

# Evaluating complementary and alternative medicine by individual response

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**Abstract.** A new methodology for the evaluation of complementary and alternative medicine (CAM) using individual response to replace randomized controlled trial (RCT) is introduced. Two research projects on “Scientific criteria for the evaluation of CAM” are discussed. The new methodology would be especially useful in the field of psychosomatic medicine. © 2006 Elsevier B.V. All rights reserved.

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## 1. Introduction

Integrative medicine (IM), which integrates modern western medicine (MWM) and complementary and alternative medicine (CAM) is considered as an important concept for future health care. Several years ago, CAM became an important topic in the medical community, but the focus is now changing from CAM to IM. Because of incidents that have occurred recently, it is essential that scientific evaluation criteria for CAM be established.

In the past, randomized controlled trials (RCT) have been considered and tried as the golden standard for evaluation; however, it is not always applicable to the evaluation of CAM, in particular to the evaluation of individual response to treatment. Therefore, it was necessary to develop a new method for the evaluation of individual response to use in place of RCT.

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Little research on scientific criteria for CAM has been reported. In the past, evaluation methods have focused on the clinical, biological and biochemical aspects of disease and treatment, with little attention to individual differences. Preclinical findings, the mind–body relationships and economics have not been sufficiently studied as potential evaluation factors. Multiple evaluation criteria are necessary for an individual evaluation.

The evaluation method on outcome is considered as the important factors. Outcome can be divided into four aspects, (1) clinical, (2) patient satisfaction, (3) QOL and (4) economical aspects. In detail, (1) clinical aspects are an improvement ratio of symptom and findings and occurrence ratio of side effect and mortality, (2) patient satisfaction aspects are accessibility, convenience and information, (3) QOL aspects are physical, mental and social ones, and (4) economical aspects are duration of admission, medical care cost and increase of income.

Candidates of variables for individual difference are classified into the field of “modern medicine” and “traditional medicine”.

In “modern medicine”, the variables are divided into (1) the feature of diseases and (2) the feature of the patient. The former one consists of exogenous disease and endogenous one, etc., and the latter one includes the physical (constitution (genome, proteome analysis), season and weather, environment, etc.), the mental (culture and religion, personality, hobby, and recognition for drug and therapy, etc.), and the social one (doctor–patient relationship, living custom, family, occupation and social status, etc.).

In “traditional medicine”, the variables are also simultaneously divided into: (1) the feature of disease (classification due to cause (exogenous, endogenous, diseases of 気血水), classification due to diseases (太陽病, 小陽病, 陽明病, 太陰病)), and (2) the feature of patient (physical, mental, social conditions=constitution and Sho, five sensation (four diag: 望診, 聞診, 問診, 切診, three diag: 視診, 問診, 触診), classification of constitution and Sho, Sho (証: 虛証, 實証, 寒証, 溫証), constitution (Vatta, Pitta, and Kappa), personality (Bloody and Bily)).

In the National Cancer Institute of NIH, the “best case series” is accepted as the method for evaluating efficacy of CAM for cancer treatment. These series are (1) exact pathological diagnosis, (2) appropriate setting on endpoint for anti-cancer therapy, (3) prohibition of cancer treatment except CAM, (4) recording of received anti-cancer therapy of patient, (5) recording of primary lesion and metastatic lesion, (6) recording of general information (age, sex, history, etc.) on patients, and (7) recording of therapy which indicated anti-cancer response.

At the present state, the two research projects on “Evaluation criteria on CAM” by the Ministry of Education and Science and Technology (MEST) in Japan: the Yoshioka project and the Nitta project—have been going on.

## 2. Yoshioka project

### 2.1. Biomarker

The sensitive “biomarker” is requested to check the pre-clinical condition which will not appear as the actual indication. The evolutionary method using “proteomics” will be expected as the fine “biomarker”.

Dr. Yoshikawa studied the efficacy of healthy food “anthoxanthin” in the animal experiments of mice using “biomarker” tip of proteomics.

## 2.2. Aromatherapy

The study of the effect of aromatherapy on patients with depression and breast cancer was conducted by Dr. Imanishi.

In order to measure the effect of aromatherapy on the depression patients, 17-item Hamilton depression rating scale (HAM), profile of mood states (POMS), and Wisconsin card sorting test (WCST), which assess the depressive levels, psychological change and frontal function of brain, respectively, are selected as the indicators.

The efficacy of aromatherapy for depression was verified resulting in increase of cerebral blood flow.

Breast cancer patients are selected under the restricted conditions, which are (1) longer than 1 month after passing chemotherapy and radiation therapy, (2) no recurrence case, (3) no case with significant lymph-edema, and (4) age from 20 to 70 years old.

As a result, aromatherapy is effective in relieving the anxiety for recurrence in the breast cancer patients using the indicator of HADS as shown in Fig. 1.

In order to evaluate the CAM using the method of biomedical engineering, many reports were presented until now, such as the effects of acupuncture, placebo, hypnotherapy, meditation, QOL, individual constitution, etc.

Dr. Ito studied the individual difference on brain-energy metabolism, phototomography, neuro-receptor-mapping in brain by using biomedical engineering.

In particular, he challenged to study the “scientific evaluation for mind”.

These studies included (1) neurotransmission function (stress-related hormone, quantitative evaluation on secretion of intracellular dopamine, and quantitative function analysis on hypothalamus by detection of intracellular histamine H), (2) immune-system (change of functions of immune system and brain by exercise therapy), (3) autonomic neuro-system, and (4) understanding of mind in integrative medicine.

Finally, Dr. Shirakawa studied the “genome analysis and individual response on efficacy of a healthy diet”.

The study is going on to detect the DNA analysis on fecal bacteria of the allergy patients as shown in Fig. 2.

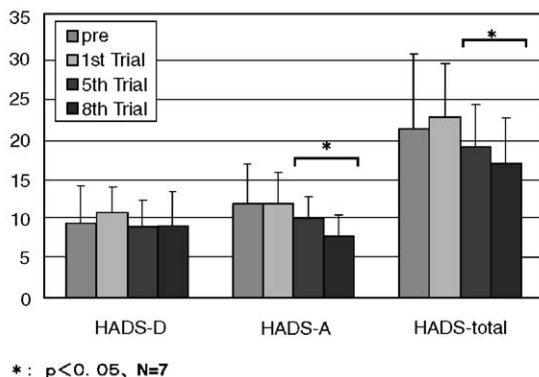


Fig. 1. Aromatherapy for breast cancer.

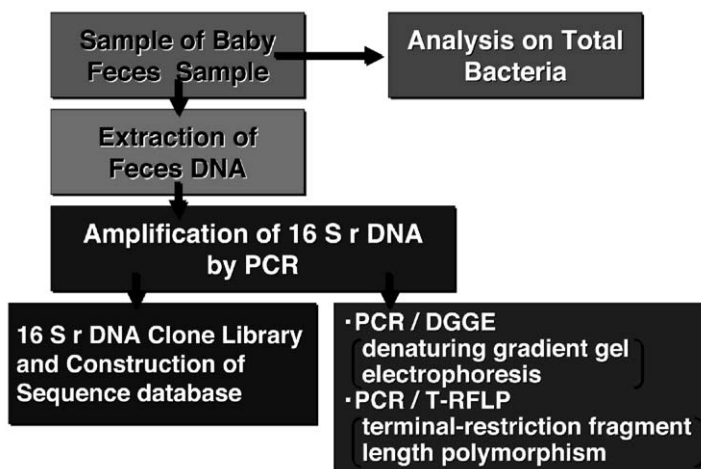


Fig. 2. DNA analysis on feces bacteria.

The DNA analysis is a very attractive method, however, it is considered to confront the sensitive ethics problems.

The studies on the database of the national gene information were performed with the aim for the application to the national policy and in health industry. (1) The studies in Iceland and Baltic states are restricted to anthropologic origin due to few populations, and the problem that genes in gene pool of the isolated from few nation groups are not applied appropriately in the large-scale and mixed group. (2) Bio-bank projects were started in US and Canada, but were now discontinued due to ethical problems. (3) In Japan, studies in Fukuoka, Yamagata and Rikagaku Institute were done.

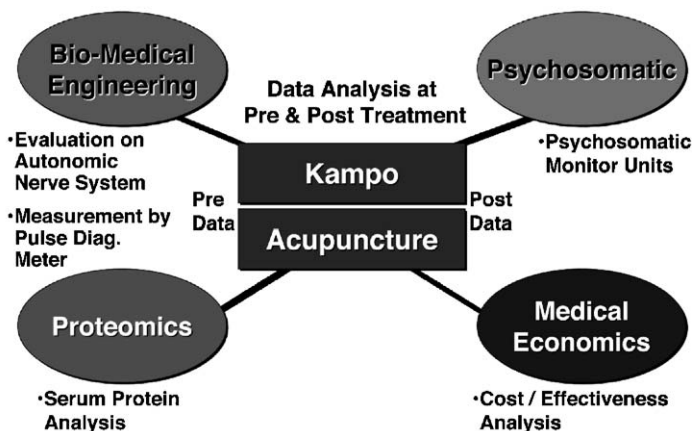


Fig. 3. Multiple evaluation methods for kampo and acupuncture.

### **3. Nitta project**

Lastly, I would like show the outline of the Nitta project shown in [Fig. 3](#).

The four approaches are going on—biomedical engineering, psychosomatic, proteomics and medical economic approaches—to detect the preclinical and postclinical data on “the patients of Kampo and acupuncture”.