

The open source protocol of clinical holistic medicine

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Abstract

We have developed the concept of Open Source Research Protocols to allow every patient, physician, researcher and medical authority full and current insight into our international research team's research and development in clinical holistic medicine (CHM). Only by openness and a free dialog with all interested parties will we be able to avoid bias and secure a high quality and speed in the development of CHM. Holistic mind-body medicine is today developed by researchers all over the world, and the ongoing publication of all aspects of the protocol enable us to guarantee that all aspects have been peer-reviewed and holding up to international standard. A standard both with regard to the quality of the research, the documentation of treatment efficacy and safety and all ethical, philosophical and methodological aspects. We encourage all medical researchers to shift to the Open Source Research Protocol format to minimize bias and accelerate medical research for the benefit of all patients. We encourage all public and private, national and international research organs, foundations and institutions to support the development of the scientific, holistic medicine and its institutions, financially and politically. Holistic medicine is consciousness-based medicine that uses conversational therapy and bodywork instead or as supplement to drugs and surgery. The experts in holistic medicine, especially its physicians, therapists and researchers, needs protection, special attention and support as they might be up against strong commercial interests.

Keywords: Holistic health and medicine, CAM, clinical medicine, ethics, human development, research.

Introduction

Research in holistic medicine needs to have the same quality as biomedical research protocols. The lack of research expertise and national organs to regulate this kind of research and assure its quality has lead us to develop the concept "Open Source Research Protocol", where all important procedures, treatment techniques, ethical considerations, documentation

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standards, systems for quality assurance, including instruments for measurement of effect like questionnaires that have been published in peer-reviewed scientific journals (see table 1). The publication of all aspects of the protocol and the research that resulted has made it possible to have an excellent standard of research. We also believe that by publishing all part of the protocol and receiving critique from internationally recognised scientific journals have avoided much of the bias that all research obviously contain.

Table 1. The peer-reviewed journals that have published the research protocols and scientific papers on quality of life research and clinical holistic medicine

• Arch Sex Behaviour (sexology)	(Medline/PubMed)
• BMJ (medicine)	(Medline/PubMed)
• Child Care Health Dev (pediatrics)	(Medline/PubMed)
• Eur J Surg (surgery)	(Medline/PubMed)
• Int J Adolesc. Med Health (adolescent medicine, pediatrics)	(Medline/PubMed)
• Int J Child Health Human Dev (pediatrics, human development)	(PsycINFO, PubMedCentral)
• Int J Disabil Hum Dev (disability, human development)	(PsycINFO)
• Ital J Pediatr (pediatrics, adolescent medicine)	
• J Altern Med Res (alternative medicine)	
• J Coll Physicians Surg Pak (Medicine)	(Medline/PubMed)
• J Compl Integr Medicine (alternative medicine)	(Medline/PubMed)
• J Pediatric Adolesc Gynecol (gynecology, pediatrics)	(Medline/PubMed)
• J Pain Management (medicine)	(PsycINFO, PubMedCentral)
• Med Sci Monit (medicine)	(MedLine/PubMed)
• Oral Health Prev Dent (dentistry)	(Medline/PubMed)
• South Med J (medicine)	(Medline/PubMed)
• Social Indicators Research (sociology)	(PsycINFO)
• ScientificWorldJournal (medicine)	(Medline/PubMed)
• Ugeskrift for Læger (medicine)	(Medline/PubMed)

The research papers have been arranged according to several systematic categories according to the headlines and topics listed in table 2. The general title of the papers is mentioned in the title of the paper to make it easy to identify all papers of a series.

Table 2. The most important series of papers that constitute the research protocol in clinical holistic medicine

- *QOL methodology* describes the method used to measure quality of life used with the Quality of Life Survey Study at the Copenhagen University Hospital (Rigshospitalet), Denmark.
- *QOL philosophy* describes the philosophy behind our work with quality of life presented in the books “Quality of life. To seize the meaning of life and get well again” (1995), “Life philosophy that heals. Quality of life as medicine” (1999), “Consciousness-based medicine” (2003) and “Principles of Holistic Medicine. Philosophy behind quality of life” (2005). These are publications describing the philosophy on which the entire project is based.
- *QOL theory* covers the related life and human points of view described theoretically.
- *QOL questionnaires* are the questionnaires used in the Quality of Life Survey Study and later studies.
- *QOL results* are results from the Quality of Life Survey Study.
- *Theories of existence* are new theories on quality of life and the human nature described coherently and concisely.
- *Holistic medicine* describes our research program for the holistic-medical project — a new research paradigm for researching alternative and holistic medicine and a theory for process of holistic healing.
- *QOL as medicine* describes results from the treatment of patients suffering from various chronic diseases, like chronic pains, alcoholism and Whiplash Associated Disorders.
- *Clinical holistic medicine* describes how to deal with the variety of problems presented by the patients in the medical clinic using holistic medicine.

- *Human development* is a series of papers to address a number of unsolved problems in biology today. First of all, the unsolved enigma concerning how the differentiation from a single zygote to an adult individual happens has been object for severe research through decades. By uncovering a new holistic biological paradigm that introduces an energetic-informational interpretation of reality as a new way to experience biology, these papers try to solve the problems connected with the events of biological ontogenesis from a single cell involvement in the fractal hierarchy, to the function of the human brain and “adult human metamorphosis”.
- *Quality of working life research* is a series of paper that addresses the fundamental needs for happiness and efficiency the working situation. This applies to physicians and therapists as well as other occupations. The series of paper analyses how we can develop in our job, and continue to learn and grow, and avoid the routine and boredom that in the end forces us to compromise with quality and patience.

Research in clinical holistic medicine

Millennia ago, around the year 300 BCE, at the island of Cos in old Greece, the students of the famous physician Hippocrates (460-377 BCE) (1) worked to help their patients to step into character, get direction in life, and use their human talents for the benefit of their surrounding world. For all we know this approach was efficient medicine that helped the patients to recover health, quality of life, and ability for which Hippocrates gained great fame. For more than 2,000 years this was what medicine was about in most of Europe.

On other continents similar medical systems were developed. The medicine wheel of the native Americans, the African Sangoma culture, the Samic Shamans of northern Europe, the healers of the Australian Aboriginals, the ayurvedic doctors of India, the acupuncturists of China, and the herbal doctors of Tibet all seems to be fundamentally character medicine (2-8). All the theories and the medical understanding from these pre-modern cultures are now being integrated into what has been

called integrative or transcultural medicine. Many of the old medical systems are reappearing in modern time as alternative, complementary and psychosocial medicine. This huge body of theory is now being offered as a European Union Master of Science degree (2-8).

Interestingly, two huge movements of the last century have put this old knowledge into use: psychoanalysis (9) and psychodynamic therapy (10,11) (most importantly STPP or short term psychodynamic psychotherapy) (12,13) going though the mind on the one hand and through the body on the other. Bodywork developed through most importantly Reich (14), Lowen (15) and Rosen (16) with sexual therapy along the tantric tradition (17). A third road, but much less common path has been directly though the spiritual reconnection with the world (18,19).

Our international research collaboration became interested in existential healing from the data that originated from the epidemiological research at the Copenhagen University Hospital (Rigshospitalet) starting in 1958-61 at the Research Unit for Prospective Pediatrics and the Copenhagen Perinatal Birth Cohort 1959-61. Almost 20 years ago we were conducting epidemiological research on quality of life, closely examining the connection between global quality of life and health for more than 11.000 people in a series of huge surveys (see 20 for a review of these studies) using large and extensive questionnaires, some of them with over 3,000 questions. We found (quite surprisingly) from this huge data base that quality of life, mental and physical health, and ability of social, sexual and working ability seemed to be caused primarily by the consciousness and philosophy of life of the person in question. Objective data were only to a small extent involved, like being adopted, coming from a family with only one breadwinner, mother being mentally ill, or the person in question financially poor or poorly educated (which are obviously very much socially inherited) (20). Clinical holistic medicine is holistic mind-body medicine, which is also clinical medicine, i.e. medicine based on patient self-exploration and self-insight for obtaining existential healing. It is also called holistic body psychotherapy, mindful mind-body medicine, and similar names.

The open source research protocol

We have always revealed the sources of funding and support in the papers constituting the Open Source Research Protocol (20-244), as we do in the present paper. Today we are in the strange situation that very few controlled clinic studies have been made, since most of the research has been conducted by using the patients as their own control.

The rationale for this is that almost all patients that seek complementary medical treatment of the holistic, existential type, has tried biomedical treatment first, and after this often several complementary and alternative types of treatment, before they came to the Copenhagen Research Clinic and entered our research protocol. In one study, the patients had their problems and suffering for 8.9 years (mean) (115). As nothing had helped these patients before they came to our clinic, we find it justified to use them as their own controls. Quite remarkably we have been able to help every second of the patients independent of the type of problem they have presented, and independent of the seriousness of the problem (126-133). In our recent protocols we have only included patients, who experienced their problem as “bad” or “very bad” on a five point Likert scale (126-133).

We have used a new research paradigm called the “square curve paradigm” (78), that documents the lasting effect of an immediate significant improvement, that comes simultaneously with the process of existential healing of the patient – the process that we call Antonovsky-salutogenesis. One of the great concerns in our project has been to cover also the philosophical (21-40), methodological (54-61) and interdisciplinary aspects (41-53,77-70,134-139) of the research, which has led to many series of papers. We have also found it extremely important to find the dimensions we need to intervene on to help the patients in many different research designs to avoid the bias from one specific research strategy. Therefore the prospective cohort design has been extremely important in our research.

The international collaboration has constantly been expanded and today about 30 different researchers have participated in the scientific work that constitutes the Open Source Research Protocol. Most importantly we have developed a unique

concept of recording the case, including measuring before and after the treatment with validated quality of life and health questionnaire, which has allowed us to monitor every side effect and unexpected event during the treatment (see table 3).

We are happy to notice that clinical holistic medicine seems to be an extremely efficient type of treatment that causes no harm without side effects (126-133,170,227-230). We also know that this kind of therapy can prevent suicide (227-230), and even side effects from biomedical, pharmaceutical treatments (170).

Table 3. Yearly itemized account of side effects and serious complications or events for the treatment with clinical holistic medicine

Itemized account 31/12 1991: No side effects or serious complications or events
Itemized account 31/12 1992: No side effects or serious complications or events
Itemized account 31/12 1993: No side effects or serious complications or events
Itemized account 31/12 1994: No side effects or serious complications or events
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Itemized account 31/12 2003: No side effects or serious complications or events
Itemized account 31/12 2004: No side effects or serious complications or events
Itemized account 31/12 2005: No side effects or serious complications or events
Itemized account 31/12 2006: No side effects or serious complications or events

Itemized account 31/12 2007: No side effects or serious complications or events

Itemized account 31/12 2008: No side effects or serious complications or events

Quality assurance

The strategy for data collection and quality assurance in the clinic for CAM (complementary and alternative medicine) and holistic medicine has been developed in the Research Clinic for Holistic Medicine, where it has been used since 2004 (168). We are using a questionnaire (QOL10) measuring global quality of life (QOL1, QOL5) (58,59,63), self-rated mental and physical health, self-rated social, sexual and working ability, self-rated I-strength, self-rated self esteem (relation to self) and relation to partner and friends. We measure before treatment, after treatment (three months) and again one year after the treatment has been completed (127).

The complete lack of side or adverse effects from ethical and professionally conducted consciousness-based medicine has been documented through a systematic review of the literature (170).

This is an extremely lucky situation, meaning that the physician, who is working with holistic medicine does not need a clinical assurance. In Denmark the Scientific Ethical Committee (Helsinki) accepted from the very beginning that our research in "quality of life as medicine" (holistic medicine) was not covered by their domain (Copenhagen Scientific Ethical Committee under the numbers (KF)V. 100.1762-90, (KF)V. 100.2123/91, (KF)V. 01-502/93, (KF)V. 01-026/97, (KF)V. 01-162/97, (KF)V. 01-198/97)

A simple way to judge the therapeutic value of a treatment is to compare the likelihood for the patient benefiting for the cure with the likelihood for the patient being harmed; this can simply be expressed as the "Number Needed to treat to Harm" (NNtH or simply NNH) over "Number Needed to treat to Benefit" (NNtB or simply NNT). The therapeutic value (TV) can thus be defined as NNH/NNT and if TV is 1 or below 1, the treatment harms more patient than it benefits.

This is of course not a fair estimate, if the benefits qualitatively are of more value than the harms –

compare surviving from appendicitis vs. the post surgical pain (TV<1 as not every patient survives, but every patients will have the pain).

To solve this problem the QALY (Quality-Adjusted Life-Years) concept has been developed, and if one converts the benefits and harms into the same global quality of life scale, they can be compared fairly (171,237,241).

Ethical aspects

The rationale for treating with clinical holistic medicine is naturally its high efficacy (see table 4) (126-133 see also 227-233,238) compared with the complete lack of adverse/side effects (126-133,170,227-230,233). Hippocrates' ethics "primum non nocera", "first do no harm", is fully respected in clinical holistic medicine, but not always adapted or possible in biomedicine (172,173,239-241). Scientific holistic medicine has had its highly developed ethics already from its first days, when it was created as a science by Hippocrates and his students (1,225,231). We have carefully considered all ethical aspects relevant for today's practice of holistic medicine and holistic sexology and have participated in the development of the ethical rules of the International Society of Holistic Health that organise holistic medical practitioners worldwide (125) (see also the society's homepage on www.internationalsocietyforholistichealth.com).

Specific ethical discussions are to be found in the papers presenting the specific holistic medical (82,109) and holistic sexological tools (84,114,115,118,120,122,124,225).

Table 4. Treatment success rate when all treatment failures (non-responders), drop-outs of the survey, and dropouts of treatment are taken as non-responders. Patient's own experience as measured self-rated with the questionnaire QOL10, and the patient is taken as cured if the state of the measured factor was bad or very bad before treatment and not bad after treatment (and one year after treatment, statistically, using the square curve paradigm). The data comes from clinical studies covering the holistic treatment of 600 patients. (CHM: Clinical holistic medicine. HMS: Holistic manual

sexology. HMS-D: Holistic manual sexology – Dodson’s method for treating chronic anorgasmia)

Physical illness (CHM) 39% (p=0.05) (126,128)
Mental illness (CHM) 57% (p=0.05) (129)
Low quality of life (CHM) 56% (p=0.05) (131)
Low self-esteem (CHM) 61% (p=0.05) (132)
Low working ability (CHM) 52% (p=0.05) (133)
Sexual dysfunction(CHM) 42% (p=0.05) (130)
Sexual dysfunction (HMS) 56% (p=0.05) (115)
Sexual dysfunction (HMS-D) 93% (p=0.05) (169)

Informed consent

The most important aspect of ethical conduct is full information to the patient and the openness of the protocol with public and scientific publications that will give every patient the possibility to see exactly what the principles, procedures, results, and side effects of the treatment are. An important aspect of communication and decision making by the patients is the selection of material for reading by the patient and also verbally explained to the patient, before initiating the treatment and making the *therapeutic contract*. The patient filling in the questionnaire and the other papers related to the treatment is legally taken as a written consent. As not every patient is able to read scientific papers, we have also published easy-to-read books on quality of life philosophy, clinical holistic medicine and the results from the research, which have been included as a part of the research protocol (209-217). In the Research Clinic for Holistic Medicine in Copenhagen, we also have one page of written patient information giving just the core information and we have put a summary of the research on our homepage (www.livskvalitet.org). For researchers we have collected the most important papers in a series of books on principles of holistic medicine (154-156).

Before treatment in holistic medicine the patient should be informed about the course of the treatment in general terms and it is recommended to also receive a written contract for the treatment signed by the patient.

Insurance

One thing that makes the practice of medicine very difficult and expensive is the need for medical insurance. This need comes from practicing medicine with a risk of harming the patient. From the very beginning the Scientific Ethical Committee accepted that holistic, consciousness-based medicine was so risk-free that we did not need insurance. This is a strong indicator of clinical holistic medicine being harmless, in spite of its efficacy. Today we know five different types of formal errors that can be made in clinical holistic medicine, but none of them are causing harm to the patients (232). Recent reviews and metaanalysis of holistic mind-body medicine and non-drug CAM in general have documented that this kind of medicine is extremely safe for the patient and even preventing suicide (227-230).

Political and financial aspects

The political and financial aspects of medical research are well known and one of the aspects that we just recently have started to explore is how to get holistic medicine accepted as valid, medical treatment in countries, where biomedicine is seen as the only medicine. We know today that many different types of pharmaceutical products are almost without therapeutic value and compared with the above-mentioned efficacy much less attractive, but strong commercial interests work against the holistic medicine and even sometimes against the researchers that develop it. We encourage everybody to analyse and discriminate carefully the facts and the fictions about the holistic physicians and researchers in holistic medicine, when stories about misconduct and abuse by such people hit the media and public authorities, as these stories might be false, fabricated, and planted by biomedical colleagues in close collaboration with the pharmaceutical industry (236).

In recent years the whole network of researchers in holistic medicine have been bothered by a diversity of hostile actions against their clinical and research practices. Rumours have often started in the media by biomedical colleges working closely together with the pharmaceutical industry, most often psychiatrists who are completely dependent on the use of

psychopharmacological drugs with false accusations of sexual abuse of patients in the media. These tactics have been common and patients have been manipulated to tell they were abused even when the physician had not touched them at all (this happened to the first author in 2005) or child pornography downloaded on computers, while the researchers were on holiday and followed by “anonymous tips” to the police. Often the researchers have been in severe shock for a long time and even ill for extended periods of time. Recently, in the Nordic countries and Central Europe, leading researchers in holistic medicine and salutogenesis have been forced to flee their country, because of continued attacks on their personal character (236).

Fortunately national authorities as well as international experts have recently started to recognize the clinical, holistic medicine as scientific and efficient. Recently the Interuniversity College, Graz, has graduated a number of therapists with the master degree on the basis of their research work in clinical holistic medicine (219-226), making Austria the first country to officially acknowledge clinical holistic medicine as a scientific complementary-medical treatment system. In USA the conflicts between biomedicine and complementary medicine (CAM including holistic medicine) has often reached the court system and the supreme court of California has in the last decade realised this and systematically judged in support of the practitioners of CAM and holistic medicine in these conflicts.

Conclusions

The Open Source Research Protocol give all interested parties – patients, physicians, therapists, researchers and politicians direct admission to all important parts of the protocol, allowing for peer review and critique of all part of it. The publication allows other researchers to be inspired and use part for their own research and practice. This is important, because the trend of chronic illness/disability in our societies has been on the increase.

We recommend that the pharmaceutical companies also start using the concept of Open Source Research Protocol; obviously if you want to keep what you are doing secret this is now attractive,

but many of the aspects of the protocol could easily be published, and this would give confidence in the industry and its products.

We encourage all public and private, national and international research organs, foundations and institutions to support the development of scientific, holistic medicine and its institutions financially and politically. The experts in the holistic medical field, especially the holistic physicians and researchers in holistic medicine, needs protection as they are often attacked by people connected to biomedicine. This presumably, because the development of holistic medicine (that in principle works though the patients consciousness and not pharmaceutical drugs), is a serious threat to strong commercial interests. We encourage the police and other public authorities to investigate all attacks from biomedicine carefully and the media not to publish stories of violent and sexual abuse of patients by the holistic physicians, therapists and researchers until these stories, that might have been fabricated and false, have been investigated by the police and found to be true.

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