

## **Meta-analysis of positive effects, side effects and adverse events of holistic mind-body medicine (clinical holistic medicine): Experience from Denmark, Sweden, United Kingdom and Germany**

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**Abstract:** About 50% of the general population has a chronic disease not cured by biomedicine. **Objectives:** Meta-analysis of holistic clinical medicine for which chronic patients were treated and outcomes were, 1) global quality of life, 2) self-rated physical/ mental health, quality of life or ability of functioning, or 3) patients felt cured for a specific disease of dysfunction. **Method:** MEDLINE and PsycINFO and specific journals were searched in January 2009. **Results:** Eleven clinical studies (18,500 participants) were identified. Positive effects: Quality of life Number Needed to Treat (NNT) = 2, physical health problems NNT = 3, mental health problems NNT = 2, sexual dysfunctions NNT = 2, self esteem NNT = 2, working/studying ability NNT = 2, anorgasmia NNT = 1, other specific sexual dysfunctions NNT = 2. Of 791 patients treated was 617, or 78.0% cured (NNT = 1). Side effects and adverse events: re-traumatization Number Needed to Harm (NNH) > 18,500; brief reactive psychosis (if mentally ill) NNH = 4,625; brief reactive psychosis (if not mentally ill) NNH > 9,250; brief reactive psychosis, all patients NNH = 9,250; depression NNH > 18,500; depersonalization and derealization NNH > 18,500; iatrogenic disturbances NNH > 18,500; minor bone fractures (ribs, hand) NNH = 4,625; serious bone fractures (spine, skull, pelvis) NNH > 18,500; suicides during or less than three month after therapy NNH > 18,500; suicide attempts during or less than three month after therapy NNH > 18,500. Suicide was prevented NNT = 1. Therapeutic value TV = NNH/NNT = 9,250. **Conclusions:** Holistic clinical medicine is an efficient complementary and alternative medicine (CAM) treatment for chronic illnesses and health related problems. Every second patient with physical and mental disorders, sexual dysfunctions, and existential problems were healed. Holistic clinical medicine had no significant side effects or adverse events.

**Keywords:** Side effects, adverse events, metaanalysis, holistic mind-body medicine, holistic clinical medicine, clinical holistic medicine

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**Submitted:** February 15, 2009. **Revised:** April 10, 2009. **Accepted:** April 22, 2009.

## INTRODUCTION

Pioneers have already documented the tremendous power of holistic medicine in improving survival and quality of life for patients with serious diseases, such as cancer and coronary heart disease (1-3). In general, the more holistic (taking as many dimensions of the human being into account, like feelings, body and sexuality) a treatment the more efficient it is in improving quality of life and sense of coherence (4-9). Such an intervention can induce salutogenesis and help to heal body, mind and existence at the same time (5,6). Another important factor is that the intervention supports the development of self-insight.

In “clinical medicine” it is a tradition that the examination and the treatment of the patient will be done in the very same process (10,11). This is very different from biomedicine, where drugs or surgery are given after careful anamnesis, examination and diagnosis. Clinical medicine is low-tech with the doctor as the tool (12) and therapy is about therapeutic talk and touch. The traditional, holistic character medicine of Hippocrates was clinical medicine that intervened on the patient’s body, mind and spirit with the intent of helping the patient to explore and find his or her own essence, character and talents (11).

Holistic medicine often uses a spiritual or shamanistic language with somewhat difficult concepts like ‘intimacy’, ‘love’, ‘trust’, ‘energy’, ‘holy madness’ and ‘crazy wisdom’ (13), where role plays, psychodrama and breath exercises are often used (14).

## HOLISTIC CLINICAL MEDICINE

During the last three decades holistic non-pharmaceutical medicine, especially body-mind medicine, has become popular again in different parts of the world (15,16) and developed into several versions with the

major being the line of clinical medicine called *holistic, clinical medicine*. In United Kingdom and Germany the physical therapist Gerda Boyesen (1922-2005) and her collaborators developed the holistic “biodynamic” body psychotherapy (17-21), in Sweden the physician Bengt Stern (1930-2002) developed holistic (“mindful”) mind-body medicine (22-26) and in Denmark several international collaborations have developed clinical holistic medicine (CHM) (27-29) and holistic sexology (30-32).

Most often the type of psychotherapy used is short-term psychodynamic psychotherapy (STPP) and the body therapy intended to support the patient’s own inner exploration of the body with subsequent release of repressed emotions from earlier traumas. Recently STPP was found superior to standard psychiatric treatment of many diseases (33-35). Physical therapy has also been efficient in 50 RCT (randomized clinical trials) regarding physical therapy for the pelvic floor for a long list of physical diseases and sexual dysfunctions (36). The idea of combining talk/conversation and touch therapy into mind/body medicine is to obtain an important synergy making the therapy more efficient. Reviews in JAMA and BMJ have indicated that mind-body medicine, often called “bodywork”, is efficient and without any side effects (15,16) and also cost-efficient (37). Holistic mind-body medicine seems to be the most efficient type of CAM (complementary and alternative medicine) (1-4) and the type most often chosen for academic courses in medical schools (38). The original Hippocratic non-drug medicine is also of this type (11). It has been found efficient for some diseases, especially chronic health conditions, where biomedicine has failed (39).

In Denmark we started our research in quality of life and holistic medicine in 1990

Table 1. *Clinical conditions that have proven treatable with holistic mind-body medicine, subtype holistic clinical medicine*

<b>Physical diseases</b>
Asthma, eczema, allergy (59,90)
Chronic infections and autoimmune diseases (63,90)
Chronic pain (musculoskeletal and inner organs) (55,56,90)
Cancer (3,57,61,90,99,100) – improving quality of life, reducing pain, and increasing survival
Coronary heart disease (1,2,90)
HIV - improving quality of life and possibly also survival (56)
Neurologic dysfunction (Brain Damage, Narcolepsy, Dementia, Intelligence Deficit) (90,101-105)
Rheumatologic disease (63,90,106)
<b>Mental disorders</b>
Eating disorders (60,68,86,91)
Low self-esteem and self confidence (60,94)
Anxiety (35,36,91)
Schizophrenia and schizotypia (69,70,83,85,91)
Borderline and other disorders of personality (35,36,69,70,85,91)
Depression and hypothyria (mood and emotional disorders) (69,70,91)
Alcoholism, ludomania, other types of dependency (62,91)
Children and adolescence with autism or behavioural disturbances including ADHD (53,60,93)
Post traumatic stress and other sequelae of violent or sexual trauma like rape and incest (24,25,40,55,60,64,66,76,77,91,98)
<b>Sexual and gynaecological problems</b>
All major sexual dysfunctions and vulvodinia (47,54,55,80,81,84,85,92)
Adolescent gynaecological problems (40,55,60,64,66,76,77,92,98)
Couples therapy (54,92)
<b>Existential and working/studying problems</b>
Poor quality of life and existential problems (24,25,68,93)
Low sense of coherence (24,25,93)
Stress, life crises, burn out syndromes – general rehabilitation (24,25,68,93)
Low working/studying ability (68,95)

at the Quality of Life Research Center, University Hospital, Copenhagen and in 1997 we established the Research Clinic for Holistic Medicine. From 1997-2006 we developed interventions for about 100 of the most common physical and mental diseases, sexual dysfunctions and existential problems (40-87) (see table 1). CHM develops the talents of the patient the patient, especially ability to love, understand, and help him or her to step into physical, mental, spiritual, and sexual

character; CHM is therefore basically personal development (24). We also call it “quality of life as medicine” (88). Recently the research protocol for CHM (87) and several papers on effects and side effects of holistic clinical medicine have been published (4,15,16,21,26,89-95).

With around 18,500 patients in four countries now treated with holistic clinical medicine we believe that it is time to make a meta-analysis of the effects, side effects and adverse events of this kind of holistic

mind-body medicine. We presume that the types of holistic medicine analysed here are similar to every type of holistic medicine that 1) uses the traditional tools of holistic medicine (11-14), 2) employs the five fundamental principles of healing identified in the European CAM Master Program at Interuniversity College, Castle of Seggau, Graz (96,97) and 3) attempts to avoid the errors that destroy therapeutic progress (97). A *cure* prerequisites *healing* (salutogenesis) (5,6) and must be discriminated from the mere *improvement of symptoms* of disease or poor thriving, which is often the aim of pharmaceutical biomedicine.

#### METHODS

As it seems that holistic clinical medicine is an effective type of complementary and alternative medicine (CAM), because patients are supported in self-exploration and existential healing (salutogenesis) by talk and touch-therapy, we have only included these CAM methods in the present study. Our objective was therefore a meta-analysis of all studies of holistic clinical medicine where chronic patients were treated and outcome was: 1) global quality of life or survival, or 2) self-rated physical or mental health, quality of life or ability of functioning, or 3) patients felt cured for a specific disease or dysfunction. Based on these data NNT and NNH were calculated for a number of outcomes.

#### Search strategy

MEDLINE and PsycINFO and the specific journals of CAM (J Compl Integr Medicine, J Altern Med Res, Evid Based Complement Alternat Med, Complementary Health Practice Review, Transcultural Psychiatry) were searched. The search was conducted in January 2009. We have also collected the data on side effects and adverse events from

the Copenhagen clinic for this study.

#### Selection criteria

Clinical trials on chronic patient serving as their own control, with dichotomized data. Positive effects: documented by high quality outcomes documenting that the patients were actually cured: global quality of life, survival, self-assessed physical and mental health, sense of coherence, self-assessed ability of functioning and self-reported cure from severe physical or mental disease. Negative effects: documented by screening of all treated patients for all most important side effects and adverse effects. We included only studies with dichotomised data. To make this review, we therefore had to exclude many of the most successful studies of mind-body medicine (1,2,3,24,25,99,100). We excluded the effects that are not seen as side effects in holistic clinical medicine, i.e. hypomania and developmental crises (89).

#### Data collection and analysis

Two review authors independently extracted the data and assessed trial quality. Meta-analysis was considered for trials with comparable key characteristics.

#### Prioritized outcomes

We have prioritized the outcomes according to the tradition in evidence-based physical therapy (36) and only included excellent and good outcomes. The outcomes that best document a curative treatment effect are the subjective factor "self-rated global quality of life" and the objective factor "survival". Good but not excellent documentation is according to Bø et al (36) self-rated improvement of physical and mental health and the ability of social, sexual, and working/studying functioning. Fair outcomes are objective data on global aspects of health and functioning. Poor outcomes

Table2. *Hierarchy of Outcomes – most valuable to least valuable as documentation for cure (based on (89))*

Excellent Self-assessed global QOL Survival QALY (survival time x global OQL)
Good Self-assessed sense of coherence Self-assessed physical and mental health Self-assessed ability of functioning (social, sexual, working/studying) Self-reported cure from experienced severe, chronic physical or mental disease.
Fair Objectively measured physical and mental health Objectively measured ability of functioning (social, sexual, working/studying)
Poor Objectively measured local aspects of health (i.e. coughing, motility etc.) Health related QOL Patient satisfaction

are objective measures of minor aspects of health, hybrid measures as “health-related quality of life” without clear meaning (107), and patient satisfaction that might not be related to improvement of health at all, but to aspects like hospital food, indoor decoration, dressing and professional behavior of staff (see table 1).

Table 2 obviously has an ethical dimension and this is highly rational. The most important aspect of life is *global quality of life* – meaning, happiness and life satisfaction. *Survival* is not of value, if there is not quality of life, so survival comes second. *Sense of coherence* seems to be causal to health and happiness (5,6), so this comes third. *Self-assessed health* is known to be the best predictor of future survival (108-113) so this comes fourth. *Ability of functioning* is what, when well used, creates value, happiness, and health, so this comes fifth. *Objective measures of health* are, in spite of being in high

regard amongst physicians and politicians, often of little value to the patient (108-113). Even less worth for patients are the *objective measures of ability, or single aspects of health*, that correlate poorly to global quality of life (114).

The soft data have been shown to be hard to deal with: “Self-evaluations of health status have been shown to predict mortality, above and beyond the contribution to prediction made by indices based on the presence of health problems, physical disability and biological or life-style risk factors” (112). The hierarchy in table 2 is thus well founded in epidemiological science.

#### **Documentation of a curative effect**

Documentation of efficient healing (salutogenesis) is reliable and least biased in studies with chronic patients that for at least a year have not improved spontaneously or treated with other methods, so we have selected these studies. As non-drug CAM use the placebo effect as part of the intervention, we cannot use studies with placebo control.

Such studies give an artificially small effect of treatment. We have therefore only included studies where a curing effect or at least a process of salutogenesis (existential healing) was documented, either through patient self report or through the documented normalization of sense of coherence (SOC) or through the documented improvement of quality of life, physical or mental health, or ability of social, sexual, or working/studying functioning. We wanted to be sure that the documentation had clinical relevance and only included the most important outcomes from group 1-7 in table 2.

#### **Non-drug CAM**

We focused on non-drug CAM and excluded studies with other kinds of CAM intervention, like for example aromatic oils. We also excluded mind-body medicine that was not clinical medicine, like traditional acupuncture and homeopathy (see (4) for a CAM systematic approach).

#### **The patient's health status**

We know that most of the patients treated in Denmark and Sweden have a level of sense of coherence, quality of life and self-evaluated health that is similar to the average chronically ill patient (23). We know less about the health status of the patients, but know that many of the patients were treated in spite of having severe mental and physical illness. We have estimated from this that half the patients had a mental disorder. Only studies in English were included. The many different names used in CAM for holistic clinical medicine makes it likely that many good, relevant studies were excluded, because they were not recognized in the search.

## **RESULTS**

Table 3 shows that one in two patients was cured from physical and mental disorders, sexual dysfunctions, and existential problems within one year. Holistic, clinical medicine seems to be equally effective on physical, mental, sexual, and existential problems and diseases, which is quite remarkable. This means that every patient can be treated with basically the same method: Self-investigation supported physically, mentally and spiritually.

Table 4 shows the findings of side effects and adverse events from the treatment of 18,500 chronic patients in United Kingdom, Germany, Sweden and Denmark. We found no significant side effects or adverse events from holistic, clinical medicine. Rare, minor and temporary side effects were bone fractures, presumably in the elderly population and brief reactive psychosis for mentally ill patients. The latter, often called a developmental crisis is in holistic medicine believed to be an integral part of the treatment, and a necessity for healing and therefore not a side effect or adverse event, nor a complication.

As about half the patients according to the estimates of the therapist had a major or minor mental disorder we find that the sum of all minor and temporary side effects and adverse events for mentally ill patients were 0.044%, or NNH (total) = 3,083; for patients without mental disorders the number was 0.033%, or NNH (total) = 4,625. The sum of all lasting side effects and adverse events were for both mentally ill and not-mentally ill patients 0.00%, or NNH(total) > 18,500. In about 80 cases an intended suicide was seemingly prevented (NNT = 1).

## **DISCUSSION**

Regarding the positive results we also need data from the treatment of patients with a variety of concrete diseases like cancer or coronary heart disease. Unfortunately we have not found the data presented of a dichotomize

Table 3. *Positive effects of holistic clinical medicine. Outcomes: Self-rated, dichotomous data on most important outcomes. Patients are cured or normalised when measured before and after treatment on a five point Likert scale (improved from “4: bad” or “5: very bad” to “3: neither good nor bad”, “2: good” or “1: very good”). \*) Results were stable and seemed to improve in the long term follow up one year after treatment (115). All results are statistically significant ( $P < 0.05$ )*

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**Self-rated QOL-Health-Ability before and after**

0NCuredCured (%)NNT

QOL (93)0553156.4%2\*)

Physical health (90)0311238.7%3\*)

Mental health (91)0543157.4%2\*)

Sexual functioning (92)0482041.7%2\*)

Self esteem (94)0432660.5%2\*)

Working/studying ability (95)0402152.5%2\*)

Cured, All patients: 27114152.0%2\*)

**Self-evaluated: cured or not cured - specific sexual problems**

Anorgasmia (32)500465 93%1

Sexual dysfunction (77) 02001155%2

Cured, all patients52047691.5%1

**All patients in total79161778.0%1**

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type easily included in this type of review. This does not mean that it cannot be done; the next natural step is to get the raw data from the researchers and make the same analysis on these data. In spite of the relatively few data, we find that there is sufficient data to make a robust conclusion on the efficacy of holistic clinical medicine.

We have found an almost complete lack of side effects and adverse events. It is difficult to believe the tables, when we are accustomed to the NNH of 2,3,4 and 5 of biomedicine. For instance how come no patients became depressed when they had to confront their own touch inner reality of repressed trauma? Is this not depressing? In clinical medicine, the

attitude is that the problem, the depression, is already there. To explore it is to heal. So the holistic philosophy of CAM solves this problem elegantly. What about implanted philosophy? Self-exploration is removing implanted philosophy, not planting it. So systematically the therapy works against the negative effects that could be seen as side effects. Of course we have wondered if the way data were collected has contributed to an overly positive view of CAM, but we have reached the conclusion that there really were very few side effects, when the intervention consisted of talk/conversation and touch with the intent of support, help and healing.

The most serious problem with this research is if we can trust the data sources, as we know that physicians and therapists could

Table 4. Side effects and adverse events of CHM modified after (89). (N: number of patients in thousands; SE/ AE (Side effects/ Adverse events): fraction of patient with side effects or adverse events in percent) (\* these patients were mentally ill before treatment)

	Denmark (87,90-95)		Sweden (26)		UK (21)		Germany (21)		All patients		NNH
	N	SE/AE (%)	N	SE/AE (%)	N	SE/AE (%)	N	SE/AE (%)	N	SE/AE (%)	
Re-traumatization	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500
Brief reactive psychosis, mentally ill	1000	0.00	4000	0.05	6000	0.00	7500	0.00	18.500	0.011	= 4,625
Brief reactive psychosis, Not mentally ill	1000	0.00	4000	0.05	6000	0.00	7500	0.00	18.500	0.011	>9,250
Brief reactive psychosis, all patients	1000	0.00	4000	0.05	6000	0.00	7500	0.00	18.500	0.011	= 9,250
Depression	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500
Depersonalisation and derealization	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500
Implanted philosophy	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500
Iatrogenic disturbances	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500
Negative effects of hospitalisation	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500
Minor bone fractures (ribs, hand)	1000	0.00	4000	0.10	6000	0.00	7500	0.00	18.500	0.022	=4,625
Serious bone fractures (spine, skull)	1000	0.00	4000	0.10	6000	0.00	7500	0.00	18.500	0.022	>18,500
Suicides during or < 3 mos after therapy	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500
Suicide attempts during or < 3 mos after therapy	1000	0.00	4000	0.00	6000	0.00	7500	0.00	18.500	0.00	>18,500

try to hide if something went wrong. The data on side effects and adverse events in case records were therefore not always as reliable as one could wish. Errors are often made in holistic therapy, but they have only the consequence that the patients are not cured; even the most serious formal error is usually not causing harm (97).

Most fortunate, the treatments at the three major therapeutic centers we have studied have been under a strong, central leadership where honest feedback and acceptance of errors and mistakes have been a part of the culture. We therefore have reason to believe that the data presented is of good quality. Our

findings are also in line with what researchers have presented in reviews in JAMA (16) and BMJ (15) and the data from the three centers are giving accurately the same picture. A recent review of side effects of non-drug medicine reviewed almost 2,000 articles and found that non-drug CAM in general had no side effects (NNH > 64,000) (4). This is also in accordance with the presented data.

The most important role of holistic clinical medicine in the future might be in replacing the modern biomedical psychiatry and return to traditional psychiatry, as the antipsychotic drugs are more likely to harm than to help patients (116). The Danish National Board of Health investigated sudden unexplained deaths among mental patients and found a large



spontaneous over-mortality of patients on antipsychotic drugs (117). A Swedish study found that antipsychotic medicine often made patients depressed and "feeling like a zombie" (118). A recent meta-analysis of chlorpromazine showed that this drug harmed one in two and only helped one in four (119). Finally it is well-known that suicides happen in connection with hospitalization, treatment and discharge from mental hospitals and especially during the first period with medication (119). In Denmark 13% of schizophrenic patients, who almost always are treated with antipsychotic medicine, commit suicide in long follow-up (121). As survival and cure are the most important outcomes (see table 1) this indicates that holistic medicine is better than pharma-ceutical medicine with high NNT numbers (122) even for the mental patients.

### CONCLUSIONS

Non-pharmaceutical CAM treatment with holistic mind-body medicine of the subtype holistic clinical medicine (in Denmark often called "clinical holistic medicine", in Sweden "mindful mind body medicine" and in United Kingdom and Germany often called "holistic body psychotherapy") has been tested on many types of physical and mental illnesses, sexual dysfunctions and other clinical conditions and in general found to be efficient. For physical disorders we found NNT = 3, for mental disorders NNT = 2, for sexual dysfunctions NNT = 1, and for existential problems we found NNT = 2. For all patients we found NNT = 1. Holistic clinical medicine has no significant side effects or adverse events (NNH > 18,500). We can therefore recommend holistic clinical medicine to be the medical treatment of first choice

for chronic conditions, the second choice being a biomedical pharmaceutical treatment to treat the symptoms, if holistic medicine fails to cure.

### ACKNOWLEDGMENTS

The Danish Quality of Life Survey, Quality of Life Research Center and the Research Clinic for Holistic Medicine, Copenhagen, was from 1987 till today supported by grants from the 1991 Pharmacy Foundation, the Goodwill-fonden, the JL-Foundation, E Danielsen and Wife's Foundation, Emmerick Meyer's Trust, the Frimodt-Heineken Foundation, the Hede Nielsen Family Foundation, Petrus Andersens Fond, Wholesaler CP Frederiksens Study Trust, Else and Mogens Wedell-Wedellsborg's Foundation and IMK Almene Fond. The research in quality of life and scientific complementary and holistic medicine was approved by the 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, and further correspondence. We declare no conflicts of interest.

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