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IMPROVING QUALITY OF LIFE USING MIND-BODY THERAPIES

**The evaluation of a course intervention
for personal self-awareness and
development**

Lotta Fernros



**Karolinska
Institutet**

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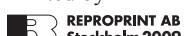
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ABSTRACT

The general aim of this research project was to conduct a research project in complementary and alternative medicine (CAM), and to evaluate an unusual course method. Since 1985 a special training centre at Vikbolandet outside Norrköping, has been holding courses in personal development, "Meet Yourself stage 1". The course includes body-psychotherapy and meditation, and exercises focusing on the importance of emotions for personal health. The old Indian chakra energy centre system for body awareness is used. As a survey of therapeutic methods, Jones' classification "primary modes of therapeutic action" (PMTA) is useful, consisting of six groups: 1 chemical, e.g. herbal medicine; 2 physical, e.g. massage; 3 mind-body medicine (MBM), e.g. meditation; 4 energy flow, e.g. acupuncture; 5 psychology, e.g. psychotherapy; and 6 spiritual, e.g. healing. The method (course) studied here is focused on the three categories of PMTA: 3 MBM, 4 energy flow and 5 psychologies.

Aims and methods *Study I* is descriptive, a cross-sectional survey of self-assessed health-related quality of life (HQOL) in participants, compared with the Swedish population. This initial study group consisted of 107 participants (age 20–70). On arrival, before the course, the participants completed three questionnaires. The first was SWEDQUAL, with 61 items for self-rating of HQOL classified in 13 areas, e.g. cognition, physical functions, sleep, pain, relations and emotions. The second was Antonovsky's Sense of Coherence with 13 items divided into three areas: comprehensibility, meaningfulness and manageability. The third was about work, education, experience of CAM, sick listing and medication. Comparisons were made with population data from Statistics Sweden, the National Insurance Office and the National Board of Health and Welfare. *Study II* is a before-and-after, case-control intervention study, and the starting values above for HQOL and SOC were compared with exactly the same questionnaire mailed six months later. Each of the participants (n=83) was compared with him/herself and the group. A control group was added consisting of earlier participants (1998–99, n=69), matched for sex and age, who had made parallel self-assessments. *A third aim* was to capture unexpected patterns in this unexplored field, by collecting responses to the open question "Has anything happened in your life, which you feel is important, during the last six months?"

Results In *study I*, six of the 13 subscales for HQOL showed pronounced and significantly low starting values ($p<0.001$) in the initial study group (n=107), namely: emotional health, cognitive, family and partner functioning. This is unusual in a group with such high education level. Long-term sick listing (>6 months) was three times as common as in the population. The outcome measures in *Study II* was changes in HQOL and SOC-13 in the followed-up study group (n=83) and in the control group (n=69). Eight subscales of HQOL showed clinically significant improvements in the study group ($>9\%$, $p<0.01$), namely: general health (9%), emotional well-being (negative 45% and positive 26%), cognitive functioning (24%), sleep (15%), pain (10%), role limitations due to emotional health (22%) and family functioning (16%). Physical, partner and sexual functioning were normal in both groups. *Self-rated SOC* was improved in the study group after the course (5.1%, $p<0.01$), challenging previous conclusions that the SOC value is stable for the same person irrespective of events. *Use of psychoactive drugs* decreased in young participants after the course. The *comments on important life events* are grouped according to six different themes. The three most important themes were *relations, work development and the awakening process*, which then leads to creative decisions to change one's life. Two concern *personal health* and the *health of family members*. The last reflects *psychological resistance*.

Conclusions This study group consisting of well-educated women and men rated their initial emotional health unexpectedly low. After the course there was a significant improvement in HQOL and SOC, up towards normal population values. *The studies also found that:* a) It is possible to perform a scientific evaluation even of soft, self-assessment data describing subjective experiences after a course intervention based on a theoretical background of alternative medicine. b) The selected questionnaire methods gave a reasonable spectrum of clear, clinically significant changes mixed with stable values. The method seems particularly effective for discovering the state of emotional well-being. c) Allowing spontaneous comments in data collection can be well worth the effort in a previously unexplored area, enabling the capture of completely new phenomena. d) The course duration of seven days means that people with fraught memories have time to get past the initial shock phase of the crisis process and can better start emotionally dealing with it in a constructive way. e) The course intervention was able to improve the participants' HQOL and SOC. f) The course improves cognitive and emotional function, which in turn increases motivation. It thus has the potential to be used as a starting point in rehabilitation for working life, for people who are forced for health reasons to cope with a readjustment crisis and establish a foundation for a new orientation.

Key words: Breathing Exercises, Complementary Therapies, Health Promotion, Health Status Indicators, Holistic Health, Imagery, Meditation, Mind-Body Relations, Movement- and psychophysiology, Qi, Quality of Life, Questionnaires.

LIST OF PUBLICATIONS

- I. **Fernros L**, Furhoff AK, Wändell PE
Quality of life of participants in a mind-body-based self-development course:
A descriptive study. *Quality of Life Research*, 2005; 14: 521-8.

- II. **Fernros L**, Furhoff AK, Wändell PE
Improving quality of life using compound mind-body therapies: evaluation of
a course intervention with body movement and breath therapy, guided
imagery, chakra experiencing and mindfulness meditation.
Quality of Life Research, 2008; 17: 367-76.

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Paper I - II

LIST OF ABBREVIATIONS

CAM	Complementary and alternative medicine
CG	Control group
EBM	Evidence-based medicine
EFT	Emotional Freedom Techniques
ES	Effect size
GP	General practitioner
HRQOL	Health related quality of life
MBM	Mind-body medicine (including relaxation techniques)
MBR	Mind-body relations (MESH term definition: The relation between the mind and the body in a religious, social, spiritual, behavioural, and metaphysical context. This concept is significant in the field of alternative medicine)
MBSR	Mindfulness-based stress reduction
PD	Psychoactive drugs (in this study): selective serotonin reuptake inhibitors, tranquillisers and/or sleeping pills.
QOL	Quality of life (in general)
SD	Standard deviation
SG	Study group
SOC	Sense of coherence
SPP	Standardised population person
SWEDQUAL	The Swedish questionnaire on Health related quality of life
WHO	The World Health Organization

1 INTRODUCTION

All over the world, people are using methods from outside scientific medicine to improve their health. There has been a shift from seeking cures for only serious diseases towards more prophylactic health and wellness promotion methods.

1.1 TERM DEFINITIONS

During the last 50 years, three terms have been used. “Alternative medicine” has usually been defined as methods with their own theory, diagnosis and treatment, chosen instead of allopathic medicine, e.g. traditional Chinese medicine for chronic pain. Later, the term “complementary and alternative medicine” (CAM) was adopted to describe the growing focus on methods for well-being and hence the possibility of a parallel use. And recently, the term “integrative medicine/care” has been introduced to describe those CAM methods that have been backed by some scientific evidence of their own. Some have even started to become integrated in the university education systems and national health care (Weil 2001; Carlson and Falkenberg 2007). The three terms are nowadays used with mostly the same meaning. For simplicity, I choose to use only the CAM term in this thesis.

1.2 CAM AND EVIDENCE BASED MEDICINE

There are thousands of ordinary people who repeatedly use CAM for empirical benefits. There are also allopathic medical personnel who request evidence-based medicine (EBM) methods to provide safe care. There is no way to lower the quality demands of EBM, and this needs scientific research (Ernst and Singh 2008), but only a few per cent of funding went to CAM research in Sweden in 2006. But it is also impossible to totally ignore the many voices of satisfied CAM users (Verhoef, Mulkins et al. 2007). In this true dilemma, we all need more non-biased scientific evaluation (Ernst, Pittler et al. 2007). CAM treatment should be relatively inexpensive and extremely safe (Dillard and Knapp 2005).

CAM intervention studies are published each year, and reviews and method evaluations are starting to enter the CAM research reports, but they are rare compared to the great CAM use. Health care personnel are trained in using awareness and neutral observations to approach new phenomena in the world, e.g. totally new viruses, bacteria and method technology. The lesser known CAM also needs humble scientific approaches. To obtain more reliable results, research on CAM should preferably emanate from the original CAM theories on mechanisms, and the studied therapists accordingly should be educated in the original context (Kerr 2002; Kemper 2007). The measurements must be chosen to give results which are explainable according to the theories, but treatment outcome can in fact be documented before we understand the mechanisms (Fonnebo, Grimsgaard et al. 2007). Therefore, basic CAM knowledge is

needed in understanding and handling grant applications for CAM research (Zaslawski and Davis 2005). There is much more research solely on attitudes towards CAM than evaluation research on original CAM methods themselves!

The World Health Organization, WHO, have paid attention to the many voices of CAM and traditional medicine users, as CAM is common in many developing countries. Four global needs about CAM have been defined by the WHO: 1) to create national guidelines for CAM use, 2) to stimulate strategic CAM research on effect and safety, 3) to make CAM methods available and affordable, and 4) to increase knowledge of CAM in the population and especially in health care professionals (WHO 2002).

1.3 CAM CLASSIFICATION

The MESH terms in the CAM area do not give a good overview, as there is a lack of superior theme structure. Tataryn synthesized existing classifications from the National Centre for Complementary and Alternative Medicine and others (Tataryn 2002). Jones developed this system into six groups of “primary modes of therapeutic action/influence”: 1) Biochemical (e.g. pharmaceuticals, herbs). 2) Biomechanical (e.g. physiotherapy, massage, hatha yoga). 3) Mind-Body medicine (MBM) (e.g. biofeedback, meditation, yoga, behavioural medicine). 4) Energy (e.g. acupuncture, laser therapy, qigong). 5) Psychological (e.g. psychotherapy, AA support group, art therapies), and 6) Non-local (e.g. prayer, healing) (Jones 2005). The complete structure is also reprinted in (Fernros, Furhoff et al. 2008). This classification, it should be noted, includes all allopathic methods too. Jones’s classification gives a very good description of the CAM field, if applied to my experiences of CAM. These categories create an easy overview of CAM as well as allopathic medicine in a common and comparable frame. The classification can thereby be used in all medical education to deepen knowledge of CAM.

1.4 RECENT MIND-BODY MEDICINE RESEARCH

This project evaluates a form of MBM training and that is no coincidence. The mind-body connection is increasingly interesting to me as a doctor. New research in the field is creating a significant understanding of complex human functions such as immunology and brain EEG changes by meditation (Davidson, Kabat-Zinn et al. 2003). New MBM treatments are also evolving in allopathic health care provided by nurses, physiotherapists, doctors etc. Accordingly, the following research description will be focused on the MBM category of CAM.

1.4.1 Review of the period 2005–2008

This period was reviewed at OVID: Medline, CINAHL, PsycINFO and AMED together. Searches for only “mind-body medicine, therapy and techniques” have resulted in about 900 articles, a little more than 200 per year. More than 200 of those 900 are interventions and/or reviews. The number of MBM intervention studies is now

larger than those on attitudes. Psychotherapy is involved in 130 studies. Some 40–60 studies are available on each of the topics of mindfulness, touch, breath, movement and imagery, and about a dozen on dance.

1.4.2 Early MBM research projects

In 2000, Luskin published a review of studies since 1990 on mind-body therapies in the treatment of musculoskeletal disorders. The review concerned studies of cognitive-behavioural therapy (CBT), meditation, imagery, music therapy, hypnosis and yoga. He found some evidence for treatment efficacy but mostly a need for further research containing controlled structure, dosage and understanding of the mechanisms, as well as cost-benefit analysis and any side effects of the MBM treatments (Luskin, Reitz et al. 2002). Barrows' review comments on the improving research methods and it supports the positive results of MBM on biofeedback, imagery, meditation and relaxation techniques (Barrows and Jacobs 2002). Regulated breathing, meditation, guided imagery, or massage for a pain sufferer was simple but beneficial aids to care, even in an emergency department (Dillard and Knapp 2005). A systematic review of massage for mechanical neck disorders was inconclusive because of insufficient study data, e.g. heterogeneity in treatment and control groups, as well as lack of detailed descriptions of the interventions and therapist training in more than half of the studies (Ezzo, Haraldsson et al. 2007). The book *Mindbody medicine: Foundations and practical applications* summarizes the basics (Rotan and Ospina-Kammerer 2007).

1.4.3 Yoga research

In a systematic review of 70 yoga studies, Innes suggested that traditional mind-body practices such as yoga, tai chi, and qigong now are safe and cost-effective ways to improve clinical outcomes in older populations, including postmenopausal women (Innes, Bourguignon et al. 2005; Innes, Selfe et al. 2008). The outcomes were reduced risk factors for cardiovascular disease including insulin resistance syndrome, improved mood and sleep, and decreased sympathetic activation. Yoga increased quality of life and physical skills, but not cognition in elderly (Oken, Zajdel et al. 2006). Gupta verified the effect of yoga intervention reducing anxiety (Gupta, Khera et al. 2006). A thorough investigation of the haemodynamics of a yogic slow breath technique was made. It appeared to reset a cardio-respiratory brain-stem pacemaker function, which was considered as the health-promotion effect of yoga (Shannahoff-Khalsa, Sramek et al. 2004).

Yoga effects on randomized fibromyalgia patients were studied in Holmer's thesis. A programme of gentle classical hatha yoga gave significant improvement in fatigue, pain, sleep, and anxiety. The programme emphasized recognition and acceptance of limits, and breath-work to foster a mind-body awareness unity (Holmer 2004). Recently, Galantino's systematic review of therapeutic effects of yoga for children showed physiological benefits, but it was inconclusive on quality of life (Galantino, Galbavy et al. 2008). Chair yoga gave significantly better well-being than chair

exercise or inactivity in an elderly study group. Self-control was proposed as the mechanism underlying the impact of yoga on psychological health (Bonura 2008). Alexander technique has shown promising findings that AT is effective in reducing the disability of patients suffering from Parkinson's disease and in improving disability in patients with chronic back pain (Stallibrass, Sissons et al. 2002; Ernst and Canter 2003; Little, Lewith et al. 2008). Breath therapy gave a significant decrease in chronic low back pain and was as good as physical therapy for six months (Mehling, Hamel et al. 2005).

1.4.4 Mindfulness research

Mindfulness-based stress reduction (MBSR) has been extensively researched since the 1980s by Kabat-Zinn and others (Kabat-Zinn 2005). MBSR has shown significant changes especially on anxiety, psoriasis, fibromyalgia and mood disturbance in people with cancer, even in EEG registration and within heterogeneous groups (Reibel, Greeson et al. 2001; Astin, Berman et al. 2003; Carlson, Speca et al. 2004; Kabat-Zinn 2004; Garland, Carlson et al. 2007). A review in 2002 said that MBSR showed some evidence but needed further "serious investigation" (Bishop 2002). Winbush defined MBSR as "a formalized psycho-educational intervention that helps individuals self-manage and reframe worrisome and intrusive thoughts". Ott defined it as "By emphasizing being, not doing" (Ott 2004; Winbush, Gross et al. 2007). In a review of MBSR for treating sleep disturbances, some studies found that MBSR significantly improved measures of sleep quality or duration. Methodologically, it also revealed a need for more standardized scales and further controlled methods (Ott 2004).

A combination of MBSR and psychotherapy gave good results, as the development of mindfulness skills had a key role in the therapeutic change into an attitude of acceptance and "living in the moment", which at its best may be applied to everyday life (Kutz, Borysenko et al. 1985; Kutz, Leserman et al. 1985; Mason and Hargreaves 2001). Support exists for the experience change that over time, participants in an MBSR programme "reperceive" what they encounter in their daily experiences (Shapiro, Schwartz et al. 1998; Dobkin 2008). In a comparison of MBSR and cognitive-behavioural stress reduction (CBSR), both reduced perceived stress and depression, but MBSR (with all variable changes significant) was more effective in increasing energy and reducing pain (Smith, Shelley et al. 2008). After MBSR intervention, Davidson found increased immune function, Bedard found improved QOL in people with brain injuries, Kreitzer found improved sleep and reduced anxiety in organ transplant recipients and Horton-Deutsch in bone marrow transplant recipients, all significant (Bedard, Felteau et al. 2003; Davidson, Kabat-Zinn et al. 2003; Kreitzer, Gross et al. 2005; Horton-Deutsch, O'Haver Day et al. 2007). Their Sense of Coherence results also suggested that the women viewed life as more meaningful and manageable following MSBR intervention. A literature review and clinician's guide by Praissman stated that there is now strong evidence that MBSR is a safe, effective, integrative approach for reducing stress in both patients and healthcare professionals providing crisis support (Praissman 2008).

1.4.5 MBM comparisons

Among touch therapies, Miller studied healing touch and guided imagery in manufacturing employees. Significant decreases in pain, stress and increase in emotional well-being (decreased anxiety and depression) were reported by the study participants following therapy. Furthermore, the mean health care coverage expenditures for the study participants continued to be significantly lower (Miller 2006). Progressive relaxation was compared to qigong in a study to improve the quality of life in cardiac patients in Hong Kong. Relaxation appeared to be particularly beneficial in somatic domains, e.g. in reducing blood pressures. A qigong group demonstrated greater improvement in psychological measures (Hui, Wan et al. 2006). A randomized, controlled MBM intervention in women with breast cancer showed an overall increase in psychosocial outcome from both meditation/imagery and standard CBT/group sharing, with minor differences (Targ and Levine 2002). Morone reviewed twenty studies of MBM interventions in elderly. As much as two of three were controlled studies, and showed some support for the efficacy of progressive relaxation plus guided imagery for osteoarthritis pain. There was limited support for meditation and tai chi for improving function or coping, indicating that large clinical trials of mind-body interventions are still needed (Morone and Greco 2007). Lee and Ernst reviewed qigong for palliative cancer treatment and found no support for prolonged life (Lee, Chen et al. 2007). Evidence for several MBM methods is quite strong for migraine headache, but there is only limited evidence for other neurology applications (Wahbeh, Elsas et al. 2008).

1.4.6 MBM theoretical research

In more theoretical research on the mind-body topic, Walach discuss the appropriateness of hierachal randomised controlled trials in CAM research, warranting more circular methods (Walach, Falkenberg et al. 2006). Pope studied the effects of group MBM programmes for individuals living with chronic illness. If one assumes that positive changes of health questionnaire data are necessarily linear and bodily, the understanding of the benefits of mind/body interventions may be lost. In-depth qualitative interviews paid better attention to the important subjective experiences of participants related to working through their “inner process” and self-discovery (Pope 2002). In 1998, Goleman formulate the definition and needs for emotional intelligence (e.g. self-awareness and empathy) in good leadership. He developed it into the wider social intelligence, which contains the functions of mirror neurons for emotional recognition and spindle neurons for behaviour adjustments (Goleman 1998; Goleman and Boyatzis 2008). Theories on the process of consciousness itself have been proposed by Vakalopoulos. Conscious and unconscious processes are suggested to be defined as functions of types of re-afferent motor input. Conscious mechanisms are thus associated with behavioural diversity, whereas unconscious output is proposed to have an association with stereotypical behaviour (Vakalopoulos 2005; Vakalopoulos 2005). Placebo definitions and treatment theories have been reviewed and suggested to be either desired or dismissed (Walach and Jonas 2004; Ernst and Singh 2008; Frenkel 2008), but Birch discusses contradictory definitions of placebo and assumptions that the

use of sham procedures is as inert as placebo when it is not (Birch 2006). Meissner talks about therapeutic understanding of the expanding mind-body relation in psychoanalysis, such as psychosomatic symptoms, emotions, alexithymia and somatization (Meissner 2006). As a fresh-in-our-time activity, MBM is shown to be effective in trauma-impact management, resulting in a practical suggestion: Provide education/training in MBM skills for health care personnel, to increase their competencies before work in disaster areas. The MBM intervention helps symptoms of secondary traumatic stress and promotes post-traumatic growth (Calderon-Abbo, Kronenberg et al. 2008).

1.5 CAM RESEARCH IN SWEDEN

The most common CAM activities in Sweden are massage, acupuncture, chiropractics and hypnosis. In the recent Swedish book *Integrativ vård med konventionella, alternativa och komplementära metoder* (“Integrative care with conventional, alternative and complementary methods”), Carlson and Falkenberg discuss the integrative process among recent pilot studies in Sweden (Carlson and Falkenberg 2007). They characterize CAM as methods combining the body with emotions, spirituality and what enhance well-being; music, touch, art and kind treatment. Strategies such as letting the first meeting take time, mindful listening, offering patient empowerment (taking part, having an individual goal) are used to achieve concordance, which is more cooperative than compliance with its position of obedience. These strategies are now also considered as important aspects in allopathic care, and these integrations are already taking place in health care programmes (Weil 2000; Weil 2001; Skarsater, Dencker et al. 2003; Wohlin Wotrich, Stenstrom et al. 2004; Kettis-Lindblad, Ring et al. 2007; Bjorklund, Sarvimaki et al. 2008). Most important for this present project is that Carlson/Falkenberg identify a need for initial research on existing “health systems”, that is, complex CAM interventions, with the intention to continue in detail in a second phase. The caregiver’s purpose is to find the key to support the life force/lust/spirit of this unique person. Stimulating the self-healing resources is the very core (Carlson and Falkenberg 2007). These characterizations are considered important aspects in the intervention of the present study.

In the last ten years an increasing number of Swedish health care personnel have started research projects on CAM methods. Recently an association of certified health personnel who are interested in CAM was founded. One example of a Swedish CAM study evaluates a model of cooperation of primary health care doctor and CAM (acupuncture, chiropractics, naprapathy, shiatsu and qigong). The study aimed for a patient-centered, interdisciplinary, non-hierarchical model of mixed conventional primary and CAM care and went on for three years. The study involved key informant meetings with all care givers, primary care administrators and county council representatives. Meeting notes were also used as ongoing working and research documents. The result was a functional model of mixed care (Sundberg, Halpin et al. 2007).

1.5.1 MBM research in Sweden

In the MBM area, behavioural medicine, psychotherapy and mindfulness meditation seem most commonly used in Sweden. The physiotherapist Gyllensten studied basic body awareness therapy in patients within psychiatric outpatient care. He found significant improvement in self-efficacy, physical coping resources and sleep (Gyllensten, L. et al. 2003). Self-administered EFT (Emotional Freedom Techniques) was studied in individuals with fibromyalgia in a randomized trial. Pain catastrophizing measures, such as magnification and helplessness, were significantly reduced, and activity level was significantly increased (Brattberg 2008). Hogberg evaluated a “multimodal psychotherapy” in suicidal adolescents. It contained psycho-education, well-being practice and trauma resolution by psychodrama and MBM techniques including “eye movement desensitization and reprocessing” (EMDR) and showed clinically significant and long-lasting improvement towards normality in function (Hogberg and Hallstrom 2008). In the emerging new paradigm of psychosomatic medicine, Sivik constructed and validated the psychosomatics test and conducted several studies on group therapy and psychological rehabilitation in patients with psycho-physiologic disorders such as somatization (Sivik, Delimar et al. 1997; Sivik 1999; Sivik, Delimar et al. 1999; Sivik 2000; Sivik and Schoenfeld 2001; Sivik and Schoenfeld 2002).

1.6 PERSONAL BACKGROUND

For 16 years, I have worked in primary health care as a specialist in family medicine. A large interest in psychosomatic and multi-symptomatic illnesses made me wonder about their connection to existential and spiritual needs and development.

In a period of life change, I intuitively found the mind-body-medicine (MBM) training centre Mullingstorp in the countryside of southern Sweden, and attended the two seven-day courses for self-management purposes, “Meet Yourself” 1 and 2 (Stern 1994; Stern 1996). Shortly thereafter, I attended another MBM therapist training at the Risk Meditation Institute in Denmark. Spread over 18 months, it consisted of eleven weeks, each comprising a seven-day course. For contents, see the therapist education description in Settings.

I then continued with the first half of formal psychotherapist training within the psychodynamic programme. There are many similar ways of seeing and interpreting a person, in MBM as well as in psychotherapy, and also some different ways. Each system has a terminology of its own, but may often describe the same phenomenon. I also was a tutor to medical students in their leadership training, where we discussed different learning styles (Kolb 1984). Mostly, they support insights about pedagogical variations, involving all five senses (six, including intuition).

All these course exercises were held in a loving and discerning atmosphere and my main impression was that it revealed so many true emotional reactions among the participants. I became curious about possible benefits from the processes, and wanted to make a scientific study.

2 AIMS

2.1 GENERAL AIMS

Although the number of scientific studies of CAM is increasing, there is still a great need for well-structured and controlled research on the CAM methods themselves. The overall aim of this thesis was to scientifically evaluate an original, CAM-based MBM training programme for personal development through advanced self knowledge. We also wanted to see if the personal characteristics of the people who are interested in MBM methods are different from the characteristics of the average Swedish population, in order to understand the CAM use and users better.

It was also judged important to collect spontaneous comments from the participants in this unknown CAM field. The researcher may otherwise be biased by expecting results in only known methods and thus miss unexpected points of the new context.

2.2 SPECIFIC AIMS

2.2.1 Describe characteristics

To describe the entry characteristics of a group of people attending one specific MBM course, with special regard to their health-related quality of life (HRQOL), ability to function in daily life (ADL), socioeconomic status and their medical situation (Study 1).

2.2.2 Compare to population

To compare these characteristics to the general Swedish population, and to get a better understanding of which people attend MBM courses (Study I).

2.2.3 Evaluate health change

To evaluate the influence that the MBM course had on HRQOL, ADL and medical situation from six months before until six months after the course (Study II).

2.2.4 Compare groups

To compare the study group levels and changes in HRQOL to those of a control group who had attended the course the previous year (Study II).

2.2.5 Evaluate sense of coherence

To describe the sense of coherence levels and to evaluate their changes in course participants (Study II).

2.2.6 The hypotheses were that:

- 1 the study group would have low HRQOL assessments before the course and significantly increase their values at the six-month follow-up, while
- 2 the control group would both start and end at the higher values.
- 3 the sense of coherence value would be a predictor of outcome.

3 SETTINGS

3.1 THE MBM TRAINING CENTRE

This study was carried out at one specific training centre in Sweden, Mullingstorp, where courses teaching health self-management are held. The centre has been holding the same MBM courses since 1985; each course is seven days long, lasts 14 hours a day and has room for 24 people. The price is Euro 3055:– per person, including the costs of the 7-day course, lodging, food and preparatory and follow-up phone contacts. It is not connected to any public health care and 61 per cent pay for the course themselves. The participants join the courses mainly on their own initiative or on a friend's recommendation, but only rarely by medical referral. About 5000 people have attended the courses to date.

3.2 THE PARTICIPANTS

All persons are asked to bring a written detailed life history, as a guide to the doctor and therapists. Many of the participants are also asked to bring a husband/family member into the course, for mutual support. They should avoid distracting things during the course such as radio, books, magazines, phone calls, sweets, coffee and tobacco. With this procedure many motivated participants have been accepted to the course despite serious personal problems such as depression with suicidal thoughts, sexual abuse, cancer disease, family relation difficulties, as well as less serious ones. The course process is in most cases suitable for these people; only on very rare occasions does the centre refuse to let a person participate. The course curriculum is not suitable for schizophrenic patients, but the centre has had experience of dealing with people with brief reactive psychosis symptoms within the course (outside of this study), and also people with strong positive metaphysical experiences. If needed, therapeutic support is available around the clock.

3.3 THE STAFF AND THEIR EDUCATION

The course staff includes one course leader, one doctor, and for every four participants there is one therapist and one assistant all week. The therapists have attended various educational courses in holistic health management that is equivalent to two to three full-time years in counselling. The educational courses include training in MBM techniques (Lowen 1994; Lowen and Lowen 1994), including non-judgemental mindfulness, guided and active meditation approaches (Osho 1992; Osho 1997), body awareness, liberating dance (Roth 1990; Roth and Loudon 1990; Roth 1998; Roth 1998), breathing therapy (Sky 1990) and facilitating honest emotional expressions and counselling skills (Stern 1994; Stern 1996; Brattberg 2008).

3.4 THE TRAINING CENTRE'S OWN STATISTICS

The training centre statistics in the late 1990s describe the characteristics and sociodemographic data of the average course participant, see Table 1.

Table 1. Sociodemographic data from local statistics, July 1997 – June 1999 at the training centre, and similar data from the Swedish population.

		Previous participants in 1997–99			Swedish population ⁵		
		Men n (%)	Women n (%)	All n (%)	Men (%)	Women (%)	All (%)
Re-	1st year			4			
-attending	2nd year			16			
Sex		126 (46)	147 (54)	273	(49.4)	(50.6)	
Age	Median			40			
Residence	City >100k/km ²			110 (52) ¹			(83) ²
	Town 11–99k/km ²			62 (30) ¹			
	Country <10k/km ²			38 (18) ¹			
	NO, SF, DK, GB			63 (23) ³			
Work	Employed	43 (34)	67 (46)	110 (40)	(41.2)	(42.3)	(41.7)
	Company	54 (43)	36 (24)	90 (33)	(4.7)	(1.9)	(3.3)
	Student/Parent	10 (7.9)	11 (7.5)	21 (7.7)			
	Unemployed, home	12 (9.5)	9 (6.1)	21 (7.7)	(7)	(6)	(6.5)
	Sick, pension	7 (5.5)	22 (15)	29 (11)			(3.4) ⁴
Partner	Single	46 (37)	60 (41)	106 (39)	(28)	(24)	(25)
	Partner	80 (63)	85 (58)	165 (61)	(72)	(76)	(75)
Family	Children age below 18 years			(50)			(26)
Education	<9 years	8 (6.3)	14 (9.7)	22 (8.1)	(29)	(26)	(27)
	10–12 years	66 (52)	58 (40)	124 (46)	(46)	(45)	(45)
	>12 years	52 (41)	73 (50)	125 (46)	(25)	(27)	(26)

¹ Percentage in Sweden. ² City and Town together. ³ Percentage of all participants.

⁴ Cumulative prevalence over a one-year period. ⁵ Population data collection, see 4.2.4.

There are more self-employed people than in the population and a large variety of professions are represented. One of two had children below age 18, and one third was single parents. The rate of singles was greater among people living in rural areas as was the sick-listing rate for women, all compared to the population. To obtain more far-reaching benefits, seven per cent of the participants chose to attend the course a second time.

3.5 THE COMPOUND COURSE INTERVENTION, THEORIES AND COURSE STRUCTURES

3.5.1 Background theory sources

The aims and focus of this intense one-week course are personal development through emotional self-knowledge. The principal course exercises consist mainly of the two method groups Mind-Body Medicine (MBM) and energy flow techniques (Fernros, Furhoff et al. 2008). The founder of the training centre created the course concepts very much from his own experiences (Stern 1994; Stern 1996), but was also inspired by MBM from therapy pioneers such as the bioenergetics body therapy of Alexander Lowen, John C. Pierrakos' the hurting child, the body-psychotherapy of Charles Kelley, David Boadella, Wilhelm Reich and C.G. Jung, as well as the contemporary methods of psychodrama, gestalt and primal therapy, and transaction analysis (Janov 1973; Lowen and Lowen 1977; Boadella 1985; Pierrakos 1987; Roth 1990; Roth and Loudon 1990; Siegel 1990; Janov 1992; Lowen 1994; Lowen and Lowen 1994). Later, in 1998, Goleman described the emotional intelligence concept, but it is mentioned here as its previously non-formulated core is an essential part of the course theories (Goleman 1998; Goleman 1998; Goleman and Boyatzis 2008).

3.5.2 The chakra energy centres

In east Indian yoga philosophy, the human body is assumed to have seven spiritual energy centres, namely the seven chakras (in Sanskrit *cakram* means “wheel, circle”): 1: Survival/breeding/sexuality, in the pelvis, 2: Relating, in the belly, 3: Power, in the solar plexus, 4: Heart, in the chest, 5: Creativity, in the throat, 6: Intuition in the forehead, and 7: Spirituality, at the top of the head (Stern 1994; White 1994; Stern 1996; White 1998; McMurray 2005). The course curriculum refers to these energy centres in most exercises. There are yet no scientific data on the chakra system, but it have been used for centuries. The different chakras mainly follow the anatomic organs and autonomous nervous system in the body segments, and the chakra system is here used as a pedagogic way to listen to your inner body signals and feelings.

3.5.3 Energy flow

Although not yet evidence based, the above described different theories were synthesized to create the course process, following the CAM theories: Everything in the universe consists of energy, as particles or as life, either in free motion, in interaction or partially blocked at some levels. The existentially aware human being is assumed to be totally free and have a rich flow of life energy through her body chakras. She listens to her spontaneous and variable feelings from moment to moment, without judging them. She goes for her own ideas, chooses partner with her heart and creates the life of her dreams, and chooses an interesting job commensurate with her skills. This aware human being is also assumed to have a good portion of civil courage, dares to express her opinion, to say no and make legitimate claims, but has at the same time a great love for and connectedness with nature, people and the whole universe. In other terms, you may describe her as a psychologically harmonious person, with a curious interest in and awareness of her interactions with the surrounding world.

3.5.4 Energy block

In contrast, the unaware person uses all her life energy to sustain psychological defense mechanisms against painful pre-intellectual emotional (cell) memories. The life energy is consumed (like flooding and choking a RAM memory in a computer) and life is dominated by muscle armor, shallow breathing, neurotic behavior, projections and – through time – illness. The blockings are supposed to be solvable.

3.5.5 The small, dependent child

The small, dependent child experiences the subliminal emotional (negative) attitudes of parents etc., and has no other choice than to block the pain (energy) to be able to survive. As an adult you can choose to meet this pain by participating in MBM such as body-psychotherapy, deep breath exercises, body position and/or movements, massage methods (compare with yoga) and activating your cell memories. The activation makes you aware of their presence, you can meet the pain with self-empathy, and forgiveness appears (Janov 1973; Janov 1992). When this happens, the energy block can disappear and a more mature handling skill evolves. In physiological terms, you discharge the emotionally overloaded memory episode and move it uncharged from the amygdale nucleus to the cortical long-term memory.

3.5.6 Teaching methods

A different teaching method has been established that relies more on experiencing experimental exercises, feelings evoked, expressed and understood, and less on verbal learning. The course contains many different and unique MBM therapy exercises; deep breathing, active meditation, liberating dance, reflections and relating practices on themes such as birth, death, freedom, co-dependency and bully-victim roles. The founder of the training centre describes them in his books (Stern 1994; Stern 1996).

In this well-staffed milieu, for 14 hours a day, seven days in a row, people are invited to safely test themselves in the exercises, going outside of their normal emotional comfort zone, reaching new experiences, all in a discerning atmosphere. Feelings of suppressed fear, sadness, anger, joy and love can reappear and be understood. These emotional processes empirically enhance integration, integrity, insights and are considered to create life change.

3.6 THEORETICAL BENEFITS OF MBM

Other examples of taking responsibility for your emotional truth are: terminating a destructive relationship or a manipulative sickness benefit, leaving a well-paid but boring job, ceasing to project your problems onto others, or quitting abuse (Stern 1994; Stern 1996). The empirical benefits are an increased life energy flow revealing itself as joy, new initiatives, power and a calm mindfulness and presence in life.

4 MATERIALS AND METHODS

The present project consists of two studies. The first one is descriptive, and characterizes course participants in comparison to the general population. The second study is an experimental, prospective, case-control study, evaluating the results of the compound course intervention.

4.1 SUBJECTS

4.1.1 The initial study group

The participants in all seven MBM courses given at the training centre in the year 2000, were invited to the first study during a personal visit by the author (LF) at the first gathering after arrival to the training centre. Out of the 121 people attending the courses 11 persons were excluded, seven from outside Scandinavia for language reasons (Great Britain, Germany), and four people because they attended the course for a second time. The others were asked if they would consent to take part in the study. Only three declined. Thus, 107 persons (50 men and 57 women) agreed to participate, here called the initial study group. The mean age of participants in the initial study group was 42.1 years, with no gender difference. Entry data were collected from the initial study group at the start of all seven courses in this year. This group was used to compare entry data to population data.

4.1.2 The study group

Of the initial study group (107 persons), 24 dropped out. The remaining 83 persons (38 men, 45 women) were defined as the study group who participated in the assessments also after six months, see the flow chart in Study I (Fernros, Furhoff et al. 2005).

4.1.3 The control group

The second study was a follow-up in the study group six months after the course intervention. Here, a control group was included (Fernros, Furhoff et al. 2008). The main reason was to illuminate the bias of the overall course attendant subpopulation, which was shown to be different from the general Swedish population data (Fernros, Furhoff et al. 2005). Among those individuals who had taken the course one to three years previously, we chose 126 people from the enrolment lists.

The control group was matched according to the understanding of Swedish, and according to gender and age (± 4 years). They were informed of the study and invited by mail to participate. Of these, 39 men and 47 women agreed to participate in the study. They were sent an entry questionnaire in the same month as their study group match participated in the course and a second questionnaire six months later.

The mean age of the control group was 44.1 years (2 years older than that of the study group), which assures that they had their course experiences at about the same ages as the study group. A 5- to 9-year difference was accepted in a few (six) people aged over 50 years, to be able to maximize data utilization.

4.2 ASSESSMENTS

Three questionnaires were used to assess HRQOL, SOC and socioeconomic status.

4.2.1 Health related quality of life

The HRQOL questionnaire SWEDQUAL 1.0 was chosen. It consists of 61 items of self-assessment distributed into 13 scales and was developed from the Medical Outcomes Study, as was the Short-Form (SF-36), see Table 2. SWEDQUAL is similar to SF-36, although it contains more items on sleep, cognition, personal energy/vitality as well as family relations and sexual functioning. There are two random samples (n=2366) of the Swedish population that were tested with SWEDQUAL in 1992 and 1995, respectively. SWEDQUAL is hereby a nationally well-known, validated and reliable instrument with a Cronbach's alpha reliability coefficient of >=78% (Brorsson, Ifver et al. 1993). The population samples have been used as comparison in studies on conditions as disparate as diabetes, glaucoma, angina pectoris and, here, MBM users (Wandell, Brorsson et al. 1997; Wandell, Lundstrom et al. 1997; Wandell, Brorsson et al. 1999; Wandell, Brorsson et al. 2000; Brorsson, Bernstein et al. 2002; Fernros, Furhoff et al. 2008).

Table 2: Quality of Life items in SWED-QUAL 1.0

Scale (no. of items)	Description
Role limitation due to emotional health (3)	Extent to which emotional problems interfere with activities of daily living (ADL)
Negative affectivity (6)	Feels nervous, tense, down, sad, impatient, annoyed
Positive affectivity (6)	A happy person, harmonious, feels liked, optimistic
Cognitive functioning (6)	Concentration, memory, decisions, confusion
Family functioning (4)	Satisfaction with cohesiveness, talking things over, understanding
Marital functioning (6)	Expressing wishes, sharing feelings, being supportive
General health perceptions (8)	Prior and current health, resistance to illness, concern about health
Physical functioning (7)	Performing activities (work, sports, stairs, dressing)
Satisfaction with physical ability (1)	Satisfaction with ability to do what one wants
Role limitation due to physical health (3)	Extent to which physical problems interfere with ADL
Sleep quality (7)	Sleep initiation, sleep maintenance, somnolence
Pain frequency, intensity (6)	Pain interference with ADL, sleep and mood
Sexual functioning (5)	Lack of interest, inability to enjoy sex, having orgasm (women), getting/maintaining erection (men)

4.2.2 Sociodemographics

In addition, the participants completed a socio-demographic questionnaire on level of education, marital status, medication, as well as the number of visits to doctors, CAM providers and sick leave during the preceding 6 months. The SWEDQUAL and sociodemographic data, from the initial study group, have been compared in an earlier study to Swedish population data collected from several national authorities (Fernros, Furhoff et al. 2005).

4.2.3 Sense of coherence

The SOC scale short form was also used, (13 items, SOC-13, with a Cronbach's alpha 0.74–0.91). This scale measures comprehensibility, meaningfulness and manageability in life (Antonovsky 1993). Swedish national medians have been presented in studies by Langius' group and Nilsson (Langius, Bjorvell et al. 1992; Langius and Bjorvell 1993; Nilsson, Trehn et al. 2001).

4.2.4 Data collection

The three entry questionnaires were completed by the members of the initial study group on arrival at the centre, before the start of the course. The members of the control group were sent the same questionnaires by mail at the same time. Both the study group and the control group were sent the follow-up questionnaire by mail six months later. A response time within 8.5 months was achieved by 94% of the study group and 82% of the control group. For logistic and dropout data, see Study I (Fernros, Furhoff et al. 2005).

Socio-demographic population data were collected from several national authorities: the Swedish National Board of Health and Welfare for data on visits to a doctor, the Swedish National Social Insurance Board for data on sick listing, and Statistics Sweden for data on education and family (2001; 2001; 2002; 2003; Fernros, Furhoff et al. 2005).

4.3 STATISTICAL METHODS

The sample size of the study group was initially assessed to 80 by Altman's graphic method. This agrees well with the Stata assessment of 88 subjects needed, which was based on alpha = 0.05, power 0.8, and an expected SWEDQUAL intervention difference of 7.5 points = 9%. This was judged to be the clinically significant level (Study I). Statistical significance was accordingly set at p<0.01, owing to multiple comparisons. The level p<0.01 was assumed to be clinically valid also for SOC-13, where Volanen also has shown significant adjusted changes as small as 2.4–4.9 points (3.8–7.8%) in six months (Volanen, Suominen et al. 2007). The study analyses were carried out on Stata version 8 software (Stata Corp, College Station, TX) updated January 2005.

4.4 ETHICAL CONSIDERATIONS

The study was approved by the local Research Ethics Committee of Karolinska Institutet at Karolinska University Hospital in Huddinge. The author has worked as group leader and consultant doctor at the training centre, but not during the data collection. The address list was administered by a nurse for the mailed questionnaires. The author has only seen the code numbers.

5 MAIN OUTCOME MEASURES

- Entry levels of HRQOL measured by SWEDQUAL 1.0 in the initial study group at the course at the training centre compared to the general Swedish population values (Study I).
- Changes in HRQOL in study group measured by SWEDQUAL 1.0 six months after the course intervention, especially “Emotional well-being” due to “Positive” and “Negative affectivity” and “Role limitation due to emotional health”, together with “Cognitive functioning”, “Sleep quality” and “General health”, and in comparison with the control group (Study II).
- Entry levels of SOC measured by SOC-13 in the initial study group compared to the general Swedish population values (Study II).
- Changes in SOC-13 in the study group, six months after the course intervention compared to the control group and to the general Swedish population values (Study II).

The results have been published as Study I and II.

In this thesis, additional data have been included: a descriptive bundle of participant's quotations on the subjective intervention changes, which are previously unpublished data (6.2).

6 RESULTS

6.1 STUDY 1

6.1.1 HRQOL in the initial study group

The main finding of this study was that the participants (initial study group), before entering a course in mind-body medicine, had a significantly lower level of emotional health than the general Swedish population (Fernros, Furhoff et al. 2005). This existed despite normal body functioning and advanced education, which, in many studies, has been correlated to normal or better health (Kersnik 2000; Lahelma, Kivela et al. 2002). In contrast, this study showed a group of well-educated men and women, who were feeling unexpectedly ill. The initial study group was compared to the Swedish population samples as far as possible. The initial study group had significant reductions in HRQOL on the scales Emotional health (Negative and Positive affectivity), Role limitation due to emotional health, Cognitive functioning, Family and marital functioning, with reduced quality in family relations compared to the general population. In contrast, the scales on Pain, Sleep, Physical functioning and Sexual functioning did not differ from the population in general. Some women (14%) and men (20%) in initial study group were clearly dissatisfied with their family functioning – a larger proportion than in the general population. The women reported equally good family function whether they had a partner or not. The men had another pattern: The family function was strongly correlated to the presence of a partner, and their health assessment was lower if they lived alone.

6.1.2 Sociodemographic data in the initial study group

Long-term sick leave (>6 months) was more than three times as frequent in the initial study group as in the average Swedish population. The sick leave was inversely correlated to general health but not to the scales on emotional health. One third of the initial study group (22 men, 44%, 15 women, 26%) did not report any visits to doctors, medication, or days on sick leave at all.

6.1.3 Other data in the initial study group

“Psychoactive drugs” (PD) stands for selective serotonin reuptake inhibitors (SSRI) depression medication, tranquillizers and/or sleeping pills. Antipsychotics were not used among our subjects. In the average Swedish population the PD medication usage rate is 10% (men 5%, women 13%). Compared to this, we found an increased PD use in the initial study group’s younger age group (<44 years, 12%) and among the men (10.5%), while the women (9%) and the middle-aged (6%) had decreased rates.

About two thirds of the participants were paying the course fees themselves. There was no correlation between payment type and HRQOL outcome.

6.2 STUDY 2

6.2.1 HRQOL changes in the study group

Starting from statistically significant low HRQOL assessments before the course (all $p<0.01$), the study group reached average population mean values after the course intervention. The HRQOL improvement was significant on the six co-correlated SWEDQUAL scales: “Emotional Well-being” (Positive and Negative affectivity), “Role limitation due to emotional health”, “Cognitive functioning”, “Sleep quality” and “General health” (Fernros, Furhoff et al. 2008). For population values, see (Fernros, Furhoff et al. 2005).

6.2.2 HRQOL changes in the control group

The control group maintained normal HRQOL levels on all 13 scales, and did not differ from the Swedish population in general.

6.2.3 Unchanged data

All other SWEDQUAL results showed only small and non-significant differences in terms of dropouts, age or gender among all data in both groups, despite the fact that some brought serious problems.

6.2.4 Sense of coherence changes in the study group

The Sense of Coherence-13 levels, changes and reference data were not published until Study II, to enhance a fruitful discussion of the stability versus increase of SOC levels. The median SOC-13 scores increased by 5.1% ($p<0.01$) in the study group after the course intervention, almost reaching the median SOC-13 range of the average population. The lowest initial assessments in the study group were seen among individuals aged up to 35 years (data not shown), which follows Antonovsky’s theories that SOC-13 increases due to people maturing (Antonovsky 1991). There were large individual variations in how much the score changed (-20 ; $+41$, $SD=13.0$).

6.2.5 Sense of coherence changes in control group

The control group maintained SOC-13 medians at about the levels of the average population, but here too with individual variation (-22 ; $+34$, $SD=12.1$). Dropouts from the control group had SOC-13 assessments similar to the entry values of the study group. The control group SOC-13 scores also co-correlated with the six increased SWEDQUAL scores mentioned above (Pearson correlation >0.4).

6.2.6 Sociodemographic changes in the study and control groups

Socio-demographic data are shown in Study II. The women in the study group had more sick leave than in the population, both in percentage of individuals and in number of days, at both entry and follow-up. The men in the study group and all people in the control group had a sick leave similar to that of the average population (Fernros, Furhoff et al. 2005). The sick leave was inversely and significantly correlated to the General Health ($p<0.01$), but not to the other scales.

6.2.7 Other data changes in the study and control groups

In the study group, the psychotropic drug use decreased overall 37% in six months ($p<0.01$), especially among the younger age group (age <44 years). There were relatively more psychotropic drug users (17%) among dropouts from both the study group and the control group, which was a slightly significant difference ($p=0.03$).

6.3 ADDITIONAL DESCRIPTIVE AND QUOTATION DATA

6.3.1 Participants' quotations and themes

The following unpublished data, concern the answers to the open question: “Has anything happened in your life, which you feel is important, during the last six months?” This question was included in all the questionnaires, both before start and at follow-up, and answered by both the study group and the control group. The comments describe the experiences at follow-up.

The aim was to illustrate the emotional states, awareness and changes that can develop after such a course, not to compare them. The answer quotations gather around six major themes, see table 3. The first two concern health situations/changes. The adversity comments illustrate the persons’ energy block. The three themes “relations”, “work development” and “awakening” describe personal awareness and reconsiderations, leading to creative decisions to change ones life.

Table 3. Quotation answers about important life events in the previous six months, sorted by the six themes found.

Answer themes	“Has anything happened in your life, which you feel is important, during the last six months?” Examples of answers, quotations:
1. Personal health	<ul style="list-style-type: none">• “Sick leave for five years. My soul ‘caught up’ with me.”• “Yes, cancer.”
2. Family member health	<ul style="list-style-type: none">• “My husband’s sick leave because of burn-out.”• “Yes, my sister’s death.”• “A close friend separating from partner.”• “My wife died of cancer. A new life must be created.”
3. Relations/ separation	<ul style="list-style-type: none">• “I have terminated a relationship that was destructive for me.”• “Yes, separation from a man (in mutual satisfaction and understanding). I have met a new man, a soul mate.”• “I have met a person to whom I opened myself, and say ‘Yes’ to, in a different way than before.”• “Separation from a lover. Disappointment/ anger towards my son.”

4. Work development/money/career	<ul style="list-style-type: none"> • “I graduated, changed job twice, and moved to a new home.” • “I don’t know what I want to work with in my life.” • “I just finished my training as massage therapist.” • “I work less now. Reduced from 70-80 h/w down to 20–25 h/w.” • “I have quit my job, following the flow of life without economic support from the state. Very exciting!” • “I have quit my job to travel and rest for six months.” • “I was dismissed from work and recently pensioned...” • “Moving abroad, change of profession.” • A 16-week computer update course as opposed to three years of sick leave. • “I had leave of absence to try another job. Then I had sick leave for two months due to life crisis/depression/burn-out. Now, I have quit my job and don’t know what to do after February.”
5. Awakening/relief	<ul style="list-style-type: none"> • “No and Yes. Nothing in particular, but I need to say that every day feels important.” • “I have opened myself to the world, two months ago. After 21 years in a closed body.” • “AT LAST, I have got insight about my life and for the first time I am responsible for my everyday life. Before I only breathed, now I LIVE!” • “I am getting more and more clarity about who I really am.” • “I feel as if I don’t need such a strong course, but I do need increased self-confidence.” • “Yes, I have stepped out of negative bonding.” • “Love.” • “Women’s workshop every two months. Good!” • A personal development group in Denmark, 26 days for six months. Great! Love, scary, wonderful, horrible, RIGHT, fear, life, very soft, Healing, Joy (at home...).” • “I have attended a lot of alternative courses and paid for them myself. The result is that I feel astonishingly well and I am very content with my life. Conventional health care, including medicine, has never been even close to helping my development into my present health. The alternative health care has been a blessing.”
6. Adversity	<ul style="list-style-type: none"> • “...my unease about work.” • “I cannot manage to see others in pain...” • “...I cannot find the strength to change my job.”

6.3.2 Recent use of CAM

Recent use of CAM in the initial study group, study group and control group is listed in Table 4. The CAM use rate in the initial study group at entry is similar to CAM attending rates in the average population (Nilsson, Trehn et al. 2001; Hanssen, Grimsgaard et al. 2005; Sundberg, Halpin et al. 2007). The rate of individuals who recently had participated in CAM use/activities (other than at this training centre), increased from 16% to 38% after the course intervention, a rate still kept up in the control group. Although with very spread use, it is noticeable that the study group reaches the use levels of the control group, which is two years ahead. The active persons in both groups have a similar mean of CAM use at about ten days per six months.

Table 4. The recent use of CAM in the last six months in the study and control groups, showing the rates of the numbers of users, and their spontaneously chosen usage frequency and type of activity.

CAM use in the last six months	initial study group at start (n=107)	study group after six months (n=83)	control group at study start (n=86)
Rate n (%) of people using CAM	14 (13)	36 (43)	30 (43)
Range of usage days (mean) in the last six months	2–35 (10.1)	3–52 (9.9)	1–30 (11.2)
Examples of CAM use	“meditation”, “body awareness”, “self-knowledge”, “emotional handling skills”, “regular sweat lodges”, “feminine essence”.	“Meet yourself part two”, gestalt therapy”, “family constellation”, “sex, pleasure and intimacy course”, “primal therapy” “Acem-meditation”.	“Participating in personal development programme 12–18 months”, “breathing pedagogue education”, “Rosen-therapy”, “yoga”, “regular women’s group”.

7 DISCUSSION

7.1 GENERAL DISCUSSION

Scientific and CAM research and results have many points in common, the requirements of both suitable methods and on results evidence. This present project shows that it was possible to characterize the subpopulation of people who spontaneously attended the course intervention at the training centre, Mullingstorp. Furthermore, the study design was appropriate for showing the clinically relevant positive changes achieved in HRQOL and SOC, after this non-invasive MBM programme. MBM is the section of CAM where there is most scientific evidence of significant result changes (Honda and Jacobson 2005; Upchurch, Chyu et al. 2007).

7.1.1 Research models in CAM

The hierarchical model of randomized controlled trials (RCTs) is also questioned by CAM researchers, who instead suggest the use of different designs with multiple methods, “counterbalancing their individual strengths and weaknesses to arrive at pragmatic but equally rigorous evidence” (Walach, Falkenberg et al. 2006). Adjusted research agendas have been developed to embrace these qualities, e.g. deep interviewing, focus groups, the correlation of cytokines to low health assessments, and new questionnaires described above (Pope 2002). Fonnebo proposes a new CAM research strategy different from RCTs. The step of clinical practice is the last one in RCTs, but CAM methods often starts in clinical practice and need an almost reversed methodological organization. This includes that the safety status and the comparative effectiveness can get evidence based even if the biological mechanisms are not yet known (Fonnebo, Grimsgaard et al. 2007).

The mental awakening process, here described in quotations, is not yet explainable by bio-physiologic mechanisms, but is still noteworthy. Even psychiatrists think that future applications will need to use combinations of allopathic, integrative and humanistic theories to be able to explain different mental disease phenomena (Lake 2007; Feinstein and Eden 2008).

Research networks have already been created. The real need is to spread, discuss and extract these new methods among CAM researchers, to assure and increase the quality of research design (Gilbert 2003). This quality process includes the requirement that the chosen methods and results must be according to the theories on mechanisms described. This quality requirement also calls on reviewers to cooperate with CAM researchers in their choices of reviewing methods to achieve the truest data.

7.2 HEALTH-RELATED QUALITY OF LIFE

The main findings of the HRQOL results supported our two hypotheses, that (1) the study group would significantly ($p<0.01$) increase their HRQOL values at six months after the course intervention, while (2) the control group started and remained at stable, normal values. The study group started from unexpectedly low entry health assessments despite good socioeconomic status. After the intervention, the HRQOL assessments increased to average Swedish population levels, especially the emotional well-being.

7.3 SENSE OF COHERENCE

The main finding of the SOC-13 assessments in the study group was that they started at significantly low levels, like the HRQOL. Although expected to be stable, the SOC scores increased by 5.1% ($p<0.01$) after the course intervention, reaching the median SOC-13 range of the average population.

When Antonovsky introduced the SOC concept in 1987 he described its stable assessments over time in many populations. In Sweden too, SOC-13 has previously shown stable levels over time in different Swedish populations ranging in age from 30 to 65 years in the early 1990s (Langius and Bjorvell 1993). But SOC has also shown a statistically significant decline in both men and women over a 5-year period in the late 1990s, but stabilizing until 2004 (Nilsson, Trehn et al. 2001; Hendrikx, Nilsson et al. 2008). Furthermore, Holmberg recently demonstrated large individual changes in SOC-29 scores (25% had more than one standard deviation change) among middle-aged Swedish men after twelve years, despite stable median values (Holmberg 2005).

These data and those of Larsson, Kallenborg and Volanen et al. support the findings of our study: SOC change can be as little as 1–8% and is still clinically relevant, as the result of life experiences, therapeutic intervention, life crises and ageing. SOC seems to be a useful variable in therapy interventions, not a predictor (Larsson and Kallenborg 1996; Volanen, Suominen et al. 2007).

The stabilities versus the changeability of the sense of coherence is interesting. The assessment instrument is now used in half a century, and may be influenced by states of world economics or politics, as well as therapeutic intervention. This project supports the changeability qualities. It would be interesting if these differences were further studied.

7.4 OTHER MAIN FINDINGS

The many distinct comments on the mental awakening process itself are interesting. This is a specific type of new results that a number of CAM researchers have recently described, and these researchers are authorized health care personnel. The awakening includes a mindful, here-and-now presence and a richness of emotional experiences and reflections. New questionnaires have been created on mindfulness, attention and awareness, showing changes as well as SOC relations (Goleman 1998; Sivik, Delimar

et al. 1999; Sivik 2000; Kabat-Zinn 2003; Kabat-Zinn 2004; Verhoef, Mulkins et al. 2005; Carmody, Reed et al. 2008; Carmody 2008; Dobkin 2008; Khalsa, Rudrauf et al. 2008; Morone, Greco et al. 2008; Morone, Lynch et al. 2008).

7.5 METHODOLOGICAL STRENGTHS, LIMITATIONS AND RECONSIDERATIONS

It was worthwhile visiting the centre at the start of all seven courses to inform the participants eye-to-eye about the study. This gave a good entry inclusion rate of 88% (107/122). The matching process (sex, age) was done before the first assessment, which was too early. It would have been easier to invite whole groups of previous participants, and then we would probably have had a larger control group.

The training centre might have been encouraged to continue to use the study questionnaires as their own quality check over the following years, thus giving an opportunity to return to the centre for follow-up during the years to come, especially as this 6-month study already yielded evidence.

The reliability of the results is strengthened by the high inclusion and response rates, the long inclusion time (a whole year), the equal gender distribution in the study group, and the use of previously validated questionnaires [SWEDQUAL (61 items), SOC-13].

The WHO quality of life questionnaire short form (WHOQOL-BREF), from 2004, may have been a more modern and global health questionnaire than SWEDQUAL, adding Spirituality, Energy and Medication and the new fourth domain Environment with Safety, Finance, Health care and Leisure assessments (1998).

In search of possible reasons for the initially reduced HRQOL scores, our interpretation might have been strengthened if we had used a validated depression scale. On the other hand, the experiences from the training centre, the physical functioning and the PD use indicated only average population depression rates. The baseline emotional HRQOL status of the initial study group was low and similar to that of a Swedish group of patients with a psychiatric disorder, even after weighting for socio-economic factors and disease (Wandell, Brorsson et al. 1999). The HRQOL increase in the study group reached average population levels after the intervention. These circumstances indicate that this course intervention had a significantly positive effect on emotional health disturbances.

The addition of registry data on sick listing might have enhanced interpretation.

Physiological parameters such as salivary cortisone levels, immune cell counts and blood pressure may have provided useful information, but these were not measured for logistic reasons. Measurements of pro-inflammatory intracellular cytokines (the brain mediators of sickness behaviour) might have been useful in this study, but they were not available during the time interval of this study (Nilsson, Trehn et al. 2001; Kelley, Bluthe et al. 2003; Lekander, Elofsson et al. 2004; Carlson, Speca et al. 2007).

The unknown CAM field, the presence of emotional health problems and the unexpected quotations indicate that further studies might benefit from adding interviews and/or focus groups (Saunders, Tractenberg et al. 2007).

The answers in Table 3, ("Has anything happened in your life, which you feel is important, during the last six months?") may seem difficult to interpret. But the most interesting parts are the many comments on the mental awakening process itself! It strengthens the general aim to get hold of crucial points of the new context. The quotations contain such a wealth of such emotional expressions, reflections and true concerns of life. They seem very useful for developing the well-being part of care, which, by definition, is important in CAM.

8 CONCLUSIONS

8.1 SIGNIFICANT EFFECTS

This study shows that this special MBM intervention gave clinically significant improvement of HRQOL (especially emotional) and in SOC-13. It also showed decreased PD need in young people, and it supports mental awakening and awareness.

8.2 COST-EFFECTIVENESS

This evidence-based course process could now be used as suitable rehabilitation for people who, after disease or trauma, have to change direction in (work) life. The course price of Euro 3055:- per person is equivalent to only 2-3 weeks of sick leave expenses for an employer or insurance board, and this is a short time compared to long term sick leave. This means, that if the course results would reduce a half-year sick leave time with only 2-3 weeks, the participation would have a good cost-effectiveness. The course could then be available as a motivational support for the rehabilitation processes directed by the Swedish National Social Insurance Board.

8.3 ORIGINAL CAM VALIDATION

The study also contributes to original validation of therapeutic MBM interventions, as a subgroup of CAM, for which there is as yet little scientific documentation.

9 FUTURE PERSPECTIVES

This course method now has some evidence. The collection of research methods has been shown to give a useful multidimensional variety and health scale differences, and might also be used for other CAM and MBM therapy evaluations or course centers, and even improved if some of the reconsiderations described above are added.

The CAM training centre setting, with each individual process enhanced by mirroring the others and where individual skills are practiced together in a group, is likely to be of interest for health care and rehabilitation economics, according to the brief cost-effectiveness analysis above.

The categorization of PMTA is quite different from the diffuse MESH-term “Mind-body relations” (MBR). We would welcome an unbiased revision of the MESH-term system for the CAM area towards PMTA, with the aim of increasing clarity and comparability for future research.

10 SAMMANFATTNING (SUMMARY IN SWEDISH)

Öka sin livskvalitet med sammansatta kropp-själ-terapier: Utvärderingen av en kurs för självkändedom och personlig utveckling

Bakgrund i alternativmedicin

Det behövs mer vetenskaplig forskning på alternativa och komplementärmedicinska behandlingsmetoder (CAM). Målsättningen med detta forskningsprojekt var att göra en vetenskaplig utvärdering av en sådan CAM metod, för att kunna ge de många intresserade patienterna ett bättre kunskapsunderlag för sina val av behandlingar. Jones har skapat ett översiktligt klassifikationsschema för behandlingsmetoder, byggt på primär mekanism hos den terapeutiska verkan, varunder all slags medicinsk behandling kan inordnas, så även CAM-metoder. De klassificeras i sex grupper av olika slags terapimekanismer: 1. kemiska t.ex. örtmedicin, 2. fysiska t.ex massage, 3. sambandet mellan kropp och själ (mind-body medicine, MBM) t.ex. meditation, 4. energiflöden t.ex. akupunktur, 5. psykologi t.ex. psykoterapi och 6. andlighet t.ex. healing.

Kropp och själ i samband

Just sambandet mellan kropp och själ är intressant för skolmedicinen i och med många nya forskningsrön om komplexa immunologifunktioner t.ex. blodcytokiners samband med självskattad hälsa och mätbara EEG-förändringar vid meditation. Nya studier av MBM och behandlingsmetoder t.ex. akupunktur och mindfulness meditation utvecklas numera också av utbildad sjukvårdspersonal, t.ex. Kabat-Zinn's "mindfulness based stress reduction". Även kurser (= interventionsmetoden) i detta forskningsprojekt är fokuserat på bara tre av de sex kategorierna av terapeutiska mekanismer, nämligen; 3. sambandet mellan kropp och själ, 4. energiflöden och 5. psykologi.

Kursgården

På en speciell kursgård, beläget på Vikbolandet utanför Norrköping, har man sedan 1985 hållit 7-dygnskurser i självkändedom och personlig utveckling, 6-9 ggr/år. Kurserna bygger på teoribakgrund enligt CAM, med bl.a. kroppspsykoterapi, meditation och chakra-systemet för kroppskändedom. Man använder många övningar vilka fokuserar på känslornas betydelse för det personliga hälsotillståndet.

I samband med personligt deltagande kom jag i kontakt med spontant rapporterad förbättrad livskvalitet efter kurserna hos flera kursdeltagare. Därför valde jag att göra ett forskningsprojekt för att utvärdera denna annorlunda kursmetod. De romerska sifforna hänvisar till de två delarbetena (I, II).

Syften Det specifika syftet i delarbetet I var en tvärsnittskartläggning av självskattad hälsorelaterad livskvalitet hos kursdeltagare, jämfört med svenska befolkningen. Delarbete II är en utvärdering av den hälsorelaterade livskvaliteten och känslan av sammanhang (KASAM), före och sex månader efter interventionen, en kurs i personlig

utveckling, på kursgården. Ett tredje syfte var att samla svar på och kommentarer till frågan: ”Har det hänt någonting som Du bedömer som viktigt i ditt liv senaste sex månaderna?” för att kunna illustrera känslloyttringar och ökad medvetenhet, och om möjligt fånga in oväntade mönster i detta utforskade forskningsområde.

Material och metoder

Kursdeltagarna rekryteras mestadels genom annonsering och personliga kontakter, enstaka personer har remitterats från Försäkringskassan. Flertalet betalar kursen själva.

Delstudie I är beskrivande och jämför livskvaliteten med motsvarande data från svenska befolkningen. Den initiala studiegruppen bestod av 107 kursdeltagare (svarsfrekvens 88 %, ålder 20-70 år). Den första deltagaren inkluderades i studien jan 2000 och den sista uppföljningen gjordes aug 2001. Deltagarna har vid ankomsten till kursgården, d.v.s. före själva kursen, besvarat tre frågeformulär. Det första var SWEDQUAL, med 61 självskattade livskvalitetsfrågor fördelat på 13 områden som t.ex. fysisk funktion, sömn, kognitiv funktion, smärta, relationer och känslor. Det andra var Antonovsky’s ”Känslan av sammanhang” med 13 självskattningar fördelat på tre områden: livets begriplighet, hanterbarhet samt meningsfullhet. Det tredje formuläret var socioekonomiska frågor om utbildning, arbete, CAM erfarenhet, sjukskrivning och medicinering. Jämförelser gjordes med befolkningsdata från Statistiska Centralbyrån, Socialstyrelsen och Försäkringskassan.

Delstudie II är en interventionsstudie med data från före respektive efter kursen, och ovanstående startvärden för livskvalitet och KASAM jämförs med exakt samma frågeformulär hemskickat sex månader senare. Varje fullföljande kursdeltagare (n=83) har jämförts med sig själv och statistiska gruppberäkningar har gjorts för att avgöra om förändringarna är säkerställda. Här har tillförts en kontrollgrupp av tidigare kursdeltagare (1998-99, n=69), matchade till kön o ålder, vilka har gjort parallella skatningar.

En godkänd etikprövning gjordes i dec 1999 av Karolinska Universitetssjukhusets etiska kommitté.

Resultat:

Delstudie I beskriver ett tvärsnitt av livskvaliteten i initiala studiegruppen (n=107) och jämförelse med befolkningen. Sex av de tretton delskalorna för livskvalitet visade uttalat och statistiskt säkerställda låga ingångsvärden ($p<0.0001$) i den initiala studiegruppen, nämligen: känslomässigt välbefinnande, känslomässig störning av vardagen, kognitiv funktion, familjetillfredsställelse och partnerrelation. Långtidssjukskrivning (>6 månader) var tre gånger så vanligt i den initiala studiegruppen som i befolkningen. Användning av depressions-, lugnande eller sömnmedicin var något ökad jämfört med befolkningen, åtminstone bland de yngre männen. Utbildningsnivån var hög, sjukvårdskonsumtionen normal och fysiska kroppsfunctioner var goda.

Delstudie II:

Utfallsmått var förändringar i livskvalitet och KASAM-13 i den fullföljande studiegruppen (n=83) och i fullföljande kontrollgruppen (n=69). Åtta delskalor av livskvaliteten visade kliniskt relevanta och statistiskt säkerställda förbättringar i

studiegruppen (>9 %, p<0.01), nämligen: allmän hälsa (9 %), känslomässigt välbefinnande (negativt 45 % och positivt 26 %), kognitiv funktion (24 %), sömn (15 %), smärta (10 %), känslomässig störning av vardagen (22 %) och familjetillfredsställelse (16 %). Fysisk förmåga, partnerrelation och sexuell förmåga i studiegruppen, och alla delskolor för kontrollgruppen, skiljde sig inte från data från den svenska genomsnittsbefolkningen.

Den självskattade KASAM förbättrades i studiegruppen efter kursen (p<0.01) och utmanar tidigare slutsatser att KASAM-värdet är stabilt för samma person oberoende av händelse. Användandet av psykofarmaka minskade hos yngre kursdeltagare efter kursen.

Kommentarerna om viktiga livshändelser är grupperade i en tabell utifrån sex olika teman. De två första berör den egna respektive närståendes hälsa. En annan speglar psykologiska motstånd/ blockeringar. De tre viktigaste grupperna gäller relationer, arbetsutveckling samt ”uppvaknandeprocessen”, vilka beskriver en ökad grad av medvetenhet, ledande till kreativa beslut om att förändra i sitt liv.

Slutsatser

Studiegruppen bestående av välutbildade kvinnor och män, skattade sin ursprungliga hälsa oväsentad lågt. Särskilt det känslomässiga hälsotillståndet var på samma nivå som för personer med kroniska sjukdomar. Efter kursen förbättrades livskvaliteten och KASAM påtagligt, upp mot normala befolkningsvärden.

Sammanfattningsvis visade studierna också att:

- Det går att göra en vetenskaplig utvärdering av också mjuka, självskattade data som beskriver subjektiva upplevelser efter en kursintervention med alternativmedicinsk teoribakgrund.
- De utvalda enkätmetoderna gav en lagom bredd av dels tydliga, kliniskt signifika förändringar, dels stabila värden. Metoden tycktes vara särskilt effektiv att upptäcka emotionella hälsotillstånd.
- Utrymme för spontana kommentarer i datainsamlingen kan vara väl värt mödan i ett tidigare utforskat område, för att kunna fånga helt nya fenomen.
- Kurstiden på sju dagar verkar ge effekt utifrån uppmätta resultat. En tolkning är att personer med laddade minnen, hinner komma förbi krisprocessens initiala chockfas och bättre kan påbörja konstruktiv emotionell bearbetning av dessa.
- Kursinterventionen kunde förbättra deltagarnas både hälsorelaterade livskvalitet och känslan av sammanhang. I och med denna förbättring, därtill med en förbättrad kognitiv och emotionell funktionsförmåga, ökar rimligen motivationen. Därmed har den potential att användas som start på en arbetslivsinriktad rehabilitering för de människor som av hälsoskäl nödgas ändra inriktnings och klara en omställningskris och skapa en förankrad nyorientering.

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