

Journal of Alternative Medicine Research

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Journal of Alternative Medicine Research

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Editorial

Alternative medicine is tested unfairly against placebo. CAM is offering highly efficient placebo cures that should be tested with respect for its nature

**Søren Ventegodt, MD, MMedSci, EU-
MSc^{*1,2,3,4,5} and Joav Merrick, MD,
MMedSci, DMSc^{5,6,7,8}**

¹Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark;

²Research Clinic for Holistic Medicine

³Nordic School of Holistic Medicine, Copenhagen, Denmark;

⁴Scandinavian Foundation for Holistic Medicine, Sandvika, Norway;

⁵Interuniversity College, Graz, Austria;

⁶National Institute of Child Health and Human Development;

⁷Office of the Medical Director, Division for Mental Retardation, Ministry of Social Affairs, Jerusalem, Israel;

⁸Kentucky Children's Hospital, University of Kentucky, Lexington, United States

Introduction

Complementary and alternative medicine (CAM) or integrative medicine is being tested scientifically and it seems that CAM is not passing the test (1). Funds are withdrawn and homeopathic hospitals closed down. Science is doing its job: Discriminating between good and bad, between efficient and inefficient. And this is exactly why we are so fond of science.

But there are problems. Imagine for a moment that it primarily is our consciousness that is responsible for our quality of life, health and general ability of functioning. Consciousness meaning our beliefs, our self-esteem, our attitude to life, self, other people, love, sex etc. This idea, how farfetched and un-materialistic as it might seem, is actually in accordance with new science (2), as well as in accordance with the whole tradition of psychoanalysis (2,3) and psychodynamic psychotherapy (4-6). Leichsenring and Leibing (6) have recently documented in a metanalysis done after the Cochrane protocol that psychodynamic therapy is more efficient than the usual biomedical treatment as usual for most of the psychiatric diseases. It thus seems that placebo treatment is the optimal treatment even for the most difficult and chronic of illnesses.

If that is the case, most of what works in medicine is the placebo effect in some way or another, placebo meaning an "induced change in consciousness that influence the patient's health positively". We have tested this hypothesis with five

* **Correspondence:** Søren Ventegodt, MD, MMedSci, MSc, Director, Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark. Tel: +45-33-141113; Fax: +45-33-141123; E-mail: ventegodt@livskvalitet.org

groups of patients with chronic mental, physical, sexual, existential (low self-esteem, poor quality of life) health problems, that could not be alleviated with pharmaca and quite surprisingly found that just by intervening directly on the patient's consciousness every second patient's experience of being ill changed into being not-ill, in only 20 hours of therapy and only one year (7-12). So it might be that it actually works, at least with some patients.

If it is the case that placebo is the real factor making the difference for the patients, homeopathy and herbal treatments should most definitely NOT be tested against placebo, because this will artificially annulate the positive effect of the treatment. One should use chronic patients for the test, and the patient should be his or her own control. Testing the patient before and after, and then aging nad living long after that seems to be an extremely efficient and scientific way to document the effect of a placebo-based cure (13).

Please be fair

Ladies and gentlemen, please be fair. Science is not fair in itself. It must be used fairly. To shut CAM down, because it is no better than placebo is killing the only medicine that might be working in the end, as we know by know that most chronic health problems cannot be solved with drugs. That is exactly why they are chronic, right?!? We do not say that all drugs are inefficient, but we need to remember that a large proportion of our population is chronically ill in spite of taking the pharmaca constantly and for years.

Our international collaboration team has designed placebo cures – using what we found was most efficient and calling the cocktail of scientific holistic medicine for “Clinical holistic medicine” for the 40 most common health problems (14-47) and it seems from our testing of them that these cures in most cases work wonders for the patients that believes in them (8-12).

By repeating again and again that the CAM-cures are not working when compared to placebo – which we believe is absolutely correct - we are weakening their real and large effect day by day, until we one day pretty soon might be left only with the drugs that we already know do not work either.

Please understand that there are strong financial and political forces working against CAM. The problem with CAM is definitely not that it does not work, according to our research. The problem is that money not only rules the world, but also the way we make science and even the way we think science. It is time to sober up and test CAM on its own conditions, not on the conditions of the pharmaceutical industry. That is were we are going to find the medicine of the future. We will have CAM under all circumstances. But only by funding the CAM-research can we be sure that the scientific and efficient methods is what will be used in the future. Do not defund CAM research; do not defund the National Center for Complementary and Alternative Medicine (NCCAM). Please start casting real money after scientific CAM, and let us develop the efficient, affordable, “adverse-effect-less”, “green” and sustainable medicine that the world so desperately needs.

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Review Articles

QOL10 for clinical quality-assurance and research in treatment-efficacy: Ten key questions for measuring the global quality of life, self-rated physical and mental health, and self-rated social-, sexual- and working ability

Søren Ventegodt, MD, MMedSci, EU-MSc-CAM^{*1,2,3,4,5}, Niels Jørgen Andersen, MSc⁴ and Joav Merrick, MD, MMedSci, DMSc^{5,6,7,8}

¹Quality of Life Research Center, Copenhagen, Denmark

²Research Clinic for Holistic Medicine

³Nordic School of Holistic Medicine, Copenhagen, Denmark

⁴Scandinavian Foundation for Holistic Medicine, Sandvika, Norway

⁵Interuniversity College, Graz, Austria

⁶National Institute of Child Health and Human Development,

⁷Office of the Medical Director, Division for Mental Retardation, Ministry of Social Affairs, Jerusalem, Israel

⁸Kentucky Children's Hospital, University of Kentucky, Lexington, United States

Abstract

Quality of life and self-rated health are important health measures. They are simple to use and highly efficient for accurate documentation of treatment effects and thus for securing the quality of a clinical practice. We have developed the 10-item QOL10 questionnaire measuring self-assessed quality of life, health and ability. We need to measure both self-rated physical health and self-rated mental health, to be certain that we know how the patients are in both these dimensions. The QOL10 combined with the Square Curve Paradigm data-collecting-procedure seem to be an extremely efficient, fast, in-expensive and valid method of documenting total treatment effect and securing high quality of a treatment facility. In this paper we demonstrate how easy data are collected and analyzed. The time consumption of administering, collecting and analyzing the QOL10 was only 10 minutes per patient. The QOL10 is free for all to use. People even without statistical training can make the statistics in a few hours. The use of QOL10 and its 10 key questions makes it possible to group the patients into treatment groups according to their health/QOL/functional problems, and follow the development of each group to see how well they are helped in the clinic. We found the following dimensions to be of primary interest in quality assurance and documentation of treatment effect: 1) Health: Self-assessed physical health, self-assessed mental health, 2) Quality of life: Self-assessed QOL (QOL1), QOL measured with a small questionnaire (i.e. QOL5) 3) Ability: Self-assessed sexual ability, self-esteem social ability and working ability.

Keywords: Quality assurance, treatment effect, research methodology, global quality of life, CAM, holistic medicine

Introduction

During the last two decades a large number of papers have documented that the most important factor and

* **Correspondence:** Søren Ventegodt, MD, MMedSci, MSc, Director, Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark. Tel: +45-33-141113; Fax: +45-33-141123; E-mail: ventegodt@livskvalitet.org

most significant endpoint in studies of effects of medical treatments is the self-rated health (1-11).

- “Self-rated health (SRH) is considered a valid measure of health status as it has been shown to predict mortality in several studies” (4)
- “Self-assessed health status has been shown to be a powerful predictor of mortality, service use, and total cost of medical care treatment” (5)
- “Self-rated health contributes unique information to epidemiologic studies that is not captured by standard clinical assessments or self-reported histories” (7)
- “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” (8)
- “The results suggest that poor self rated health is a strong predictor of subsequent mortality in all subgroups studied, and that self rated health therefore may be a useful outcome measure” (11)

Self-rated health has been documented to predict survival time and future health better than any other known health parameter. This means that self-rated health has been found to be a valid and possibly the most valid health measure. To document improvement of health we need to measure self-rated health; and to measure health we need to measure self-rated health. Most unfortunately the research has worked with a single item questionnaire of self-assessed health, making it very difficult to understand what is measured by the questionnaire. We have as a part of the validated QOL5 questionnaire included two items on self-assessed physical health and self-assessed mental health (see appendix 1). We have found that these two items function extremely well in quality assurance and in documentation of treatment effect (12,13). We therefore recommend that these two measures, together with measures of self-assessed global quality of life (like the single item QOL1 (14) or QOL5 (14)) and self-assessed measures of ability are used for quality assurance and documentation of

research effect. We have combined ten key questions into the QOL10-battery measuring self-assessed health, quality of life, and ability in general, and found this to be of immense value.

The use of QOL10 and its ten key questions makes it possible to group the patients into treatment groups according to their health/QOL/functional problems, and follow the development of each group to see how well they are helped in the clinic setting (12,13,15-18).

The QOL10

The idea behind QOL10 is the *sense of coherence (SOC)*, a very important dimension in life developed by Aaron Antonovsky (1923-1994). The subjective experience of sense of coherence stem from a line going from life inside us to reality outside us (19). Sense of coherence is thus closely related to the concept of meaning of life and global QOL, as we find it for example in the IQOL theory (20). You can say that sense of coherence is the experience of being an integrative part of the world. The world is your home, you have come home in the world. Psychologically the secure base that your mother was, when you were a child has become the whole world. In religious terms, you live in God, or in Sunya (the great emptiness), and no longer in Maya, the illusionary world.

QOL is determined by the global state of the person, while self-assessed health is determined by the inner state of this person. Self-assessed ability in the relevant dimensions (work, social, sex, love) is determined by the social state of the person. In our experience health, QOL and ability are improved simultaneously, when the person is healing his existence though the process of salutogenesis.

Due to our experience with the symmetric 5-point Likert scales for psychometric research (21), we selected this scale for all items. The QOL5 and QOL1 questionnaire was validated earlier (14) and we also plan to validate the QOL10 questionnaire.

Analysing the data

For research in treatment effects and quality assurance you need about 20 patients in each group for a valid test. You need according to our experiences to measure the patients before and after treatment with a one year follow-up questionnaire. If the treatment is taking place over a long period of time you need to measure before treatment, then three months later and then again a year after treatment. If you do it this way, you can measure a change in health that is highly likely to be the effect of your treatment, meaning that you can use the patients as their own control (we call this the Square Curve Paradigm) (22).

The simplest way to analyze data is by dichotomizing the scale in a “bad” and “well” part. We normally use the bottom values [4 and 5] on the Likert scale as an indication of “bad” and the top part of it [1,2 and 3] as “well”. You include all starting participants in the study. Only patients who comply with the treatment and answer the questionnaire in the end of the study, and report that they are well now, are included in the “cured” group; all the dropouts, non-responders of questionnaires, and not-cured are treated as not cured. We finally used a statistical table (23) to establish the confidence interval.

The time consumption of administering, collecting and analyzing the QOL10 were only ten minutes per patient. The QOL10 is free for all to use. The statistics can be made in a few hours and by people with no statistical education. We found in our study of the treatment effects of clinical holistic medicine (CHM) (24-58) that the six following dimensions measured by the QOL10 questionnaire were of primary interest:

1. Self-assessed physical health (12)
2. Self-assessed mental health (13)
3. Self-assessed QOL (measure with QOL1) (17)
4. Self-assessed sexual ability (16)
5. Self-assessed self-esteem (relation with self) (15)
6. Self-assessed working ability (18)

1) and 2) are the self-assessed physical and mental health, and the average of this corresponds well to the single item questionnaire of self-assessed

health (statistical validation of this statement is planned).

An example

Data is taken from one of our studies (13). 54 patients felt mentally ill before treatment (rating 4 or 5 on the 5-point Likert scale of self-assessed mental health of QOL5). 31 Patients did not feel mentally ill any more after treatment (rating 1, 2 or 3 on the Likert scale). Six patients still felt mentally ill after treatment (rating 4 or 5). 17 patients were non-responders upon follow-up of withdrew during the study.

We thus treated 54 patients, who rated themselves mentally ill before treatment, 31 patients did not do so after treatment. From this we calculate a curing rate of 57,4%. The table (23) gives us 95% CI: 43.21% - 70.77%. From this we estimated: $1.41 < \text{NNT} < 2.31$. We then analysed the changes in all QOL10 measures for the treatment responders using paired samples T-test, and found that all measured aspects of life improved significantly, simultaneously, and radically (see table 1): somatic health (from 2.9 to 2.3), self-esteem/relationship to self (from 3.5 to 2.3), relationship to partner (from 4.7 to 2.9 [no partner was rated as “6”]), relationship to friends (from 2.5 to 2.0), ability to love (from 3.8 to 2.4), and self-assessed sexual ability (from 3.5 to 2.4), self-assessed social ability (from 3.2 to 2.1), self-assessed working ability (from 3.3 to 2.4), and self-assessed quality of life (from 4.0 to 2.3) (see table 1). Quality of life as measured with QOL5 improved (from 3.6 to 2.3 on a scale from 1-5 ($p < 0.001$)). Most radically the self-rated mental health improved by 1.97 steps on the Likert scale, from a bad mental health to a good mental health. This documents that the patients were not just “flipped” over the artificially defined border between the two dichotomised groups, but their mental health were actually radically improved.

All this data documents a general improvement that strongly indicates that the patient had healed existentially and experienced what Antonovsky called “salutogenesis” (59,60), defined as the process exactly the opposite of pathogenesis.

Table 1. 31 patients who changed from feeling mentally ill to mentally well (defined as “not ill”), healed all measured aspects of life due to Antonovsky salutogenesis: Somatic health, relationship to self, relationship to partner, relationship to friends, ability to love, and self-assessed sexual ability, self-assessed social ability, self-assessed working ability, and self-assessed quality of life. Paired samples T-test

	Paired Differences					t	df	Significance (2 – tailed)
	Mean	Std. Deviation	Std. Error mean	95% confidence interval of difference				
				Lower	Upper			
Physical health	.6000	.89443	.16330	.2660	.9340	3.674	29	.001
Mental health	1.9677	.79515	.79515	1.6761	2.2594	13.778	30	.000
Self esteem	1.2258	1.11683	1.11683	.8161	1.6355	6.111	30	.000
Relation to friends	.5161	.92632	.92632	.1764	.8559	3.102	30	.004
Relation to partner	1.8065	2.27185	2.27185	.9731	2.6398	4.427	30	.000
Ability to love	1.3548	1.60309	1.60309	.7668	1.9429	4.706	30	.000
Sexual ability	1.0323	1.35361	1.35361	.5358	1.5288	4.246	30	.000
Social ability	1.1613	1.12833	1.12833	.7474	1.5752	5.730	30	.000
Work ability	.9000	1.06188	1.06188	.5035	1.2965	4.642	29	.000
Quality of life	1.7097	1.03902	1.03902	1.3286	2.0908	9.162	30	.000

As reference value we have “2” (good) on the 5-point Likert scale, which corresponds to being well and normal (this is in accordance with what have been found empirically in large population surveys in Denmark) (61). We therefore see that the 31 mentally ill patients, that were helped with holistic therapy, actually almost normalised all their scores, signifying that they were indeed cured, not only improved.

It is very important to have a system to collect side effects and we therefore observed for brief reactive psychosis, suicide attempts, suicide, and signs of re-traumatisation (62), but did not observe these side effects in over 500 patients. The therapy was found to be safe, (estimated from this: $NNH > 500$). We then could present the $NNtH/NNtB$ as $500/(1.41 < NNT < 2.31)$. As we for medical-ethical reasons need to use the most pessimistic number for the calculation we find $NNtH/NNtB/NNtH = 500/2.31 = 216.5$.

We can compare this with the treatment of mentally ill schizophrenic patients with Clorpromazine (63): *Number Needed to Treat*: Prevents relapse, longer term data: NNT 4 CI 3 to 5. Improves symptoms and functioning NNT 6 CI 5 to 8. *Number Needed to Harm*: Sedation: NNH 5 CI 4 to 8. Acute movement disorder NNH 32 CI 11 to 154. Need for antiparkinson drugs NNH 14 CI 9 to 28. Lowering of blood pressure with accompanying dizziness NNH 11 CI 7 to 21. Considerable weight gain NNH 2 CI 2 to 3. Thus we find

$NNtH/NNtB = 2/5 = 0.4$. If we treated schizophrenics only, our treatment would have been 543.5 times more valuable than the treatment with chlorpromazine, but we did not as our group was an undiagnosed, mixed group of patients feeling mentally very ill.

Conclusions

The QOL10 combined with the Square Curve Paradigm data collecting procedure seems to be an extremely efficient, fast, in-expensive and valid method of documenting treatment effect and securing quality of a treatment facility. Self-rated health seems to be the most important health measure we have. It is simple to use and eminent for documenting treatment effects and securing quality of a clinical practice.

The use of QOL10 and its 10 key questions makes it possible to group the patients into treatment groups according to their health/QOL/functional problems, and follow the development of each group to see how well they are helped in the clinic. We found the following dimensions to be of primary interest in quality assurance and documentation of treatment effect:

- Health: Self-assessed physical health, self-assessed mental health,

- QOL: Self-assessed QOL, QOL measured with a small questionnaire like QOL5
 - Ability: Self-assessed sexual ability, self-assessed self-esteem (relation to self), self-assessed social ability, and self-assessed working ability.
- friends, and self-assessed I-strength (ability to love). We thus recommend the QOL10 (see appendix 1) measuring the global quality of life, self-rated physical and mental health, and self-rated ability for inexpensive, fast and reliable clinical quality-assurance and for research in treatment-efficacy in biomedicine, complementary and holistic medicine.

Also important are the self-rated quality of relation to partner, self-rated quality of relation to

Appendix 1

The QOL10 – a 10 item questionnaire on health, QOL and ability including the validated QOL5 and QOL1

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Q 1 How do you consider your **physical health** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 2 How do you consider your **mental health** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 3 How do you **feel about yourself** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 4 How are your relationships with your **friends** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 5 How is your relationship with your **partner** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad
- 6 I do not have one (This is scored like “5” very bad)

Q 6 How do you consider your ability to **love** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 7 How do you consider your **sexual functioning** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 8 How do you consider your **social functioning** at the moment?

- 1 very good
- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 9 How is your **working ability** at the moment?

- 1 very good

- 2 good
- 3 neither good nor bad
- 4 bad
- 5 very bad

Q 10 How would you assess your **quality of your life** now?

- 1 very high
- 2 high
- 3 neither low nor high
- 4 low
- 5 very low

The Endpoints you collect are:

QOL1: Self assessed (global) quality of life[]

QOL5: Measured global quality of life[]

QOL10: QOL+Health+Ability/3

To calculate QOL1: Q10

To calculate QOL 5: $((Q1+Q2):2+Q3 + (Q4+Q5):2):3$

To calculate QOL 10 "Health-QOL-Ability":

$(([\text{Health}] ((Q1 + Q2):2) + [\text{QOL}] ((Q10)+(Q3+Q4+Q5):3):2) + [\text{ability}] ((Q6+Q7+Q8+Q9):4)):3$

The result is comparable to a five point Likert scale of global QOL but more informative. QOL10 is a "global life status", we like to think of this measure as a "subjective sense of coherence(SOC)" measure. We just call the measure "Health-QOL-Ability".

The normal values for Danes for QOL1, QOL5 and QOL10 are around "2" [Ventegodt, S. (1995) *Livskvalitet I Danmark. Quality of life in Denmark. Results from a population survey.* [partly in Danish] Copenhagen: Forskningscentrets Forlag.] (you will see that "2" equals "70%" in the Table if you transform the result to "percent of maximum" as described in [Ventegodt, S. (1996) *Measuring the quality of life. From theory to practice.* Copenhagen: Forskningscentrets Forlag.].

To keep it simple we recommend the use of this scale for comparison:

Q 10 Measured quality of your life:

- 1 very high
- 2 high
- 3 neither low nor high
- 4 low
- 5 very low

Interpretation: 1 is great, 2 is normal, 3 is bad for QOL1 and very bad for QOL5 and QOL10; 4 is very bad for QOL1 and deadly for QOL5 and QOL10; 5 is dying for QOL1, QOL5 and QOL10 - you cannot survive for very long with this low rating.

I would say; if your patients in average are doing worse than QOL1=3 and QOL5= 2.7.5 and QOL10 =2.5 then a significant number of your patients might have severe existential problems and significant suffering.

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Spirituality, physics, psychology and medicine: Towards a new paradigm for healthcare in the 21st century

Gowri Anandarajah, MD*

Department of Family Medicine, Brown University,
Alpert Medical School, Memorial Hospital of Rhode
Island, Providence, Rhode Island, United States of
America

Abstract

There is a paradigm shift occurring in our understanding of ourselves and the world around us. Findings from previously separate fields of study are beginning to overlap and point towards a new and unified understanding of the world. This is particularly apparent in the field of medicine, where objective scientific evidence and subjective human experience meet on a daily basis. This article discusses the relationships between recent findings in the areas of spirituality, psychology, physics and medicine. Further study of these relationships may slow the trend towards the continued dissociation between the science and the art of medicine and is laying the groundwork for the emergence of a new paradigm for healthcare in the 21st century.

Keywords: Integrative medicine, spirituality, religion, psychology, physics, healthcare.

Introduction

We are standing at the threshold of a radical new paradigm in our understanding of ourselves and the world around us. Research in such apparently disparate fields as physics, spirituality, psychology and medicine are beginning to converge and point towards a unified understanding of the world, in which previously held boundaries and assumptions are beginning to be challenged. There is no place, where this is more apparent than in the field of medicine. The practice of medicine is, at its core, dedicated to the care of suffering human beings. However, a study of the history of western medicine reveals a gradual loss of the unification of the art and science of medicine. In its place is a system which, although magnificent in its technologic advances, has become increasingly devoid of the art of healing.

Evidence based medicine challenges us to examine and prove the effectiveness of our

* **Correspondence:** Professor Gowri Anandarajah, MD, Department of Family Medicine, Memorial Hospital of Rhode Island, 111 Brewster Street, Pawtucket, RI 02860, United States. Tel 401-729-2236; Fax 401-729-2923; E-mail: gowri_anandarajah@brown.edu

treatments. What is the “proof” that the art of medicine - a kind word, a few minutes of genuine listening, the ability to provide comfort - is effective medicine? The answer seems to be arising in fields of study that have not been traditionally linked to medicine including spirituality and religion, psychology of human consciousness and physics. It is becoming increasingly clear that these fields of study are intricately intertwined and that each gives us a glimpse into the health and well-being of the whole human being.

Spirituality and health

There is now over 30 years of evidence supporting the positive role of spirituality in health, including work in the area of religious commitment, meditation, prayer and compassion.

Religion

Numerous studies have looked at the effect of religion on health and the number of studies published in mainstream medical journals has increased exponentially in the last decade (1-8). Although there has been some controversy about the validity of the earlier studies, research in this area is becoming increasingly rigorous and precise regarding factors associated with better health and well-being. The preponderance of the evidence is pointing to a beneficial relationship between religion and health. Harold Koenig’s group at Duke has been particularly prolific in producing high quality research in this field (4,5). What is still unclear is how healthy religious commitment effects health. Many researchers have undertaken study of biological mediators for the effects of religion and spirituality on health, including brain anatomy, neuroimmunology, and neuroendocrine mediators (9-15). However, very few scientists have tried to explore whether these effects are entirely due to factors within an individual (ie. mind-body factors) or whether, as most religions attest, they are due to other, perhaps divine, influences on the individual. A major barrier to exploring this question lies in the limitation of the commonly employed “scientific method” based on Newtonian

physics and Cartesian duality. How do you study factors influencing health when they do not necessarily conform to the usual rules of predictability, cause and effect?

Meditation

Meditation is a technique for quieting the mind, controlling the body and attaining spiritual growth that has been present in all the major world’s religions in one form or another for thousands of years. Scientific study of the effects of meditation has been seriously undertaken in the United States for the past 30-40 years and is consistently pointing to both physical and psychological benefits (16-18). For example, regular meditation practice has been shown to decrease heart rate, blood pressure, oxygen consumption and rate of breathing. Benson’s relaxation response and Kabat-Zinn’s mindfulness based stress reduction are probably the two most well known adaptations of meditation to the practice of western medicine. Both groups have demonstrated beneficial effects of incorporating these methods into patient care. In addition, there has been much work done on the biologic mediators of meditation in the body (18-22). Like with the study of religious commitment, it may be possible to explain these effects through psychological and physical mechanisms alone. Interestingly, Benson’s work shows that 25% of people who practiced the relaxation response regularly experienced feeling the close presence of the divine and that these same individuals also experienced better medical outcomes than those who did not have this experience (16). Whether this can be explained by psychological phenomena alone is still unclear. The field of consciousness research is doing much work to inform this line of inquiry.

Prayer

Studies on the effects of prayer and distance healing have been more controversial than those on religious commitment and meditation but raise intriguing questions regarding local and non-local healing effects. Prayer is the most widely used

complementary and alternative medicine (CAM) modality in the United State and the rest of the world (23). Although the psychological benefits of prayer are widely accepted, there is significant controversy regarding the effectiveness of prayer for specific health outcomes and prayer from a distance (petitionary and intercessory prayer). Studies in these topics have yielded mixed results (24-28). However, Larry Dossey, among others, argue that there is enough evidence in both non-human and human studies to suggest that people can effect the health and well-being of others from a distance, through prayer and thoughts (28). Whether these effects, if they exist, are due to the untapped potential of the human mind or due to divine intervention, we may never really know. However, this line of scientific inquiry raises some very interesting questions regarding local and non-local healing effects and forces us to seek explanations that lie outside the usual “box” of medical scientific study. The fields of quantum physics and string theory may help give us insights regarding how this type of healing may occur.

Compassion

Other areas of intriguing research are in the fields of altruism and compassion. There is a body of data now supporting the positive effects of these phenomena on health and well-being. Steven Post, Lynn Underwood and others have done and compiled numerous studies showing the beneficial effects of altruism and compassionate love on others and on self (29-30).

This area of research has significant implications for medicine because it begins to shed light on the possible healing effects that are inherent in the doctor-patient relationship. Like studies on the effects of distance prayer and thoughts, this line of study opens avenues for exploring whether such things as positive intension, compassion and presence can have tangible effects on health, and prompts us to consider non-local mechanisms to explain these effects.

Human consciousness and health

All the areas of research described above lead us to consider that at the very least the human mind has a much more powerful effect on health and well-being that we have previously believed. Many investigators have undertaken the challenge of exploring the limits of human consciousness (31-35). At this stage in our understanding it seems that the more we learn, the more we realize there is to learn. Ken Wilber has been a leader in the exploration of human consciousness and describes complex states, streams and waves of consciousness that tie the human being to the rest of the universe (31-32). In the context of this kind of theoretical framework it is possible to begin to grasp ways in which the healing effects of such things as religious belief, meditation, prayer and compassion can be mediated through the intricacies of the human mind.

Human energy fields and health

Another field of study that is broadening our vision regarding the health and well-being of human beings is that of complementary and alternative medicine (CAM). CAM therapies encompass a wide range of therapeutic modalities, approaches and theories regarding human health (23). However, one thing they all have in common is that they challenge the limits of medical treatment offered in traditional western medicine and cause us to re-examine how “effective medicine” is studied. One subset of CAM therapies that are particularly divergent from mainstream western medicine are those that are based on the existence of an “energy body” and much work is being done to try and understand this aspect of the human body (35-38). Acupuncture, Ayurvedic medicine and homeopathy, among others, all assert that healing effects on the body can occur through manipulation of the human energy field. This energy field can be accessed directly through such things as acupuncture needles or from a distance. There is still much controversy regarding whether these energy fields exist and there is currently no reliable method for measuring or “seeing” these fields. Since modern “evidence-based medicine” relies on the ability to reproducibly measure effects of a particular treatment,

the inability to prove the existence of the human energy field and measure it remains a barrier to better understanding the ways these treatments effect health and well-being.

Physics and medicine

Breakthroughs in the area of physics may hold the key for us to better understand many of the phenomena described in this article (35-40). Modern allopathic medicine is predicated on an understanding of the human body based on Newtonian physics and the macroscopic universe. Measurement of cause, effect, predictability and reproducibility are all based on these Newtonian principles. The discipline of physics now accepts that there is much more to the material world and consequently the human body than what was envisioned by Newton and even Einstein.

Quantum physics

Quantum physics (39) described a subatomic world in which an electron can be simultaneously a particle and a wave (matter and energy) and will manifest in one form or the other depending on how one measures it. By extension, part of every atom in the human body has the potential to be both energy and matter. How it behaves and manifests depends on how we measure it or think about it. This concept provides very interesting food for thought regarding the power of the mind to influence the body. Is it possible that thinking a certain way can have an effect on the physical body? Can religious belief, meditation, prayer, positive thoughts, and compassion actually mold the body into a different form?

String theory

String theory (40) takes our understanding of the universe one step further. This popular modern theory suggests that at the most fundamental level, all matter in the universe is made of strings of energy, vibrating at different frequencies. These strings of energy manifest in a particular form depending on how they vibrate. If this theory holds true, then human beings

are, at the most fundamental level, vibrating strings of energy and our health and well-being depends on how these strings are vibrating. Are we in harmony or in discord? What determines how these strings vibrate?

These breakthroughs in modern physics help provide a new lens through which to view and understand the findings we are seeing in the areas of spirituality, psychology, CAM therapies and health. Findings which are seen as “unexplainable” and therefore probably not “real” in the view of modern, allopathic medicine, may now have a theoretical home from which to explain their mechanism of action.

Conclusions

We are beginning to understand that human health and well-being are much more complex and fascinating than modern allopathic medicine acknowledges. However, we are still a long way off from tying all these different fields of study together. Do these strings of energy, or clouds of electrons have anything to do with the levels, streams and waves of consciousness described by Wilber? How do religious belief, prayer and meditation interact with human consciousness or the human energy body? What are the biologic mediators and mechanisms linking spirit, mind and body? How does the concept of a divine presence effect how we interpret and understand the findings in all these fields of study?

Clues from the areas of spirituality, psychology and physics point to interesting new avenues of research regarding human health and each new discovery challenges us to re-examine previously held assumptions. It is very possible that this journey of exploration will result in a fundamental shift in our model of health and well-being which will open up improved treatment approaches for our suffering patients. Maybe we will even be able to “prove” the effectiveness of the healing art of medicine! There is still a long way to go on this exciting journey, and we are in for an interesting ride.

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The open source protocol of clinical holistic medicine

Søren Ventegodt, MD, MMedSci, EU-MSc-CAM^{*1,2,3,4,5}, Niels Jørgen Andersen, MSc⁴,
Isack Kandel, MA, PhD^{6,7} and Joav
Merrick, MD, MMedSci, DMSc^{5,7,8,9}

¹Quality of Life Research Center, Copenhagen, Denmark;

²Research Clinic for Holistic Medicine

³Nordic School of Holistic Medicine, Copenhagen, Denmark;

⁴Scandinavian Foundation for Holistic Medicine, Sandvika, Norway;

⁵Interuniversity College, Graz, Austria;

⁶Faculty of Social Sciences, Department of Behavioral Sciences, Ariel University Center of Samaria, Ariel, Israel;

⁷National Institute of Child Health and Human Development;

⁸Office of the Medical Director, Division for Mental Retardation, Ministry of Social Affairs, Jerusalem, Israel;

⁹Kentucky Children's Hospital, University of Kentucky, Lexington, United States

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. Clinical holistic 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 all the ethical, philosophical and methodological aspects. We encourage all medical researchers to shift to the Open Source Research Protocol format to minimise 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 a supplement to drugs and surgery. The experts in the holistic medical field, the holistic physicians, therapists and researchers of holistic medicine, needs protection, special attention and support as they might be up against strong commercial interests.

Keywords: Holistic health and medicine, 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

* **Correspondence:** Søren Ventegodt, MD, MMedSci, EU-MSc-CAM, Director, Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark. Tel: +45-33-141113; Fax: +45-33-141123; E-mail: ventegodt@livskvalitet.org

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)
• J Coll Physicians Surg Pak (Medicine)	(Medline/PubMed)
• J Pediatric Adolesc Gynecol (gynecology, pediatrics)	(Medline/PubMed)
• J Pain Management (medicine)	(PsycINFO, PubMedCentral)
• 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)	
• Med Sci Monit (medicine)	(MedLine/PubMed)
• Oral Health Prev Dent (dentistry)	(Medline/PubMed)
• South Med J (medicine)	(Medline/PubMed)
• Social Indicator 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

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- *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.
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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).

The open source research protocol

We have always revealed the sources of funding and support in the papers constituting the Open Source Research Protocol (20-208), as we do in the present paper. Today we are in the strange situation that very few controlled clinic studies have been made, sine 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 the 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 lead 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. We also have reasons to believe that this kind of

therapy can prevent suicide, and even side effects from biomedical, pharmaceutical treatments.

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
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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 1/7 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 month) 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 are 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 that 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).

Ethical aspects

The rationale for treating with clinical holistic medicine is naturally its high efficacy (see table 4) compared with the complete lack of adverse/side effects. 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). 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). 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 is to be found in the papers presenting the specific holistic medical (82,109) and holistic sexological tools (84,114,115,118,120,122,124).

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.

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 (218).

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.

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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Nutraceuticals and nutraceutical supplementation criteria in cancer prevention: A literature survey in years 2002-2009

Rakesh Sharma*, MS-PhD, MS-PhD (Tech),
BAMS, DipHA

Department of Engineering and Technology, Florida
State University and Tallahassee Community College,
Tallahassee, Florida, Medical Healing Center,
Tallahassee, Florida, United States of America

Abstract

Nutraceuticals are natural and bioactive products with food value to keep energy balance in the body and promise substantial therapeutic value in several diseases. Major nutraceuticals are now part of nutrition supplements at nonprescription counters and their self-prescription is increased at large scale. The current literature suggests the nutraceutical use in most of cancer prevention and management. The biochemical mechanism of nutraceuticals is poorly reported and most of the literature indicates the success of nutraceuticals in experimental animals. Broadly nutraceuticals are antioxidants, omega-3 fatty acids, vitamins, minerals and dietary fibers. Most of the nutraceuticals are derived from plants and animal origin and act as biochemical metabolites either by direct intermediary metabolism or regulating immunity.

Keywords: Cancer, immunity, nutraceuticals, metabolites, diet, cancer prevention, nutraceutical supplementation.

Introduction

Nutraceutical was first defined in 1989 by Stephen De Felico "as foods, food ingredients or dietary supplements that demonstrate specific health or medical benefits including the prevention and treatment of disease beyond basic nutritional functions". Later nutraceuticals emerged as potential cancer preventive natural sources from food (1).

The concept of nutraceuticals was initially considered as natural foods to provide energy as recommended daily requirement in the body for health till year 1990. Later the importance of nutraceuticals was realized as beneficial in different nutritional disorders with growing use of the nutraceuticals as self prescription in cardiovascular, cancer, developmental conditions in the last decade. In new era of 21st century showed enormous growing

* **Correspondence:** Rakesh Sharma, 2525 Pottsdamer Street,
Florida State University, Tallahassee, Florida 32310
United States of America. E-mail: rksz2004@yahoo.com

awareness of nutraceuticals as potent therapeutic supplements with accepted concept of nutraceutical medicine as new branch of complementary and alternative medicine (CAM). In last nine years, national and federal bodies accepted nutraceuticals as possible nutraceutical therapy in main stream of medical education and health. The healthcare industry demonstrated the shift of growing population from medical treatment of cancer towards non-prescription nutraceuticals as self-medication in cancer management and prevention. The growing awareness of nutraceutical benefits and shift of healthcare economics in favor of nutraceuticals brought nutraceutical medicine in spotlight of government health policy on systematic use of nutraceuticals in prevention and control of various chronic diseases. In last six years, National Cancer Institute (NCI) and other global efforts have documented fact sheets and several health documents on nutraceuticals in cancer management as shown in figure 1.

The major efforts were devoted in investigation of inhibitory effect of active nutraceutical component(s) on cell proliferation, cancer oncogenesis to result the reduced metastasis, delayed apoptosis, reduced necrosis and rate of malignancy growth in initial stages. In last two years the use of nutraceuticals in prevention and disease control has been extended further as protective nutrition supplementation policy of center of disease control (CDC) under its independent supervision. However, mechanisms still remain unproven and unvalidated but practice of nutraceuticals as food supplements in cancer prevention is acceptable.

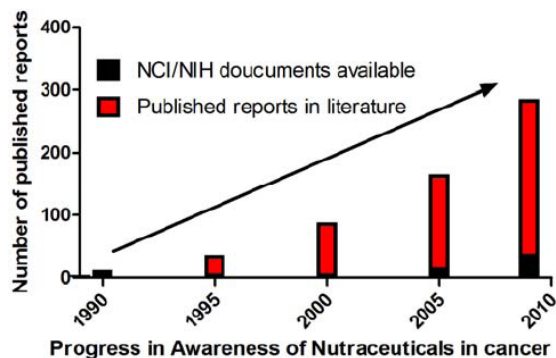


Figure 1. The figure represents the time line of nutraceuticals in cancer prevention and growing awareness as documented in literature available in last 15 years.

What are nutraceuticals?

Nutraceuticals are natural bioactive chemical compounds. Nutraceuticals have value in health promoting, disease preventing or semi-medicinal properties. Nutraceuticals are found as natural products from a) the food industry, b) the herbal and dietary supplement, c) pharmaceutical industry, and d) the newly emerged bioengineered microorganisms, agroproducts or active biomolecules. It may range from isolated nutrients, herbal products, dietary supplements and diets to genetically engineered “custom” foods and processed products such as cereals, soups and beverages (2). Chemically the nutraceuticals may be classified as isoprenoid derivatives (terpenoids, carotenoids, saponins, tocotrienols, tocopherols, terpenes), phenolic compounds (coumarins, tannins, lignins, anthocyanins, isoflavones, flavonones, flavanoids), carbohydrate derivatives (ascorbic acid, oligosaccharides, non-starch PS), fatty acid and structural lipids (n-3 PUFA, CLA, MUFA, sphingolipids, lecithins), amino acid derivatives (amino acids, allyl-S compounds, capsaicinoids, isothiocyanates, indols, folate, choline), microbes (probiotics, prebiotics) and minerals (Ca, Zn, Cu, K, Se) (3).

Broadly, the nutraceuticals were reported as active natural compounds. Recently, Tripathi et al (4) reported the chemotherapeutic value to nutraceuticals in cancer. Majority of cancer prevention evidence comes from animals studies on phytochemicals, fat, flavones, phytoestrogens, isoflavonones, genestein, curcumin, capsaicin, epigallocatechin-3-gallate, gingerol, lycopene, antioxidants, vitamins, minerals (3,4). Self-described testimonies of nutraceutical medicine and its success accrued over years in favor of liquorice (for peptic ulcer), isoflavones (for cholecarotenoids, saponins, tocotriesterol lowering, osteoporosis), phosphatidylcholine (for hepatitis), ginger (for emetic disorder, dizziness, carminative), kambocha tea (for arthritis), glucosamine (for chondroitin), vitamins C,D,E, minerals Zn,Se,Cu, lycopene, lutein (for pain), leupeptin, urokinase inhibitor (for prostate cancer), fenugreek (for osteoarthritis), lycopene, glucans (for cardiovascular disease), green tea (for cancer), carotenoids, *Trigonella foenum-graceum* (as anti-diabetic, anti-cancer), *noni Morinda citrifolia* (for relief blood pressure, muscle pain), *Thymus vulgaris*, *rhus coriaria*

(for antibacterial activity), sorrel (for immune system), *Geranium sanguineum* (as antiviral) over years (3,5). Lycopene, silbinin, shark cartilage, vitamin D (to decrease osteoporosis and bone pain), green tea, Selenium and vitamin E, Grape seed extract, modified citrus, pectin, Soy, PC-SPES are cited as prostate cancer protective food supplements (5).

Dilemma of nutraceuticals: Nutraceuticals may act as essential nutrient, as drug like, as regulatory biochemical metabolite and as phytohormone in the body. Recently, some prominent evidences are reported in favor of cancer inhibitory metabolic activity of nutraceuticals in the human body:

- Nutraceuticals may act as essential amino acid drug like essential nutrients. For example, tryptophan is needed for protein synthesis at low dose in humans. At high dose, it increases brain 5-hydroxytryptamine levels and thus acts as a drug to treat the insomnia (6).
- The nutraceutical preparations containing phytosterols are effective in lowering LDL cholesterol and osteoporosis.
- Bovine milk fat globule act as anticancer, anticholesterolemic, coronary heart disease (7).
- The phytonutrients prevent cell proliferation and play significant role in the prevention of chronic degenerative diseases. Notable examples are ginseng, spirulina, ginkgo biloba, amino acids, glucosamine, chondroitin and *Aegle marmelos*. Herbal and medicinal plants have shown significant inhibition of cell proliferation (8). Phytoestrogens play role in reducing necrosis.
- Vitamin C, vitamin E, β -Carotene, lycopene (carotenoids), lipoic Acid, glutathione(thiols) play role in cancer prevention and inhibition of necrosis; Co-Enzyme Q-10, super oxide dismutase (enzyme), selenium, copper, manganese, zinc (minerals) act as anticancer nutraceuticals in cancer management by delayed apoptosis observed in isolated cancer cells (9).
- Oligosaccharides were tested in animals. Fructo oligosaccharides, inulins, lactulose,

galacto-oligosaccharides, soybean oligosaccharides, lactosucrose, isomalto-oligosaccharides, gluco-oligosaccharides, xylo-oligosaccharides showed reducing cancer cell divisions (10).

- Polyunsaturated fatty acids (PUFA) such as safflower oil, corn oil, soybean oil, mustard oil, evening primrose oil, flax oil, hemp seeds, borage seeds showed protective effects in heart disease and stroke, rheumatoid arthritis, inflammatory arthritis, inflammatory bowel disease, asthma, cancer, chronic lung failure, kidney transplant, and bone formation (11).
- Dietary fibers such as oats, dried beans, legumes, chicory as water soluble fibers, Apple, orange, apricot, plum, pine apple contain 18-30% fiber contents. The vegetable sources such as cabbage, carrot, lettuce, onion, tomato containing 9 to 12 % fiber contents showed antioxidant and cell proliferation inhibitory properties (12).
- Wild foods are other major source of nutraceuticals and phytoestrogens. Most of the wild plants, wild mushrooms, wild fungi, wild vegetables, wild nuts, wild fruits and wild flowers as whole are considered as potential natural therapy alternatives (8,13).
- Soy isoflavones, genistein, curcumin, capsaicin, epigallocatechin-3-gallate (EGCG), gingerol, lycopene have emerged as established cancer protective nutraceuticals (14).

Animal studies

A large volume of literature is available on nutraceutical inhibitory effect on cancer cell growth based on observations of cultured cancer cell proliferation, enhanced apoptosis, antioxidant action etc. Still attempts are in the direction of morphological, cytomorphic, histopathology evidences of nutraceutical induced tumor shrinkage, arrested cell growth, delayed premalignancy, delayed oncogenesis, cell DNA cycle inhibition by using 3D localized molecular imaging techniques. Our previous studies on micro-MRI and immunostaining suggested

the reduced apoptosis in experimental rat MCF-7 explanted breast and mice PC-3 explanted prostate animal tumors. The increased sodium and enhanced apoptosis of tumor cells showed the tumor shrinkage after anticancer intervention to animals after 24 hours as shown in figure 2 (15). Major evidence was the slowed down apoptosis rate (less nuclear beads), reduced proliferation, less cyst size, less necrosis, single strand DNA breaks and poor carcinoma and

neoplasia growth in treated groups (16). The mechanism of these nutraceuticals still not established and it remains to investigate more scientifically diet controlled experimental methods. Moreover the beneficial effects of nutraceuticals in experimental animals were reviewed and two third literature reports on nutraceuticals are documented on experimental animal cancer studies as either reviews or animal bench experiments on cancer prevention.

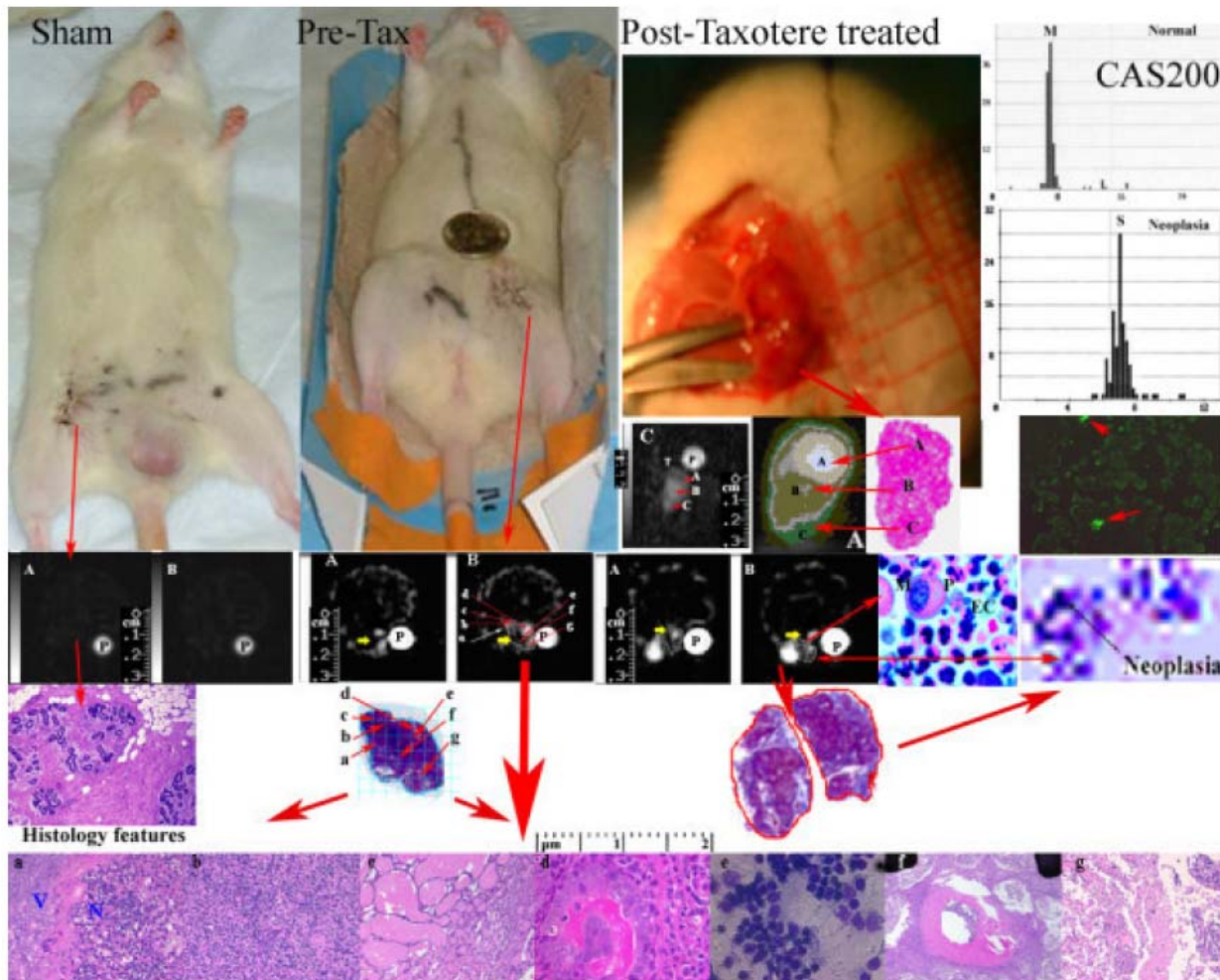


Figure 2. The sham control, pre-treatment and Taxotere post-treated animals (top panels on left) show tumors as SQ sodium (A) and IR sodium (B) images at 0 hr pre-Taxotere and 24 hours post-Taxotere treatment (panels A and B on second row). On third row on left, control tumor histology shows normal vesicles. Pre- and post treated excised tumor histology by trichrome staining is shown with delineated area. On fourth row on left, the excised tumor histology features in high power fields are shown with arrows (active viable cells (a), proliferation (b), necrosis (c), apoptosis (d), mitosis (e), fibrous cyst (f), and infiltrating ductile carcinoma (g) in different x- and y- coordinate locations after coregistration with IR sodium images). On right, panels on top show a IR sodium MR image before (C) and after non-parametric segmentation by Optimas 6.5 to highlight the different signal intensities that appeared hyperintense, isointense, and gray-green colored on segmented image and histology features showed them as apoptosis (A), necrosis (B) and neoplasia (C). On right, second row shows corresponding S DNA histograms of neoplasia features by CAS 200 (panels on top), apoptosis staining (panel with green stain). On right, third row shows a post-Taxotere treated tumor histology by pentachrome stain to highlight mitotic figures (M) with active PMN cells (P) and high EC volume (EC) and corresponding digitized map of DNA cycle, with neoplasia shown as arrow. Reproduced from reference [15].

The clinical evidence of nutraceutical cancer prevention success is still based on biochemical mechanisms of nutrients in diets reported over several decades. Some mechanisms of nutraceutical action are reported as immune modulatory, induced apoptosis, removal of free radicals, inhibited cell proliferation, inhibited necrosis. New ayurved (Indian traditional

medicine) concepts are also emerging as powerful nutraceuticals in cancer prevention.

The growing literature on mechanism of nutraceutical action in the cancer is supporting the extended benefits of nutraceuticals but it further needs more investigations as described in following separate section of new literature evidences.

Table 1. The examples of nutraceuticals are shown with their benefits in different cancers and mechanism of chemoprotective action in the body. The structure of active nutraceuticals are shown with mechanism and their structure with formula in chemical nomenclature

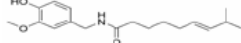
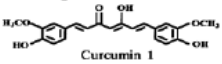
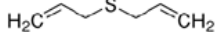
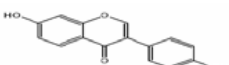
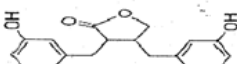
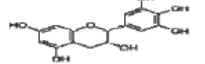
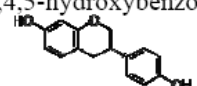
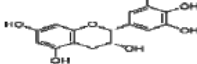
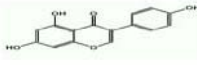
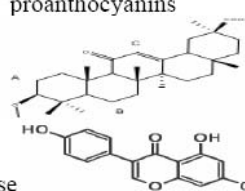
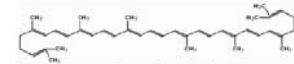
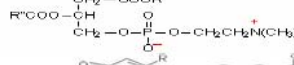

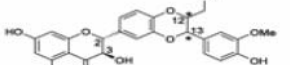
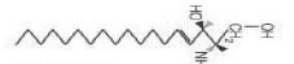
Nutraceuticals	Cancer	Mechanism	Structure
Ajoene (garlic)	PtK2	antineoplasia cytotoxicity	Trithiadodeca-1,6,11-triene-9-oxide
Antioxidants	B,Br,P,C,O,G	free radical scavenger	HO ⁻
Citrus	G	delayed apoptosis	limonoids
CLA	Br	?	conjugated linoleic acid
Capsaicin	P,Br	VR1receptor/ion channel	
Carnosol	C	O [*] H scanenger	diterpenes
Curcumin	C,P	NKX 3.1gene, cytokines	 Curcumin 1
Dallyl sulphide (garlic)	B,C,P	Cyt Oxidase, LDH,Glu reductase	
Daidzein	C,I	antioxidation upregulation	
Enterolactone	G,I,P	antioxidative	
Epigallocatechin-3-gallate	C,L	DNA metTrans, LDH inhibitor	
Ellagic acid	C,Br,P	antioxidant protection	3,4,5-hydroxybenzoic acid
Equol	C,P	??	
Fenugreek	Br,C,G,I,CO,P,PN	cytokines, redox reactions	??
Gingerol	Br,C,G,I,CO,P	VR1 receptor, caspase	methoxy phenyl decanone
Green tea	Br,C,P,CO	reduced MMP 2,9;cell proliferation	

Table 1. (Continued)

Genestein	Br,P	antiestrogenic, antiangiogenic DNA endonuclease, caspase	
Grape seed extract	G,L,PN,CO,P	cytotoxicity, antioxidant	proanthocyanins
Glycyrrhizin	G,I,CO	peroximase proliferation	
Isoflavones	Br,P,PN	HMG CoA-LDH inhibitor, caspase	
Kambocha tea	Br,C,G,I,CO	free radical scavenger	??
Lactobacillus acidophilus	G,I,CO	α,β dehydroxylase	membrane phospholipids
Liquorice	G	estrogen receptor agonism	methyl Glabridins
Limonene	Br,CO	farnesyltransferase inhibitor	1 met-4-propenyl-cyclohexene
Lutein	B,S,P	antioxidant	xiazaanthin
Lycopene	Br,P,G,I,CO	antioxidant, superoxide scavenger	
Meditarranian diet	G,I,CO,P	antioxidant	hemocyanins, low fat ??
Pectin	G,P	lenninin, fibronectin conjugation	galectins 2, 3 in apoptosis
Phosphatidylcholine	G,CO,I	choline transport, phosphorylation	
Phytoesterogen (soy)	Br,C,G,I,CO,P	antioxidant (lunasin, coumestan lignan)	
Silbinin	L,CO	apoptosis, reduced cell growth	
Selenium and vitamin E	Br,C,CO,G,I,P,PN	cdk2,PKC, G1/S DNA breaks	selenoproteins, S-Se-S,S-Se
Sphingolipid	Br,P,G,I	cell cycle arrest, apoptosis, senescence and differentiation	
Soy, PC-SPES	Br,C,CO,G,I,P,PN,O	G2M cell cycle kinase, cytokines	chalcones
α Tocopherol	Br,P,CO	antioxidant, antiproliferation	α tocopherol
Vitamins and minerals:	all cancers	cyclooxygenase inhibition, apoptosis	γ tocopherol
A		oxidative phosphorylation	active vitamin forms
B		proton pumps	retinal
D		phosphorylation, redox reactions	pyrophosphates
Folic acid		1,25 dihydroxycholecalciferol	calciferol
Calcium		5-methyltetrahydrofolate	folate bound form
Copper		calmodulin, Ca^{++} channels	hydroxyapatite
Potassium		catalase inhibitor, angiogenesis	ceruloplamin
Zinc		Na/K channels	K^+ or bound protein
		Zn-endopeptidases(MMP) inhibition	cofactor in enzymes

A: Arthritis cancer; B: Bone cancer; Br: Breast cancer; C: Common malignant cancers; CO: Colon cancer; H: Liver cancer; G: Gastric cancer; I: Intestinal cancer; L: Leukemia; P: Prostate cancer; PN: Pancreatic cancer; O: Ovarian cancer (source: Mazzio E Souleman K. US Patent 20070248693 <http://www.freepatentsonline.com/y2007/0248693.html>).

Biochemical basis of nutraceuticals in cancer prevention

Natural vegetables, herbs, plants, wild foods are complex in structural composition. The biochemical basis of individual source of these foods is not explored due to their complex nature. Some of the

evidences are in favor of the active food principles as nutraceuticals to show anticancer or preventive cancer supplements. Some of nutraceuticals are in the phase of clinical trial or already available as food supplement. Complementary and alternative medicine is emerging in prevention of chronic premalignancies as safe practice because of the high risk of mortality

and long-term morbidity associated with surgical procedures of cancer management and high side effects of chemotherapy. Herbal medicines have shown reduced cell proliferation in cultured cells. The vitamins, minerals and dietary fat play a role in relation to cancer prevention and control.

The mechanisms of nutraceutical action can be discussed broadly in following categories based on active metabolites present in nutraceuticals.

- The glutathione is the liver's most abundant protective constituent of antioxidant glutathione reductase enzyme. Glutathione functions as a substrate for the two key detoxification processes in the liver: 1) transforming toxins into water soluble forms, 2) neutralizing and "conjugating" with toxins for its elimination through the gut or the kidneys. If either of these processes is impaired for any reason, toxins gets accumulated in the body and lead to disease. The best nutrition with liver cancer focuses on improving the body's glutathione reserves (4).
- Some nutraceuticals rich in opiads are tumor inhibiting and these nutraceuticals showed the activity to get rid of toxins such as heavy metals, chemicals, digestive byproducts, etc. Tobacco plants may also help person to fight against lymphoma (17).
- The Soy isoflavone Haelan951 (genistein and genistin) was reported to have some role as a chemopreventive agent against cancer in humans (18). Beta-glycoside conjugate, genistin is abundant in fermented soybeans, soybean products such as soymilk and tofu. Beta-glycosyl bond of genistin is cleaved to produce genistein by microbes during fermentation to yield miso and natto. Soy sauce has high isoflavone but low miso and natto contents. How much soy isoflavones

needed? 1.5-4.1 mg/person miso isoflavone and 6.3-8.3 mg/person natto respectively (18,19).

- Green tea has always been considered by the Chinese and Japanese peoples as a potent medicine for the maintenance of health, endowed with the power to prolong life (19). Recently researchers (14,20) looked at the effects of the main active green tea constituent, epigallocatechin-3-gallate (EGCG) on chronic lymphocytic leukaemia B cells isolated from leukaemic patients. These cells were characterized by their resistance to apoptosis because they secrete and bind with vascular endothelial growth factor.
- Some herbal plants act as medicine. The herbal extracts are known to reduce the cell proliferation.

Apoptosis and immunological loss as basis of cancer and role of nutraceuticals

Cell mediate immunity is active and strong in youth and deteriorates with age. The major cytokines including interleukines, VEGF, EGF, TNF alpha, IFN γ , PDGF-BB, PIGF, b-NGF, SCF and NFKappaB lose their synergy response and affect cell mediated immunity to synthesize enough IgG, IgM, IgD antibody molecules. Humoral immunity also gets affected by less helper and suppressor lymphocytes. The possible metabolic points likely changed by nutraceuticals in apoptosis cascade and immunity loss are shown in figure 3.

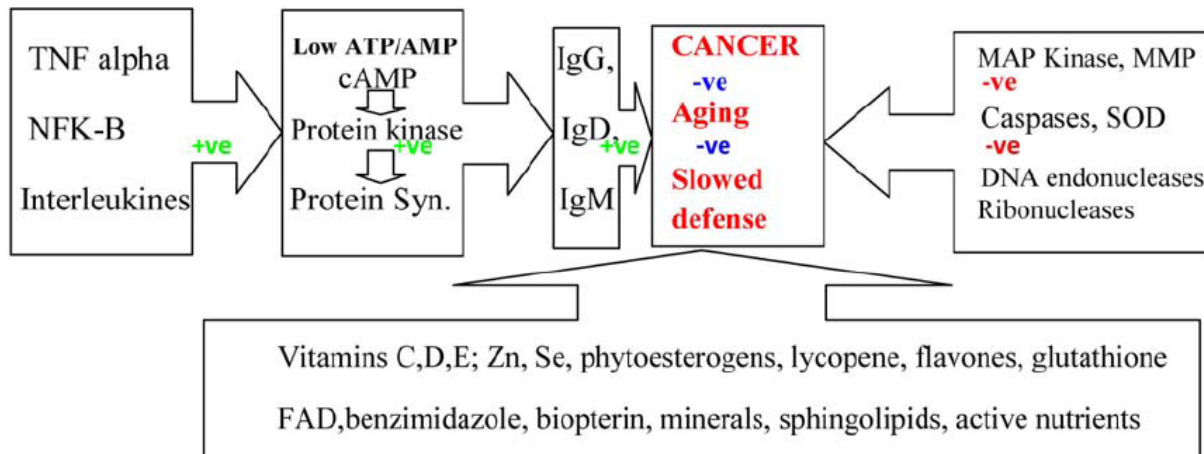


Figure 3. The figure represents the model sketch of cascade of steps to show delayed and slowed down apoptosis and immunity recovery by nutraceuticals based on literature data. Note the possible points where nutraceuticals may likely regulate or control for further metabolism in cell and tissues. +ve sign represents stimulated and -ve sign represents inhibited action of nutraceuticals based on reported literature. (source: <http://www.freepatentsonline.com/y2007/0248693.html>.)

Alternative approaches of nutraceuticals in cancer

Children below 18 years probably do not need nutraceuticals. Adults over 20-40 years need nutraceuticals and monitoring cancer. Persons over sixty years in age, need cancer watch and nutraceuticals as mandatory daily dietary supplements in practice. These senior persons may show the following major symptoms as causes of cancer development (21).

- Abrupt and sudden weight loss, infection, overgrowth of localized tumor.
- Poor cytokines, inflammatory proteins gradually lead to apoptosis, loss of immunity.
- Arteries and veins (and other tissues) become less elastic, as evidenced by our skin. Blood pressure may rise, as arteries lose their elasticity. (The amino acid taurine, found in fish, softens arteries and veins, as well as other connective tissue.)
- Inflammation and cholesterol-filled growths (plaques) in our blood vessels reduce their rates of flow. The loss of elasticity causes the heart to pump with less power and force.
- Joints become inflamed, as the immune system ages and disease condition attacks the collagen of the joints.

- Insulin levels begin to rise as old cells become less responsive to insulin, and the pancreas increases its output to compensate. This eventually leads to Type II diabetes and pancreatic cancer in which old cells no longer respond to insulin and end up with heavy cardiovascular damage and cancer.
- Kidneys lose reserve capacity, gradually fail to do normal function and develop renal cancer.
- Reduced cell mediated immunity and humoral immunity leads to immune deficiency and cancer.

Present state of art on nutraceutical medicine in cancer prevention

The UNISCI article, "Diet Called Most Important Breast Cancer Risk Factor", discusses the relationship between breast cancer and vitamin D, and between breast cancer and animal-derived versus plant-derived foods (22). Bottom line: diet and environment exposure and are two major risks. Major question is if nutraceuticals can reduce the chance of getting cancer through dietary modifications? Answer is not clear. The statement of National Cancer Institute's recommendations is "to eat at least five servings of brightly colored fruits and vegetables a day, to restrict ingestion of animal products (excluding farm-bred fish) while upping vegetable sources of protein (e.g.,

beans), to consume cooked tomato sauces, and to insure that we get, perhaps, 200 mcg. a day of selenium. (found in Walmart's OneSource multivitamin capsule)" (23). FDA requires appropriate scientific evidence regarding safety of nutraceutical use as daily prescription. However, new recommendations suggested that daily diet must contain 6.25 grams of soy protein per serving, micro-compound allicin (a small component of garlic) ad libitum amount, eicosapentanoic acid/docosaheaxanoic acid as polyunsaturated fatty acids (PUFAs) from fish or fish oils. The complementary medicine and alternative medicine approach is emerging as regulated tool to prescribe the norms of nutraceuticals as daily supplements in cancer and other diseases (24).

Insurance and prescription

National and federal agencies such as NCI and FDA need evidences and established data in large trials to approve nutraceuticals in clinical practice. In lack of such evidences and database, still nutraceutical practice remains at the door steps as nonprescription or self-prescription food supplements available on counter. As a result, insurance companies still shy to accept nutraceuticals as prescription.

Criteria of suggested practice of nutraceuticals in cancer prevention

- The criteria of nutraceuticals supplementation was determined by experience and practice based norms globally and approved schemes of nutrition and health departments of different governments. The use of complementary and alternative medicine (CAM) is increasing rapidly in developed countries (24).
- Functional foods and nutraceuticals in cancer prevention were highlighted as tomato, dietary fibers, soy, phytoestrogens, herbs, cruciferous vegetables (25).
- NTP-2000 and NIH-07 diets were reported rich in nutraceuticals to meet recommended daily allowances. NTP-2000 diet has lower

protein, higher fiber, and higher fat than the NIH-07 diet. Both diets were suggested as preventive in cancer. Main causative factors of cancer were free radicals, vitamin C,D,E deficiency, Se deficiency in daily diet and loss of cellular immunity (26).

- Recently, National Cancer Institute put forth the efforts on alternative ways of cancer prevention as public awareness to main focus on life style, prevention and control care measures, eating habits, hazardous contaminants with several successful attempts of antioxidants, garlic, vitamins (27).

New literature based evidences of nutraceuticals in cancer: years 2002-2008

In recent years during 2002-2008, the major focus was on more evidence based wider use of multivitamin-multimineral combined with isolated bioactive components from plants and functional foods in various cancer types. In last four years maximum efforts were devoted on reviews and compilation of evidenced experimental results on nutraceuticals in reducing cancer progress and identification of associations of active food components in diet with reduced cell proliferation, necrosis and apoptosis. However, NCI views that sequential events during the nutraceutical treated cell growth or arrest cancer are controversial (31). The literature during years 2002-2008 suggested major information for following: 1) direct link of vitamins, minerals in cancer prevention; 2) new bioactive food components with new mechanism of arresting cell growth; 3) more controlled trials and regulated studies under federal support; 4) new awareness of unpopular foods in cancer prevention; 5) new federal and statutory guidelines on nutraceutical recommended allowances and marketing.

The following information is grouped based on literature on nutraceuticals and nutraceuticals in cancer management with major focus on controlled randomized trials in experimental cancers and clinical cancer subjects. The description is divided into three sections.

Nutraceuticals in cancer prevention during years 2002-2008: The major nutraceuticals were reviewed and reported as vitamins and minerals, phytochemicals. The vitamins A,B6,B12,D,E, folate have been reported as anti cancer, immunoprotective and reducing cancer risk in population at risk of cancer and individuals who used self-medication (32-40). These reports provided the information of growing self-prescription style among population without any harmful effect and growing confidence of cancer bearing and avoiding chemotherapy. These nutraceutical supplements were reported in controlled epidemiological surveys to reduce morbidity and cancer incidence in clinical studies (41-47]. New information was investigated on successful nutraceutical supplements in present day life style, affluence and daily nutraceutical rich diet with reduced cancer prevalence in these studies. Major minerals as magnesium (48), zinc, micronutrients (51,52), selenium (53-57), calcium and were scientifically explored for their efficacy and safety in cancer prevention. Other new concepts emerged on the role of dietary vitamins as antioxidants in primary and secondary cancers in meta-analysis, randomized trials and epidemiological evidences with established metabolic and biochemical mechanism of these nutraceuticals (58-66). The fatty acids (67,68), polyphenols and phytochemicals emerged recently as promising chemopreventive agents to reduce cell proliferation and necrosis, enhanced apoptosis, reduced free radicals (69-75). Soy phytoestrogens and isoflavones emerged as single potent chemopreventive agents to reduce the cancer risk (76-78). Around the globe federal and government efforts have accumulated on consensus for statutory policy to use nutraceuticals on their daily requirements, supplementation, combinations and dosage to prevent or manage the cancer (79-83). Randomized and double blind control trials indicated the increased importance of vitamins, herbs and fresh vegetables as likely protective supplements (84-90), tomato (lycopene) in prostate cancer prevention (91-93), nutritional intervention in different cancers of different body organs in the body (94-100). New concept of Mediterranean diet was introduced to reduce the risk of cancer along with cardioprotection (101-103). However, these reports are not conclusive and remain to establish the effectiveness of

nutraceuticals if these effect on cancer cell senescence, oncogenesis, transformation, cell-cell contact inhibition, DNA fragmentation, ploidy and anisonucleosis without showing any adverse effect on normal cells.

Mechanism of cancer prevention by nutraceuticals

Several approaches have been reported to investigate the role of nutraceuticals on reduced cell damage in the normal cells of the body and possibility of delayed apoptosis, DNA interaction, reduced necrosis, cell proliferation, signaling and maintaining metabolic integrity in the cancer tissue as cancer prevention mechanisms (104-107). The biomarker of cancer such as metalloproteinases (108), vitamin D hydroxylase (109), interleukins (110), omega-3 fatty acids (111), induced neutropenia (112), DNA adducts (113), DNA methylases (114), polymorphism (115), superoxide dismutase (116) have been discovered as potent indicators of nutraceutical chemopreventive mechanism. Still the action of phytochemicals and role of bacteria is not understood (117,118). Recently mechanisms of nutraceuticals were reviewed thoroughly (119). Sharma et al (120) established the mechanism of intracellular sodium as major player in prostate tumors to induce delayed apoptosis and DNA fragmentation. The MRI and PET techniques evidenced the coexisting mechanism of reduced glycolysis and intracellular sodium release in breast tumors as chemosensitivity assay (15,120).

Cancers in the human body and nutraceutical protection

The awareness of cancer prevention by nutraceuticals began in late of the last decade. Still federal agencies restricted the regulatory policies of nutraceutical use in cancer prevention. Complementary and alternative medicine began a new era of harmless non-prescribed drugs with rampant success of self-prescription and on-counter sale of nutraceuticals. In last five years evidenced wider acceptance of nutraceuticals in both public and federal agencies. The major health hazards were identified as

breast, prostate, colorectal, ovarian, pancreatic, skin cancers.

The breast cancer was identified as single major health hazard three decades ago and still it remains a major risk among women. Different nutraceuticals have been reported in reducing breast cancer risk at both self-medication at homes and health centers. The major impact of experimental animal studies was distinct observations of reduced cancer cell growth by nutraceutical intervention and it supported the role of nutraceuticals in cancer prevention and treatment. The major examples of breast cancer preventive nutraceuticals are soy genestein (121-123), isoflavones, multivitamins as scavengers of free radicals, antioxidant, mitochondrial oxidative phosphorylation (124-131).

The prostate cancer is still recognized as single major health hazard among males and remains as main focus of nutraceutical intervention to reduce cancer risk by randomized control clinical trials. The major examples of cancer protective nutraceuticals are multivitamins and antioxidants (132,133), soy isoflavones (134,135), soy-tomato combo products (136-138). Majority of experimental animal cancer studies supported the reduced prostate cancer by nutraceutical supplementation. Still it remains to establish the value to nutraceuticals in clinical prescription of health centers. In this direction, lot of academic and global federal efforts are going on to establish to long term benefits of nutraceuticals in prostate cancer risk (139-144). The increased awareness and self-prescription of nutraceuticals among public for prostate cancer benefits is present major concern of health authorities (145-152).

Lung cancer and esophageal cancer remained as ignored health hazard perhaps due to other responsible environmental factors as main causative determinants of respiratory diseases with possible cancer risks. Recently few reports suggested the possible increased nutraceutical benefits of vitamins A and E in protection against lung cancer (153-156).

Colon and colorectal cancers have been identified as health hazards of modernization in food processing, artificial foods and affluent eating life style in metro cities and fast pace society (157). The increased incidence of colon, colorectal cancers have shown the processed food diet as main source of cancer. The colorectal and colon cancer is widely

reported as reduced by use of nutraceuticals such as folate (158-162), calcium (163-166), tomato-soy diet (167,168), fiber (167-170) and vitamins (171).

However, there are hypes and controversies in risk assessment of nutraceutical in esophageal and gastrointestinal cancer management (172). The several reports highlighted the trade-off between increased neoplasia in gastric cancer and the limits of nutraceuticals to reduce cancer growth (172,173). Still efforts are in the direction of antioxidant nutraceuticals to prevent or arrest the gastric cancer growth (174). The ovarian and endometrial cancers are at increase among privileged woman population and increased awareness of vitamins and minerals have shown a new hope to reduce the risk of cancer. Vitamin A, D, antioxidants, calcium, folate nutraceuticals still remain a choice as cancer preventive supplements (175-177).

Still efforts are in progress to observe more and more growing use of nutraceuticals in less known cancers. Recently less reported and newly investigated cancer protection by nutraceuticals were evidenced for lymphoma (178), skin cancer (179), pancreatic cancer (180-182). Recently vitamins and minerals were validated in chemoprevention trial of different cancers (183). In other recent reports the investigators showed a positive response of different nutraceutical supplements and foods in cancer prevention of different organs in the body as shown in table 2 with nutraceuticals and references.

Challenges, hypes, hopes and futuristic role of nutraceuticals

Most of the success of nutraceuticals is based on self-prescription and own individual experiences. Still it is far to realize the miraculous benefits of nutraceuticals unless controlled clinical trials support the evidences and facts of nutraceutical preventive therapeutic efficacy.

Table 2. The table represents the FDA approved major nutraceuticals with recommended quantity and sources of nutraceuticals on shelf in super markets

Nutraceuticals	Quantity needed	Common American Sources
Vitamin D	400 IU a day(2000 IU)	Walmart's "OneSource" multivitamins
Multivitamin-minerals	As 1 pill daily	Centrum Silver A-Z with minerals
Natural Vitamin E (4 tocopherols + 4 tocotrienols)	Two 400 IU capsules a week (800 mg)	GNC natural Vitamin E
Selenium	200 mcgs. a day	Walmart's "OneSource" multivitamins
Coffee	Ad libitum	home made, Food emporium
Aspirin or ibuprofen*	Baby aspirin a day	nonprescription counter
Chocolate (best if fat-free)	?, 3 servings	home made, Food emporium
Green tea	?, 3 servings	home made, Food emporium
Black tea	?, 1 serving	home made, Food emporium
Lycopene	Cooked tomato sauces	Domino's Pizza
Fish (tuna, salmon, mackerel)** or EHA+DHA	Two servings a week	Fresh phytosterols at Publix
Soy "meat", cheese, milk	Ad libitum	Publix, at the edge of the produce section. mozzarella, sausage, burgers
Broccoli, cabbage, cauliflower	Sulphydrals ad libitum	Piccadilly's tastes pretty good.
Blueberries	A few tablespoons a day	Publix' frozen foods (N. side, S. aisle)
Strawberries	4 or 5 large a day	Publix' frozen foods (N. side, S. aisle)
Orange	One a day	Publix, all supermarkets
Old-fashioned oatmeal	One ounce?	Publix, all supermarkets
Legumes (beans)	Two servings a week	Publix, all supermarkets
Low-fat blueberry yogurt	2 or 3 times a week	Publix, all supermarkets
Yellow vegetables	Ad libitum	Publix(Piccadilly's tastes pretty good).
Purple grape juice, or red wine	A glass a day	Publix, for Welsh's grape juice
Turmeric roots	Two capsules daily	GNC natural body products
Herbs	Two pills daily	St John Warts natural source
Garlic, Soy products	Ad libitum	Walmart's "OneSource" ampoules

* aspirin and ibuprofen primarily act as anti inflammation. (Other agents such as fish also have anti-inflammatory properties.); ** Tuna and mackerel contain mercury, dioxin, and PCB's. The salmon fish is safe. Winn Dixie farm-raised salmon. canned salmon provides omega-3 fatty acids and , taurine which are vital to the nervous and cardiovascular systems (modified from the Source (27, 28, 29, 30)).

Table 3. The table represents the documented or approved use of nutraceuticals in prevention or management of cancer in different organs

Cancer	Nutraceuticals	References
Bone cancer	soy isoflavones	[5]
Breast cancer	lycopene, phytoestrogen	[122-132]
Common cancer	cruciferous vegetables	[25,184]
Colon cancer	nuts, fibers	[158-172]
Gastric cancer	herbs	[173-175]
Intestinal cancer	sphingolipids	[64,65,176]
Liver cancer	silbinin, citrous flavonoids	[25]
Lung cancer	vitamins A and E	[154-157]
Ovary cancer	vitamin A, D, antioxidants	[176-178]
Pancreatic cancer	vitamins and isoflavones	[182-184]
Prostate cancer	lycopene, phytoestrogen	[133-153]

Major challenge is early detection of premalignancy and timely effective oncological treatment. In spite of all tools available, cancer is major health hazard. The major available data on nutraceuticals in cancer comes from epidemiological health and population statistics. The reduced cancer incidence due to nutraceuticals seems a hype but greater hopes are anticipated with advancements in food science. However, still cancer remains a major threat because of high mortality compounded with incomplete success of chemotherapy, oncotherapy and surgery intervention. In future, bioengineered nutraceuticals will play significant role in cancer prevention as alternative oncotherapeutics.

Conclusions

Nutraceuticals still are growing in number and investigations suggest high hopes of nutraceuticals in cancer prevention. The role of governments and globalization will certainly support the health risks and clinical trials on nutraceuticals. The nutraceuticals are becoming popular as they are harmless and natural food constituents. The nutraceuticals are still food supplements and last five years demonstrated enormous change in the perception of nutraceuticals as cancer preventive and therapeutic supplements in cancers of different organs.

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Psychodynamic psychotherapy, therapeutic touch and cancer. A review of the method of intervention and study of 75 cases

**Frederick B Levenson, MA, PhD, LP¹,
Micah D Levenson, LMSW¹, Søren
Ventegodt, MD, MMedSci, EU-MSc-
CAM^{*2,3,4,5,6} and Joav Merrick, MD,
MMedSci, DMSc^{6,7,8,9}**

¹Private practice, Manhattan, New York, United States of America;

²Quality of Life Research Center, Copenhagen, Denmark;

³Research Clinic for Holistic Medicine

⁴Nordic School of Holistic Medicine, Copenhagen, Denmark;

⁵Scandinavian Foundation for Holistic Medicine, Sandvika, Norway;

⁶Interuniversity College, Graz, Austria;

⁷National Institute of Child Health and Human Development;

⁸Office of the Medical Director, Division for Mental Retardation, Ministry of Social Affairs, Jerusalem, Israel

⁹Kentucky Children's Hospital, University of Kentucky, Lexington, United States

Abstract

Cancer treatments based upon holistic health, psychosocial interventions utilizing talk therapy and/or therapeutic touch techniques with the primary goal of improving quality of life, have shown a positive effect on patient longevity and both observed and reported patient quality of life. In 1974, Levenson began treating cancer patients with the primary goal of aiding their capacity to regulate and discharge irritation. In a holistic medical framework, this process might be envisioned as limiting psychoform and somatoform irritation with the patient's sense of coherence rehabilitated through this existential healing process (salutogenesis). In this paper the Levenson method is described and the 75 cases treated during 1974 to 2008 discussed. Almost all patients were diagnosed with epithelioid cancer by oncologists at esteemed medical centers. All subjects within this sample, with the exception of two who died immediately after the initialization of treatment, experienced an improved quality of life according to case records and reviewed documentation. 33 (44%) are still alive, 80% survived for more than five years and 45% survived for more than 10 years. A noticeable trend of improved patient quality of life and longevity had occurred as Levenson refined and improved his treatment methodology over the decades. The patients often sought treatment after a terminal diagnosis and were informed that allopathic biomedical interventions could not alter their prognosis. There seemed to be an improvement in longevity and several spontaneous remissions were noted in the hospital documentation. This holistic health approach (clinical holistic medicine) appears to have improved the quality of life and prolonged survival.

Introduction

In 1992, Ulrich Abel found that the positive effects of chemotherapy in the treatment of epithelioid cancer, such as breast cancer, uterine-cervical cancer, and colon cancer were minimal, at best (1). Abel presented a comprehensive analysis of over 3,000 clinical trials and publications examining the efficacy

* **Correspondence:** Søren Ventegodt, MD, MMedSci, EU-MSc-CAM, Director, Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark. Tel: +45-33-141113; Fax: +45-33-141123; E-mail: ventegodt@livskvalitet.org

of cytotoxic chemotherapy utilized to treat advanced epithelioid cancer. Abel discovered that those cancer patients treated with cytotoxic chemotherapy experienced a lower quality of life and a shorter survival time in comparison to patients with similar cancer diagnoses that did not receive chemotherapy. Abel concluded that “many oncologists take it for granted that response to therapy prolongs survival, an opinion which is based on a fallacy and not supported by clinical studies.” These conclusions were expanded by a review of the original data collected from over 100 cancer researchers and Abel detailed the data he gathered in two books (2,3). His conclusions have yet to be scientifically challenged, but he has been the subject of numerous personal attacks as a result of his findings. Interestingly enough, Abel was held in rather high regard before publishing his conclusions regarding chemotherapy.

The unfortunate result of Abel’s research has been a shift in the scientific study of the efficacy of chemotherapy on the progression of epithelioid cancer. After 1992, the scientific literature is virtually devoid of studies examining chemotherapeutic drug effects on epithelioid cancer in comparison to control groups that received “no treatment”. Due to this shift in research the pharmaceutical industry has successfully avoided an examination of the efficacy of these drugs compared to the results of epithelioid cancer treatment methods that did not utilize chemotherapy. This situation has led to the fact that chemotherapy treatment for epithelioid is not evidence-based. Instead, these treatments are based upon the assumption that chemotherapy could be effective by simply killing the rapidly dividing cancer cells.

Abel’s review of cancer statistics also showed that surgical intervention and the use of radiation treatments had a very limited effect on metastatic cancer (1-3). Population studies also showed that regardless of the use of combinations of chemotherapy, surgery and radiation in order to treat cancer, these treatments have not reduced the number of patient deaths (4) and some researchers even believe that the large screening programs for breast cancer at best has been clinically unproductive (5). Improvements in detecting cancer during earlier stages has simply generated the paradox of the outward appearance of better results, when

chemotherapy, surgery, and radiation treatments are utilized within the context of an increasing number of diagnosed cancers. When statistically examined within this context, the net results have not changed and have hardly provided substantial scientific evidence as to the efficacy of these interventions (4,5).

Cancer treatments based upon clinical and holistic medicine, psychosocial interventions utilizing talk therapy and/or therapeutic touch techniques with the primary goal of improving quality of life have in some studies shown a positive effect on patient longevity and both observed and reported patient quality of life (6-8).

What is cancer?

Cancer is a process in which cells appear to rapidly and randomly reproduce, in a manner replicating the reproduction of cells during infancy, without a positive metabolic or morphologic purpose. The currently accepted biomedical hypothesis is that cancer is generally “caused” by genetic mutation. The holistic-medical hypothesis is that the cancer process is *generated* by either local or global irritation (9,10). We know that anything that results in tissue irritation can generate a cancer process. We also know that there are no pathogens or hereditary factors, which adequately explain the cancer process in spite of myriad attempts to scientifically prove this association. For instance, in the example of genital human papilloma virus, the virus serves as a carcinogenic irritant as opposed to a pathogenic “cause” of cervical cancer.

The biomedical “cure for cancer” is one of destroying the mutated cells by cutting, poisoning, or burning (radiating) the organism. The holistic approach is to stop the cancer process by not only altering the organism’s present hyper-irritated state, but also aiding the organism in a re-adaptive process geared towards altering the manner in which the organism regulates irritation in the future. The cancer-tumor we observe is not a disease in itself, but a symptom of a disturbed capacity to process endogenous and exogenous carcinogenic irritation (9-20). The individual that can regulate and discharge irritation in a manner that efficiently impedes the

internal accumulation of irritation is much more likely to avoid developing cancer or has a greater potential to experience spontaneous remission after the cancer process has been generated (9,10). According to the theoretical framework of Levenson, the pre-cursor states for the development of the cancer process are most likely established during the neonatal or autistic stage of life (21). It is hypothesized that as the biological, genetic expression of the organism is altered by carcinogenic irritation, a concurrent genesis of a psychological state of addiction to irritation develops. Thus, in the holistic framework, the psychology predicts the biology, and vice versa. As a final step in the hypothesized development of precursor states for acquiring a cancerous reaction, the individual develops what is described as the *anaclitic depression*. This depressive response to an irritating early environment is marked by a resistance to bonding. The organism refuses to be comforted and soothed and instead experiences the hyper-irritated state as a state of maladaptive equilibrium. There is no joy in being, no capacity to experience relatively irritation-free homeostasis, for these infants. Instead there is a fear of closeness and as the individual develops, the bonding experience is dissociated from sexuality. This form of depression, the anaclitic depression, is pandemic in the Western world. So is cancer. To make it simple, the cure for cancer is guiding a psychotherapeutic process that allows the patient to readapt his or her nervous system's response to bonding experiences that are soothing and dissipates stored irritation. In other words, healing psychoform and somatoform dissociation, or rehabilitating sense of coherence with other people, is the essence of Levenson's cure for cancer (21).

Biological analysis of "irritation"

The concept of "irritation", although intuitively meaningful, is difficult to define in a mechanistic interpretation of reality; it signifies a dual state of negative experience and biological disorder. The connection between mind and matter in biology is still not understood, often called the "hard problem". If we only think that we are simple biochemistry, how then can this chemical soup have consciousness and emotions? The likely philosophical solution to this is

that the cells are conscious in themselves (22) and that our consciousness emerges as a collective consciousness-field, as all the small consciousnesses merge together (12-17). The psychobiological links are only understandable, if one thinks in expanded concepts like deeply structured quantum chemical fields carrying the biological information and consciousness of the individual (18-20). Having this kind of model, the concept of irritation causing the biological disorder we know as "cancer" makes complete sense. It is only a different style of cognition, more similar to the creative and spiritual thinking of pre-modern cultures; it is a very different way of thinking, much closer to the magic thinking of premodern cultures than the materialistic thinking of the post-modern western world.

The Levenson cancer treatment method

Starting in 1974, Levenson has treated cancer patients with the primary goal of aiding their capacity to regulate and discharge irritation (21). In a holistic medical framework, this process might be envisioned as limiting psychoform and somatoform irritation. It is likely that this irritation reflects traumas from early childhood (23,24). The patient's sense of coherence is rehabilitated through this existential healing process, often called *salutogenesis* in reference to the work of Aaron Antonovsky (1923-1994) (25,26). The Levenson cancer treatment method consists of *general principles* (see table 1) and *concrete tools* (see table 2). The primary intervention is one of bonding, more precisely therapeutic, maternal-infant bonding established during the first session with the patient and maintained throughout the course of treatment. As the cancer patient frequently enters treatment in an infantile state (especially if the prognosis is gloomy), there is an unconscious need to develop an intense transference maternal-infant bond.

Aiding in the treatment is the patient's introjection of the practitioner's (the symbolic mother as per the transference state) implied powers of healing and protection. For instance, one technique utilizing this intervention would be repeated visualization exercises in which the patient visualizes the cells of his or her immune system fighting (and

defeating) the cancer. The practitioner instructs the patient to personify the immune system cells and incorporate some physical factor related to the practitioner, such as similar facial features, eye or hair color, etc., during the patient's visualization exercises.

Levenson believes open and expressive rapport between practitioner and patient is also crucially important and contact must be maintained on a *daily* basis. This daily contact, in addition to days in which regular sessions are scheduled, consists of short telephone calls made by the patient, preferably right before sleep. This verbal "tucking the patient in for the night" strongly reinforces the maternal-infant transference state on an unconscious level.

As noted above, the vast majority of Levenson's patients entered treatment with terminal diagnoses (diagnosed by specialists in oncology before coming to Levenson) and an understanding that the practices of allopathic medicine will not "cure" their cancer, as the oncologists have basically given up on the patient after a period of time utilizing the conventional treatments (surgery, radiotherapy and/or radiotherapy). It is vitally important that all irrational beliefs that are not evidence-based regarding the treatment of cancer be forcefully unlearned during the beginning stage of the therapy. The practitioner should be quite prepared to provide scientific evidence, such as that referenced in this article, to aid in this process. Even more importantly, dangerous alternative treatments and practices, such as injections of massive concentrations of vitamin C or highly irregular dietary changes, must be stopped immediately.

During times of crisis, such as facing surgery or significant loss, the practitioner can physically soothe and comfort the patient in the form of hugging/holding. This highly selective touching serves to further reinforce the transferential maternal-infant bond as it creates a sense of safety similar to the soothing experienced by an irritated infant, when held and comforted by calm and loving mother. However, in Levenson's psychodynamic treatment orientation, this activity must be very selective to avoid over-stimulation of an eroticized transference. Additionally, the power of touch, when utilized by a practitioner of holistic medicine (27-32), in physical therapy (33), or in sexology (34), has been proven in other studies.

Table 1. The Principles of the Levenson cancer treatment method

Emotional holding and selective touch

- Immediately establish the maternal-infant bond within the transference
- Allow healthy dependency on the therapist to develop throughout the course of treatment – the therapist *takes responsibility* for reversing the cancer process. The patient is told, "if you could have reversed the cancer process alone, you would have. Reversing the cancer process is my (the therapist's) responsibility".
- The patient's need for isolation and being alone in dealing with his or her cancer must be confronted. Emphasis is placed on the concept of teamwork with the therapist serving as the party responsible for reversing the cancer process.
- Strongly discourage the patient's use of non-evidence-based treatments and correct the patient's incorrect ideation regarding cancer and the treatment of cancer.
- Utilize touch/hugging/holding selectively to generate feelings of protection and safety; it can also strongly reinforce the transference. Within the context of long-term psychodynamic psychotherapeutic modalities, touching/hugging/holding must be used with caution during crisis situations that replicate the patient being soothed and calmed by a maternal figure.

Processing

- Focus on the therapeutic goal of teaching the patient to discharge the irritation onto the therapist and other pre-objects. The irritation must be shifted from the patient to the therapist.
- Strive to remove somatoform and psychoform dissociation; the mind and body must be conceptualized as one system.
- Utilize a modern psychoanalytic framework with a focus on pre-verbal transference and the use of reflective psychological techniques as opposed to classical interpretation.
- Perform classical Reichian resistance work (43); the patient must be instructed to do the opposite of the impulses generated by the

cancer. The patient must eat, socialize, exercise, engage in sexual relations with his or her partner, etc.

- Educate the patient regarding the lack of efficacy of certain cancer treatments and produce evidence-based data that confirms the practitioner's methodology.
- Confront the patient's fears, anger, erotic feelings, loss, etc.
- Treat the patient's addiction to irritation.
- Reinforce teachings and philosophies of life that aid in the patient's capacity to experience a powerful, confident, and positive attitude towards life; philosophically quiet the patient's nervous system.
- Therapeutic touch: When patients are hugged and physically supported, as outlined above, study the resistance to this sense of closeness to determine if it is over-stimulating. Efficiently handle eroticized transference (44). Patients must obtain as much skin-on-skin contact as possible from their significant other. Massage is almost always strongly recommended as a substitute for skin-on-skin contact from a loved one and to aid in the discharge of irritation housed within the skeletal-muscular system.

The psychotherapist

- Psychotherapists with a personal history of cancer or an active cancer diagnosis should not treat cancer patients under any circumstances.
- The psychotherapist must be holistically balanced and possess a low irritation state of equilibrium; he or she must utilize effective methods of discharging the absorbed irritation transferred from the patient (exercise, massage, martial arts, meditation, etc.).
- The psychotherapist must take extra precautions in regards to self-care and the personal discharge of irritation if treating same-sex-specific cancers.
- The psychotherapist should not treat patients with a specific form of cancer likely to generate a negative countertransference due to personal reasons. An example of this would be the death of a loved one due to the same form of cancer as the patient.

Table 2. Psychotherapeutic tools utilized in the Levenson cancer treatment method

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- Capitalize on the patient's state of fear and infantile regression to immediately generate a therapeutically useful transference.
 - The patient must cognitively accept that there are cancer treatment options that can either complement or replace the allopathic approach of surgery, chemotherapy or radiotherapy.
 - A focal point of the therapy is to aid the patient in re-adapting his or her homeostasis from one of hyper-irritation to an equilibrium in which irritation is properly regulated and discharged.
 - The patient must eat, socialize, and move his or her body.
 - Any obsessional patterns of thought or behavior exhibited by the patient must be quickly addressed.
 - The patient must be aided in giving up "what if...?" worry and anxiety-generating processes.
 - The patient must be encouraged to strengthen or seek intimate relationships; sexual activity should be regular and the connection between loving bonding and sexual activity with the patient's partner must be reinforced during psychotherapy.
 - The patient must utilize the power of therapeutic touch; within the framework of long-term psychodynamic psychotherapy the patient should be instructed to have as much soothing skin-on-skin contact with loved ones as possible, make use of therapeutic massage, and investigate holistic medicine touch therapy approaches.
 - Within this framework, the patient should only be physically comforted (hugged/held) by the psychotherapist on a highly selective basis during crisis situations in which the patient's emotional containment is limited and the hug serves to reinforcement the transference mother-infant bond. The possible development of eroticized transference as a result must be closely examined.
 - The patient must maintain daily phone contact with the psychotherapist, preferably a short "check-in" and "good night" right before the patient goes to bed in order to emphasize the transference maternal-infant bond.
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Table 2. (Continued)

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- The treatment schedule consists of two 50 minute sessions per week; once the patient's cancer has been medically declared in remission the schedule is reduced to one weekly session.
 - Use of a psychoanalytic couch is essential. The patient's prone position is an infantile one, with the body relaxed and the eyes frequently closed. This aids tremendously in the discharge of irritation and minimizes the patient's avoidance of pre-verbal transference as a result of face-to-face psychotherapy.
 - The psychotherapist strongly encourages a warfare mentality; this is a life-or-death battle for which the patient's aggression must be mobilized. The patient's immune system is to be conceptualized as a personified group of soldiers or warriors. This personification of the immune system must also relate strongly to the psychotherapist in regards to physical characteristics or appearance in order to support the introjection of the psychotherapist.
 - Semantics are extremely important; the patient must not view cancer as a disease or sickness, but instead as a temporary disorder or physical process.
 - The patient must engage in an activity that utilizes the hands and fine motor skills as a mechanism of discharging irritation through the fingers; this activity is an adult recapitulation of the infantile Moro reflex.
 - The patient must avoid mass media reports regarding cancer or discussing cancer causes and treatments with others. The psychotherapist must be relied upon to find and present accurate, scientific, and evidence-based information regarding cancer and cancer treatment.
 - The patient must stop all cancer treatments that are not evidence-based, such as radical diets, injections with high concentrations of vitamin C, macrobiotics, or aggressive allopathic treatments that have not scientifically shown efficacy in clinical, randomized trials with control groups that did not receive the treatment.
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As noted above, the cancer patient generally enters therapy in a state of intense fear, and in many cases panic. This state of crisis results in the cancer patient's emotional regression to the point of infancy. The psychic energy fueling these extreme anxiety states must be sublimated into the development of the transference maternal-infant bond. Loss is a common theme (divorce, widowhood, loss of employment, removal of body parts, changes in living environment, etc.) during the treatment of cancer patients, and these losses must be processed during therapy. The patient suffers from anaclitic depression, addiction to irritation, and obsessive anxiety ("what if...?"). Frequently patients identify strongly with sources of irritation. All of these facets of the patient's being must be treated. Any pre-morbid condition that defines the patient's personality should be closely analyzed. For example, in people suffering from repressed anger, anger should be encouraged. Individuals that regularly exhibit anger as part of their personality should be encouraged to repress this anger. It is important to realize that cancer can occur in individuals throughout the character spectrum, but the practitioner's therapeutic focus must be on how the individual processes irritation. When a patient is able to discharge irritation within the transference, he or she has reached the *salutogenic turning point*, a concept found within the framework of complementary, integrative, and psychosocial medicine (36-42). Once the patient has developed a stable capacity to discharge irritation the focus shifts towards recovery. The case studies demonstrate some people will be able to recover to the point of complete remission.

Communicative metaphors

The psychotherapist can use metaphors and symbols to effectively address both the conscious and unconscious understanding and emotions of this cancer treatment method.

- *The law of entropy (entropic psychodynamics)*: The natural state of the universe is one of dissipating energy in terms of reducing "ordered" high-energy states to "disordered" low energy states. Given the

hypothesis that the cancer process is generated by irritation, one can define irritation as a form of energy. One can continue down this metaphoric path and equate irritation to heat. If a hot bowl of soup is left on a table, the heat from the soup will slowly dissipate as per the law of entropy. One can greatly increase the rate of this dissipation of heat by placing a cold, metal spoon into the bowl of soup thereby allowing the spoon to absorb a significant portion of the heat. "If we change the bowl of hot soup [in this metaphor] to a baby and the metal spoon to the mother, the dissipation of autistic stage irritation can easily be seen as occurring through the psychological fusion of the mother and baby" (21, p.41). In the context of the Levenson cancer treatment method, the psychotherapy provides the entropic function of discharging the hyper-irritation from the cancer patient to the psychotherapist. The psychotherapist then discharges this irritation in the manner noted above. It is the transference maternal-infant bond that serves as the conduit for this dissipation of irritation to the mother substitute, the psychotherapist.

- *The inner gong*: When the patient is stuck in an obsessive pattern and/or fixated on "what if...?" anxieties, the patient is instructed to visualize striking a symbolic gong in order to provide an internal distraction mechanism from the obsession anxiety feedback loop. This is followed by a deliberate conscious distraction from the "what if...?" thoughts. Continued use of this visualization technique and the metaphoric materialization of a calming, inner sound will aid the patient in re-adaptively negating the obsession thought process.

The therapy as emotional "resistance work"

Generally, the practice of psychotherapy creates resistance on the part of the patient. Levenson utilizes joining and reflective techniques to overcome the

resistance *to the discharge of irritation*. Quite frequently the cancer patient will make statements born out of the anaclitic depression such as, "I am the most miserable, rotten, horrible person I know. I can't stand my life." Levenson will typically respond along the lines of, "You know what? You really are the most miserable, rotten, and horrible person I know. I can't imagine how difficult it is to stand being you." This technique is a form of joining the resistance in order to induce the patient into directing aggression and thereby irritation, towards the psychotherapist. If a patient is fixating on his or her physical pain caused by the cancer, Levenson is likely to respond by complaining about what is ailing him, effectively minimizing the patient's statements, resulting in the mobilization of aggression and subsequent discharge of irritation towards the psychotherapist. After the patient has experienced catharsis and the irritation has been discharged, Levenson will verbally support, soothe, and comfort the patient. Resolving resistance via methods such as these is by no means unique, as Wilhelm Reich (1897-1957), Irvin David Yalom (born 1931) and many other psychodynamic psychotherapists engaged in similar interventions (43,45). Levenson's therapeutic focus is on facilitating the flow of irritation from the hyper-irritated patient to the psychotherapist. It can be understood as systematic resistance work at the level of the body (releasing the informational layer of the organism – sometimes called "the ethereal double" - for its emotional charges and tensions).

Review of 75 cases

All case reports and documentations of the patients treated by Levenson have been reviewed by SV and JM. During 1974 to 2008, Levenson treated 75 cancer patients; almost all of these patients were diagnosed with epithelioid cancer by oncologists at esteemed medical centers. All subjects within this sample, with the exception of two who died immediately after the initialization of treatment, experienced an improved quality of life according to case records and the documentation reviewed. 33 of these subjects (44%) are still alive, 80% survived for more than five years and 45% survived for more than 10 years. A noticeable trend of improved patient quality of life

and longevity has occurred as Levenson has refined and improved upon his treatment methodology over the decades.

From 1974-1998, Levenson treated 57 cancer patients and 29 (51%) survived for over 10 years. From 1974-2003, Levenson treated 66 cancer patients and 52 (79%) survived more than five years. From the 1974-1988 period 30% survived for more than 20 years. From 1974-1992, during the period when Abel (1-3) discovered that chemotherapy was an ineffective treatment for epithelioid cancer, Levenson treated 41 cancer patients and 27 (66%) lived for more than five years, 18 (44%) of the sample size, lived for 10 years and 12 (29%) lived for over 16 years and some are still alive.

In the case of breast cancer, Levenson found that 14 out of his sample size of 18 patients (78%), survived for more than five years, and 13 subjects (72%) survived for more than 10 years, and 11 patients (61%) are still alive. Levenson has a sample size of six patients diagnosed with malignant melanomas, 100% of these subjects survived for more than five years, four subjects survived for more than 10 years and three (50%) are still alive. Levenson has a sample of seven patients diagnosed with colon cancer and found that 5 out of 7 survived for more than five years, four survived for more than 10 years, and three subjects are still alive.

All of the cancer patients in Levenson's clinical study were diagnosed by established medical practitioners in oncology. The vast majority of this sample of subjects sought treatment with Levenson only after being given terminal diagnoses by the oncologists and told that allopathic biomedical interventions could not significantly alter their prognosis. In all cases of spontaneous remission among Levenson's patients, the status of cancer remission was declared and documented by the patients' established medical system practitioners and facilities.

Discussion

It is possible that the subjects in Levenson's clinical study are not representative of the "average" cancer patient as they actively sought alternative treatment methods in spite of virtual death sentences from

oncologists. Perhaps they were fixated on survival and therefore Levenson's population is skewed by unidentified psychological traits shared by this particular group of cancer patients. In other words, it is possible Levenson's treatment methods did not result in the positive impact on patient quality of life and extended longevity as related to the prognoses made by the medical establishment; Levenson simply collected a sample from a population highly motivated to survive coupled with a presently unknown factor aiding in the subjects' capability to self-induce significant medical and quality of life improvements and rather statistically atypical rates of spontaneous remission. It could be argued that the validity of the results is suspect as the collective sample of cancer patients were given 10 different cancer diagnoses by the establishment medical system and many identified forms of cancer have shown varied rates of progression. Lastly, it is plausible that Levenson's methodology is not specifically a treatment for cancer, but he has instead discovered a more generalized treatment method to increase immune system functionality, reinforce the will to live when diagnosed with a terminal condition, and improve patient quality of life.

Levenson's approach to cancer patients shares a striking similarity to the Aaron Antonovsky (1923-1994) concept of salutogenesis (26,27). Levenson took this process to its deepest, existential level, where love and intimacy transcend into natural and original inter-human bonding: "I belong to you, and I belong to the world at large". In a religious language one would say that Levenson leads the patient into an experience of being home in the universe, or being loved by God. The guided healing of the patient's whole existence is basically about helping the patient surrender the Ego. Unfortunately, this process is so emotionally difficult for most of us, that it requires 100 percent dedication and will on our own part. It takes the competent aid of an expert in the art of helping; ever since Hippocrates, the role of the physician has been to help the patient to develop self-insight, character, the courage to surrender, and to regain a sense of coherence (26,27).

Levenson's approach to what we call clinical holistic medicine, in terms of the application of a highly refined version of psychodynamic psychotherapy combined with hugs/holding and other

types of physical contact (therapeutic touch), appears to improve the cancer patient's quality of life and prolong survival. Partial or complete spontaneous remission also in some cases appears to have been induced. Further research is necessary in order to establish the treatment modality's efficacy in regards to different forms and stages of cancer as identified by the biomedical cancer model. The combination of Levenson's techniques with other clinical holistic medical interventions also shown to improve cancer patient quality of life and prolong longevity should be considered for research studies.

Therapists come from all walks of life practice many different modalities based upon their personal character and the purpose of the work to which they have dedicated their lives. At the core of Levenson's method is the direct use of the maternal-infant bond; this is a highly particular and specialized form of psychodynamic therapy. Levenson's warm and maternal demeanor coupled with the infantile regression many of his cancer patients initially exhibit aids in the development of this powerful maternal-infant transference. Therapists of other personality types and orientations might utilize therapeutic touch as a method to generate the same degree of closeness, intimacy, and proximity.

Levenson's focus on bonding as a core principle is the product of examining the close bonds that he experienced serving as a United States Marine during the conflict in Southeast Asia. Myriad life experiences can result in a therapist gaining a personal understanding of deeply emotional, bonding relationships and life or death struggles. At minimum, practitioners of Levenson's method must have a deep understand of human bonding and maternal-infant transference. They must be able to handle the emotional stresses of this work.

In any study comparing the results of chemotherapy to clinical holistic medicine therapies, randomizing subjects into each treatment group would be impossible as the cancer patients should have fully informed freedom to choose their treatment methods. One possibility is to restrict the study of clinical holistic medicine therapies to those patients declared terminal by their traditional biomedical oncologists or patients whom have already decided to refuse chemotherapy. The patients must be fully informed about the treatment protocols and the findings in this

and similar papers. Case studies documenting prior application of these treatment methods to similar cancer diagnoses would also be presented.

National and international Levenson teams should be linked to a central location for documentation. Study subjects will be helped through the process of both objective and subjective healing. We recommend a small, generic quality of life questionnaire like the QOL5 and the QOL1 (46-48) and measuring the patient before, three months after, and several years after the initial treatment (49). Cancer patients that are accurately diagnosed should not deviate from statistical models, and can serve control purposes, simplifying prospective research design. We recommend that the treatment is holistic, i.e. it must address the body, mind, and soul of the patient at the same time; only therapists with a truly holistic world view should be included in the project. Regardless of funding, the patient must contribute financially in some format, to both generate a feeling of "investment" in the treatment as well as a replication of the standard therapeutic format.

The Levenson treatment method should be understood as a potentially explosive example of clinical holistic medicine in action, but not as rigid dogma to be followed without frequent revision as evidence warrants. A prevailing goal of any large scale application of the Levenson treatment method would be to always incorporate new scientific knowledge and insights. Equally important is deriving wisdom and purpose from the Hippocratic roots of the healing arts throughout the future development of clinical holistic medicine approaches to cancer. Balint groups must be established with the therapists, and the quality of the treatment of each therapist must be monitored in a way that stimulates trust and development, not control and defensive closure.

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An ethical analysis of contemporary use of coercive persuasion (“brainwashing”, “mind control”) in psychiatry

Søren Ventegodt, MD, MMedSci, EU-MSc-CAM^{*1,2,3,4,5}, Niels Jørgen Andersen, MSc⁴ and Isack Kandel, MA, PhD⁶

¹Quality of Life Research Center, Copenhagen, Denmark;

²Research Clinic for Holistic Medicine

³Nordic School of Holistic Medicine, Copenhagen, Denmark;

⁴Scandinavian Foundation for Holistic Medicine, Sandvika, Norway;

⁵Interuniversity College, Graz, Austria;

⁶Faculty of Social Sciences, Department of Behavioral Sciences, Ariel University Center of Samaria, Ariel, Israel

Abstract

Coercion is every day practice in psychiatry. Coercive persuasion, 50 years ago called “brainwashing”, “mind control” and “thought reform” has recently been recommended by some psychiatrists as an efficient psychiatric tool, which is often not felt as coercion by the patients. The intensive use of antipsychotic drugs, which in Cochrane metaanalyses has been shown to reduce hallucinatory behavior without improving the patient’s mental state significantly, seems to facilitate coercive persuasion; it reduces patient resistance and autonomy by sedating him or her into a passive, cooperative, weak, and obedient state. Lifton found eight criteria or themes for coercive persuasion and when we compare these to modern biomedical psychiatry we find astonishing similarities. The patients must accept the “sacred psychiatric science”, an imposed “categorical” psychiatric diagnosis as a personal fault, and must obey and comply with the “treatment”: taking the prescribed, often sedative drugs, staying in hospital until behavior is normalized. Biomedical psychiatry has long been criticized for reducing its patients to “zombies” or robots, and about 2% of patients commit suicide or attempt to do so shortly after the initiation of psychiatric treatment. It is alarming that both the process and the outcome of biomedical, psychiatric treatment share unmistakable similarities with brainwashing. In conclusion, coercive persuasion that harm patient integrity and autonomy, decreases the feeling of meaning of life, sense of coherence, and quality of life, can explain the pattern of damage often inflicted by psychiatric treatment and we would like to question the ethical aspects of such a treatment.

Keywords: Holistic health, psychiatry, psychotropic drugs, mind control.

Introduction

Coercion is still common practice in psychiatry (1-3), in spite of a growing awareness of the inflicted harm

* **Correspondence:** Søren Ventegodt, MD, MMedSci, EU-MSc-CAM, Director, Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark. Tel: +45-33-141113; Fax: +45-33-141123; E-mail: ventegodt@livskvalitet.org

(4). Of the many different forms of coercion, coercive persuasion seems to be the only form that is generally accepted and even recommended among psychiatrists, with the argument that “positive symbolic pressures, such as persuasion, do not induce perceptions of coercion and such positive pressures should be tried in order to encourage admission before force or negative pressures are used” (5).

If you think about it, this is extremely worrisome: Coercive persuasion – what was called “brainwash”, “mind-control” and “thought-reform” 50 years ago - is not felt like coercion at all. This means that if you are coercively persuaded, you are not even likely to be able to observe it. This makes coercive persuasion, which can change patient’s attitudes, preferences and loyalties – that is why it is used of course - an extremely strong measure, as the patient cannot really resist it. Therefore coercive persuasion is likely to be much more harmful than open and visible use of coercion, which you can resist and distance yourself from. Coercive persuasion is, when it makes you change and degrades your personal philosophy of life, like an invisible poison that stays in your flesh and bones forever. You might have a feeling that you picked up something that was very bad for you, but you can’t know what it was, or where you picked it up, so you can’t get rid of it.

As our consciousness is the primary source of everything we do and are, including our health, quality of life, and ability in general (6), we are extremely vulnerable to influences and manipulations that shifts our consciousness away from what could be called our “natural philosophy”, our inner account of who we really are what we really want from life, into an alienated philosophy of life. Large shifts in people’s philosophy of life can happen in accidents where traumas give strong, emotionally charged, negative learning (7,8).

The question is how easy it is for other people to impose such a major shift in our consciousness, if they want to use us for their own purposes. We know that commercials are exactly about that. You cannot avoid looking, and then you are sold, but then again, not completely. This is on a small scale, and the coercion is subtle – you want to be fancy, so you buy fancy clothes.

But what if you are a parent and you persuade your child? We all know that this is easy. What if you

are a physician who wants to stop a mentally ill patient from creating problems for him and others, how easily could you “thought-reform” this patient, and change his behavior by coercive persuasion?

We all know, as we have tried to persuade other people many times, that most people do not voluntarily let go of their autonomy and personal favorite philosophy of life, attitudes and values; the shift in consciousness takes a yield, and the external pressure causing it needs sometimes to be extreme. But at other times, the person’s consciousness is very moldable, especially if the person is in serious trouble and has confidence in our good intentions and us. And if you are the doctor, and the patient’s life depends on you, the power-relation is similar to the parent-child relation, and modifying the patient’s consciousness is really easy.

The main characteristic of an intended shift, and the reason that it has been called “coercive persuasion”, “brainwashing”, “mind control”, “thought reform” is that it fundamentally violates the victims autonomy, and thereby destroys quality of life, as quality of life is the realization of self (9-12). Brainwashing is thus the complete opposite of existential therapy that aims in freeing the person, rehabilitating autonomy, and improving quality of life and health (13,14). In clinical holistic medicine (14-16) this is done by rehabilitating the patient’s character, life mission and natural philosophy of life (17-19).

Most interestingly, existential therapy will also deliberately implant philosophy of life in the patient, but this is done after consent – not that this means too much if the patient is severely ill and will consent to anything the physician suggests - but the philosophy is a positive, life-supporting philosophy, implanted as a part of the therapeutic contract, and meant for later de-learning, when the patient reaches his final destination of autonomy and self-insight (14).

From a psychodynamic perspective we know that coercive persuasion this is an obligatory part of every harsh childrearing practice (20-25), as the child being relative powerless constantly must yields to and obeys its parents; in spite of this often being highly traumatic this seems to be generally accepted in our culture. When the person is an autonomous adult we find coercive persuasion in principle unethical,

especially if the inflicted harm is obvious, unless the person is criminal or insane.

Most interesting unethical, coercive persuasion have mostly been associated with religious leaders of sects and cults (26-28) and political totalism especially in Russia and China (28-30), while the traumas and harm from coercive persuasion inside the modern western societies, especially towards the criminals and the insane have been almost ignored in research.

The harm caused by coercive persuasion is alienation and loss of autonomy; the symptoms of this is a reduction of the person to a more primitive being, or if taken further to an unconscious zombie-like being with little free will and initiative, and severe problems related to meaning of life (31) and sense of coherence (32). The most severe cases of brainwashing has systematically been seen to lead to suicide in cults, although other courses might exist (33-35); coercive tools have been sedating drugs, physical, and mental restrains.

This paper addresses the well known theme of coercive persuasion in psychiatry (1-4,36); another paper will address the unnecessary violation of suspected criminals that often harm these in principle still innocent people, just to make everything worse. Our intent with the present analysis is not to give suggestion on how to solve the problems of crime and insanity from the societal point of view, one possibility of cause being the elimination of the burdening person by coercive persuasion, another more constructive than healing and development of him or her. We just want to make everybody professionally involved in patients and criminals more aware of the serious ethical problems of coercive persuasion, which can be extremely harmful to the vulnerable existence and vital autonomy of a human being. We want to prevent professionals victimizing the already vulnerable, disturbed person. Mentally ill patients have in general few resources, a poor social network, and low self-esteem, making them especially vulnerable to coercive persuasion.

Drugs and coercion in psychiatry

In Denmark the annual use of antipsychotic drugs corresponds to 6% of the population – about 300.000

patients - taking such drugs every day, with another 6% taking antidepressive drugs. The prize of the antipsychotic and the antidepressive drugs in 2007 were 122 million EURO and 106 million EURO respectively, accounting for 14% of the national turnover on drugs (37).

The massive use of drugs in psychiatry happens in spite of recent scientific metaanalysis have documented, that these two large groups of drugs in principle are of questionable therapeutic value. The antidepressive drugs are active placebos (38), giving the patients adverse effects that make them believe that he or she gets help, while they are actually harmed by the adverse effects of the drugs. The antipsychotic drugs have in Cochrane metanalysis and similar studies been shown to have no effect at all on the mental health; they seems only to pacify, and this effect is likely to be a consequence of chronic poisoning by the drugs (39).

Most interestingly the drugs pacify the patients and makes it difficult not to “cooperate” (NNT=4 for “cooperativeness”); in an authoritarian, coercive system “cooperation” is exactly the same as “obedience”, so the documented effect seems to be a documentation of the antipsychotic drugs efficiency in facilitating the coercive persuasion. Psychiatric treatment with the antipsychotic drugs have been criticized for reducing the patients to “zombies” (40) and to a very disturbing degree it has been documented that suicide among mentally ill patients occurs very often and this is statistically related to intensive psychiatric treatment and hospitalization (41).

Taken all together this looks like psychiatry uses coercive persuasion as its primary tool, facilitated by the drugs and other techniques like electroshock (42,43); the use of coercion might explain why biomedical psychiatry in general does not improve mental health (39).

Theories of coercive persuasion

Brainwashing has often been a legal issue both in the United States and Europe (26,27), but a surprisingly limited number of scientific theories of brainwashing and coercive persuasion could be found in a combined Pubmed/MedLine and PsycINFO search, in spite of

300 references, and most of the proposed theories have been seriously disputed. The most acknowledged research in brainwashing is probably done by Lifton (28,30), who studied brainwashing in China and found eight central conditions or “themes” for brainwashing (see 44):

1. *Sacred science.* The group's doctrine or ideology is considered to be the ultimate truth, beyond all questioning or dispute. Truth is not to be found outside the group. The leader is above criticism.
2. *Doctrine over person.* Member's personal experiences are subordinated to the sacred science and any contrary experiences must be denied or reinterpreted to fit the ideology of the group.
3. *Loading the language.* The group interprets or uses words and phrases in new ways so that often the outside world does not understand. This jargon consists of thought-terminating clichés, which serve to alter members' thought processes to conform to the group's way of thinking.
4. *Milieu control.* This involves the control of information and communication both within the environment and, ultimately, within the individual, resulting in a significant degree of isolation from society at large.
5. *Demand for purity.* The world is viewed as black and white and the members are constantly exhorted to conform to the ideology of the group. The induction of guilt and/or shame is a powerful control device used here.
6. *Confession.* Sins, as defined by the group, are to be confessed either to a personal monitor or publicly to the group. There is no confidentiality; members' "sins," "attitudes," and "faults" are discussed and exploited by the leaders.
7. *Dispensing of existence.* The group has the prerogative to decide who has the right to exist and who does not. This is usually not literal but means that those in the outside world are not saved, unenlightened, unconscious and they must be converted to the group's ideology. If they do not join the

group or are critical of the group, then the members must reject them. Thus, the outside world loses all credibility.

8. *Mystical manipulation.* There is manipulation of experiences that appear spontaneous but in fact were planned and orchestrated by the group or its leaders in order to demonstrate divine authority.

Hassan (45) developed this further into his BITE model with some of the major criteria for brainwashing listed below:

1. *Behavior control*
 - Need to ask permission for major decisions
 - Need to report thoughts, feelings, and activities to superiors
 - Rewards and punishments (behavior modification techniques positive and negative)
 - Individualism discouraged; "group think" prevails
 - Rigid rules and regulations
 - Need for obedience and dependency
2. *Information control*
 - Use of deception
 - Access to non cult sources of information minimized or discouraged
 - Compartmentalization of information; Outsider vs. Insider doctrines
 - Extensive use of cult generated information and propaganda
3. *Thought control*
 - Need to internalize the group's doctrine as "Truth"
 - Use of "loaded" language (for example, "thought terminating clichés").
 - Only "good" and "proper" thoughts are encouraged.
 - Manipulation of memories and implantation of false memories
 - Rejection of rational analysis, critical thinking, constructive criticism. No critical questions about leader, doctrine, or policy seen as legitimate.

- No alternative belief systems viewed as legitimate, good, or useful
4. *Emotional control*
- Manipulate and narrow the range of a person's feelings
 - Make the person feel that if there are ever any problems, it is always their fault, never the leader's or the group's
 - Phobia indoctrination: inculcating irrational fears about ever leaving the group or even questioning the leader's authority. The person under mind control cannot visualize a positive, fulfilled future without being in the group.
 - A researcher who defined coercive persuasion as "psychotechnology, which can involuntarily transform beliefs and loyalties", have stressed *deception* and *seductive pseudosolidarity* as standard elements in brainwashing (26).

The process of brainwashing "is fostered through the creation of a controlled environment that heightens the susceptibility of a subject to suggestion and manipulation through ... cognitive dissonance, peer pressure and a clear assertion of authority and dominion. The aftermath of brainwashing is a severe impairment of autonomy and of the ability to think independently which induced a subjects unyielding compliance and the rupture of past connections, affiliations and associations" [Peterson v. Sorlien 1980, quoted in 26]. A physical threat intensifies the coercion (26). Brainwashing leads to "feeling of guilt, dependency, low self-esteem, worthlessness, anxiety and hopelessness in vulnerable individuals" (43), severe reduction of autonomy, and in the most extreme cases, suicide (26,27,33,34). Other researchers have found a triad in brainwashing of "deception, dependency, dread" (46).

A simple way of understanding brainwash is the three-step-process of: 1) gaining control of the victim's time, activities, and mental life; 2) placing the victim in a position of powerlessness; and 3) suppressing the victim's former identity (47).

If you think about it, this is to a large extent what every school child is exposed to every day and to a much smaller extent, what every employee to some

extent must accept (25). So coercive persuasion is not something mystical and strange; it is our practical reality as human beings. Luckily most of us are not very vulnerable and very receptive for brainwash; as soon as the pressure goes and we get resources for healing, we return to our natural identity and philosophy (7). The fraction of people who are vulnerable are the people who did not get sufficient love and support during childhood from their parents, or maybe even were physically or sexually abused. Most unfortunately this is exactly the group of people that often becomes our mentally ill patients. Coercive persuasion therefore becomes extremely problematic with these people.

In conclusion coercive persuasion can inflict serious harm and turn people into chronic patients; it must be mentioned that there are few regular scientific studies documenting this and the negative effects of coercive persuasion have therefore been disputed in relation to a number of lawsuits (48-50).

Coercive persuasion in psychiatry

Schein (51) found in 1962 remarkable similarities between brainwash in totalitarian regimes and treatment in mental institutions. Independent of the scientific scheme of coercive persuasion used it was easy to find large similarities to the situation that a mentally ill patient finds himself in, coming to the psychiatrist, and the brainwashed member of a authoritarian state of cult:

- *Sacred science.* Only psychiatrists understand the patient's mental illnesses and the diagnosis and treatments, or the science behind it or rationally and applicability of the treatments cannot be disputed. The patient must surrender fully to the psychiatric authority, accept the diagnoses as truth, and comply obediently with the prescribed treatment that most often is drugs.
- *Doctrine over person.* The patient's personal experiences are subordinated to the sacred science and any contrary experiences must be denied or reinterpreted to fit the psychiatric science.

- *Loading the language.* The group interprets or uses words and phrases in new ways so that often the outside world does not understand. This jargon consists of thought-terminating clichés; the acceptance of “disturbed brain chemistry causing the mental disease” to be “compensated by the drugs” (the dopamine hypothesis) is such a cliché, often used but obviously falsified by the facts that antipsychotics do not improve mental health [39].
- *Milieu control.* The mental institution is often very restrictive when it comes to communication outside, and physical restrictions are normal; medication by force is a complete control of the patient’s inner, biochemical milieu.
- *Demand for purity.* The patient is told to control unwanted “hallucinogenic” behavior, like conflicts, aggression, critique, blame, justifications, theorizations etc. Such expressions of the patient’s autonomy are considered impure.
- *Confession.* The “group therapy” often used (comp. Jack Nicholson’s famous appearance in the sharing-circle in the movie “One flew over the Cuckoo’s Nest”(52)) in this way breaking down patient’s integrity and autonomy; patients’ mental diseases are discussed and exploited by the leaders.
- *Dispensing of existence.* The psychiatrists have the prerogative to decide who has the right to exist and who does not; other therapists are unenlightened, inefficient and harmful. Healing and help from the outside world loses all credibility.
- *Mystical manipulation.* The psychiatric environment is highly structured, and the patient has no possibility for understanding how his or her experience is manipulated.

Hassan’s criteria (45) listed above are almost all met in contemporary biomedical psychiatric standard treatment with antipsychotic drugs. Thus the critique raised more than 40 years ago seems still valid. When it comes to “psychotechnology, which can involuntarily transform beliefs and loyalties”, deception and “seductive pseudosolidarity” seems

also to be present in psychiatry; the psychiatrist pretends to be the patient’s good doctor with the intention of healing the patient, but he knows very well that there is not cure. The true nature, purpose and function of the psychiatric institution are hidden for the newcomer; the highly structured environment catches the patient and absorbs him or her.

Biomedical psychiatry is deceptive in that the institution, the drugs etc. all are named after helping and curing the patient, i.e. “mental hospital”, “antipsychotic drugs”, but the drugs does not at all improve the patients mental health and the patient is not at all cured at the “hospital”, but just drugged down into convenient passivity and obedience (39). Thus the patient is giving consent to the treatment in the expectation to get help, but this help will never come as it is not possible to cure any disease or improve mental health with the drugs; the essential purpose of the mental institution is thus not to cure the mentally ill – as is evident after all statistics - but to rid society for its burden of difficult, unfit, and troublesome people. An interesting question is if it really is legal to “deceiving [people] into subjecting themselves, without their knowledge or consent, to coercive persuasion” (26).

Deep existential problems follows often from accepting the categorical, psychiatric diagnosis, which in itself leads to marginalized in all social and societal aspects. The patient is facing the “fact” that the incurable and chronic mental disease never will allow success at work or in education. The patient is there by effectively excluded from ever being of any substantial value to the surrounding world; he or she will never get a normal life. The meaning of life and the sense of coherence are sadly lost, and suicide in this situation can be a fairly rational decision (35) from the patient’s new perspective planted by coercive persuasion. The suicidal intent is often noticed, as this is a part of the standard procedure, and the coercive prevention of suicide, which philosophically is depriving the patient the last remains of autonomy, leads to a final repressed state of complete resignation and pacification, and this is the state of the “zombie” or robot, as already Hunter said (53,54): A person deprived of all will to live and even all will to die; with no hope, no joy, and no autonomy left.

The analysis of psychiatry as coercive persuasion looks surprisingly accurate, and this calls for a number of questions: What is really going on here? Why are the patients accepting the psychiatric diagnosis, and the drugs, in spite of the drugs have been proven not to improve mental health at all and being highly poisonous and sedating? Why are psychiatrists not behaving rationally, and stopping the combined use of drugs and coercive persuasion, when it is now clear that it is not at all based on scientific evidence? Why are the national health authorities accepting such a malpractice that seems to severely harm thousands of mentally ill patients, especially when there are so many successful alternative treatments (55-57)? Somehow the authorities, the psychiatrist and the patients all together have become fixed in the belief, that the drugs helps and is the correct treatment, and that the categorical diagnosis are the final truth about the patient, in spite of science telling us the complete opposite, but how come?

Coercive persuasion as weapon

Coercive persuasion has often been used in war (58-61). On a smaller scale, it has been used in the “war” between pharmaceutical industry - including on its side many biomedical psychiatrist- and the CAM-therapists (62). Psychiatrists have according to this book often accused CAM-therapists of harming the patients, an often used testimonial from former CAM-patients, that later came into psychiatric treatment; vice versa have CAM-therapist often quoted patients who had ETC or antipsychotic drugs for statements about these treatments as severely destructive and ruining the patient’s whole life. A vulnerable patient takes the role of a child in relation to his or her doctor, and this always opens up to the possibility of coercive persuasion; the patient can thus be made to think and say almost anything by her former therapist or physician. In such cases the only rationale thing is to look at the facts (34) of what happened, what was the outcome of the therapy? Did the therapy make the patient better with regards to quality of life, self-assessed physical or mental health, self-esteem etc? Was the patient general abilities reduced during treatment? Was the patient hospitalized during the treatment? Was emotional withdrawal cured or

intensified? Was libido and sexual relations opened up, or closed down? Were there any suicide attempts, or death wishes? Was the relation with the outer world improved during treatment or did the patient become more isolated?

All these subjective and objective factors related to autonomy, empowering, meaning of life, and sense of coherence, feeling of guilt, dependency, low self-esteem, worthlessness, anxiety and hopelessness, social isolation, and suicide must be analyzed to see the whole picture, and answer the difficult question: Was this constructive therapy or destructive, coercive persuasion.

A most difficult issue is the issue of consent and free will. A mentally ill patient needs care, and is dependent; free will is thus reduced, and consent must be seen in this light. If a patient gives consent to psychiatric treatment, in a mental state where he or she feels very bad, this is not really a valid consent. Such consent is important not to violate the patient’s feeling of autonomy, but the consent have little meaning in its philosophical sense as the illness puts a strong force on the patient; we therefore need to monitor the process and the outcome of every treatment very carefully to be sure to help and not harm a vulnerable, ill patient. Luckily this is easily done with a small questionnaire on quality of life (62). Every patient needs to fill in such a questionnaire before treatment is initiated; if the patient is not able to do so, the quality of life questionnaire should still be rated by an external observer (63) and corrected by the patient when he or she is able to do so.

An important ethical obligation we have as therapist in this turbulent time is not to use the patients as weapons in our internal combats; in the end all coercive persuasion will harm our vulnerable patients.

Discussion

Coercive persuasion, or “brain washing”, is possible if somebody is in a weak and vulnerable relation to another more powerful person, similar to that of a small child with its parents. The powerless position is often the one mentally ill patients have in relation with their psychiatrist; it is so tempting to put all hope

of salvation and cure into a relation with an authoritarian doctor, who seems to know everything and promise to help. Most unfortunately, the biomedical psychiatrist believes in the dopamine hypothesis, and therefore also in the antipsychotic drugs, but these drugs does not improve mental health according to the statistics (38); when a physician believes in the drugs he does not have the intent of curing the patient himself, and thus he will not provide the resources needed for recovery and spontaneous healing (7). His biochemical understanding of life, brain and mental diseases and consciousness does not allow this either. The psychiatrist carries instead the intention of fitting the patient into society; he wants to help the patient to assume a role that is non-destructive and unproblematic, and the only role that is possible is as chronically mental patient, with the conflict-causing, hallucinatory behavior pacified by antipsychotic drugs.

The coercive psychiatrist is empowered by society to use force to make the patient behave normally; in the patient's experience this is often a battle where the patient fights for his autonomy but loses; the psychiatrist ends up destroying the patient existentially, but he does this to serve society and find himself in good intent, while the patient often see him as an enemy.

A strong belief in tradition, and what seem to be obsolete, biochemical hypothesis of mental illnesses, makes it difficult for psychiatrists to disregard all the new scientific studies, including the many large Cochrane analysis, that have shown that the patients' mental state – the measured mental health – is not improved by the drugs. New studies have also documented very embarrassing data on the adverse effects, suicide and spontaneous death from the drugs (40,64). As long as the psychiatrist simply stick to the belief that mental illness is a genetically inherited brain-defect that only can be compensated by antipsychotic drugs, he simply will be in denial, when it comes to the urgent needs of reforms; and in this denial he will not consider other therapeutic methods.

It is an interesting idea that the reason for the psychiatrists insisting on using the "antipsychotic", sedative drugs is coercive persuasion during his medical training. Only if these ideas and theories were accepted, he could become the physician he wanted to

be; this "coercive learning" could be called "professional deformation". Generations of physicians have thus been brainwashed to believe in biochemistry as the final answer to the mysteries of life, and the dopamine hypothesis as the final answer to the mystery of psychotic mental illnesses; so when new science shows that the dopamine hypothesis is not likely at all, he simply sticks to it anyway. The lack of openness to new ideas and the strong irrational conservatism that we see here could very well be another symptom of coercive persuasion.

About 5% of the western population is on antipsychotic drugs, making this one of the largest pharmaceutical industries in the world. The industry uses billions of Euros and dollars on highly biased, randomized clinical studies (38) and all these studies are made by doctors getting payment, prestige, and important degrees from their involvement. The medico-industrial complex is highly integrated in society, and the industry is returning so much of the money it makes to the doctors that this can fairly be compared to bribe. But it is done in smart ways so nobody can officially blame the doctors; and often the doctors do not even them self realize that they are being manipulated.

The politicians need psychiatry to take care of the mentally ill, to get quiet and stable, productive societies; and a successful pharmaceutical industry also bring wealth to the nation. The fact seems to be that millions of patients, who believe that psychiatry helps them, are little by little reduced to zombies by mental and chemical repression. The patients are in reality losing their life and whole existence due to drug-facilitated, coercive persuasion; but when it comes down to it nobody really cares about the mentally ill.

Conclusions

Coercive persuasion, or brainwash, as it is known from war and totalism (29) seems to be the normal practice of western psychiatry of today; it is strongly facilitated by the sedative and highly poisonous, "antipsychotic" drugs that have been shown not to improve mental health in a number of recent Cochrane metaanalyses. After the patient is tricked to believe that psychiatry is about healing the mentally

ill, which most unfortunately is not the case in biomedical psychiatry, as patients are not healed, the tool of coercive persuasion is used to repress and pacify the patient into the convenient role of a chronic, mentally ill patient.

Most unfortunately the psychiatrists of today have completely lost contact with scientific reality and have drifted away in obsolete ideas and illusions that are in no way substantiated or even the least supported by facts. But the money and the prestige connected with a high position at a mental hospitals are still so attractive, that the psychiatrist simply loses common sense, and accepts a role as terminator for naïve patients, being horribly manipulated and existentially destroyed by the combined effects of coercive persuasion and strongly sedative and poisonous drugs taking the patients ability of autonomy and resistance away.

Every year about a million, mostly young people, enter the psychiatric system and become patients (65) and every year a million of so good people who could have had wonderful, blossoming lives, are turned into existentially reduced “zombies” or even into dead by suicide. We have been so busy criticizing the other societies and cultures that we completely have missed that we in the western world could be the most repressing, evil, violent and un-containing of all people that have inhabited the planet till this day.

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Bio- and alternative medicine in conflict. Human rights protection of the alternative therapist

Søren Ventegodt, MD, MMedSci, EU-MSc-CAM^{*1,2,3,4,5}, Niels Jørgen Andersen, MSc⁴ and Isack Kandel, MA, PhD⁶

¹Quality of Life Research Center, Copenhagen, Denmark;

²Research Clinic for Holistic Medicine;

³Nordic School of Holistic Medicine, Copenhagen, Denmark;

⁴Scandinavian Foundation for Holistic Medicine, Sandvika, Norway;

⁵Interuniversity College, Graz, Austria;

⁶Faculty of Social Sciences, Department of Behavioral Sciences, Ariel University Center of Samaria, Ariel, Israel

Abstract

In spite of strong commercial interests in biomedicine we now observe that complementary, alternative and holistic medicine (CAM) are being used more frequently than biomedicine in the western world. Many physicians have lost faith in pharmaceutical drugs and integrate existential psychotherapy, therapeutic touch, clinical holistic medicine and other CAM techniques into their clinical practice. In response commercial forces impact the media and national health authorities to promote the use of biomedical drugs. CAM-researchers and therapists are frequently “quack-busted” following a rigid pattern: 1) First a fabricated accusation is presented to the public and the health authorities via the media, 2) that will start a public investigation often conducted by biomedical doctors, who are strongly biased against CAM, 3) accusations of sexual or violent abuse make insecure patients re-interpret the treatment and complain in the media, 4) as this feedback-loop takes off more and more “evidence” gathers against the CAM-researcher or therapist culminating in a public “witch burning” scandal, 5) even if investigations by the police and the court of law shows that the original accusations was unsubstantiated – which is normally the case - the researcher or therapist will still be found guilty in malpractice by his biomedical colleagues, 6) in the end the prosecution process generates by itself the evidence against the CAM-researcher or CAM-therapist that takes him out of business and 7) the national health authorities’ participation in the persecution of CAM-researchers and therapists based on rumors violates the physician and therapist basic human rights and is a serious hindrance to research and development of CAM.

Keywords: Integrative medicine, holistic health, human rights.

Introduction

Two industries have economies larger than even small countries: the weapon industry and the medical industry. In capitalistic society money rule and these

* **Correspondence:** Søren Ventegodt, MD, MMedSci, MSc, Director, Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark. Tel: +45-33-141113. E-mail: ventegodt@livskvalitet.org

industries have been known to employ thousands of lobbyists and use billions of money on direct and indirect bribes (1). The sharing of the turnover from the pharmaceutical industry have been so efficient it made Ross Scholes say: “The highly trained medical professionals is like an accessory to the vast pharmaceutical and health-care industry, as a stewardess is to a jet airliner and the aviation industry” (1, p 37). This is of course not completely true; many doctors know that biomedicine like penicillin is highly efficient for syphilis, but has its limitations when it comes to pain and chronic diseases. Recently many physicians have realized that biomedicine is not the only kind of medical science, but when they were in medical school they were trained to give “the magic bullet” or pill and therefore not able to understand the process of healing and offer psychodynamic psychotherapy, bodywork or the two combined as in scientific holistic medicine (2-4).

Strong commercial interests promote drugs, but many physicians today believe that CAM (complementary and alternative medicine) would help the patient more than the drugs alone. This has become so obvious in countries with nationalized biomedicine, like in Denmark, where all ill people are treated with drugs at no cost for them, but for chronic disease the drugs do not cure the patients. Quite on the contrary literally half the nation has been turned into chronic patients: 40-60% of the Danish population is chronically ill now, half with mental and half with somatic illnesses in spite of the free biomedical healthcare (5). For these patients the alternative non-drug CAM therapies are the only alternative, but the regular physicians are not able to provide it. Because of this some physicians now take complementary education in scientific CAM, like the European Master of Science degree (MSc) in complementary, psychosocial and integrative medicine, which has become increasingly popular (6).

Biomedicine or CAM?

It is even more depressing that some drugs are giving the patients a false hope of cure, while the adverse effects of the drugs often are so strong that they constitute a severe hindrance to spontaneous healing and recovery. We have seen that with chemotherapy

for cancer and with antipsychotic drugs for schizophrenia and other severe mental illnesses. Long-term survival was not improved at all for metastatic cancers in the latest general review made by Ulrich Abel (7) and antipsychotic drugs are definitely not improving mental health according to the latest Cochrane metaanalyses of the treatments of psychotic patients with antipsychotic drugs (8).

We also know that total Number Needed to Harm (NNH) of many biomedical treatments are one, two or three, i.e. the fraction of patients getting an adverse effect is often one in three or more. At the same time we know that for many drugs Number Needed to Treat to Benefit (NNT) is often 5 or more, meaning that 20% or less of the patients are getting better on the drugs. Statistically many patients are harmed and few patients cured by the drugs. The conclusion to all this has been that “the drugs don’t work” (9), if we have to put it very dramatically.

CAM on the other hand is harming no patient, and is often helping one in two or three, at least according to the patient’s subjective report of feeling being helped, making alternative and holistic medicine likely to be the rational choice with most diseases. Interestingly more and more physicians are starting to doubt the pharmaceutical industries methods of documenting the effect of the drugs. When it comes to depression, we know that the most efficient antidepressive drugs according to a recent Cochrane metaanalysis are no better than active placebo (10). This means that the antidepressive drugs most likely only have adverse effects, no beneficial effect at all and most of these drugs have serious adverse effects.

Attack on the alternative

In spite of non-drug CAM and holistic medicine being helpful and not harmful with sometimes biomedicine being the opposite, biomedicine has managed not only to survive, but also to repress the majority of the CAM-practitioners and CAM-researchers on this planet. When you look only at the NNT (number needed to treat) and NNH (number needed to harm) figures, remembering that all modern physicians have sworn to rational and evidence-based medicine, this is a riddle. But when you look to the formation of public

consciousness in different societies, you will soon realize that the media is running the show. The media is bringing one story after the other on “CAM-quacks” harming and violating their patients and biomedical doctors saving them with new drugs and biochemical discoveries, so that biomedicine and the pharmaceutical industry will stay in power.

Most interestingly it seems that the pharmaceutical industry has found an ingenious solution to the threat from complementary and holistic medicine: *Directing whom the public health care system will investigate*. The process can be small and invisible for the public with some accusations of violations, medical errors, and harm done to a patient, making the health authorities look into the practice of the CAM-researcher or therapist, finding all the things that can be criticized, especially all the things that deviate from “biomedical standard treatment”.

The public employed medical experts that evaluate a controversial CAM research or treatment are normally biomedical doctors, often biomedical psychiatrists with a collective, close link to the pharmaceutical industry and no understanding of or sympathy for CAM. The CAM-practicing physician will therefore end up being blamed in public for not treating correctly according to standard.

The political system, which is under severe pressure from the biomedical pharmaceutical lobby, often accepts “preponderance of evidence” against the CAM-therapist and finds him guilty. In the recent period, when these cases have been brought in front of the court system (not the medical system) with demands of “clear and convincing evidence”, then the CAM-therapist is almost always found not-guilty (11)

Witch hunting in the media

Often the CAM opponents are using the media to obtain the intended public investigation. Most often biomedical physicians, again often psychiatrists, go to the media with severe accusations of sexual and violent abuse, horrible errors and serious harm done by the CAM-therapist. If the media buy into the story, which they are likely to do as sex, violence and news connected to medicine attracts enormous attention and sell newspapers more than anything else. Afterwards the public health authorities are politically motivated

to engage and demonstrate strength and efficiency by attacking the CAM-therapist, taking license etc. Often “leaks” to the media will bring a continuous flow of hot stories about the “bad” doctors/therapists.

As soon as a CAM-therapist is brought in this position, his patients lose faith and confidence and often they start re-interpreting what actually happened in the clinic and can even complain, in spite of feeling helped and completely satisfied with the treatment only yesterday. A strong wish to distance them and to get rid of an embarrassing association with the “CAM-witch” it often makes them terminate their treatment and change their opinion of the CAM-therapist. This is a normal psychological mechanism; we know from the New Testament that even the disciples of Jesus repudiated him, when he was caught by the Romans to be crucified.

Even in the unlikely case that the CAM-therapist is a true saint, a strong negative campaign in the media will still make him look like a criminal. So the strong negative, evil-intended exposure of the CAM-therapist, most often with fabricated evidences and untrue accusations, will destroy the CAM-therapist practice. The national health authorities could save a good doctor by investigating the case that is brought to attention in the media, and tell everybody what they found out; but this is not how it works. It seems the reality around a government is too politically and financially motivated to be guided primarily by truth and honesty. Instead of investigating the actual case, the public organs normally start to investigate the CAM-therapist himself. They normally go through all his case-records, many hundred of them, to see if he have done some errors in the past. Often this investigation goes back for many years. And the criteria for an error is seldom that a patient were harmed, or not helped; even if every single patient is helped and perfectly satisfied, the CAM-physician will be blamed that he is not treating according to normal biomedical standard.

The patients who start complaining will win their cases just because of this, in spite of knowing what treatment they originally accepted, and in spite of this treatment actually helping them. Most sadly, as soon as the CAM-therapist is seen as a non-healing and a destructive, harmful therapist, much of the therapeutic gain is actively destroyed by the patients, to disengage and distance himself or herself from the therapist. So

many hours and years of good therapeutic work with the patients can be wasted in a single evil campaign. Non-drug intervention is always using the placebo effects (12), and the placebo effect is as strong, just reversed. So the patients can easily destroy their therapeutic gains.

The double fork-attack by the media and the public health authorities are mutually reinforcing each other, making life a true hell for the CAM-therapist, who can literally lose everything in a few days or weeks. CAM-therapists who experience this are often forced to flee their own country, and in practice almost all basic human rights are seriously violated (1,11, see also appendix). It is worth to underline that it is the national health authorities that have the faith of the citizens, as it is normally expected that these national organs are there for the sake of the citizens. Everybody knows of course that the boulevard press or media are living from lies about sex, violence and all evil. So the responsibility for the massive violation of the human rights of the CAM-therapists is with the national health authorities.

Witch burning/hunting of the CAM-therapists is a social phenomenon fueled by a combination of several strong interests in society: The people want entertainment, and this must be about sex, violence, abuse, failure etc. The “evil doctor” abusing his patients is one of the archetypical stories that never stops entertaining. The media makes lots of money on twisting reality and adding sex and violence to the stories and the best stories are about people intending to do good, but instead being sexually violent or abusive. CAM-therapy is strongly provocative as it is body-and sex positive, believing strongly in the healing powers of nature. It has lots of enemies, like the pharmaceutical companies, the biomedical physicians, conservative people in power positions etc. Witch burning of CAM-therapists often involve politicians taking a free ride to exploit the situation and gain political position and power. This often leads to strong activation of public health organizations to investigate and even arrest the CAM-therapist and a strong motivation to “save the patients” by proving his guilt. Often this process creates its own evidence against the CAM therapists, very much like the famous processes against the witches.

In the process of being torched as a witch the CAM-therapist often loses all human rights, all

material and intellectual properties and his family/friends are often also prosecuted, making it impossible for him to stay in his own country. He often ends up like a refugee, who not even in the neighboring countries can live and practice his CAM-therapy. Even if the CAM-therapist in the end of the process wins in the court of law and all accusations turn out to be false, he will often have lost everything, because of his bad public standing. It is most problematic that witch-burning seems to be systematically used as a weapon against the CAM-therapists in processes started all over the world by powerful organizations like the Quackwatch with 130 employees seemingly being used the pharmaceutical industry (11). It is therefore important that every person professionally involved in health and justice understands the mechanism of witch burning to avoid to participate in it.

What should be done?

To prevent the national health authorities violating the basic human rights of the CAM-therapist and destroy good therapists that the country desperately needs and hinder the development of medicine into a more efficient, more holistic, and less harmful medicine, it is absolutely necessary that:

1. The national authority only investigate the actual case or complaint, and only when this is substantiated by facts - “clear and convincing evidence”, and not by “preponderance of evidence”. If it is substantiated then there is a reason to investigate the general practice of the CAM-therapists.
2. All investigations should be done in absolute confidentiality regarding the public and the media, and in complete openness regarding the CAM-therapist, who must be heard before any decision regarding the (mal)treatment is made.
3. Educated experts in CAM, not biomedical experts and psychiatrists, must do the investigation. In Europe for example we have the Master of Science in complementary, psychosocial and integrative medicine at the

- Interuniversity College in Graz based on a dedicated and long CAM-practice.
4. As non-drug therapy always use placebo, shift in consciousness and implanted philosophy of life (13), and so far we do not have a developed science of consciousness, the actual treatment must be judged only from its results, not from its scientific or un-scientific basis. Holy madness, crazy wisdom etc might be highly efficient, but un-scientific (14). Obvious evil behavior can be a tool, as traumas from evil acts according the principle of similarity, can only be healed by the repetition (in a smaller scale) of the evil act (2,3,4,15,16). The CAM-therapist acting "evil", or saying "evil things" (example: Yalom) (17) can and will be a part of holistic existential therapy.
 5. When the results of a non-drug CAM-treatment are investigated, it is worth to remember, that side effects are almost non-present in CAM-therapy without violent or sexual abuse (18), and if these two aspects are involved this is clearly a police matter. As in psychiatry, coercive persuasion is often used in CAM; in CAM this normally happens after consent and mutual agreement, in contrast to the coercive treatment in psychiatry. The signs of coercive persuasion, or "brain-washing" is "feeling of guilt, dependency, low self-esteem, worthlessness, anxiety and hopelessness in vulnerable individuals" (19), severe reduction of autonomy, and in the most extreme cases, suicide (20-23). Without these signs coercive persuasion is not likely to have happened. Implanted memories of for example incest can be very harmful to the patient's social and family life; this can be a product of coercive persuasion, but are more likely to be a symptom of a sexually related personality disorder (13).
 6. When damage is obviously present, as in suicide, it must be considered that a substantial number of psychiatric patients commit suicide with several percent doing it during admission to a mental institution, and several more percent doing it after admission (24). Only when the therapist obviously has failed the patient, is it fair to blame him for this. If the patient becomes psychotic, it will often be a brief reactive psychosis with full recovery in a few days or weeks (18). This is a rare state that some patients spontaneously enter often without being provoked at all, so it is not fair to consider this an inflicted damage. We know that the use of the placebo effect often has some minor, temporary adverse effects in a few percent of the patients; this is not to be considered as harm.
 7. Sexual abuse can in therapy happen in spite of consent as it per definition is abuse when a physician/therapist has sex with a patient (25,26). It is important to notice that sex means coitus, cunnilingus or felatio, or the patient for any reason touching the therapist's naked genitals. If these kinds of sexual behavior are not present, the patient has not been sexually abused (27). The reason for this strict definition is the need for the physician to be able to talk freely about sexuality and to use all available, gynecological procedures and all sexological tools, including bodywork to help his patient.
 8. Information and consent: The patient can be deceived by false information and false promises, which is a serious violation of good CAM-practice. A non-drug intervention is either talk or bodywork, and neither of these needs special information or consent. If an orifice is penetrated digitally or with an instrument, consent is always needed.
 9. Research in non-drug therapy is always allowed and encouraged; data that can reveal the identity of the patient cannot be shared. Quality assurance is best done with a validated questionnaire on quality of life and self-assessed health (i.e. QOL5 (28)), before, after and a year after treatment (28)
 10. The ethical code can also be violated in spite of no harm done. We strongly recommend the ethical code of the International Society for Holistic Health (26).

Conclusions

In conclusion, non-drug therapy without coercion or coercive persuasion and without sexual abuse is not dangerous or harmful (18). Therefore it is wise for any national health authority to expect that this is an evil-intended campaign and not the truth, when it comes to a CAM-therapist being blamed of harming a patient, especially if this comes from his biomedical colleagues or an organization in any way related to the pharmaceutical industry.

In the case of a CAM-therapist being accused, as well as in all other cases, the CAM-therapist is innocent until proven guilty. The media can often destroy a CAM-therapist clinical practice and the therapeutic gains of his patients and raise doubts about his methods, in a few days, and even make satisfied patients complain. There should be laws against that but such are difficult to have in a country

with free speech. But the national authorities that have the trust of the people should under no circumstances engage in such evil-intended campaign. The national authorities should do their very best not to share any suspicions with the public, and only announce faults and harm, when they are certain to have happened. It is extremely important that governments and their organizations and employees keep clear of every connection to the pharmaceutical industry, financially or otherwise. Only when experts in CAM are evaluating other CAM-therapists can the evaluation be fair. This does not mean that acupuncturists must evaluate acupuncturists, but the evaluating person must be both a trained CAM-therapist and scientifically trained in the healing principles of CAM.

Appendix

Frequent violations of the human rights of CAM-physicians and CAM-therapists following from prosecution by a national health authority when provoked by biomedical opposition.



all human rights for all
 FIFTIETH ANNIVERSARY OF THE UNIVERSAL DECLARATION OF HUMAN RIGHTS
1948-1998

Universal Declaration of Human Rights

Adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948

On December 10, 1948 the General Assembly of the United Nations adopted and proclaimed the Universal Declaration of Human Rights.

The National Health Authorities participation in the biomedical physicians and pharmaceutical industries “witch-burning” of CAM-physicians are causing the government to violate almost all the physicians humans rights. We will give examples of this in the following.

Article 1.

All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

Comment: Starting an investigation of a CAM-physician who is being accused of harming a patient, without first establishing certain knowledge of the nature and extend of the possible harm, is violating the CAM-physicians fundamental rights of being treated equally to other doctors, and with dignity. This is not done in a spirit of brotherhood, but in a spirit of going for a criminal, even before it is known if the accusations are in any way true.

Article 2.

Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Furthermore, no distinction shall be made on the basis of the political, jurisdictional or international status of the country or territory to which a person belongs, whether it be independent, trust, non-self-governing or under any other limitation of sovereignty.

Comment: The low status of a CAM-physician just being accused of quackery and harm of patients is being used against him.

Article 3.

Everyone has the right to life, liberty and security of person.

Comment: That the Health Authorities acts before it is established, if the patient has been harmed or violated in any way, seriously deprive the CAM-physician his liberty and security; the process of witch-hunting puts the CAM-physician in position, where his fundamental liberty and security is completely gone, and the government engaging in that is putting the CAM doctor though an experience very similar to torture, and many CAM-therapists end up broken and unable to work, very much like victims of torture.

Article 4.

No one shall be held in slavery or servitude; slavery and the slave trade shall be prohibited in all their forms.

Comment: The persecuted CAM-therapist is often reduced to a position where he would be better off as a slave, and he often ends up abandoning his own country.

Article 5.

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.

Comment: The treatment by a national health authority engaging in and by this act justifying the “witch-burning” is extremely cruel, inhuman and degrading indeed. When quality of life is very low suicide can be a rational act, and if the CAM-physician commits suicide during a campaign partly run by a national authority, this authority is partly responsible for the suicide.

Article 6.

Everyone has the right to recognition everywhere as a person before the law.

Comment: “Witch-burning” of a CAM-physician is in effect similar to severe physical, invalidating harm and even murder in some cases, and should be considered similar to that by law.

Article 7.

All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.

Comment: The treatment of the CAM-physician by the health authorities, as if he was bad or evil because of his preference for CAM instead of biomedicine is discrimination per se.

Article 8.

Everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law.

Comment: The national health authorities should protect CAM-physicians from encroachment, not participate in them.

Article 9.

No one shall be subjected to arbitrary arrest, detention or exile.

Comment: The social status of a “witch-burned” CAM-physician is similar to an arrested or exiled citizen.

Article 10.

Everyone is entitled in full equality to a fair and public hearing by an independent and impartial tribunal, in the determination of his rights and obligations and of any criminal charge against him.

Comment: When the national health authorities are making up the evidence against the CAM-physician, the tribunal becomes anything but impartial.

Article 11.

(1) Everyone charged with a penal offence has the right to be presumed innocent until proved guilty according to law in a public trial at which he has had all the guarantees necessary for his defense.

(2) No one shall be held guilty of any penal offence on account of any act or omission, which did not constitute a penal offence, under national or international law, at the time when it was committed. Nor shall a heavier penalty be imposed than the one that was applicable at the time the penal offence was committed.

Comment: By participating in the public witch burning of the CAM-physician, the national health authorities do NOT presume the CAM-therapist innocent; this violates Article 11(1). As the evidence created by the health authorities are often used in the court against the CAM-physician, the trial is not fair at all.

Article 12.

No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honor and reputation. Everyone has the right to the protection of the law against such interference or attacks.

Comment: The national health authority should work actively against the attacks on CAM-physician’s honor and reputation, not participating in it.

Article 13.

(1) Everyone has the right to freedom of movement and residence within the borders of each state.

(2) Everyone has the right to leave any country, including his own, and to return to his country.

Comment: Returning to ones country is often impossible for the torched CAM-physician.

Article 14.

(1) Everyone has the right to seek and to enjoy in other countries asylum from persecution.

(2) This right may not be invoked in the case of prosecutions genuinely arising from non-political crimes or from acts contrary to the purposes and principles of the United Nations.

Comment: When the CAM-physician seeks asylum in another country, the witch-burning often starts all-over again.

Article 15.

- (1) Everyone has the right to a nationality.
- (2) No one shall be arbitrarily deprived of his nationality nor denied the right to change his nationality.

Comment: The witch-burning can deprive the CAM-physician his nationality.

Article 16.

(1) Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to found a family. They are entitled to equal rights as to marriage, during marriage and at its dissolution.

(2) Marriage shall be entered into only with the free and full consent of the intending spouses.

(3) The family is the natural and fundamental group unit of society and is entitled to protection by society and the State.

Comment: By false accusation of harmful behavior and sexual abuse in the witch-burning process, the CAM-physician's family life is often violated; when the national health authorities participate in the witch-burning they become guilty in violating article 16.

Article 17.

- (1) Everyone has the right to own property alone as well as in association with others.
- (2) No one shall be arbitrarily deprived of his property.

Comment: The process of witch-burning often deprive the CAM-therapist all his property, as he cannot make a living anymore and thus loses everything if he chooses to stay in his own country.

Article 18.

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance.

Comment: When the CAM-therapist is forced to abandon his CAM-practice because of not conforming to or believing in biomedicine, this is a violation of article 18.

Article 19.

Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.

Comment: When the hearing of the CAM-physician is not correct and sufficient, and when the answers are not taken into consideration, this is a violation of article 19.

Article 20.

- (1) Everyone has the right to freedom of peaceful assembly and association.
- (2) No one may be compelled to belong to an association.

Comment: It is when the physician chooses to become CAM-therapist instead of belonging to the biomedical society that he is torched.

Article 21.

(1) Everyone has the right to take part in the government of his country, directly or through freely chosen representatives.

(2) Everyone has the right of equal access to public service in his country.

(3) The will of the people shall be the basis of the authority of government; this will shall be expressed in periodic and genuine elections, which shall be by universal and equal suffrage and shall be held by secret vote or by equivalent free voting procedures.

Comment: When the CAM-physician is given a bad reputation in society his political carrier is ruined.

Article 22.

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.

Comment: The which-burning deprives the CAM-therapist of his dignity and often also his possibilities for personal development (the money necessary for therapy etc).

Article 23.

(1) Everyone has the right to work, to free choice of employment, to just and favorable conditions of work and to protection against unemployment.

(2) Everyone, without any discrimination, has the right to equal pay for equal work.

(3) Everyone who works has the right to just and favorable remuneration ensuring for himself and his family an existence worthy of human dignity, and supplemented, if necessary, by other means of social protection.

(4) Everyone has the right to form and to join trade unions for the protection of his interests.

Comment: The process of which-burning most often deprives the CAM-therapist of his work and income; after the process he will often only earn a fraction per hour of what he earned before. If he did research he will often be deprived of his funding. The process will almost always burden his family and often lead to family break-up. His children will often have severe disadvantages from his poor social standing, like the other kids will not be allowed to come in the home etc. His company and trade unions will almost often be compromised.

Article 24.

Everyone has the right to rest and leisure, including reasonable limitation of working hours and periodic holidays with pay.

Comment: The process of which-burning most often deprives the CAM-therapist all rest and reduces leisure significantly; money for holidays etc are often short.

Article 25.

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

(2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Comment: The witch-burning often completely deprives the CAM-therapist of his standard of living and very often he will become sick from the pressure, prosecution and lack of sense of coherence with his society. Friends and colleagues will often turn their back on him.

Article 26.

(1) Everyone has the right to education. Education shall be free, at least in the elementary and fundamental stages. Elementary education shall be compulsory. Technical and professional education shall be made generally available and higher education shall be equally accessible to all on the basis of merit.

(2) Education shall be directed to the full development of the human personality and to the strengthening of respect for human rights and fundamental freedoms. It shall promote understanding, tolerance and friendship among all nations, racial or religious groups, and shall further the activities of the United Nations for the maintenance of peace.

(3) Parents have a prior right to choose the kind of education that shall be given to their children.

Comment: The CAM therapist will normally lose the value of his education or therapeutic training, as he often will lose his license and/or ability to practice.

Article 27.

(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Comment: The witch-burning process normally deprives the CAM-therapist of his free participation in society and his scientific etc. production is often losing its value as his name is ruined.

Article 28.

Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.

Comment: The witch-burning destroys the social order around the CAM-therapist.

Article 29.

(1) Everyone has duties to the community in which alone the free and full development of his personality is possible.

(2) In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.

(3) These rights and freedoms may in no case be exercised contrary to the purposes and principles of the United Nations.

Comment: The witch-burning process deprives the CAM-therapist of his possibilities to exercise most of his formal rights and freedoms.

Article 30.

Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein.

Comment: Unfortunately the State often plays the most central role in the which-burning of the CAM-therapists.

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Original Articles

The effect of antipsychotic drugs and non-drug therapy on borderline and psychotic mentally ill patient's quality- adjusted life-years (QALY)

Søren Ventegodt, MD, MMedSci, EU-MSc-
CAM^{*1,2,3,4,5}, Niels Jørgen Andersen, MSc⁴,
Isack Kandel, MA, PhD^{6,7} and Joav
Merrick, MD, MMedSci, DMSc^{5,7,8,9}

¹Quality of Life Research Center, Copenhagen,
Denmark;

²Research Clinic for Holistic Medicine;

³Nordic School of Holistic Medicine, Copenhagen,
Denmark;

⁴Scandinavian Foundation for Holistic Medicine,
Sandvika, Norway;

⁵Interuniversity College, Graz, Austria;

⁶Faculty of Social Sciences, Department of Behavioral
Sciences, Ariel University Center of Samaria, Ariel,
Israel;

⁷National Institute of Child Health and Human
Development;

⁸Office of the Medical Director, Division for Mental
Retardation, Ministry of Social Affairs, Jerusalem, Israel

⁹Kentucky Children's Hospital, University of Kentucky,
Lexington, United States

Abstract

It is impossible for patients, physicians and health-politicians to know, which treatment to choose if the treatment outcome is not in one integrative measure. To evaluate the total outcome of the treatment of borderline and psychotic mentally ill patients with antipsychotic drugs compared to non-drug treatments, we choose the two major outcomes "quality of life" (QOL) and "survival time" integrated into one total outcome measure, the Quality-Adjusted Life Years (QALY).

Methods: We estimated total outcome in QALY (Δ QALY) by multiplying the estimated difference in global QOL (Δ QOL) and the estimated difference in survival time (Δ survival time): Δ QALY = $\sum_{\text{all outcomes}} (\Delta \text{QOL} \times \Delta \text{survival time})$. We included factors like suicide and spontaneous drug-induced death that is normally not included in clinical randomized trials of antipsychotic drugs.

Results: We found that the total outcome of treatments with antipsychotic drugs was about -2 QALY; the total outcome from non-drug therapies (psychodynamic psychotherapy, clinical holistic medicine) was about $+8$ QALY.

Conclusions: When the total outcomes of the treatments were measured in QALY, antipsychotic drugs harmed the patients, while the patients benefited from the non-drug therapies. Antipsychotic drugs violate the medical ethics of Hippocrates, "First do no harm"; non-drug therapy is therefore the rational treatment for the borderline and psychotic mental illnesses. Treatment with antipsychotic drugs is only justified, when prolonged non-drug therapy has failed.

Keywords: Psychiatry, mental health, quality of life, holistic health, antipsychotic drugs, clinical holistic medicine, suicide, adverse and side effects, spontaneous drug-induced dead, QALY.

* **Correspondence:** Søren Ventegodt, MD, MMedSci, MSc, Director, Quality of Life Research Center, Classensgade 11C, 1 sal, DK-2100 Copenhagen O, Denmark. Tel: +45-33-141113; E-mail: ventegodt@livskvalitet.org

Introduction

To evaluate the total outcome in medicine there are two general outcomes of primary interest: *survival* and *global quality of life*. These two measures can easily be integrated into Quality-Adjusted Life Years (QALY) (1). A positive QALY-contribution comes from positive effects of a treatment, and a negative QALY-contribution comes from a negative effect, called the adverse or side effects, like for example the patient's death caused either by drug-induced suicide or by the toxic adverse effects. Recent studies on all mentally ill patients in Denmark revealed a high risk of suicide (2) and unexplained death associated with psychiatric treatment and antipsychotic drugs (3). NNT (number needed to treat) and NNH (number needed to harm) numbers have been calculated for the treatment with antipsychotic drugs (4) and for the non-drug treatment (5), and the NNHs have been added up to a total NNH (4,5). Only some aspects of effects and side effects were related to QOL judged from the empirical from the QOL-research (6-10); the NNT and NNH related to global QOL were thus evaluated on an empirical basis to estimate the size of the impact on QOL both of the positive and negative effects, to find the total impact on QOL of the treatment. Then the treatments impact on survival was evaluated. All in all the results made it possible to estimate the total positive and negative impact of the two alternative treatments in the dimensions *QOL* and *survival time*. From this we calculated the QALY impact of the different treatments of mentally ill with antipsychotic drugs and without these drugs, to compare them and find the rational, evidence-based treatment.

The borderline and psychotic, mentally ill patients and their physicians can today choose between either a drug treatment or a non-drug therapy like psychodynamic psychotherapy (11-15) or scientific CAM (complementary and alternative medicine i.e. clinical holistic medicine) (16-18). Till this day many different outcomes and adverse effects have made the picture highly unclear to the patients, the doctor, and the political decision maker. This study aims to provide the integrated outcome data needed to make a scientific comparison of the therapeutic value of the competing treatments and thus the data needed for a rational choice.

Methods

The QALY analyses of the effect of the non-drug treatments were rather trivial; although we had no data on survival, we had no reason to believe that any patient's life was shortened because of non-drug therapy (5). Quite on the contrary it seemed the therapy would prevent suicide and prolong life, but no accurate data could be found, so we did not include this in our calculations. We found QOL to be improved (11), or more often positive effects indicating that QOL was improved for the mentally ill patients (6-8) including patients with schizophrenia (9,10), thus giving a positive QALY outcome of non-drug therapy for mental illness.

The analysis of the QALY outcome for the treatment of mentally ill patients with antipsychotic drugs was much more complicated, so we had to build it partly on a meta-analysis on the total outcome of antipsychotic drugs (4), and partly on other studies as there were factors difficult to include in the traditional effect study due to lack of data. Factors like suicide rates and spontaneous drug-induced over-mortality were most often not included in the randomized clinical trials, so this information needed to be collected from separate studies. So we build the QALY-meta-analysis on the outcomes of antipsychotic drugs, and included the factors that were not included in the studies, to get a more complete picture of the positive and negative effects of antipsychotic drugs. Thus the present analysis contains more information and therefore is likely to give a more accurate picture than the documentation provided by the pharmaceutical industry.

We estimated the total outcome in QALY by multiplying the estimated difference in global QOL and the estimated difference in survival time: $\Delta \text{QALY} = \sum_{\text{all outcomes}} (\Delta \text{QOL} \times \Delta \text{survival time})$. We made all estimations conservatively, to avoid adding a bias here. We estimated conservatively the average patient to be 25 years old at treatment start; we know that most persons with schizophrenia are diagnosed between 15 and 25 years of age. The antipsychotic treatment is normally continuing for the rest of the patient's life, which we conservatively set to last for 65 years (which is shorter than the average life span of about 75). We used the measure "global QOL" and not health-related QOL, which is not based on QOL-

theory, but only on ad hoc measures (19) and preferred values confirmed with many different measures to large values only confirmed by one measure. We avoided the problems related to QALY described in an earlier paper (1).

Results

Recent Cochrane meta-analysis has shown that all antipsychotic drugs share the effect profile of chlorpromazine with a similar toxicity (20). We only found the outcome “mental state” relevant to QOL, as “relapse”, “behavior” and “global state/global impression” all related to behavior, or to a mix of behavior and mental state. For comparison a normal life in Denmark is 75 life-years (21) of a mean 70% QOL (12,13) equivalent to 52.5 QALY.

Antipsychotic drugs, positive QALY-contributions: For antipsychotic drugs we found no improvement in mental state in our meta-analysis of 79 Cochrane meta-analyses of antipsychotic drugs (4). The analysis included all relevant data on subjective dimensions like fear, agitation, hallucinations, confusion etc. None of the dimensions related to global QOL showed any improvement; thus the positive contribution from improvement of mental state was 0.00 QALY.

Antipsychotic drugs, Negative QALY-contributions: We found in our meta-analysis (4) that severe adverse effects were very common with antipsychotic drugs, on average every patient had at least 1.66 adverse effects (11). We know from an earlier study that people with one or two health problems on average have a global quality of life that is 74.2% compared to people without health problems who have a global QOL of 76.1% (12); the health problems is therefore associated with a loss of global QOL of 1.9% for as long as the drugs are taken, which is normally all life if treated with antipsychotic drugs. This sums up to a QALY impact of $-1.9\% \text{ QOL} \times 40 \text{ Years} = -0.76 \text{ QALY}$.

2.04% of the patients in the schizophrenic spectrum committed suicide in direct connection to starting the drug treatment (during psychiatric admission) and another 2.80% committed suicide immediately after admission (0-6 month) (22) giving a total of 4.84% of the patients with psychotic mental

illnesses committing suicide in connection to the treatment with antipsychotic drugs, which is standard treatment in Denmark. As these patients are normally young (estimated mean of 25 years) and life expectancy of at least 65 years (conservative estimate), with at least a QOL of 41.4% (schizophrenia) (the global QOL for schizophrenic patients in Denmark (13)), this sums up to a QALY impact of $-4.84\% \times 41.4\% \text{ QOL} \times 40 \text{ Years} = -0.80 \text{ QALY}$.

We know that antipsychotic drugs is associated with an 25% increased likelihood of unexplained sudden death, which normally is about 0.3% a year (23) and this continues for every year the drugs are taken; this sums up to a total of 40 years \times 0.25 overmortality/year, equal to 10 times the normal mortality from spontaneous death of 0.3%; each death takes in average 20 years from the persons life. The total likelihood for spontaneous death is thus 3%. This sums up to a QALY impact of $-3\% \times 20 \text{ years} \times 41.4\% \text{ QOL} = -0.25 \text{ QALY}$. The total QALY outcome of antipsychotic drugs is -1.81 QALY (see table 1).

Non-drug therapy, positive QALY-contributions: Psychodynamic psychotherapy have in uncontrolled studies cured 1/3 to 1/8 of the schizophrenic patients (9,10) and clinical holistic medicine have cured 57% of patients who felt mentally ill (11); a conservative calculation of non-drug therapy gives us a permanent improvement of QOL of 20%; the QALY contribution is thus 40 years \times 20% QOL = 8 QALY. The 20% improvement in global QOL is conformed by measuring the global QOL before, after and one year after non-drug treatment (11,24).

Non-drug therapy, negative QALY-contributions: Adverse effects are generally considered not to be a problem in non-drug therapy, and suicide is very rare and actually more likely to be prevented than to be provoked (5-11,25). There is no indication of spontaneous death happening more often than usual (5). Conservatively estimated the QALY contribution from this is $+0.00 \text{ QALY}$. The total QALY outcome from the non-drugs treatment psychodynamic psychotherapy and clinical holistic medicine is thus about 8 QALY (see table 1).

Table 1. QALY outcome from treatments with antipsychotic drugs and the non-drug treatments (PP= psychodynamic psychotherapy; CHM= clinical holistic medicine)

Treatment	QALY contribution
Antipsychotic drugs, positive treatment effect	+ 0.00 QALY
Antipsychotic drugs, adverse effects	-0.76 QALY
Antipsychotic drugs, suicide	-0.80 QALY
Antipsychotic drugs, spontaneous death	-0.25 QALY
Total QALY contribution, antipsychotic drugs	-1.81 QALY
Non-drug treatment (PP, CHM), positive treatment effects	+8.00 QALY (ref)
Non-drug treatment (PP, CHM), adverse effects	- 0.00 QALY
Non-drug treatment (PP, CHM), suicide	+ 0.00 (preventive effects, size unknown)
Non-drug treatment (PP, CHM), spontaneous death	- 0.00 QALY
Total QALY contribution, non-drug treatment (PP, CHM)	+ 8.00 QALY

Discussion

The method of QALY has been criticized because of the many different ways QOL can be measured (1), giving very different results depending on the QOL-measure. We find this critique to be correct when it comes to health-related QOL; we have therefore measured global QOL in 11 different ways (12-15,19) and have learned that the measure of global QOL is fairly robust, and surprisingly independent of theory and composition of questions in the questionnaire (12,13,19).

This means that global QOL can be seen as a real, measurable phenomenon, and the measure of global QOL as an expression of a person's global state of life. The multiplication of global QOL and life years have been criticized also for being too simple; a long life with poor quality of life could be worse than being dead (1) and suicide could therefore be a rational act. We do not find any of these considerations conflicting with our estimations. We conclude that the presented conservative estimates are fair and free from bias.

Conclusions

In the treatment of the psychotic mentally ill patient, the total outcome of the treatment with antipsychotic drugs is -2 QALY, while the total outcome of non-drug therapies (psychodynamic psychotherapy and clinical holistic medicine) is +8 QALY (see table 1). The treatment with antipsychotic drugs is harming the patient, while the treatment with the non-drug therapy is beneficial judged from a QALY analysis. We must therefore strongly recommend non-drug therapy to patients with borderline and psychotic mental illnesses, whenever possible and warn against the extensive use of antipsychotic drugs.

Acknowledgments

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Double blind, randomized placebo controlled mono centre clinical study on the influence of Rescue® Bach flower remedy on erythrocyte rouleaux formation

**Kerstin Fringes, MSc, Beatrix
Wulkersdorfer, MD and Heinz Spranger,
MD***

Interuniversity College for Health and Development
Graz, Castle of Seggau, Austria

Abstract

The current study investigated the effect of Bach flower Rescue®-drops on erythrocyte rouleaux formation. Bach flower Rescue®-drops were used, because they are said to be useful in situations of emergency stress. Erythrocyte rouleaux formation was monitored as the main parameter because it is physiologically linked to vasodilatation, which is a counteraction to stress. A double-blind, randomized, placebo controlled mono centre clinical study was performed including 32 healthy test persons in a relaxed state. Volunteers in group 1 received Rescue®-drops, whereas test persons in group 2 obtained a placebo solution. Blood samples were analyzed under a dark field microscope before and after intake. Statistical analysis showed a highly significant difference between group 1 and 2 ($p=0.000$), which leads to the conclusion that Rescue®-drops cause vasodilatation with a following erythrocyte rouleaux formation.

Keywords: Integrative medicine, holistic health, stress, Rescue® Bach flower remedy, vasodilatation, erythrocyte rouleaux formation.

Introduction

The concept of “stress“ was first documented by Selye in 1936 (1). In the course of his investigations it was found to be a major causative factor for the development of psychosomatic diseases. The economic costs of stress are manifold. Data from the European Union have shown that the overall costs associated with mental health problems due to stress have been estimated to be in the range of about 265 billion Euros creating an enormous economical damage(2).

Different treatments are currently available in order to manage stress and its symptoms. Psychotherapy offers different strategies, such as the

* **Correspondence:** Heinz Spranger, MD, Interuniversity College for Health and Development Graz, Castle of Seggau, Austria. E-mail: college@inter-uni.net

time-, stimulus-, excitement- and harassment-management. Relaxation methods, such as autogenic training, yoga, Jacobsen's progressive muscle relaxation technique, and other treatments for stress equalization and adaptation are available.

An incredibly high amount of money (only in Germany about € 9 billion) spent on anxiety related drugs, gives a clear insight into patient's preferred treatment of stress coping.

The Bach flower therapy (3,4) is basically a form of plant therapy. It is applied to influence somatic and psychogenic phenomena. The so called Rescue®-drops, to name one of the applications, has been recommended especially in situations of emergency. These Bach flower Rescue®-drops are a combination of: Clematis, Impatiens, Rock Rose and Star of Bethlehem.

We decided to use this blend in the study presented here to determine a reaction, especially because no medical concerns regarding its application were expected. Vasoconstriction, the physiological reaction of the human body under acute stress, is controlled by the sympathetic nervous system. Counteraction is induced by the endothelial nitrogen monoxidase (eNOS) causing vasodilatation (5). Different vessel diameters are generated by specific intravascular pressure ratios. So called "rouleaux" formation, the physiologically erythrocyte agglomeration, is caused in dilated vessels and disrupted under vasoconstriction due to a pressure increase (6,7). Based on this knowledge, we assessed the erythrocyte rouleaux formation, in stress, as a parameter worthwhile of being investigated (8).

Our study focused on the question if Bach flower Rescue®-drops composition may cause erythrocyte rouleaux formation in a healthy test population. The main goal was to investigate the effect of Rescue®-drops on the physiology of stress.

Methods

In the following work we performed a double-blind, randomized, placebo controlled mono-centric clinical study. Forty nine healthy volunteers, 29 women and 20 men, at ages ranging from 18 to 75 years were included in this study. Persons under anti-coagulation, anti-hypertensive and anti-hypotensive drug therapy,

as well as alcohol addicts were excluded from participating. None of the participants was under special stress during the study period.

We used dark field microscopy, a special type of light microscopy. It visualizes transparent and low-contrast objects without staining, which demonstrated an ideal means to analyze the unaltered blood flow. The fact that no staining is required makes an observation of cellular components of the blood very simple.

For the examination we used a laboratory microscope (Modell Novel N-400, Hengtech Optical Instruments, Viernheim, Germany) with a dark field condenser N. A. 1,25 (oil) (Hengtech Optical Instruments, Viernheim, Germany) at 100x magnification. Archival storage and documentation was performed using a digital camera for microscopes (HDCE, Hengtech Optical Instruments, Viernheim, Germany) and special software (Software Novel INOVO®-USB.2.0-Cam, Hengtech Optical Instruments, Viernheim, Germany).

Blood samples were taken from the finger pad of healthy test persons and analyzed under the dark field microscope regarding the presence and length of rouleaux. Seventeen volunteers had to be excluded from further attendance due to a significant initial rouleaux formation.

From the remaining 32 test persons 16 volunteers received, randomly, solution number 1, containing the Bach flower Rescue®-drops as are commercially available (containing 27% grape alcohol). The second test population obtained solution number 2, a placebo solution (pure 27% grape alcohol). Solutions (4 drops) were administered orally for one time. Subsequently, a second examination regarding erythrocyte rouleaux formation was performed with the goal to determine differences before and after the treatment. Basic and second exploration was digitally photographed and archived.

Statistical analysis

For statistical analysis, we chose an analysis of variance for repeated measures with time as factor 2. It turned out to be an ideal approach to investigate the effects on the two experimental groups in relation to the time.

Results

Table 1 shows a significant relation between the group and the point in time of measurement (“factor one”). At time point 1 no difference between the groups was determined, which lead to the decision to ignore the presence of main effect for group 1 (significant difference between the groups over a certain time frame) and factor 1 (significant difference between the time points within the groups). F evaluates the effect of the groups.

Table 2 shows a highly significant (F (1/30) =119.339, p=0.000) change between different time points in group 1 only, but not in group 2.

Each F determines the multivariate simple effects of factor 1 within each combination of level of other shown effects. Statistical analysis showed a highly significant change of group 1 = verum group after Rescue®-drop intake. A significance in group 2 = placebo group was not found. In all 16 test persons receiving the Rescue®-drops (verum group), an increasing erythrocyte rouleaux formation (figure 1) was found. One case the control group showed an increase in erythrocyte rouleaux formation. A single test person featuring slightly increased erythrocyte rouleaux formation on primary checkup was free from further changes after the intake of placebo solution.

Table 1. Uni-variate analysis showing the relation between group and point in time of measurement

Faktor 1		Sum of squares (SS)	Df	Mean of squares (MS)	F	Significance (p)
1	Contrast	.125	1	.125	1.000	.325
	Error	3.750	30	.125		
2	Contrast	162.000	1	162.000	51.702	.000
	Error	94.000	30	3.133		

Table 2. Multivariate analysis showing changes between different time points in group 1 and group 2

Group		Value	F	Hypothesis Df	Error df	Significance (p)
1	Pillai-Spur	.799	119.339	1.000	30.000	.000
2	Pillai-Spur	.003	.083	1.000	30.000	.776

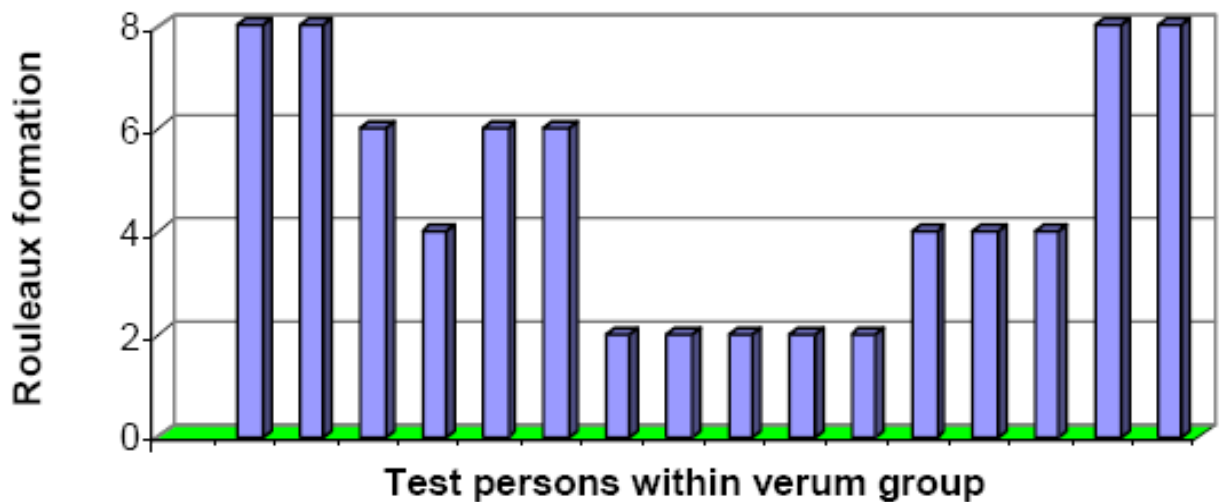


Figure 1. Degree of rouleaux formation in verum group. See text for explanation.

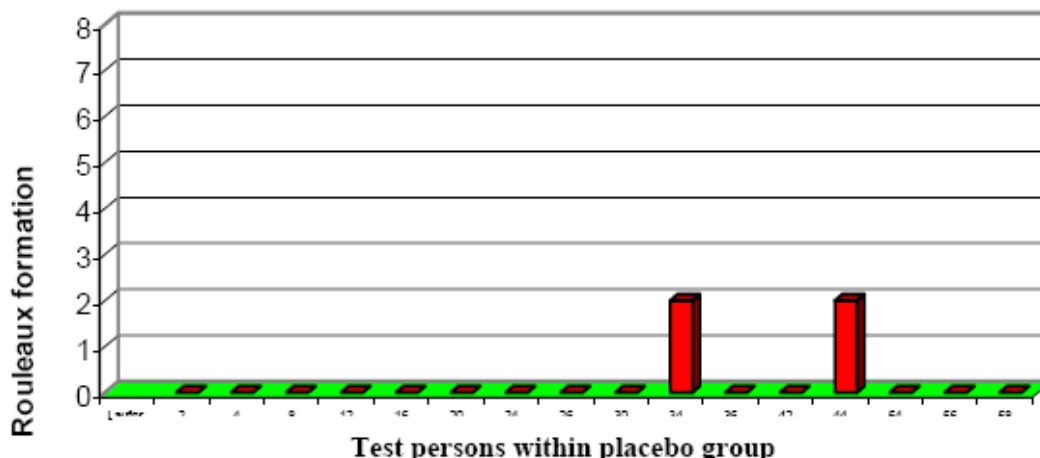


Figure 2. Degree of rouleaux formation in placebo group. See text for explanation.

Discussion

Aim of this study was to determine the possibility of effect detection after the application of Rescue®-drops using a physiological indicator. Therefore, the model of a placebo-controlled, double-blind study was used. Erythrocyte rouleaux formation as a sign of counter reaction to stress was investigated in a healthy test population. A highly significant effect of Rescue®-drops was determined. Effect was identified by presence of rouleaux formation using a dark field microscope. This physiological reaction was interpreted as a sign of capillary vasodilatation and secondarily as stress regulation.

According to previous studies, the above documented physiological effect may not be strong enough to cause a subjectively detectable improvement when compared to the placebo group. It is recommended to repeat the present study involving an independent laboratory.

Further investigations will be necessary using a larger test population. The combination of clinical and psychological interventions would be a useful approach in this regard, and quality of life assessment may be an important tool.

Conclusion

Rescue®-drops caused erythrocyte rouleaux formation. It can be assumed, that this is caused by vasodilatation in terms of stress management.

Conflict of interest

None. There is no commercial connection between the authors and Bach flower pharmaceutical industry.

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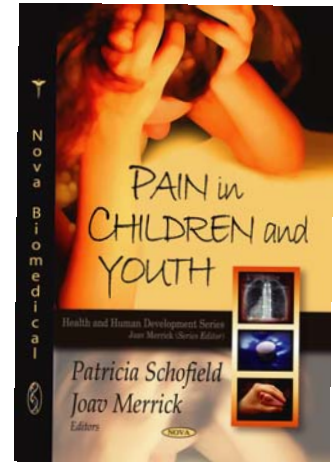


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PAIN in CHILDREN

Patricia Schofield
Joav Merrick
Editors

and YOUTH



For many years it was believed that children, and in particular babies, did not feel pain. But over the last twenty years or so this perspective has changed, and we have seen many highly specialised pain clinics being set up around the world, which are dedicated to addressing the needs of the younger members of the population. This acknowledges that children in pain are not simply "smaller adults", but that they have particular experiences and requirements that can only be addressed by experts in the field, who are aware of the developmental factors that may influence their pain experience. The age of the child, past experience with pain, and family and cultural aspects influence the child's response to new, painful situations. The reactions of parents, who can serve as role models, are important, but gender differences are also important when it comes to pain in children.

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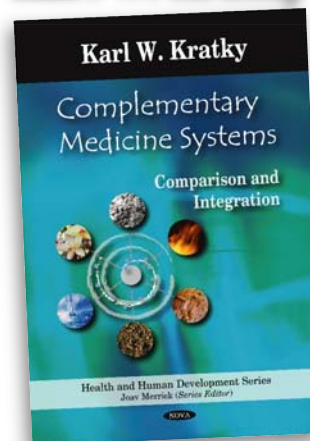
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Complementary Medicine Systems

Comparison and Integration

Karl W. Kratky

For almost all of us the question of health and illness is essential but although a considerable amount of relevant literature is available, the confusion concerning this subject matter still seems to grow. In general people tend to trust no less than their own personal approach, while alternate positions find themselves either ignored or opposed. This book chooses a different path as it investigates not only the potentiality of communication among the various disciplines but also considers four basic views or perspectives as interpretations of reality. In the process it becomes apparent that classical science and more recent developments, like chaos theory, no longer speak the same language. Furthermore, several well-known modes of healing are compared (like orthodox medicine and homoeopathy from the West, as well as Indian, Tibetan and Chinese medicine from the East). Apart from the expected differences, surprising parallels are emerging, above all the assertions concerning fundamental reactions of the human organism. This comparison leads to an integration of common results regarding the various medicine systems, which can be illustrated using a geometrical model (health disc, life spiral). Thus, the basis for the translation of insights and findings from one medicine system to another has successfully been established; therefore the utilisation of the (ancient) knowledge of one method of healing in other therapeutic systems proves to be possible.



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Health and Happiness from Meaningful Work

Research in Quality of Working Life

**Soren Ventegodt
Joav Merrick**

Work is an important part of the life of the modern man, as it always has been, but work has become more complicated than before. Today what we do is often done as a part of a large organization, and the value created by the single member of the organization has become increasingly difficult to measure.

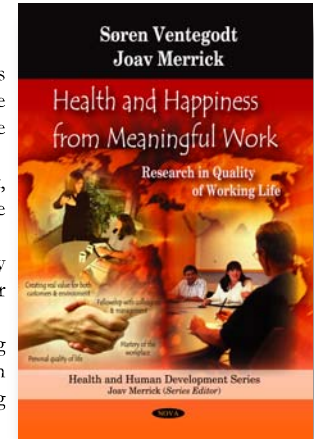
Organizations have become increasingly responsible for not only the physical work environment, but also for the mental working environment, and factors like stress and sexual harassment are becoming more and more regulated by company rules and culture.

The health of employees has become a major financial interest of the company as only healthy employees and leaders can perform optimally. Often the companies have health insurance for their people.

Today employees and leaders also expect work to provide their life with meaning and stimulating experiences and developing challenges. Society is developing fast and only companies with modern, well-oriented and culturally integrated employees can win the competition by offering costumers, clients or patients the best products and services.

In many studies a strong association between quality of life, development of personal character, self-realization, development of talents and skills, physical and mental health, meaning of life, sense of coherence and similar core concepts of modern medical and psychosocial sciences have now been strongly associated with work satisfaction, joy on the job and similar concepts.

We have created a formula according to which the actual integrated status of worker can be calculated. We have decided to call the integrated concept of all above mentioned dimensions for working life quality, similar to the well-known global quality of life concept in medicine and social sciences. We are proud to present, in the present book, a mathematical formula from which the created value of an employee or leader can be known, if only the working life quality is known. We also provide a questionnaire for measuring the quality of working life, based on a theory of quality of working life. In a study on a random sample of the Danish population we have found a strong statistical association between the measured quality of working life and health.



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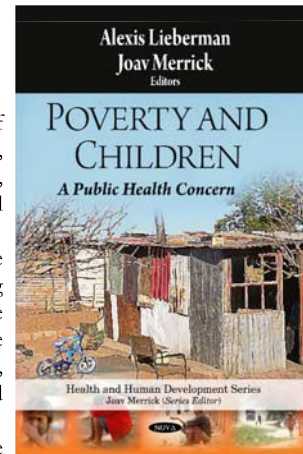
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POVERTY AND CHILDREN

A Public Health Concern

Alexis Lieberman
Joav Merrick
Editors



Poverty, while not a disease process, is well-known to have far-reaching effects on the health of children and adolescents. In developing countries, poverty is associated with inadequate shelter, unsafe water and inadequate nutrition, leading to increased rates of infectious diseases, including malaria and diarrheal illnesses, as well as increased rates of infant and maternal mortality.

Even in wealthy, industrialized countries, poverty negatively impacts child health, starting life with increased rates of prematurity, low birth weight and maternal depression, and continuing into childhood with increased rates of asthma, dental caries, inadequate or inappropriate nutrition, as well as increased exposure to trauma and abuse, violence and crime. By the time these children become teen-aged patients in our clinic, they have increased rates of aggression, mental health problems and delinquent behaviors, as well as lower reading and math scores and increased rates of prematurely leaving their education.

In this book edited by two leading experts we have asked people from different parts of the world to focus on the comorbidities of poverty.

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