to examine patient centered effects and benefits.

Because physical therapists may intervene at multiple levels sometimes assessment of outcomes can be complex. For example, in working with a patient who has atelectasis, secondary to a lung infection, a therapist is working on an impairment (a dysfunction of the pulmonary system) in an attempt not only to change the state of the impairment but also in an effort to have an effect on the pathology itself (e.g. provide a less desirable environment for infectious organisms). In addition, there can be little doubt that resolution of the atelectasis would enhance function and could lead to the elimination of disability. This example highlights the benefit of using a disability model to evaluate outcomes.

The model allows us to identify what we expect when we start treatment and relationships between pathologies, impairments, and disabilities can be hypothesized more clearly. As a result we test whether effects at one level influence performance at other levels and we do not simply assume associated benefits. In this patient, for example, we could, theoretically, influence the pathology and impairments and have no effect on their disability status. In other words we may have had some positive outcomes, and some less than positive outcomes. By considering each in a context of goal setting the

value of therapy can be considered. For this rather unique patient I could see a benefit to treatment even though it may not have had an effect on disability. This, however, is not always the case.

The example of the patient with atelectasis illustrates that no single level is most appropriate for all patients. Outcomes could have been assessed at the level of pathology, impairment, or function. In general, however, physical therapists tend to intervene at the level of impairments for the sake of altering disability (or functional levels). As a result physical therapists have spent considerable effort in recent years on the assessment of impairments, and in an effort to mimic the general trends of the biomedical sciences we have often seen measurements of impairments as more scientific than assessments of disability.<sup>5,6</sup> This approach has often led us to consider the remediation or alteration of impairments as a clinical success, regardless of whether this affected any aspects of the patient's function or quality of life. This mentality is often characterized by the way goals for patients are written. We see a focus on altering impairments, such as increasing ROM, improving muscle strength, altering tone, increasing joint play, etc. with a lesser emphasis on changing functional status.

### **Examining assumptions**

We have been too comfortable in our assumptions of cause and effect, presumed relationship between impairments and disability. For example, many therapists assume changing abdominal muscle strength alters posture and the tendency for low back pain (or hyperlordotic postures). Yet there is no evidence for this assumption and some evidence to the contrary.<sup>7</sup> Echternach and I recognized this behavior and have suggested the use of an algorithm to test assumed relationships between impairments and disability.<sup>8,9</sup> Our purpose was to use the patient's own goals (stated in terms of disabilities) to determine clinical success, and to allow therapists to hypothesize relationships between measurable impairments and measurable disabilities. Most importantly, however, our algorithm required the collection of data that would reflect on the appropriateness of the hypothesized relationships and the usefulness of treatment.

The time has come for physical therapists to recognize a conundrum central to our existence. We are blessed because there is almost no one alive who cannot not benefit from our services. Who does not have an impairment, a postural deformity, a weakness, a loss of motion, or some similar limitation? In almost all people we can change the level of impairment. Sometimes these changes may be small while at other times they may be quite large. Rarely are there impairments that are absolutely resistant to our interventions, although some changes may be barely discernable. The world, then, is full of potential patients but this blessing is also a curse because it requires us to identify those who really need our services, and those who would really have meaningful gains from therapy.

Only by facing this second issue can we begin to examine outcomes. Inherent in any such consideration are personal and societal values. What is worth doing for someone in some cultures may not be so worthwhile elsewhere. What is affordable and what can be practically offered will also vary. These issues are beyond the scope of this paper and such determinations should never be solely within the province of physical therapists. Therapists must, however, be prepared to participate with the broader community in such discussions. Therapists should participate not only by expressing

their values, but also by offering expert and knowledgeable dialogue about what therapy can offer and what resources are needed to achieve identifiable outcomes. For therapists to be credible participants they need to better understand current practice and they need to be prepared to describe in scientific rather than anecdotal terms what works and what does not.

Some suggest we have empirical data to support our efforts because our own observations provide ample evidence about outcomes. I contend, however, that such observations are colored by our expectations. Empirical means to know by observation or experiment. Observations not verified are potentially flawed and limited. For example, we observe the moon as larger at the horizon than when it is in the middle of the sky. The classic moon illusion<sup>10</sup> illustrates that appearances can be deceiving. To know something by experimentation implies a level of scientific testing than is often lacking in our self evaluations, and in our profession's evaluation of itself. In addition, it implies the use of systematic observations guided by decision rules and measurements to be credible (reliable and valid).

### **Scientific methods**

A commitment to understanding outcomes means that therapists must abandon the profession's tradition of depending on authorities, tenacious ideas, and a priori assumptions. All of these sources of knowledge have a common element, idea and assumptions go untested. We need now to test in reality what we have long believed as articles of faith. We need to assume the responsibility for examining all assumptions using scientific methods. In this manner we not only study outcomes we study practice itself and do so in a way that allows for the refinement and growth of practice.

Pragmatic approaches have long characterized physical therapists. This 'can do spirit' has become an international hallmark of the field and has won the profession many admirers. Unfortunately there is downside to our willingness to be always practical and to see what we can do. Too often we have failed to pay due respect to the need to develop therapy.<sup>11,12</sup> Theories have existed but they have not been elucidated and as a result we have had little opportunity to test and refine theories. I can easily see a central theory in the neurodevelopmental approach to persons with central nervous system disorders but there are no seminal papers offering such a theory and no papers that critiqued and offered refinements of the theory.

Because we have not felt an obligation to develop and share theories through peer reviewed publications much of our practice and inquiry is not theory driven, and as a result it remains unfocused. Any type of evaluation driven patient care must be theory based. Therefore, theory should exist when we examine and treat patients but we have not felt a need to identify our theoretical frameworks. As a result much thought is often focused on techniques and the manner in which they are applied, rather than on the context in which techniques are used. The development of theory allows for the emanation of testable hypotheses about patient care. A theory for example, that suggests the primary cause of motor dysfunction following a stroke, relates to excessive reflex activity could be examined by the generation of specific hypotheses. In the absence of theory research is limited to dealing with applications of techniques. Research should focus on the overall approach one brings to patient care, rather than on isolated elements.

While the development of theory and the elucidation of theory would greatly benefit practice we must avoid the temptation to assess outcomes based on the attractiveness of theories. Ideas relating to the synaptic activity were central to many of the concepts associated with neuropsychological approaches to patients, ideas that became popular more than two decades ago, ideas that guided persons such as Knott, Voss, Bobath, Rood, and Brunnstrom.<sup>13</sup> Because the science and the theory were so attractive some concepts were accepted without critical evaluation or tests in reality. Theory should provide a basis for inquiry, not a substitute. In the market of ideas too often theory is offered in lieu of evidence of outcomes not as a prelude to the attainment of data.

### **Theory driven research**

Perhaps because we have not had carefully elucidated and refined theories there has been considerable research that has been clinically irrelevant. Often, for example, the efficacy of some physical therapy modality such as moist heat for the relief of low back pain may be examined. Who, however, uses this modality in isolation? In the absence of coherent stated management approach to patients with low back (a theory driven approach) there is temptation to conduct such studies although they bear very little relevance to practice. Such studies are akin to examining the pharmacological effectiveness of part of a molecule rather than examining the effectiveness of an intact drug.

Examination of part of a molecule's clinical effectiveness is warranted only when there is reason to believe that the smaller moiety would be pharmacological active and useful. In other words, only when there is a conceptual (theoretical) basis for such an examination. The same should be true for physical therapy approaches to patient care. In the absence of theory, however, we invite mischief and provide no framework for investigation.

### **Effectiveness and efficacy**

Within the biomedical sciences the randomized control double blinded trial (RCT) has been considered the sine qua non of clinical research. Recently, however, some have suggested that the RCT may have limited usefulness as currently conducted and a new approach, one aimed at looking at the *real world effectiveness* of interventions has become popular. The simplest way to characterize the differences between classical efficacy studies and the recently popularized effectiveness studies would be to consider a fictive example.

If I were to develop an anti-hypertensive agent that worked with 100% success in 100% of patients 100% of the time this would be a remarkable feat. But imagine that in order for the medication to be effective it had to administered every four hours and would not work if it was taken more than 10 minutes off schedule. The traditional way of testing this drug would be to conduct a carefully controlled trial with some subjects receiving an alternate drug or a placebo. We would use monitors who where also naive to which drug each person was getting to check whether patients took the medication as prescribed. Because of the conditions of my imaginary example we know that we would find the drug 'efficacious', in other words we would show that it worked. The controls we built into our study (the use of people to monitor compliance) would ensure the timely taking of medications.

In the real world, however, what would be the likelihood the drug being so effective? Could we really expect patients to take the drug within the time constraints needed? A study that examined what happens under real world conditions would be an *effectiveness study*, whereas our original study was an *efficacy study*. Each could, however, use double blind randomized methodology but they would differ only in their generalizability.

Each type of study has its benefits and weaknesses. From the efficacy study we learn what is possible, from the effectiveness study we learn what actually happens. If we did not know what was possible we could have discarded our new wonder drug as not working when in fact the problem would have been in the manner in which it needed to be taken. The effectiveness study would tell us whether we are making a clinical difference but without the efficacy study we would have no way of knowing where problems may lie. The two approaches are complimentary and each offers unique insights. When combined they provide potent information for clinical practice and the development of research agendas. Our example could lead us to find better ways of getting patient compliance (a totally clinical approach) or lead us to expend efforts modifying the drug so that the time window was less critical (a research and clinical approach).

As physical therapists struggle to examine the treatments that are already being offered to patients they should consider the use of effectiveness studies wherever possible. Although results may offer little insights into the reasons why outcomes occur this could be an efficient way of overcoming a paucity of efficacy studies. In addition, because treatments are already being offered in a given manner there can be little question about the need to examine outcomes in that practical context. Efficacy studies, on the other hand, should become a pre-requisite for the introduction of new treatment approaches.

#### **Immediate needs**

There is little doubt that efficacy and effectiveness studies are needed to assess outcomes. The state of knowledge, or more correctly, the current lack of knowledge about practice, however, precludes many forms of inquiry. Can we test the most common approaches to the management of patients with patellofemoral dysfunction? Yes, but only if we know what approaches are being used -- and we do not! There is very little literature that describes practice. We lack operational definitions and common language for much of what we do.

The development of credible clinical literature, a body of case studies is needed. Through case reports we would have public airing of approaches, critical dialogues about descriptors of practice and measurements of outcomes. This refining process then provides fodder for experimental approaches. Case reports should be the business of practitioners and although such reports can never prove that a treatment works (because of the absence of controls) they can suggest what methods seem worthy of study. They also provide documentation as to how to evaluate patients and how to administer and describe treatment.

Case reports also do not require the cost of experimental studies. In addition they allow therapists to do what they normal do, treat patients unencumbered by research protocols or ethical dilemmas about withholding or modifying treatments.

Physical therapy is primarily in a pre-experimental phase. We are at a point in time where we desperately need descriptions which can foster the development of theory. Theory in turn can generate testable hypotheses which would directly examine outcomes. Unless we know what is occurring in practice there can be very little research that examines practice. Outcomes research can never be meaningful when it is driven by those out of touch with practice. But, unless practitioners provide case material and a credible body of clinical literature research will be conducted by those with impractical and skewed views of physical therapy services. This scenario can and must be avoided.

### Summary and conclusion

We know little about physical therapy outcomes. The reasons are multifaceted but there is clearly a need for therapists to now justify and refine what they do through scientific inquiry. Impediments to this inquiry are a paucity of theory driven approaches and an almost complete absence of literature describing practice. Case reports describing individual patients and groups of patients are needed. Practitioners, academicians, and researchers can each play a role in an exciting new era in physical therapy, an era in which we illuminate what we do through public discourse, peer reviewed publications, and the use of efficacy and effectiveness studies.

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## **4. IMPROVING QUALITY OF PHYSIOTHERAPY**

**P.J.M. Helders**

Focus of today's meeting is on the quality of physiotherapy. Physiotherapists today are faced with issues of policy and the need to consider at what level of care interventions are needed and how it is best delivered to achieve physiotherapy goals, as well as to meet quality standards of care. Physiotherapy practice has developed to a level, far removed from the easily described components it was based on. Practice, education and research however, did not have the same direction, with no linking purpose. As Tynne-Lenne (1) pointed out in her presentation at the WCPT in London: "Physiotherapists have not succeeded in establishing their identity and character, nor have they developed a substantial physiotherapy theory". In particular that last remark, not having a theory, is of utmost importance for discussing quality and physiotherapy. For, without an own, identifiable body of theory, one can raise the question what is meant by physiotherapy and likewise what is meant by the quality of this.

Not only the lack of an accepted substantial theory, but also the wide diversity of treatments and the threatening proliferation of so-called physiotherapy-specialisation's, have invited criticism. We are facing questions, and we are lacking answers, but we can deal with it with professionalism and maturity.

So, what about the quality of physiotherapy. First of all, a treatment consists of more than one component or modality. Considering the quality of physiotherapy, one should look into the treatment as a whole and not solely into one single modality. Considerable research into physiotherapy has dealt with just one single modality. So, based on current literature, a general conclusion on physiotherapy as a whole is not possible and not justified. It does not mean that research into specific modalities is not justified, but it is just a part of the professional domain. Besides the modality versus the treatment issue, research into physiotherapy raises some specific problems. Let me point out some of these for you.

### **Medical diagnosis as an inclusion criterium**

Most studies still regard the medical diagnosis as decisive for inclusion in the study. In daily practice however, the physical therapist determines the intervention on the basis of his or her own diagnosis. For one patient with rheumatoid arthritis restricted mobility may be the prominent feature, whereas for another pain might be more prominent. Patient's compliance may vary considerably from patient to patient.

A group of RA patients may appear to be homogeneous, but is in fact very heterogeneous. Research for this particular patient group for instance, should therefore be structured more in terms of patients characteristics with relevancy to physiotherapy than it is done at present. Outcome will almost certainly be different than it is today.

### **Interventions**

In most studies the physiotherapeutic interventions are inadequately described. The differences found in these studies therefore can hardly be interpreted. The inconsistencies may also be attributed to the lack of appropriate research instruments available to the physical therapist. At present the profession suffers from a lack of

specific instruments as well as a specific methodology, and the expertise necessary for using and applying them.

That is one of the reasons why it is not yet possible to record clinically relevant kinesiological and functional changes in time in a patient. This specifically applies to the quality of movement and the qualitative changes in movement as a result of our interventions. Further investigation into the current available research instruments, as well as the development of instruments specifically geared to physiotherapy are prerequisites for future physiotherapy research.

### **Placebo effect**

The effect of an intervention in which the therapist spends a long period of time in a treatment room, is partly determined by the interpersonal relationship and respect for the patients, both of which influence co-operation and compliance. These non-specific factors are seen in physical therapy, as well as in psychotherapy, as conditional to the effects of the placebo effect. The outcome of an intervention may then be corrected for this placebo effect, after which the specific nature becomes evident, such as for example, is done in drug research.

### **Specific effect measures**

Another important issue is the choice which measurement to use in assessing the effect of the intervention. The physical therapist focuses on the kinesiological and functional effects of an illness or disorder and not primarily on the diagnosis and therapy of the underlying pathology. This particular difference distinguishes the physical therapist from the medical doctor. Treatment is directed towards easing the effects rather than curing the underlying pathology.

Inappropriate effect measures are often used in effect studies. Clinically relevant effect measures, the so-called ecological measures, that record relevant clinical changes in time, are urgently needed.

It should be clear to you now from what I have mentioned, that a final conclusion regarding the effectiveness and quality of physiotherapy is difficult. Although the fact that we are not unique in this, from many medical interventions long-term outcome is also unknown, we do have a responsibility. Researchers not only need to consider what physiotherapy knowledge is required in practice today and how to develop and extend it, they also need to assess the suitability of current methods of treatment and the ways they should be evaluated. These efforts highly contribute to the quality of care.

As I said earlier, our profession is facing many questions today. We are not talking a European or National problem. Physical therapists all over the world are dealing with the same problems. The most basic one concerns physiotherapy itself. As today, we have not sufficiently succeeded in establishing our identity and character, nor our theory on which our practice is based and the methods and tools by which it is carried out. I agree with Richardson (2) as she states that "there is a risk that physiotherapy practice may be seen merely as a list of exercises or procedures, or worse, a personality cult if it cannot be placed into the history of professional thinking and experience of human movement". Indeed, one of the biggest threats of all is that we do not succeed in establishing a worldwide acceptance and understanding of what we mean by physiotherapy as a profession and as a science. In order to do so, we need

a body of knowledge that is identifiable and different from that of other health professions. Our research efforts should be directed to adding to that body of knowledge, and by that developing our own standards of education and practice. Crucial for physiotherapy as a profession as well as a science, is having its own specific diagnosis. At this moment, the diagnosis of the physical therapist is almost completely dependent on the treatment procedure used in a particular patients. Physical therapy diagnosis as practised today is merely a summing up of an orthopaedic assessment, neurological procedures, manual therapy techniques, cyriax manoeuvres, NDT components, and by that seems to be dependent on the view the therapist holds. Does it reflect the specificity, the uniqueness and identifiable body that goes with a professional diagnostic procedure? I am afraid the answer is not unequivocally positive, and that should worry us as professionals. If we are not capable of giving an own, specific to our body of knowledge related statement concerning the health status of the patient, than we really do have some major problems.

For instance:

1. The medical diagnosis insufficiently directs physical therapy.
2. The development of diagnostic categories is necessary to clarify what the physical therapist can diagnose by virtue of his education and expertise.
3. Diagnostic categories will provide means of communication with colleagues and medical doctors, it provides the classification for deriving treatment effectiveness and prognosis, and it directs our research efforts.

So, having our own diagnosis indeed seems to be of utmost importance. It certainly does not implicate that we adopt the ICDH as a diagnostic tool. The key diagnostic question for treatment planning is certainly not "What are the patients impairments?" but "Which impairments are related to the functional limitations and can also be treated by physical therapy?". Integrating these two observations allows us to sort out the data on impairments to identify which impairment probably caused the functional problems and should therefore be the key focus of intervention (3).

Those impairments that are identified during the diagnostic procedure, but not associated with any current functional problem are excluded from treatment planning.

So, the basic step is to organize the findings to identify the key problems that has led to the cascade of secondary impairments, rather than treating patients, who have isolated symptoms and/or impairments. Only this type of approach will lead to the most effective intervention, and by that to quality care.

Why do we have so much difficulties in developing our own worldwide accepted diagnosis? In my opinion there are three main reasons. First of all, physiotherapy is composed of several forms of therapies and modalities, all subsuming under three main categories: exercise therapy, massage therapy and the physiotherapy modalities like electrotherapy. Within each category there is wide variety of treatment procedures and applications. All these procedures and applications are applicable to a wide variety of dysfunctions, impairments and disorders. There is hardly any interlinking theory and or therapy specificity. Secondly, we have to consider the historical course of physiotherapy. There has been a strong influence from orthopaedic medicine and neurology. From this period we all remember the development of the hubbard tank, the Bobath concept, the Zander method, Sister Kenny's approach to polio patients, crawling according to dr. Klapp, the almost endless list of German orthopaedic

surgeons with their massage techniques as there have been Metzger, Hoffa, Cornelius, Kirchberg etc.

This strong influence from orthopaedics and neurology is still reflected in the physiotherapy diagnostic procedure, as there still is a subdivision in a neurological and in an orthopaedic assessment. The third and by far the most important reason for not having our own specific diagnosis, is the fact that here still is no coherent theory of physiotherapy, backed up with a well defined philosophy of care to provide the basis for this. This lacking of a coherent theory of physiotherapy undeniably has its impact on diagnostic thinking, on the scientific merits, on the development of new, scientific sound interventions, and by that on the quality of physiotherapy.

I want to focus first on the first two and than on the last item. The fact that most of us deal with physiotherapy as a summing up of all the participating therapies, not only reflects the vulnerability of the profession, but could also turn physiotherapy into a rigid profession. Let me explain this. Earlier I mentioned Zander, sister Kenny, Hoffa, Klapp and others. What happened to their theories? What happened to the interventions they developed? Indeed, they were turned over by scientific developments. So, it seems that interventions are science based and by that time dependent. As there is a huge turn-over of scientific knowledge in a ten year period, some authors (4) suggest it is 75 percent, it means that more of our interventions will disappear in time. When physiotherapy indeed is a summing up of all the existing therapies at this moment, it could mean that the profession is not only a rigid, but viewed from the rapid development in biomedical science, also a dying one. In my opinion physiotherapy is a very dynamic profession, indeed science based and science dependent. All our interventions should therefore be science-based, or at least be based on a scientific sound theory. Yes, it means that we should carefully look at all of our existing interventions and monitor whether or not they are scientifically valid or sound. To put it in modern business terms: we have to look into our core-business. We have to face the question what has and what has not to be considered as physiotherapy. Is everything we are doing at this moment physiotherapy? Why? Because we are doing it? Not only existing therapies, but more so, new therapies should be carefully monitored before adding them to our daily practice. If we do not succeed in that, or are afraid to do so, with increasing scientific evidence that some of our interventions are obsolete, or even harmful, other professionals will do so. And I support Dean in her plea for a more theoretically based physiotherapy when she says: "When there are weak links with a bona fide clinical science, physiotherapy will increasingly fall prey to financial trimming". Again, whether we like it or not, we are forced to look at all our interventions and give up the out of date one's and more so, the fake one's.

Let me show you some criteria regarding therapies as published by Golden in 1990(5):

1. Interventions should be based on a theory that is consistent with current scientific concepts.
2. Effectiveness should be based on properly designed studies published in peer-reviewed journals.
3. The interventions should be effective against potential for harm.
4. A specific patient population or disorder should be mentioned.
5. There should be room for discussion.

What are the characteristics of non-standard therapies? According to current literature there are several, as there are:

1. Their theories are not based on current scientific concepts or are not congruent with these concepts.
2. They are effective in a broad range of disorders, with poorly defined diagnostic criteria (so, they are believed to be effective against anything).
3. They have no harmful side effects.
4. Adequately controlled studies published in peer reviewed journals do not exist. They are usually described in books or non peer-reviewed journals.
5. They have often an emotional appeal. Opponents are usually attacked defensively.

I am aware of the fact that according to these criteria, a lot of our interventions look non-standard and out of date, and may be they are. What it means is that we ourselves have to define criteria and ways to monitor the scientific value of our practice, and that we do have to stop embracing everything that sounds new and promising before we really know what it really holds.

Again if we do not sort out our therapeutic arsenal, others will. It also means that students in physiotherapy must be taught not just how to perform an intervention, but also why to perform it, as well as the theory on which it is based and the scientific criticism, if any. Here I want to quote Helen Hislop (6), a professor in physiotherapy from the US, when she says "If the capacity for logical thought and scientific values is not acquired early, there is little hope such qualities will surface later". That means great responsibilities for educators in physiotherapy, as they are the principle investors in the future quality of physiotherapy.

Dear colleagues, I sincerely hope that by now you do agree on my opinion, that physiotherapy is not the summing up of all existing therapies, but that our therapies should logical follow from a coherent physiotherapy theory. As you probably can recall, not having a physiotherapy theory was my third reason for not having our own diagnosis.

Why is a physiotherapy theory that important? I will give you some reasons:

- \* It distinguishes us from other health care professions by providing us an identified body of knowledge.
- \* It formally and explicitly specifies relationships among ideas and data.
- \* It is independent of time, space and place of applicability.
- \* It is the fabric whose threads are ideas and whose raw fibres are valid empirical data.
- \* It predicts and explains phenomena, it is equally useful in research and clinical practice.
- \* It helps to explain why rather than whether an intervention is useful. By exploring the reasons why the treatment works, you may discover mechanisms pertinent to many treatments.
- \* It provides the scientifically responsible framework for speculation about the unknown.
- \* It is testable, allowing its underlying ideas to be supported or falsified.

Theory is certainly not the answer to all problems, I agree, but it is a vital and crucial element in the ongoing development of the profession. What do we mean by theory?

The word theory encompasses two notions: view, observation and reflection, and is derived from the greek word 'thea' as comprised in the word theatre.

So, theory has to do with experiences, ideas and interpretations, or as put by Tammivaara (7): A theory is a system of wide ranging ideas about some centrally important issue. It does not mean that every theory immediately can be implemented in daily practice. A prerequisite for implementing a theory in daily practice is that it should give insight in the why as well as in the how. In other words: why do things happen the way they happen. For those interested in how to do things now and at this moment, theory can be very irritating and boring. The force and impact of a theory seldom arise from the theory itself, but from its implementation in daily practice. It means that a theory should hold perspectives for understanding as well as for effective intervening, and that the development of a physiotherapy theory significantly improves the quality of our professional care.

This view on physiotherapy, that it is not a summing up of a list of therapies, but an identifiable, unique body of coherent knowledge, will raise the opportunity for answering some important questions we are faced with today. Let me put some of these questions important for both researchers and practitioners to you:

- \* what are the underlying mechanisms of a given disorder;
- \* how does treatment compare with spontaneous improvement over time;
- \* what is the optimal sequence for a given treatment;
- \* does a particular treatment work better for some patients with a certain condition than others?

It should be obvious that without a physiotherapy theory, without the development of a physiotherapy diagnosis, without a system-view instead of a treatment-view of physiotherapy, we will increasingly run into problems explaining why we are doing what we are doing. As you noticed, I used the term 'system-view of physiotherapy' and I want to elaborate on that.

As a result of the way physiotherapy had developed, the great emphasis that was placed on the various therapies, the way we used a therapy-coupled diagnosis, we have narrowed our view of physiotherapy as part of medicine. It is reflected in our approaches to patients problems. Some therapists hold a biomechanical approach, some a neurophysiological approach, others a biomechanical-neurophysiological approach, some a sensorimotor approach, a psychosomatic approach and I could go on for quite a while. Some patient approaches have even turned into a therapy itself. What does it mean? In my opinion it means that all those therapists direct their interventions to isolated symptoms and impairments, without organizing the identified problems into syndromes and identify the key problem. The patient is split up in several part or fragments and anyone is free to pick up the pieces he or she likes or most wants, because if fits with his or her own opinion or view of the world or of society. The system-approach (8) however, considers an individual, in both the individual and social dimension, as a hierarchy of natural systems, interconnected by various patterns of information flow in feedback systems. Health may then be defined as the harmonious interaction of all components. Disease, according to that view, is the result of a disruption of that structure. A complex system as the human being is, has subcomponents, called organs, which can be viewed as natural systems in their own right. From this view, it follows that a person can be seen as a system of inter-

related subsystems, with extensive feedback loops for inter- and intrasubsystem information exchange. As mentioned before, disease is a disruption of a well balanced, interconnected system with subsystems. So it seems obvious that an intervention should be directed to a system or subsystem, instead of firing at anything the patient or therapist can come up with. It also follows that diagnosis in physiotherapy should be based on a problem-solving behaviour, as the patient's complaints, the medical diagnosis, and the physiotherapy diagnosis should have a certain degree of correlation. If there is no correlation found, the question whether treatment by a physiotherapist should be started is justified.

When discussing the advantages of having a physiotherapy theory with you today, I mentioned the possibility of discovering underlying mechanisms pertinent to many treatments. Knowing underlying mechanisms not only gives insight into the problems, but more so raises the opportunities for developing new interventions. In my opinion, theory, diagnosis and system-approach in physiotherapy fit perfectly, and indeed show possibilities for discovering underlying mechanisms as well as for the development of new therapies. Moreover, this view of physiotherapy has options for clinical and fundamental research, the development of concepts on which our own body of knowledge, and by that improving the quality of physiotherapy.

We stand at the dawn of a new era. Let me finish by quoting Robert C. Bartlett (9) from his twenty-fifth Mary McMillan Lecture: "Your destiny is in your hands; the profession's destiny is in our hand - all of us. Let us learn from the past as we dream for the future, and success cannot help but follow". It means that choice is a privilege, not a burden. May I wish you a fruitful discussion and a provoking conference. Thank you for your time and listening.

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## **5. IMPROVING THE QUALITY OF CLINICAL TRIALS IN PHYSICAL THERAPY**

**L.M. Bouter**

In the Netherlands every year 12% of the population is treated at least once by a physical therapist, most frequently for back and neck pain. Each series of treatment consists on an average of 20 sessions, and the number of physical therapy sessions has increased by 16% over the last decade. About 60% of the sessions involve exercise therapy, while in 70% or more physical therapy modalities are used, such as ultrasound or laser therapy (1). In order to obtain an insight into what is known about the efficacy of the most prevalent forms of physical therapy for the most common indications, we summarized the literature in a number of meta-analyses (2). This presentation will start by explaining the strategy we used in reviewing the literature and will formulate some impressions regarding the state-of-the-art. Secondly, I will focus on the four most prevalent methodological flaws we identified (3), and discuss options to prevent them. Thirdly, some concluding remarks will be made on the desirable future course of efficacy research in physical therapy (1,2,3).

### **Eligibility for meta-analyses**

From the literature we identified both explanatory and pragmatic randomized clinical trials dealing with indications and interventions relevant to physical therapy. Outcome measures should include pain, mobility, functional capacity or activities of daily living. Although we identified a large number of RCTs for a wide variety of indications, I will restrict myself in this presentation to the global results of 10 meta-analyses covering some 200 RCTs in total (4-10).

### **Search strategy**

Starting from an explicit question regarding efficacy, we initially search bibliographical data-bases, such as Medline and Embase. In our experience, this typically identifies 40-50% of the eligible studies. Subsequently, this is supplemented by screening of non-indexed journals or proceedings, and by citation-tracking. Finally we ask experts and authors in the field whether they consider our list to be complete.

### **Review methods**

Although randomized clinical trials offer the best chance for a valid study of efficacy, even RCTs can be seriously biased (11,12). Therefore, in reviewing we used a predefined set of methodological criteria and corresponding weights (13). These criteria were operationalized explicitly for every meta-analysis, and were applied independently by 2 or 3 reviewers. These were blinded for the authors, the journal and the outcomes of the study. Typically, there was 70 to 80% initial agreement on item level. Differences were resolved by discussion, and for every trial a methodological score was calculated on a scale of 0 tot 100. In the resulting article only the outcomes of the best studies were discussed. Sometimes for each study the difference in success rate between the groups and the corresponding confidence interval was calculated. Due to the fact that populations, interventions and outcomes always differed substantially over the studies, we never decided to pool the data statistically (14).

Table 1: Methodological criteria and weights used in the meta-analyses

Criteria	Weights
Study population e.g. < 10% loss to follow-up	35 ( 4)
Interventions e.g. co-interventions avoided	25 ( 5)
Measurement of effect e.g. blinded outcome assessment	30 (10)
Data presentation and analysis e.g. intention-to-treat	10 ( 5)

Table 1 shows the four categories of methodological criteria, each with an example, and the corresponding weights. Of course, these weights are arbitrary to some extent, but all our meta-analyses allow for recalculation using different weights. It usually turns out that the methodological ranking is not very sensitive to a change in weights (7).

Table 2: Methodological scores in the meta-analysis on traction for back and neck pain (6)

study	total score	indication	overall conclusion
1	68	chronic LBP	neg
2	52	acute LBP	neg
3	51	chronic cervical pain	neg
4	46	acute LBP	pos
5	45	prolapsed disc	neg
6	44	acute LBP	neg
7	41	cervical pain	neg
8	39	LBP	neg
9	36	subacute cervical pain	pos
10	36	prolapsed disc	neg
11	36	prolapsed disc	neg
12	34	acute LBP	neg
13	34	acute LBP	neg
14	28	prolapsed disc	neg
15	25	chronic LBP	pos
16	24	LBP	neg
17	23	chronic LBP	pos

The range of methodological scores is often large. For traction in back and neck pain, for instance, the total score ranges from 23 to 68 points (6). Four out of 17 trials conclude that traction is more effective than the reference treatment or a placebo. Among the 7 studies with the highest score, only one is positive. Of course, the cut-off at 40 points is completely arbitrary. Therefore, it is preferable to present the relation between the methodological quality and the outcome of the studies as a cumulative frequency distribution.

Figure 1: Spinal manipulation for back and neck pain: Relation between methods score of trials and their results (4)

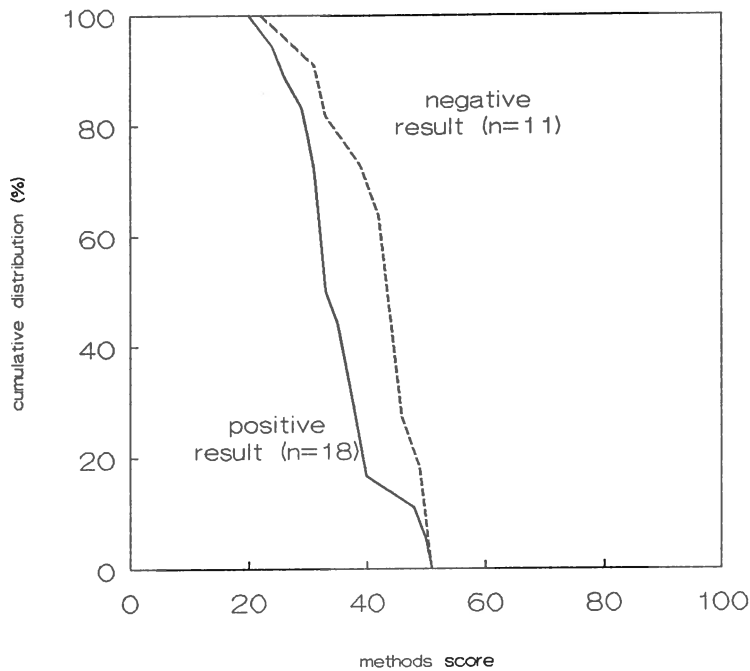


Figure 1 shows such a distribution for 18 positive and 11 negative trials dealing with the efficacy of spinal manipulation for back and neck pain (4). If the boundary between acceptable and unacceptable methodological quality would again be drawn at 40 points, it would be concluded that less than 20% of the positive trials were of acceptable quality, while this was the case for about 70% of the negative trials. From the graph you can see that for the whole range of possible cut-off points the negative studies tend to be better.

This is by no means necessarily so. As you can see, when studying the efficacy of physical therapy exercises for back pain (5), the positive studies tend to be of higher methodological quality (see figure 2).

Figure 2: Physiotherapy exercises and back pain: Relation between methods score of trials and their results. (Positive result shows exercise is better than reference treatment, negative result shows exercise is no better or worse than reference treatment) (5)

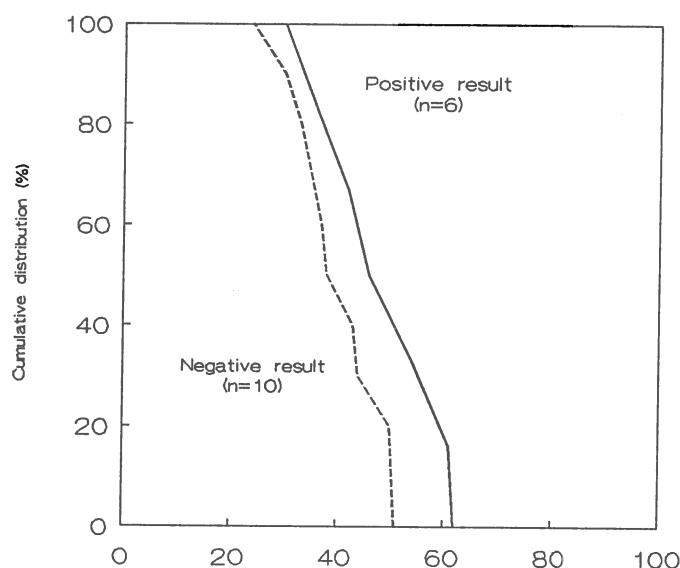


Table 3: Overview of meta-analyses

Indication	Intervention (reference)	Number of RCTs	Median score (range)
Back pain	Spinal manipulation (4)	30	35 (20-56)
	Exercise therapy (5)	16	40 (24-61)
	Traction (6)	17	36 (23-68)
	Back schools (7)	16	36 (16-70)
Neck pain	Spinal manipulation (4)	5	39 (26-50)
	Traction (6)	3	39 (36-51)
Shoulder complaints	Physiotherapy (8)	18	49 (22-76)
Knee disorders	Physiotherapy (1)	63	29 ( 6-52)
Musculoskeletal disorders	Ultrasound therapy (9)	16	41 (17-70)
	Laser therapy (10)	33	40 ( 4-72)

In table 3 an overview of the 10 meta-analyses is presented (4-10). Although we were surprised by the large number of RCTs available in the literature, we were generally disappointed by the methodological quality of the studies. While the best studies included in a meta-analysis usually scored something between 60 and 70 points, the median scores were typically low and in the range between 30 and 40 points. Consequently, we hesitate to draw strong conclusions regarding efficacy in the resulting meta-analyses, and we tend to concentrate on the most prevalent methodological flaws.

The wide range of variation regarding methodological quality suggests that there is certainly room for improvement. The current unclarity about the efficacy of widely used physical therapy interventions is, in my view, a very undesirable situation. I can see no good reason why new drugs should prove their efficacy and even superiority over agents which were already available before they entered the market, while physical therapy interventions can be introduced (and may even become very popular) without any substantial evidence regarding efficacy. I'm strongly in favour of the use of similar standards for all types of intervention, and will argue later that physical therapy trials can, indeed, meet most of the criteria currently applied to drug research.

### **Flaw 1: Heterogeneous population**

A common problem is inclusion in the trial of a group of patients which is too heterogeneous, often on the basis of a vague diagnosis like lumbago or frozen shoulder. In such a population the susceptibility for the intervention at issue may vary substantially. Dilution of efficacy will be the consequence of this. More attention should be paid to diagnosis, and especially prognosis, to enable inclusion of homogeneous groups in a trial. In my view, this is one of the major challenges for physical therapy research today. The fact that most musculoskeletal disorders are still defined as syndromes consisting of a mix of signs and symptoms is clearly unsatisfactory.

Looking up-stream at etiology and pathogenesis, to enable the identification of causally defined diagnostic entities, has not been very successful, I might say. Alternatively, I would suggest considering the diagnostic problem in terms of predicting the prognosis. More specifically, identification of groups of patients who will most likely benefit from specific physical therapeutic interventions, seems to have a high priority. These questions regarding the crucial prognostic indicators cannot be answered by RCTs, but demand creative exploratory studies using, for instance, well-documented case-series or a single case design (15). Of course, once a prognostically homogeneous category of patients seems to be identified, the 'proof of the pudding' ought to be provided by another randomized clinical trial. In such future trials the similarity of relevant characteristics at baseline should be carefully evaluated and all drop-outs should be identified, including their reasons for leaving the study.

### **Flaw 2: Incompletely described intervention**

A related problem is posed by the often incomplete description of the interventions used. This makes implementation of positive results unfeasible. Furthermore, we got the impression that the interventions were often clearly sub-optimal. For instance, it turned out that the dosages used in many laser trials were so low that a specific effect became very improbable (10). Of course, the solution to this problem would be the use of more explicit and optimal treatment protocols.

Often physical therapists participating in intervention research strongly object to the use of a strict treatment protocol, because they rightly consider it sub-optimal to treat all patients allocated to the intervention in exactly the same way. In my view, such strict uniformity is only necessary when an explanatory trial is at issue, which uses a placebo contrast to study the specific effect of the central component of the intervention. However, in many physical therapy trials the main question is of a pragmatic nature, involving a contrast between realistic treatment strategies. This excludes the use of a placebo intervention by definition, and positively asks for treatment protocols which allow treatment to be guided by relevant characteristics on entry into the trial, and

subsequently by early treatment responses. So, high quality trials do not depend on rigid treatment protocols, but will often involve flexible treatment strategies. Of course, the options available within a treatment strategy should be restricted to a workable optimum, and all decisions regarding treatment modification ought to be made according to explicit criteria.

### **Flaw 3: Wrong outcome parameters**

The clinical relevance of the outcome parameters is often doubtful, for example sophisticated measures concerning range of motion or muscle strength in low back pain. Also the validity and precision of outcome measurement is typically unknown and probably not very impressive. We fear that a lot of the outcome parameters may be insensitive to a clinically meaningful change over time. Consequently, real treatment effects may be missed. It seems urgent to give more attention to the design of outcome measures in physical therapy trials (16,17).

Quite a lot of physical therapy trials still focus exclusively on the impairment level. In my opinion, the popularity of outcome measures dealing with impairments has two reasons. The first is a general reluctance to rely on 'soft' subjective data, which often leads to a 'hard' objective and precise measurement of the wrong phenomenon (16). The second reason seems to be confusion between the questions whether an intervention is effective and how it works. Once clinical efficacy is established on the disability level, data on the corresponding changes in impairments, of course, can offer an insight in the mechanism involved, but can never be a substitute for it. In designing outcome measures dealing with impairments, it is important not to rely on the standard psychometric criteria only, but to also pay special attention to sensitivity for clinically meaningful change over time (17).

Successful recent examples of the development of suitable outcome measures are the Quebec Back Pain Disability Scale and the Shoulder Pain Disability Questionnaire.

Similar to their attitude with respect to treatment protocols, physical therapists participating in a trial often object to using the same outcome phenomenon for all patients included in the trial. They argue that the main complaint may differ substantially among prognostically similar patients. In my view, this problem can be avoided by identifying the main complaint for each patient at randomization, and by making change in the severity of that complaint the primary outcome parameter. In our experience, these individualized outcome measures are often very sensitive to change over time. Because in pragmatic trials blinding by the use of a placebo intervention is not only often unfeasible, but also undesirable, special attention should be paid to unbiased outcome assessment. For this purpose trials should exclude patients who strongly favour one of the interventions under comparison, and the treating physical therapist should have no role in effect measurement. Whenever possible, blinded research assistants ought to assess the main outcome phenomena. Also, more attention should be paid to the duration of follow-up: many trials provide data on short-term results only. Recurrences of the original complaint, and treatment outside the framework of the trial, deserve special attention towards the end of the follow-up.

### **Flaw 4: Insufficient sample sizes**

Before concluding from a negative finding that there is no difference in effect, one should always have a look at the statistical power of the trial. The data in table 4 show

clearly that sample sizes in physical therapy trials are often very small (2). Consequently, the chance of making a Type II error is substantial. In other words: a fairly large proportion of the negative findings may be 'false negatives'. The solution to this is obvious: enlarging sample sizes to, say, more than 50 patients per group. I would like to add to this that, in my view, it is not a matter of sample size determination, but of recruitment. The formulas can be found in any textbook on biostatistics, and the main decision you have to make is about the magnitude of the difference in efficacy you would like to be able to detect. Once you have decided upon the minimal difference in effect you consider to be clinically relevant, there is no point in aiming at making smaller differences statistically significant by increasing the sample size further. The real problem is getting the number of patients you need, which will often make a multi-centre design obligatory.

Table 4: Sample sizes

Type of study	No. of studies	Median no. of patients in smallest group	(25% and 75% percentiles)
Explanatory trials	67	15	(12 and 33)
Pragmatic trials	107	20	(10 and 31)

Avoidance of Type II errors is not the only reason to advocate large sample sizes. In small studies randomization might result in unbalanced groups with respect to prognosis. For known and measured prognostic factors, adjustment for dysbalance is possible in the data-analysis. But for unknown, and therefore unmeasured factors this is, of course, not possible. Another argument in favour of large sample sizes is the expectation that large trials are likely to be published, irrespective of the study results. Small trials with a negative result might have little chance of appearing in print. This introduces publication bias, because small positive studies would be over-represented in the literature.

### **Future developments**

This brings me to the third and last part of my presentation, in which I will formulate my views concerning the future course of intervention research in physical therapy. These views concern methodological developments, use in patient care, influence on policy decisions and the setting of research priorities.

While for the majority of the methodological problems identified the standard general solutions can be applied, in my view two important challenges seem to be fairly specific for the physical therapy domain. The first challenge consists of a meaningful demarcation of categories of patients which are prognostically homogeneous with respect to the intervention at issue. The second challenge deals with the development of outcome parameters that combine all desirable test characteristics, and offer a fair chance to physical therapy interventions to prove efficacy. For both challenges the RCT-design is inappropriate, although exploratory sub-group analyses may be of some use. In this field I can see an opportunity for a number of different study designs, of which single-case studies and longitudinal follow-up of case-series are illustrative examples (15).

Individual patient care will always involve decision-making in uncertainty, no matter what evidence from intervention studies is available. RCTs generate knowledge about average effects only, while the effects among the individual patients usually differ substantially, and some may benefit most from the on the average less effective intervention. For patients who do not meet the eligibility criteria of the trial at issue, even extrapolation of the average efficacy is uncertain. The validity of extrapolation in these instances will depend on the existence of differences compared with the trial population that will modify the efficacy. Of course, this is a matter of judgement, adding up to the amount of uncertainty. Although the state-of-the-art is currently rather sad, I can see no alternative to the accumulation of knowledge on average efficacy by RCTs. In my view, this knowledge should provide a firm basis for standardized physical therapy care. Explicit standards, like those formulated by the Dutch general practitioners for a wide range of indications, seem to me to be clearly superior to the alarming variety of interventions given nowadays to some categories of patients.

Assuming that resources for health care are essentially limited, decision-making on the policy level cannot be avoided. Although there is clearly no place for ineffective treatments, setting priorities among budgets for interventions that do have some effect is certainly no easy task. Unfortunately, empirical data concerning efficacy, cost-effectiveness and safety usually play only a minor role in these policy decisions. However, this role is likely to increase in the near future. Several Dutch agencies have already stressed the importance of studying critically the benefits and the costs of currently very widely used forms of physical therapy for their most prevalent indications.

This brings me to my last point: to me this demand of evidence, similar to the evidence concerning drug efficacy, only makes sense when a fair chance is given to the physical therapy profession. The fairness of this chance will largely depend on the funding available for (1) the training of qualified investigators, (2) the necessary infrastructure, and (3) the execution of the intervention studies at issue. Although the funding of physical therapy trials is certainly not easy, some progress has definitely been made during the last few years. Currently, in the Netherlands a number of RCTs are being executed, aimed at avoiding most of the flaws identified in this presentation.

Let me end by expressing the hope that this challenging field of intervention research in physical therapy will, in future years, continue to blossom.

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## 6. UNDERSTANDING THE BASICS OF PHYSICAL THERAPY: THE MAIN CONDITION FOR IMPROVING THE QUALITY OF PHYSICAL THERAPY

R.A.B. Oostendorp, H.W.A. Wams and A.T.M. Bernards

### **Transparency: a condition for quality**

For some years now considerable attention is being paid to the development, implementation, and assessment of quality systems for improving the quality of physical therapy.

Effectiveness of actions for improving the quality requires transparency of physical therapy. The implicit character of physical therapy, or in other words the non-transparency of physical therapy, hinders the scientific development of physical therapy. Therefore we will try to give a view on the basics of physical therapy, in order to create a more transparent picture of physical therapy.

We can distinguish four basics:

- \* development from the biomedical model to the biopsychosocial model
- \* physical therapy in relationship to disease and illness
- \* arousal, illness and illness behavior
- \* adaptability and adaptation.

### **Development from the biomedical model to the biopsychosocial model**

Physical therapy has evolved during the last ten years from the narrowly focused biomedical model into a broader-based model. The traditional focus on etiology and pathology has proven to be too limited for many patients who are referred for physical therapy treatment. Such a model is not able to reflect the full range of factors that brings people to contact a practitioner or a physical therapist.

Medicine is focused on etiology, pathology and clinical manifestation. A valid requirement for a medical disorder to be classified as such is a causal relationship between an etiological factor and the nature of the disorder. For many disorders of the loco-motor system a specific etiological factor cannot be indicated. These disorders are often multifactorial determined. This questions monocausal thinking, especially where this concerns the role of psycho-social and behavioral factors in disease. A physiotherapist's analysis of a disorder should therefore entail more than the monocausality from the biomedical tradition. It is essential to recognize that physical therapy focuses on the consequences of diseases in terms of impairments, disabilities and handicaps, which should be expressed in elements of the physical therapy diagnosis.<sup>1</sup> In stead of the biomedical model which supposes a monocausality, the biopsychosocial model stresses the fact that in most patients the onset and maintenance of disease is not explained sufficiently by one factor, but that, according to this model, illness is the result of the complex interaction of physical, physiological, psychological and social variables. Diversity in expression in any illness, including its severity, duration and functional consequences for the individual, is accounted for by his perceptions and responses to diseases which are shaped by interrelationship between physical and physiological changes, psychological status and social context.<sup>2,3</sup>

### **Physical therapy in relationship to disease and illness**

The distinction between the biomedical and biopsychosocial model implicates the differentiation between disease and illness.

Disease is not usefully defined as a biological event representing a disruption of a body structure or organ system as a result of anatomic and/or physiological change. The disease process may involve single or multiple organs or organ systems, may advance, regress, or remain dormant and may or may not be clinically apparent.<sup>4</sup> Illness is defined as the subjective experience of physical discomfort, emotional perturbation, behavioral limitations and psychosocial disruption of activities and relationships.<sup>4</sup>

One of the most important aspects in changing from the biomedical model to the biopsychosocial model is that the illness' manifestations and the illness' behavior become important aspects to analyze in patients. For most patients it is difficult to understand that the perception and appraisal of physical symptoms does not require the presence of pathology or a pathophysiological process. Both laboratory and clinical research confirm the possibility of eliciting symptoms in the absence of observed pathology. Many patients describe their pain and other complaints in terms of a supposed disease. Many practitioners prescribe physical therapy also in these terms (for example low back pain, degeneration of the disc, and so on). Conversely, the presence of pathology or a pathophysiological process is neither necessary nor sufficient to yield illness behavior. This point of view is one of the basics of physical therapy.

The basic step in a functional assessment is the question: "Are the illness' manifestation and the illness' behavior related to a biomedical disease or not?" and "Which time-related factors threatened or are threatening the health status of the patient?". A functional assessment is organized across three levels: organ, person and society. Within each, the prevailing condition results, directly or indirectly, either in impairment, disability, or in handicap. The unifying concept here is that each of these represents limitations in function, whether in using skills, performing activities, or in fulfilling social roles. Anatomical, physiological, or psychological defects determine impairment or organic dysfunction. Performance defects within the physical and social environment contribute to disability or difficulties in performing. Environmental or societal defects create handicaps or social disadvantage.<sup>5</sup>

Generally in patients with chronic pain and complaints, attempts to correlate anatomical, physiological and psychological data in the arena of illness' behavior were not successful. On the one hand, there are numerous examples of behavioral situations in which the perception of noxious stimuli is reduced. It is well known for instance that humans can be indifferent to, or completely unaware of pain induced by physical damage in a specific state of the central nervous system, such as would occur during competitive work and sport. On the other hand, there are many patients in which the perception of pain is dramatically increased without such damage.

### **Arousal, illness and illness' behavior**

The central nervous system contains low and high ordered 'programs', that enable the organism to react adequately to threatening stimuli. The programs recognize the threatening messages and initiate the coordinated reactions. Low-order reactions can already be found in the spinal cord.<sup>6</sup> Higher-order reactions are found in the brainstem, hypothalamus and limbic system. These reactions are an integrated response that consists of autonomic, endocrine and motor components.<sup>7</sup> Higher-order

programs use the lower-order programs to adapt the behavior of the organism. One of the higher-ordered functions is the so-called **AROUSAL** function of the central nervous system.

Arousal is defined as a general physiological and psychological activation of the organism. The state of organism may vary from deep sleep to intense excitement.<sup>8,9</sup> It is a mistake to conceptualize arousal as a unitary construct.<sup>10</sup> Arousal may be the result of cognitive interpretation or appraisal, but also depending on homeostatic changes and reflects therefore different physiological and psychological components. This means that the interaction between arousal and behavior must be seen in relation to the different sources of activation.

The term 'arousal related state' is used to reflect the multidimensional nature of arousal and that interpretation of arousal is difficult without knowledge of its nature. Arousal points at physiological and psychological fluctuations in the activity of the organism, characterised by programmed and non-programmed rhythms.

**Short-term fluctuations** in arousal level (so-called phasic fluctuations) can occur in situations in which there is a stimulus which requires attention. An unexpected stimulus or event, such as a collision from the rear by a car, precipitates a series of reactions which are part of the so-called orientation reactions. The orientation reactions maximise the processing of information. If the event or stimulus is perceived as threatening, the arousal is enhanced and intensified. The arousal related state is called the alarm phase.

It is well known that in persons with chronic complaints the orientation reactions are less adequate. It is argued that this phenomenon has to do with a decreased capability of these patients to discern relevant information from irrelevant information. The absence of adequate orientation reactions is prognostic unfavourable for, for example the development of chronic pain.<sup>11</sup>

Besides the short-term fluctuations the arousal level may be increased for a **long-term**. This tonic increase can be **specific** and **aspecific**. Specific arousal is task and goal specific and directed by intention and motivation. Aspecific arousal becomes manifest when the arousal regulation strategy is inadequate and insufficient. Long-term aspecific arousal is characterised by impairments in selective attention, motivation, emotion, and by sleep disturbances; in other words by a generally decreased tolerance and loadability. Next to this generally decreased loadability also a regional decreased loadability might exist without a traumatic or acute event, based on the neural and hormonal consequences of the long-term aspecific activation. Areas of preference for a regional decreased loadability are the back (low back pain about 70% without medical diagnosis), the neck (neck pain also about 70% without medical diagnosis), the head (tension headache) and the shoulder (shoulder pain about 40% without medical diagnosis). On the basis of a persisting general and regional disbalance between load and loadability illness' behavior can develop.

### **Adaptability and adaptation**

In the context of the balance between load and loadability there are two keywords 'adaptability' and 'adaptation'.

Adaptability is the ability to react physically, physiologically, psychologically and socially adequate to stress factors and situations. Adaptation is the result of the adequate reaction. Stress is viewed as referring to a (chronic) state of disbalance between (perceived) load and (perceived) loadability.<sup>12</sup> In a chronic state of stress, the patient is not capable and does not have the ability to adapt. Physical therapists,

interested in assisting patients in enhancing their performance through arousal regulation, are faced with three issues. These include:

- . identifying what arousal related states are being discussed when patients refer to illness' behavior;
- . understanding the relationship between arousal and behavior;
- . identifying what techniques can be used to facilitate the regulation of patient's arousal.

Arousal changes the energetics of stimulus-response relations. Special arousal reflects a state of activation in which there is an increase in energetics of task specific functions and response-selection is adequate. Aspecific arousal reflects a state of activation in which there exist an increase in energetics of stimulus-response relations with a insufficient and inadequate response-selection.

The activation in function of orientation is aspecific. It takes a little time to search for an adequate response selection. Normally the orientation phase is of short duration and is immediately followed by the adaptation phase. The aspecific arousal changes in a specific arousal.

Characteristics of the adaptation phase are:

- \* specific activation of those neural and homonal systems, involved in coping with the local and general stress factors
- \* selection of information, judging what is relevant and what is irrelevant
- \* an adequate response selection.

In patients many stress factors or situations are perceived as threatening in the time, resulting in an enhanced and ongoing alarm phase.

The alarm phase is chracterized by:

- \* aspecific activation of neural and hormonal systems with a decreased adaptability to local and general stress factors
- \* no selection of information, no judgement what is relevant and what is irrelevant
- \* an inadequate response selection with intensified stimulus-response relations.

The alarm phase means, there is a disregulation in the higher-ordered programs and a disregulation in the lower ordered programs on spinal level. If noxious input exists also a disregulation on spinal level can be seen. This disregulation is characterized by a segmental pattern, including the sympathetic component.<sup>14</sup>

If the situation persists for a long time, the entire organism becomes exhausted and the tissues become more vulnerable. The sensory, motor and autonomic reactions are no longer meaningful but rather purposeless.

The enhanced and ongoing alarm phase is threatening to the health status of the patient. An ongoing state of aspecific arousal will lead to a total disregulation in organism.

Physical therapists should be able to recognize the arousal related states (orientation, alarm, adaptation and exhaustion) and the type of activation (aspecific and specific). The physiotherapist's strategy, when assessing patients with disorders of the locomotor system, should be guided by insight in the ratio load/loadability according to the biopsychosocial model. Before the physical therapist can formulate a plan for treatment, he weighs these factors in relation to the health problem of the patient.

The effectiveness of therapeutic stimulation, information and approach may depend on the physiological and pathophysiological characteristics of tissues, organs, and organ system and on the psychological and social characteristics of patients.

### **Transparency of physical therapy**

Now, if we turn again to the basics of physical therapy, attention is given to four basics:

- \* development from the biomedical model to the biopsychosocial model
- \* physical therapy in relationship to disease and illness
- \* arousal, illness and illness' behavior
- \* adaptability and adaptation.

The general accepted biopsychosocial model for health and health status is suitable for empirical findings in physical therapy, and is appropriate for structuring and validating data in future studies, and may also serve as a frame of reference for a better understanding of the basics of physical therapy, in other words make physical therapy more transparent which, we think, is necessary for improving the quality of physical therapy.

Attempts to develop and to apply these four basics in the research methodology and in the field of physical therapy however are problematic for two reasons. First, the changes in thinking about and adapting to the basics of physical therapy need much time for acceptance in the field. Second, the quality of measurement technology, has been generally weak. There are several encouraging trends, however. In the last years progress has been made in addressing the issues of the biopsychosocial model, in terminology, in classification and in standardization.

Hopefully, this view on the basics of physical therapy has given a more transparent picture of the physical therapy.

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## **7. BEHAVIORAL SCIENCE AND PHYSICAL THERAPY**

**J. Dekker**

### **INTRODUCTION**

Behavioral science and physical therapy are closely related disciplines. There is a strong behavioral component in both the disorders treated by physical therapists and the interventions used by physical therapists. For example, patients tend to avoid activities which cause pain. This avoidance causes muscle weakness and stiffness. This is an example of the behavioral component of disorders. Exercise therapy may be cited as an example of an intervention which concerns the behavior of the patient.

The interface of behavioral science and physical therapy seems to be a highly relevant area of research. Theories and methods developed in behavioral science can be fruitfully applied in physical therapy and vice versa. But, although highly appropriate, there is a dearth of research in this area. In daily practice, behavioral scientists and physical therapists do tend to cooperate in the treatment of patients. But, at the scientific level, the interface of the two disciplines is poorly conceptualized.

The goal of my presentation is to describe the interface of behavioral science and physical therapy. Three main areas in this interface will be identified. These areas include:

- the nature and assessment of patients' disorders
- the mechanisms of these disorders
- the interventions used to treat these disorders.

I will describe each of these areas and I will cite an example of relevant research in each of these areas. In these examples, I will demonstrate how theories and methods developed in one discipline can be applied into the other.

### **DISORDERS**

Patients treated by physical therapists exhibit a wide range of disorders. To a certain extent, these disorders can be characterized by a medical diagnosis. The medical diagnosis describes specific pathology. An example of a medical diagnosis is osteoarthritis, which refers to degeneration of cartilage and formation of new bone in joints. However, the medical diagnosis is not sufficient information for the physical therapist. The physical therapist performs his or her own diagnostic examination. This examination is concerned with the consequences of pathology (or disease), instead of the pathology itself. For example, in a patient with osteoarthritis, the physical therapist is concerned with pain, muscle weakness, reduced range of motion, disabilities in walking etc. These are the consequences of the underlying pathology of the joint.

These consequences can be classified into two major categories: impairments and disabilities (Dekker et al., 1993). Impairments are consequences at the level of organs (e.g. muscle weakness). Disabilities are consequences of disease at the level of the person (e.g. disabilities in walking).

Figure 1: Medicine, physical therapy and behavioral science

<b>Medicine</b>	<b>Physical therapy</b>	<b>Behavioral Science</b>
Pathology/disease	Consequences of disease: impairments and disabilities	Consequences of disease: quality of life

Behavioral scientists have also been extensively concerned with the study of the consequences of disease. Using the label 'quality of life', behavioral scientists have studied the consequences of disease. There exists a huge literature on behavioral approaches towards quality of life in various diseases. Using the label 'quality of life', behavioral scientists have studied symptoms, disabilities, emotional disturbances, and social and economic consequences of disease.

It may be clear that physical therapists and behavioral scientists come very close to each other, here. Although physical therapists and behavioral scientists start from different positions, both are concerned with the consequences of disease, instead of the disease itself.

Because the two disciplines come very close, methods developed in one discipline can be fruitfully applied into the other discipline. This applies, for instance, to methods which have been developed to assess symptoms and disabilities. In behavioral research on quality of life, a wide array of methods to assess symptoms and disabilities have been developed. These methods include interviews, questionnaires and observational methods.

These methods can be used in physical therapy to assess outcome of treatment. A well known example is the assessment of pain: various rating scales have been developed to assess pain. In addition, many questionnaires have been developed which assess disabilities. A somewhat less well known example is the assessment of disabilities by means of observational methods. I will present an example of an observational method, which is used to assess disabilities.

This method has been introduced by Frank Keefe (1987). The method concerns the assessment of disabilities or pain behavior as it is called in behavioral science. The method has been applied in patients with back pain, rheumatoid arthritis, osteoarthritis and even cancer. With this method the patient is instructed to perform a series of standardized tasks, such as walking, sitting down, reclining on a bed etc. The performance of these tasks is videotaped and subsequently scored on a number of dimensions. I will show you the dimensions which are scored in OA patients. These include:

- duration of movement
- \* stand/sit time
- \* stand/recline time
- \* 5-m walking time
- guarding
- rigidity

- unloading of joint

We have extensively tested this method in OA patients (Dekker et al., 1990; 1993b). We have found that the reproducibility or reliability of these scores is very high. Two observers, who independently observed and scored the videotapes, agreed to a very high degree on their scores (see table 1). Thus, the method is highly reproducible or reliable.

Table 1: Reliability of the assessment of disabilities in osteoarthritis patients: intraclass correlation

Intraclass correlation	
* Duration of movement	
- stand/sit	.98
- stand/recline	.99
* Guarding	.92
* Rigidity	.88
* unloading of joint	.97

We have also determined whether this method is valid in physical therapy (Dekker et al., 1993c). To this end, we have determined whether muscle strength in patients with OA was associated with disability. The strength of various groups of muscles around the hip and the knee was assessed in OA patients. We calculated a composite score on muscle strength. As expected, the loss of muscle strength was associated with a higher degree of disability (see table 2).

Table 2: Pain and disability in patients with weak and normal muscles: mean scores (and standard deviations)

	Knee muscles			Hip muscles		
	Weak (n = 7)	Normal (n = 51)	Significance†	Weak (n = 37)	Normal (n = 21)	Significance‡
Pain						
1st trial	3.4 (1.6)	3.2 (2.2)	N.S.	3.7 (2.2)	2.3 (1.7)	**
2nd trial	4.4 (2.4)	3.2 (2.5)	N.S.	3.7 (2.6)	2.6 (2.2)	*
Disability						
Walking time	9.2 (2.6)	5.6 (1.0)	**	6.5 (1.9)	5.2 (0.9)	***
Sit time						
1st trial	6.6 (2.8)	4.4 (1.4)	*	5.2 (2.0)	3.8 (0.8)	***
2nd trial	4.8 (1.0)	4.2 (1.2)	N.S.	4.6 (1.2)	3.7 (1.1)	**
Recline time						
1st trial	13.3 (6.6)	7.1 (2.7)	*	9.0 (4.2)	5.8 (1.0)	***
2nd trial	12.9 (4.4)	7.4 (3.5)	**	9.3 (4.3)	5.9 (2.2)	***
Guarding	7.1 (1.9)	3.7 (3.3)	***	5.3 (3.0)	2.0 (3.0)	***
Rigidity	3.7 (2.0)	1.6 (2.0)	*	2.4 (2.4)	0.8 (1.3)	***
Unloading joint†	2.0 (1.3)	0.1 (1.0)	**	0.7 (1.3)	-0.3 (0.8)	***

†Logarithmic transformation.

‡t-test (separate variance estimate).

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

These associations show that disability, as assessed with this method, is related to variables such as muscle strength, which is a highly relevant variable in physical therapy. In other words, this method can be validly applied in physical therapy.

Currently, we are using this measure in a clinical trial on exercise therapy in OA-patients.

This example shows how methods of assessment developed in behavioral science can be applied in physical therapy. This is possible because both physical therapy and behavioral science are concerned with the consequences of disease.

## MECHANISMS OF DISORDERS

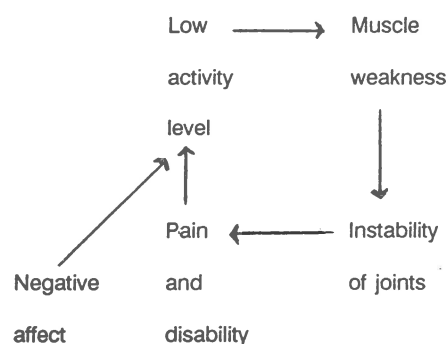
Now, I will turn to the mechanisms of disorders. I will argue that there exists interactions among factors belonging to the domain of physical therapy and factors belonging to the domain of behavioral science. Jointly, these factors determine the complaints of patients. I will illustrate this with data on pain and disability in OA patients.

Pain and disability are the cardinal symptoms of OA patients. We have reviewed the literature on the determinants of pain and disability in OA patients (Dekker et al., 1992). In this review we have drawn three major conclusions:

1. Degeneration of cartilage and bone is weakly associated with pain and disability in OA patients.
2. Muscle weakness and reduced range of joint motion are associated with pain and disability.
3. Anxiety, coping style and depression are associated with pain and disability.

We wondered which mechanism causes the association of negative affect (anxiety, depression etc) and pain/disability. We hypothesized that negative affect exerts its influence on pain and disability through muscle weakness. This hypothesis is illustrated in figure 2. This figure depicts a vicious circle which physical therapists are very well aware of. OA patients tend to avoid activity, because activity induces pain. The avoidance of activity is a two-edged sword, however. A low activity level enhances muscle weakness and instability of joints. Instability of joints causes strain in innervated tissues and thus pain. Also, instability causes limitations in activities and tasks. We hypothesized that negative affect enhances this vicious circle. Negative affect is thought to enhance the tendency to avoid pain related activity. This mechanism could explain the association of negative affect and pain/disability.

Figure 2: Proposed causes of pain and disability in OA patients



We have tested this hypothesis in a pilot study (Dekker et al., 1993c). We predicted that the association of negative affect and pain/disability would be particularly marked in patients with weak muscles. In patients with normal muscles, there is no particular reason to expect an association, because a necessary mediating factor -muscle weakness- is lacking. But, in patients with weak muscles, our model does predict an association of negative affect and pain/disability.

In patients with OA we assessed pain, disability (using the method I mentioned earlier), muscle strength and negative affect. Our hypothesis was confirmed with regard to disability, but not with regard to pain (see table 3). The correlations between negative affect and disability were stronger in patients with weak muscles: this applied to both muscles of the knee and muscles of the hip. The correlation between negative affect and pain did not show the expected pattern, however. Thus, there is preliminary evidence that muscle weakness is a mediating factor between negative affect and disability (but not pain) in OA patients. Negative affect seems to exert its influence on disability through muscle weakness.

Table 3: Correlation between negative affect, pain and disability

	Fatigue	Depression	Anger	Tension	Catastrophizing
Pain					
1st trial	0.37***	0.14	-0.10	0.27*	-0.04
2nd trial	0.35***	0.08	0.01	0.20	0.08
Disability					
Walking time	0.22*	0.13	0.04	0.20	0.10
Sit time					
1st trial	0.12	-0.04	0.10	0.08	0.15
2nd trial	0.15	0.04	0.10	0.07	0.12
Recline time					
1st trial	0.24*	0.08	0.17	0.10	0.25*
2nd trial	0.27*	0.07	0.16	0.17	0.19
Guarding	0.09	0.04	-0.13	0.10	0.12
Rigidity	0.05	-0.07	-0.02	-0.11	0.18
Unloading joint†	0.32**	0.07	0.15	0.17	0.07

†Logarithmic transformation.

\* $P < 0.05$ ; \*\* $P < 0.01$ ; \*\*\* $P < 0.005$  (one tail).

This example illustrates how concepts from physical therapy -such as the vicious circle of avoidance of activity, muscle weakness, instability of joints and disability- can be applied in behavioral science. Because the two disciplines are both concerned with the consequence of disease, concepts from one discipline can be fruitfully applied into the other.

## INTERVENTIONS

The third area of the interface of behavioral science and physical therapy concerns interventions. In physical therapy, successful treatment frequently requires patients to change their behavior. The physical therapists performs exercises with the patient and instructs the patient to do these exercises at home. In addition, the patient is given advice on living rules, advice on how to perform activities, and advice on changes in daily routines etc. Both the performance of exercises at home and the changes in living rules seem to be essential ingredients of the treatment. In fact, successful treatment frequently is dependent on the willingness of the patient to continue exercising and the willingness to change daily routines. In other words, successful treatment is dependent on the willingness of the patient to change his or her behavior.

There is reason to believe that physical therapists are only moderately successful in achieving this kind of behavioral change. Physical therapists estimate that during actual treatment approximately 60 % of the patients comply with their instruction and advice. Furthermore, they estimate that after the actual treatment only 20% of the patients comply with their instructions and advice (Sluijs, 1991). These are not very encouraging figures. Interviews with patients confirm this rather gloomy conclusion: patients themselves frequently indicate that they do not comply with the therapists' instructions and advice. This situation is certainly not unique to physical therapy. It is well known that compliance with health care regimes frequently is rather poor. Nevertheless, there is every reason to try to improve compliance in physical therapy.

One way to improve compliance is to adopt theories and methods from behavioral sciences on how to change behavior. Sluys and Knibbe (1991) have done a rather elegant proposal in this respect. They made a distinction between compliance during the actual treatment period and compliance after completion of the treatment.

During the actual treatment period, the therapist is in the position to exert direct control over the behavior of the patient. The therapist can use principles from behavioral conditioning theory to control the patient's behavior. For example, the therapist can suggest to the patient cues that remind the patient of his exercises. A sticker on the phone that reminds the patient of doing her pelvic floor exercises. Furthermore, the therapist can reinforce the desired behavior by giving appreciation and praise contingent on the patients performance of exercises. The use of cues and reinforcement are established principles in behavioral conditioning theory.

After the end of the actual treatment period, the therapist is no longer in the position to exert direct control over the behavior of the patient. Sluys and Knibbe propose -in order to enhance compliance after the actual treatment period- to use principles from self-regulation theory. This means that the therapist aims at promoting the patient's own responsibility for his behavior. In order to promote this responsibility, the therapist explains to the patient why exercises are so important. In addition, the therapists explains also why it is important to change daily routines. Furthermore, the therapist encourages patients to interpret pain and other symptoms as warning signals; these signals can be used to remind the patient of his exercises.

This example concerns interventions as the third area of the interface between physical therapy and behavioral science. This example shows how knowledge on how to change patients' behavior can be applied in physical therapy.

## CONCLUSION

Now I will come to my conclusion. Physical therapy and behavioral science each have its own domain. The body of knowledge of these two disciplines is clearly differentiated. However, physical therapy and behavioral science are both concerned with the consequences of disease. Because both disciplines are concerned with the consequences of disease, these disciplines come very close to each other. I have identified three main areas in the interface of behavioral science and physical therapy:

1. To a certain extent, the two disciplines are concerned with the same kind of disorders. As a result, methods of assessment developed in one discipline can be

applied into the other. I have illustrated this with the example of an observational method to assess disabilities in OA patients.

2. The mechanism of disorders: there seem to exist interactions among factors typically belonging to the domain of physical therapy and factors belonging to the domain of behavioral science. Jointly, these factors determine the complaints of patients. I have illustrated this with the example of negative affect and disability in OA patients: the vicious circle of avoidance of activity and muscle weakness seems to play a mediating role between negative affect and disability.
3. The treatment of disorders: The physical therapist frequently advises patients to change their behavior. Behavioral change may be facilitated by the application of principles developed in behavioral science. I have illustrated this with the example of compliance with instructions on exercise and living rules.

In their education physical therapists get a firm introduction into medical sciences including anatomy, pathology etc. Physical therapists clearly need this introduction into medical science. I hope that I have convinced you that physical therapists likewise need an introduction into behavioral science. Behavioral science has much to contribute to physical therapy. Further exploration of the interface between the two disciplines is urgently required. I do hope that physical therapists and behavioral scientists will increase their research efforts in this area.

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