Chapter 3

The Dutch complementary and alternative medicine (CAM) protocol: to ensure the safe and effective use of CAM within Dutch mental health care


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Abstract

Background:
Complementary and alternative medicine (CAM) is subject to heated debates and prejudices. Studies show that CAM is widely used by psychiatric patients, usually without the guidance of a therapist and without the use of a solid working method, leading to potential health risks.

Aim:
The judicious use of CAM alongside conventional psychiatry in an outpatient psychiatric clinic.

Methods:
A search through scientific and legal articles and discussion in focus groups.

Results:
In the Center for Integrative Psychiatry (CIP) of Lentis in the Netherlands some carefully selected CAM are offered under strict conditions, alongside conventional treatments. Because of the controversy and the potential health risks, Lentis designed a protocol that is presented.
Introduction

In 2002 Silvia Millecam, a famous Dutch actress, died of breast cancer after refusing conventional medical treatment while trusting herself to practitioners treating her with CAM. The Dutch Healthcare Inspection did an extensive inquiry into the matter. Three doctors were put to trial for malpractice and were convicted by the Medical Disciplinary Tribunal. Two of them lost their medical licence. In the years that followed there were heated debates on the use of alternative medicine in the Netherlands.

Supporters of CAM claim that conventional treatments have too many side effects, lack effectiveness and room for patients' wishes and needs. On the other hand, opponents state that CAM is quackery and that the effects are based on placebo and 'ridiculous principles' (Renckens, 2004). This reaction reminds us of earlier resistance to change in medicine; for instance, in 1911 Herrick was almost laughed out of medicine for stating that atherosclerosis causes myocardial infarction (Olshansky & Dossey, 2003).

Previous and current bias against new developments is undesirable because both patients and doctors are uncertain about safety and effectiveness of CAM. This is all the more important because about half of the population in a variety of western countries (Bodeker & Kronenberg, 2002) and almost half of Dutch psychiatric outpatients use CAM annually (Hoenders et al., 2006). A majority of patients gets information on CAM via internet, friends or family. The quality of this information varies greatly, leading to potentially harmful and dangerous situations (Crone & Wise, 2000).

In the Netherlands many doctors do not inform their patients about CAM and they certainly avoid prescribing or referring to CAM. Recently the Dutch Minister of Health has announced more severe punishment for practitioners who harm their patients either by applying unsafe therapies or by delaying the start of conventional treatment (NRC Journal, 2009). Therefore, in the Netherlands patients and doctors are informed about what cannot be done concerning CAM, while it remains unclear what could or should be done. Despite calls from the World Health Organization (WHO, 2003) and the European parliament (European Parliament, 1997), until now the Dutch government did not formulate a policy on this matter.

In an effort to fill this gap and inspired by the North American consortium of 55 academic health centers for integrative medicine (CAHCIM, 2004), Lentis (a community mental health facility in the North of the Netherlands) founded a Center for Integrative Psychiatry (CIP) in 2006. It consists of an outpatient clinic, a research department, an educational department, and organizes an annual conference (with approximately 1000 attendees) (Hoenders et al., 2008). Its main purpose is to provide safe and effective integrative mental health care.

What is Integrative Psychiatry?

Integrative psychiatry is based on the principles of ‘integrative medicine’: reaffirming the importance of the relationship between practitioner and patient; focusing on the whole person; using all therapeutic approaches (conventional and CAM) based on the principles of evidence-based medicine (EBM); and achieving optimal health and healing.
The debate in the Netherlands focuses mainly on the principle of EBM, i.e. the use of CAM within conventional treatment centers, and the correct definition of evidence-based medicine. In this regard it is noteworthy that Sackett et al. (2000) defined EBM as: (1) the best available evidence for effective and safe treatment options, (2) the preferences and needs of the patient, and (3) the clinical expertise of the professional. These three together should be decisive in making treatment choices.

This definition is in contrast with the present-day more reductionist explanation of evidence-based medicine in which the first and third principle are emphasised without paying much attention to the patient’s preference (Offringa et al., 2003). The original definition therefore accommodates therapies that still lack (sufficient) evidence-based proof. It is also important to realize that according to some researchers only about one third of culturally and professionally accepted interventions in western medicine is proven effective by RCTs (Booth, 2006; Tataryn & Verhoef, 2001).

Prejudices

Some reasons why opponents feel doctors should not use CAM seem to be based on prejudices. Table 1 compares the most common prejudices against CAM with information from scientific studies.

Table 1: Prejudices against CAM

<table>
<thead>
<tr>
<th>Prejudice</th>
<th>Refutation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Only few people use CAM</td>
<td>1. 30-70% of the population uses CAM¹ and 42% of Dutch psychiatric outpatients²</td>
</tr>
<tr>
<td>2. My patients do not use CAM because they never ask or tell me about it</td>
<td>2. 60-75% of patients using CAM do not tell their doctor out of fear of a negative response³</td>
</tr>
<tr>
<td>3. CAM users are less educated and easily influenced</td>
<td>3. CAM users are typically female, highly educated, high income with chronic disease⁴</td>
</tr>
<tr>
<td>4. They use CAM instead of conventional medicine</td>
<td>4. 80-95% combines⁵</td>
</tr>
<tr>
<td>5. They use CAM because of negative reasons (against conventional medicine)</td>
<td>5. Besides disappointment about side effects and limited results, also positive reasons play a part: good relationship with therapist and a shared belief about health and disease (holism)⁶</td>
</tr>
<tr>
<td>6. CAM effects are due to placebo</td>
<td>6. Several CAM are more effective than placebo⁷</td>
</tr>
<tr>
<td>7. CAM and EBM are incompatible</td>
<td>7. CAM can be offered based on the principles of EBM⁸</td>
</tr>
<tr>
<td>8. CAM are not endorsed by influential institutions</td>
<td>8. The CAHCIM⁹, the WHO¹⁰ and the EP¹¹ endorse the integration of effective CAM in conventional clinics</td>
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¹ Bodeker & Kronenberg, 2002  
² Hoenders et al., 2006  
³ Van De Creek et al., 1999  
⁴ Astin, 1998; Eisenberg et al., 1998  
⁵ Furham, 1996  
⁶ Ernst, 2006; Lake & Spiegel, 2006; Mischoulon & Rosenbaum, 2008  
⁷ Wilson & Mills, 2002; Hoenders et al., 2010  
⁸ CAHCIM, 2004  
⁹ World Health Organization, 2003  
¹⁰ European Parliament, 1997  
¹¹ European Parliament, 1997
Similarly, those in favor of CAM also seem to have prejudices. Those are mentioned in table 2. We therefore argue that CAM needs serious attention, both within conventional treatment centers and in the alternative field.

**Table 2: Prejudices for CAM**

<table>
<thead>
<tr>
<th>Prejudice</th>
<th>Refutation</th>
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<tbody>
<tr>
<td>1. If it does not work, at least it will not harm</td>
<td>1. Some supplements or herbs can cause severe side effects or interactions¹</td>
</tr>
<tr>
<td>2. Natural substances are more healthy than chemicals</td>
<td>2. Nature contains severe toxins, besides natural medicines</td>
</tr>
<tr>
<td>3. CAM do not need to be researched; I know it works from experience</td>
<td>3. Experience is not enough; research is needed to distinguish from placebo and bias²</td>
</tr>
<tr>
<td>4. CAM are not suitable for research because of their specific nature</td>
<td>4. Science can be applied to all phenomena; it is essential to choose the right design³</td>
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</table>

¹ Ernst, 2003  
² Sackett et al., 2000  
³ Walach et al., 2006

The CAM protocol

One of the primary tasks of our center was to formulate a scientific model based on the requirements that it would (1) answer patients’ needs and wishes; (2) respect their freedom of choice; (3) would offer western medicine and CAM that are safe and effective; (4) would protect against quackery and abuse; (5) should be based on Dutch law, the jurisprudence of the Medical Disciplinary Tribunal and the rules of the Dutch Association of Medical Practitioners (KNMG); and (6) be based on scientific evidence.

The authors reviewed documents, the scientific literature and collected information with the help of focus groups (De Jong et al., 2010). This resulted in the CAM protocol (Hoenders et al., 2010). In this protocol we distinguish (between) complementary and alternative medicine. The first is defined as “approaches based on mainstream biomedical theory and supported by research evidence but not part of mainstream practice because of social, political or ideological reasons”. Examples are St. John’s wort and massage. Alternative medicine is defined as “approaches that are based on concepts that are outside mainstream Western medicine”. Examples include homeopathy and healing (Lake, 2007). Based on an analysis of the results we produced the algorithm shown in figure 1.
Figure 1: Decision tree
This is the working method of the Center for Integrative Psychiatry. The first step of the algorithm clarifies that CAM can only be used after an extensive and precise stepwise process. They can only be started if conventional treatments have been applied before or at least advised as suggested by guidelines and protocols. In addition, CAM is considered if there is no danger when a patient refused treatment (for instance: a manic or psychotic patient with severe symptoms will be strongly advised first to accept conventional medication even when asking for CAM).

After deciding to start CAM, the second step is based on the principles of EBM (i.e. alternative treatments with a lower level of evidence can be provided on a patient’s request when there is no contraindication). However, these treatments will not be offered within the CIP. Patients will be referred to an external network that provides these treatments in conjunction with proven treatments provided by CIP and not instead of them. In addition, there are the following required conditions:

- The therapists are members of a (para)professional organization with a formal procedure for complaints and malpractice.
- The therapists base their treatments and their way of working on the professional guidelines of the organization.
- The therapists conform themselves to legal demands concerning patient files.
- The clinic or office where patients are being treated meet privacy and hygiene demands, as common in conventional medicine.
- The therapists have malpractice insurance.
- There has to be at least monthly contact between the CIP and the alternative practitioner.
- After finishing the alternative treatment there will be at least one contact with the CIP to evaluate.
- The alternative therapists agree to be included in scientific evaluation by routine outcome measurement (ROM) of the effect of the treatments and agree with publication, regardless the results.

### Center for Integrative Psychiatry

In the Center for Integrative Psychiatry of Lentis only conventional and complementary medicine that have been proven effective and safe are being practised. That means that they have to be based on (reviews of) several well-designed scientific studies. Examples are St. John’s wort for depression (Linde et al., 2008), valerian for insomnia (Mischoulon & Rosenbaum, 2008), relaxation for anxiety (Eppley et al., 1989), mindfulness-based stress reduction (Baer, 2003; Grossman et al., 2004) and mindfulness-based cognitive therapy for depression (Teasdale et al., 2000), massage for stress, anxiety and depression (Moyer et al., 2004), exercise for depression, anxiety and sleep disorders (Craft & Landers, 1998), heart-rate variability training for anxiety and stress-related and depressive symptoms (Karavidas, 2008; McCratty et al., 2001), single vitamins as a supplement to medication for depression (like folic acid) (Taylor et al., 2008), food supplements like s-adenosylmethionine (SAMe) for depression (DelleChiaie et al., 2002), melatonin for sleep disorders (Zhdanova & Friedman et al., 2008), inositol for depression, panic and obsessive compulsive disorder (Belmaker & Levine, 2008), and dietary changes for depression (Freeman, 2010). These treatments, integrated with conventional psychiatry, have been offered since three years to psychiatric outpatients.
Alternative medicine like homeopathy, reiki or healing are not being offered. However patients can be referred to these treatments under strict conditions, which are explained above. All treatments are evaluated by routine outcome measurement (ROM). In addition, we study the outcome of innovative treatments with individual outcome measurements (IOM) such as N-of-1 design, single-subject experimental design and time-series analysis. ROM consists of six questionnaires: psychopathology, quality of life, resiliency, costs, satisfaction and one self-report personalized outcome indicator, chosen by the patient. Patients fill out these forms before treatment starts, every half year, at the end of treatment, and half a year after their discharge. Patients with IOM fill out diaries concerning items that are most relevant to their treatment and symptoms, to assess subjective improvement on core symptoms and complaints.

Conclusion

Because of the increasing demand of patients for alternative medicine and integrative treatments and because of social, political, scientific and ethical reasons, and inspired by the CAHCIM, Lentis has founded a CIP. Here it offers selected complementary treatments alongside conventional ones under strict conditions. By doing so, the CIP responds to a call from the Word Health Organization and European Parliament, even though the Dutch government still hasn’t made policy on this subject. Because of the controversy surrounding CAM, because of the lack of clear information and because we do not only need an open attitude but also a critical one, the CIP has formulated the CAM protocol. It believes that in this way CAM can be offered in a safe and effective way within conventional treatment centers. It hopes in this way to better serve and respect the individual needs and preferences of the diversity of patients who need mental healthcare in our Dutch multicultural society. It believes the protocol also protects against quackery, abuse and false hope.
Acknowledgments

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References:


http://vorige.nrc.nl/binnenland/article2161797.ece/Hogere_straf_alternatieve_en_fale%20de_arts


Part III: Effectiveness