

## Effect, side effects and adverse events of non-pharmaceutical medicine. A review

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**Abstract:** Non-drug medicine has become popular with patients and physicians worldwide as it is realised that CAM (complementary and alternative medicine) is efficient for physical and mental diseases, sexual dysfunctions and existential problems without the side effects of pharmaceutical medicine. We have identified five healing principles related to seven classes of CAM to identify efficient types of treatments. Based on clinical studies where the patients act as their own control we have estimated: Class 1-CAM (Chemical CAM) NNT $\geq$ 10, NNH=25; Class 2-CAM (Physical therapy but not high-energy manipulations): NNT=2-4, NNH>64,000, Class 3-CAM (Psychotherapy): NNT=3, NNH>64,000; Class 4-CAM (Spiritual therapy) NNT=10, NNH>64,000; Class 5-CAM (Mind-Body medicine): NNT=2, NNH>64,000; Class 6-CAM (Holistic medicine): NNT=2, NNH>64,000, Class 7-CAM (Shamanism with hallucinogenic drugs) NNT=1, NNH $\geq$ 1000. We compared this to Biomedicine: NNT=5-50, NNH=1-4. Efficient CAM cures exist for subjectively poor physical health (NNT=2), coronary heart disease, (NNT=2-3); cancer (QOL NNT=2, survival NNT=7); chronic pain (NNT=2-3), subjectively poor mental health (NNT=2-3), schizophrenia (NNT=3-5), major depression (NNT=2-3), anxiety (NNT=3), social phobia (NNT=3), subjectively poor sexual functioning (NNT=2); male erectile dysfunction (NNT=2), female orgasmic dysfunction (NNT=1); female lack of desire (NNT=2), female dyspareunia (NNT=2); vaginismus (NNT=2), vulvodynia (NNT=2); infertility (NNT=6); subjectively poor quality of life (NNT=2); sense of coherence (NNT=2-3); suicidal prevention (NNT=1)L; low self esteem (NNT=2); poor working ability (NNT=2). CAM seems cost-efficient. We recommend that nations with nationalised medicine shift to CAM as a primary type of medicine provided.

**Keywords:** Integrative medicine, complementary and alternative medicine, side effects

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### INTRODUCTION

There has been an increasing awareness of lack of efficiency and high incident of side effects and adverse events in pharmacological medicine, which has created a renewed interest in the classical non-pharmacological medicine. The western tradition of scientific medicine started in Greece 400 BCE, where the physician Hippocrates and his students had a hospital on the island of Cos. The original writings are preserved as the Corpus Hippocraticum (1). The medicine of Hippocrates was holistic as it intervened on all aspects of man - body, mind and spirit - at the same time. For over 2000 years this medicine was practiced all over Europe almost completely without the use of drugs. Its fundamental idea was to induce salutogenesis (2,3)—i.e. healing of the patients whole life and existence—by

helping the patient to increased self-insight. This was done through the concept of talents and character. When the patient understood him or herself and was able to use all talents—bodily, mental and spiritual—to create value to self and others, he or she recovered the *sense of coherence* (SOC), and improved quality of life (QOL), health, and ability (4). This route of “quality of life as medicine” or personal development for health is the fundamental principle of CAM today (5).

### NON-DRUG MEDICINE

As natural science, especially chemistry, developed a long list of pharmaceutical drugs that became available to the physician in the 20<sup>th</sup> century, many medical schools accepted biomedicine as the dominant type of medicine, while other kinds of medicine was defined as

Table 1. *The seven levels of integrative medicine*


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Level 1:	CAM
Level 2:	Non-drug CAM
Level 3:	Mind Body Medicine
Level 4:	Mind Body Medicine without high energy manipulation
Level 5:	Holistic Mind Body Medicine
Level 6:	Holistic Mind Body Clinical Medicine = Holistic Clinical Medicine
Level 7:	Hippocratic Character Medicine, Clinical Holistic Medicine, Holistic Manual Sexology, Vaginal Acupressure, Osho's Psychic Massage, Grof's Holotropic Breath Work, Boyesen's Holistic (Biodynamic) Body Psychotherapy, Stern's Holistic (Mindful) Mind-Body Medicine, Ornish's Holistic Heart Cure, Levenson's Holistic Cure for Cancer etc.

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Table 2. *Classification of CAM into seven principal classes according to area of intervention (cells, body, mind and/or spirit)*


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<b>Chemical medicine (working on the cellular level).</b>
A. <i>Chemical biomedicine</i> (pharmaceutical medicine using highly bioactive often toxic drugs)
B. <i>Chemical alternative medicine</i> (alternative diets, herbal medicine with mildly bioactive often nontoxic drugs: low fat diet, herbal tea, flower medicine, aroma therapy, color therapy, crystal healing, "orthomolecular medicine", "vibrational medicine", "quantum medicine" etc.)
<i>Body-medicine</i> (i.e. Swedish massage, Thai-style massage, no-talk acupuncture/acupressure, reflexology, physical therapy, physiotherapy, spa, sauna, dance therapy)
<i>Mind-medicine</i> (i.e. psychotherapy (psychodynamic, cognitive, gestalt, primal etc.), psychoanalysis, meditation, integral psychology, positive psychology, no-touch sexology, couching, healing music, psychodrama, dream work, art therapy)
<i>Spirit-medicine</i> (philosophical interventions, energy medicine, prayers, spiritual healing (i.e. "Reiki healing", "aura healing", "DNA-activation", theosophical "astral journeys")
<i>Mind-body medicine</i> (acupuncture/acupressure with talk, chiropractics, homeopathy, manual sexology, body-psycho-therapy, Reichian bodywork, Neo-Reichian bodywork, Alexander technique, Rosen therapy, ergo therapy etc.)
<i>Holistic</i> (body-mind-spirit/existential) medicine (holistic medicine, clinical medicine, clinical holistic medicine, holistic body-psychotherapy, holistic bodywork, the sexological examination, holistic mind-body medicine, biodynamic body psychotherapy, tantric bodywork and massage, holistic sexology, Native American drug-free rituals).
<i>Chemical-body-mind-spirit medicine</i> (Shamanism with peyote, Ayahuasca, magic Psilocybin mushrooms etc.), Grof's LSD-psychotherapy, MDMA psychotherapy etc.)

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"alternative". Table 1 gives a classification of non-drug medicine as revision of an earlier classification (6). A more thorough hierarchy can be made as the seven levels of integrative medicine (see table 1). Only the path that leads to the classical Hippocratic Character Medicine and related methods is shown.

Clinical medicine can be seen as the use and exploration of the patient with the patient as medicine (4). High energy manipulations (i.e. in chiropractic) are associated with side effects and therefore not used in holistic medicine (7). We have found it practical to keep it simple and suggest that the classification in table 2 is generally used.

#### HEALING PRINCIPLES

The most impressive aspect of non-drug medicine is that it offers healing—or you could say a true cure—for many diseases, as it addresses the causes of the diseases. This approach stands in contrast to most biomedical interventions, where the drugs modify only the symptoms of disease. The Interuniversity College, Graz in Austria has collected all existing knowledge on CAM (complementary and alternative medicine) from 40 academic institutions in Europe and made the Masters degree program EU-MSc-CAM (8-15). The body of knowledge has crystallised five central principles of healing, which are used in CAM (see table 3).

Table 3. *The five central principles of healing in non-drug therapy (i.e. clinical medicine, holistic medicine, clinical holistic medicine, and CAM) from the curriculum of the EU-master in CAM*


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1. The principle of salutogenesis: the whole person must be healed (existential healing), not only a part of the person. This is done by recovering the *sense of coherence* (2,3), character and purpose of life of the person.
2. The similarity principle: only by reminding the patient (or his body, mind or soul) of what made him ill, can the patient be cured. The reason for this is that the earlier wound/trauma(s) live in the subconscious (or body-mind).
3. The Hering's law of cure (Constantine Hering, 1800-1880): that you will get well in the opposite order of the way you got ill.
4. The principle of resources: only when you are getting the holding/care and support you did not get when you became ill, can you be healed from the old wound.
5. The principle of using as little force as possible (*primum non nocere* or first do no harm), because since Hippocrates (460-377 BCE) "declare the past, diagnose the present, foretell the future; practice these acts. As to diseases, make a habit of two things – "to help, or at least to do no harm" has been paramount not to harm the patient or running a risk with the patient's life or health (1).

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Table 4. *NNT and NNH numbers of the seven CAM classes estimated from clinical studies (with chronic patients, see text) (21-44,53-67).*

	Short term effect (0-6 month)	Long term effect (6-24 month)	Side effects and adverse events
Class 0-Biomedicine	NNT=5-50 (16)	NNT=10-100	NNT= 1-4
Class 1-CAM (Chemical CAM)	NNT $\geq$ 10	NNT $\geq$ 20	NNH=25 (allergy)
Class 2-CAM (Physical therapy)	NNT=2-4	NNT=6	NNH>64,000
Class 3-CAM (Psychotherapy)	NNT=3	NNT=6	NNH>64,000
Class 4-CAM (Spiritual therapy)	NNT=10	NNT=20	NNH>64,000
Class 5-CAM (Mind-Body medicine)	NNT=2	NNT=4	NNH>64,000
Class 6-CAM (Holistic medicine)	NNT=2	NNT=1-2*	NNH>64,000
Class 7-CAM (Shamanism w. drugs)	NNT=1	NNT=1	NNH>1000

\*The effect of clinical holistic medicine and similar medical systems seem to continue to increase though time (53). (NNT: Number Needed to Treat. NNH: Number Needed to Harm).

#### QUALITY OF DATA

In CAM we cannot control for placebo as CAM use the placebo effect for the cure. We therefore use studies, where chronic patients acted as their own control. The studies are often giving non-dichotomised data making it necessary to estimate a NNT (number need to treat). These estimates are base on the size of the total effect and the statistical data presented. Often the estimate is not accurate; a NNT=3 could be 2 or 4. In this review, when we make a general evaluation of the efficacy of CAM, this is of limited importance to the big picture. We will accept that sceptical readers add 1 to all the presented NNTs. We have given the estimated NNTs

and NNHs (number needed to harm) that we believe are correct. We need more research to estimate the NNTs accurately. We find the NNHs to be very accurate. The NNTs and NNHs of general biomedicine come from the medical industry and are believed to be correct (16).

#### EFFICACY OF CAM-THERAPY ACCORDING TO CLASS

As a rule of thumb, the therapy is more efficient and NNT therefore smaller, when more aspects of the patient (body and also mind) is influenced by the therapy (16). The trend is therefore to combine therapies from different areas into a more holistic therapy (i.e. physical therapy and psycho-

therapy into mind-body medicine, and mind-body medicine with spiritual intervention i.e. mindfulness, into clinical holistic medicine). The primary focus of successful intervention seems to be body and mind (Class 2,3,5) The intervention might be enhanced by spirituality i.e. a holistic philosophy (Class 6). The most effective healing with the most lasting results seems peculiarly to happen in shamanistic healing rituals with hallucinogenic drugs (Class 7), but we assume that for cultural reasons this is of little interest to contemporary physicians. In general the most efficient CAM methods we have today helps one in two of the patients (NNT=2) (17-26). At the same time most researchers seem to agree that these methods have no side effects or adverse events (7,27-30).

If one looks at the long term results, the spiritual and philosophical dimension of the intervention seem to be important; a lasting result seems to need a change in consciousness and attitude. This is why it is generally suspected that the real active component in CAM treatment that give improvement of health, quality of life and ability (salutogenesis) (1,2,3) is the development of the patients' consciousness. Examples of treatments from the seven classes:

- Class 1: Flower medicine (31) and diets (32) has a NNT=10-∞.
- Class 2: Physiotherapy (26) has a NNT=2-4 for a number of diseases.
- Class 3: Psychodynamic psychotherapy for example with schizophrenia (22,33) with NNT=3
- Class 4: Prayer (see 34). Effect size unknown.
- Class 5: Body psychotherapy (35,36) has NNT=2.
- Class 6: Clinical holistic medicine (37-44) has NNT=2
- Class 7: LSD-psychotherapy (45-52) has NNT=1.

The Hippocratic character medicine was holistic and it seems that many types of problems could be treated. Interestingly there was only one cure: To help the patient to gain self-insight and step into character. Table 5 shows the efficacy of different CAM-cures for different diseases, dysfunctions etc.

In non-pharmaceutical CAM we cannot meaningfully randomize to placebo, as all interventions presumably are on the patient's consciousness and therefore in essence placebo cures. If you give strychnine to rats and randomise to control with strychnine all the rats will die, but you can conclude that the drug is not poisonous. If you randomize massage to psychotherapy you do the same in principle. Therefore you have to study patients with chronic conditions you know will not disappear by themselves and use the patient as their own

control. In acute disease you must randomise, because you need to know the efficacy of a treatment in a situation where most patients heal spontaneously.

#### SIDE EFFECTS AND ADVERSE EVENTS

Drugs are known to have many and serious adverse effects and events, while CAM is known to have very few (19,20,27,34). Table 5 present data from 18,500 patients treated with the most intensive holistic medicine (7,28,29,37-44,63). A review of the literature estimated in accordance with this NNH=65,000 for all non-drug therapies in general (7).

Table 5. *Estimated NNT-numbers of the CAM treatments of physical, mental, existential and sexual health issues and working disability (mostly based on clinical studies using chronic patients as their own control, see text)*

CAM for physical health	
Subjectively poor physical health	NNT=3 (17,18,39)
Coronary heart disease	NNT=2-4 (65,66)
Cancer (QOL, survival)	NNT=2,7 (67,68,69)
Chronic pain	NNT=2-3 (20,39)
CAM for mental health	
Subjectively poor mental health	NNT=2-3 (17-20)
Schizophrenia	NNT=3-5 (22,33,)
Major depression	NNT=2-3 (58-60)
Anorexia Nervosa	NNT=3 (58-60)
Anxiety	NNT=3 (58-60)
Social phobia	NNT=3 (58-60)
CAM for sexual dysfunctions	
Subjectively poor sexual functioning	NNT=2 (41,61,62,63)
Male erectile dysfunction	NNT=2 (62)
Female orgasmic dysfunction	NNT=1 (63)
Female lack of desire	NNT=2 (61,62)
Female dyspareunia	NNT=2 (26,44,62)
Vaginismus	NNT=2 (26,62)
Vulvodynia	NNT=2 (26,44,62)
Infertility (close ovarian tubes)	NNT=6 (57)
CAM for psychological and existential problems	
Subjectively poor quality of life	NNT=2 (35,36,42)
Sense of coherence	NNT=2-3 (35,36)
Suicidal prevention (with decisions)	NNT=1 (29)
Low self esteem	NNT=2 (43)
CAM for low working ability	
Subjectively poor working ability	NNT=2 (38)

Table 6. *Side effects and adverse events caused by physical therapy, psychotherapy, mind-body medicine, and holistic therapy (body-mind-spirit intervention) (based on 18,500 patients) (modified after (7))*

	Number needed to harm (NNH)
<b>Psychotherapy</b>	
1. Re-traumatization	NNH>18,500
2. Brief reactive psychosis	NNH>18,500
3. Depression (and hypomania)	NNH>18,500
4. Depersonalisation and derealization	NNH>18,500
5. Implanted memories and implanted philosophy	NNH>18,500
6. Iatrogenic disturbances	NNH>18,500
7. Negative effects of hospitalisation	NNH>18,500
8. Suicide and suicide attempts	NNH>18,500
<b>Bodywork</b>	
1. Brief reactive psychosis	NNH>18,500*
2. High-energy manipulations of the body in chiropractics can cause damage to the spine of vulnerable patients.	NNH>18,500
3. Damage to the body if the therapists are unaware of illnesses or for example fractures.	NNH> 4,500
4. Suicide and suicide attempts	NNH>18,500
<b>Psychotherapy and bodywork/ holistic medicine (i.e. manual sexology like the sexological examination, clinical holistic medicine (CHM), and holotropic breath work)</b>	
1. Brief reactive psychosis	NNH>18,500
2. Implanted memories and implanted philosophy	NNH>18,500
3. (Developmental crises)	NNH>18,500
4. Suicide and suicide attempts	NNH>18,500

\* Found to be NNH=1000 (estimated) if patients have been mentally ill before (29)

## DISCUSSION

The standard of documentation used for the pharmaceutical industry is not applicable in CAM. In CAM chronic patients must serve as their own control. In this review we have looked at these studies and we found that CAM has no side effects or adverse events and the intervention able to help patients with many sorts of physical and mental diseases, sexual dysfunctions, existential and psychological problems. Also low working ability was efficiently solved with CAM. We have observed that only CAM involving an intervention on body and mind were efficient and the combination into mind-body medicine seems to be the best solution. The addition of a holistic philosophical framework might increase efficacy further. The most efficient treatment seems to be shamanistic ceremonies with hallucinogen drugs, but we believe these rituals to be irrelevant to modern medical practice, although still of academic interest.

The quality and efficacy of the provided CAM varied with the number of healing principles used – or

put in another way with the number of formal errors being made in the therapy (70). To ensure a high quality of service we suggest combining efficient training and supervision of therapists with the use of a system for quality assurance (71). The same type of CAM can be extremely efficient or totally inefficient depending on the therapist's ability to bond, give holding and processing to the patient (70).

Researchers have suggested that the placebo effect, the health-improving change in the patient's consciousness, which is the principal core effect of CAM, is nonexistent (72). It is important to remember that the studies used for this analysis all have intended to document effect of a treatment in contrast to a placebo treatment; the placebo cure was therefore intentionally designed to have the smallest possible positive impact on the patients' consciousness and it is most unfortunate that the researchers forgot to adjust for this fact in their analyses, making their conclusions incorrect; Kaptchuk et al (73) found the most important factor was a supportive patient-practitioner relationship.

The authors concluded that “the patient-practitioner relationship is the most robust component.” And we know that this dimension is intentionally eliminated in almost all industrial studies giving a strong bias I favor of the drugs. We know today that just using an active, poisonous drug boost the placebo effect enough to destroy the effects of a drug i.e. antidepressants (74).

For diseases and health problems non-pharmaceutical medicine can be the cure of choice. We have observed that its antibiotic and antiparasitic potentials have not been explored. We would also expect CAM to be efficient in the treatment of HIV, but this remains to be clinically tested (75).

CAM is cost-efficient (19,20,76). The biggest challenge of CAM today is how it can be turned into a comprehensive science. Most fortunate the European masters program has already done an important job here, crystallising the fundamental principles of healing in CAM, and accordingly the errors that can be made in CAM. CAM has become a science and we recommend all medical schools to include non-pharmaceutical medicine, especially the classical Hippocratic type, in the medical curriculum. We will be more than happy to assist any academic institution that needs our help in this process. We must also recommend that all nations with nationalised medicine shift to CAM as a primary type of medicine provided, with biomedicine only given to the patients that cannot be helped with CAM.

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