

### **Abstract**

Standard clinical trials require greatly simplified methodology, targeting western diagnoses. Complementary medicine does not use the same diagnostic criteria and is by nature multifaceted. Studies which attempt to make it fit standard trial methodology by distorting the therapy's normal clinical protocol frequently fail, thus reinforcing the commonly held belief that unconventional therapies are mainly of placebo value. Recent workers are now questioning whether the term placebo should be allowed to dominate the acceptance or rejection of complementary therapies. Because their practitioners may give greater time and apparent sympathy is not scientifically relevant. The outcome and its cost benefit is. Nutritional therapists, like other complementary practitioners, believe that outcome studies would allow their therapy to be more realistically evaluated. Such trials need not exclude randomisation nor a control group.

Although standard trial methodology has been developed in order to eliminate bias, is this in fact possible, since blinding is automatically broken if the treatment studied is effective or if it produces side effects? Many conventional medical procedures cannot be tested blind and this is not expected of them. Any therapy which requires the co-operation of the patient likewise cannot be blinded. The therapy should not be penalised for this, whether conventional or "unconventional".

This paper sets out the essential pre-conditions which must be met before nutritional therapists can consider future research proposals. Nutritional therapy is defined and its context within holistic medicine is discussed.

### **Position Paper**

#### **Nutritional Therapy Research**

##### Clinical trials

The standard procedure in medical research is currently to gather a group of patients with the same diagnosis, and subject them to the same treatment to determine whether this treatment is safe and effective. If possible, there should be a 'control' group - that is to say patients with the same diagnosis but given a dummy (placebo) treatment. Ideally the patients should be randomised - assigned at random to the treatment or control group - and neither they nor the clinician should know which group they are in. The outcome in the two groups of patients is compared and if the treatment group shows a statistically significant improvement compared with the control group, the treatment is deemed to be a success. This is known as a randomised double-blind placebo-controlled clinical trial. If a trial does not follow these rules, the procedure being investigated is, generally speaking, unlikely to be embraced by mainstream medicine in spite of the fact that this is far from being the only assessment protocol with scientific validity. Trials which show normalisation of biochemical data, and properly conducted audit programmes should carry equal weight.

When attempts are made to fit complementary (unconventional) medicine disciplines into the standard research framework, results are generally poor. This is because this research method centres around a diagnostic system which is usually foreign to the complementary therapy. If not very carefully done, taking the diagnosis of one system of medicine and using it as the basis for researching another can be like trying to play the game of cricket using the rules of football. It just doesn't work.

##### Diagnosis

The term "diagnosis" has come to be associated with the western sense of the word. Examples of western diagnoses are "arthritis", "atherosclerosis", "psoriasis". The western diagnosis is frequently a description of the patient's symptoms or of the appearance of the patient or the patient's diseased organs. But the original Greek word "gnosis" means "knowledge". "Diagnosis" implies helping the patient "through knowledge". To "diagnose" is defined as determining the type and cause of a health condition.

The greatest successes of western medicine have been in infectious diseases, where the diagnosis involves determining both the type and the cause - the sole infectious agent which can be treated with a single "magic bullet", antibiotics. This is a relatively rare phenomenon in western medicine. Most diagnoses of chronic disease in particular fall into the description-only category. For instance "arthritis" means "inflammation of the joints". "Migraine" means "a pain in part of the head, accompanied by nausea or other symptoms". Because the causative factor(s) are assumed to be largely unknown, the treatments which have been developed cannot specifically address them. Most orthodox treatments of chronic disorders are in fact palliative - that is to say if used perpetually they can help the patient to cope with the disease but they do nothing to eradicate its cause. Indeed they may in time cause biochemical abnormalities of

their own via toxic metabolic intermediates, leading to worsening ill-health. Indeed a substantial number of hospital admissions are occasioned by the side effects of pharmacological treatments [1].

It is suggested that the rigidity of the accepted trial design encourages palliation-based medicine. Rigidity requires simplicity: does substance A improve a group of people with disease X? Often only palliative treatments will fit into this framework.

### Complementary medicine diagnosis

All complementary medicine disciplines have their own forms of diagnosis. The Chinese medical herbalist will, for example, assess criteria such as yin, yang, heat, cold, wind, dryness and chi in an individual's organs. A mixture of several dozen different herbs may then be prescribed, with the aim of improving the balance of these criteria and thereby to stimulate improved function in the organs which have been identified as out of balance by the therapist. As function improves, physiological and biochemical self-repair processes can become more efficient. (These are often referred to as the "self-healing process".) Twenty patients with the same western diagnosis may receive twenty totally different herbal formulae. It must never be assumed that because one treatment pattern worked for one of these patients it will have any effect on the rest. The treatment is based on the herbalist's diagnosis, not the western diagnosis.

Attempts to subject Chinese medical herbalism to the double-blind randomised placebo-controlled clinical trial have been made, using standardised herbal preparations [2,3] but this methodology has distorted the clinical outcome. The researchers admitted that although benefits were seen, results were clearly inferior to those obtained from the use of individually formulated preparations.

To take another example the homoeopath prescribes on the basis of a minutely detailed symptom analysis and by defining the patient's "constitutional type" to arrive at an individual treatment formula. Again twenty people with the same disease may be given twenty different treatments.

In effect, the complementary medicine practitioner does not set out to treat a western diagnosis. Hoping to facilitate self-repair, he or she seeks to improve function by influencing the factors that affect function (electrical, "vital force", nutritional/biochemical, excretory, psycho-neurological, circulatory, musculo-skeletal).

### Nutritional therapy

Nutritional therapy can briefly be summarised as a health care system which seeks to improve or restore physiological and biochemical function in chronic illness by manipulating the raw materials which are either present in food or are normally synthesised from food within the body.

In a clinical audit carried out on 300 NHS patients treated by a nutritional therapist from 1990-1993[4], the following percentages of patients reported a "definite, lasting improvement":

Headaches or migraine	85%
Digestive problems	82%
Hormone-related problems	70%
Chronic tiredness	55%
Skin diseases	54%

In practical terms nutritional therapy is a process whereby a trained and knowledgeable practitioner carries out a diagnostic procedure to develop a tailor-made regime with a therapeutic goal, which is carried out under the practitioner's supervision. The concepts of *diagnostic procedure* and *therapeutic goal* are crucial in distinguishing between nutritional therapy as a complementary medicine discipline, and conventional dietetics<sup>1</sup>.

Although almost uniquely pragmatic among complementary therapies, and largely based on modern scientific research, nutritional therapy is nevertheless firmly in the "alternative" camp. This is because it does not draw the same conclusions as conventional medicine from the results of that research. [For a fuller discussion, see Notes, page 6.]

### Nutritional therapy diagnosis

The nutritional therapist is trained to screen patients by looking for indicators of the following three broad diagnoses.

1. Food or environmental allergy or intolerance.
2. Toxic overload due to heavy metals or chemicals in the environment, intestinal dysbiosis, poor eliminative ability or poor liver function.
3. Nutritional deficits due to poor diet, special needs or malabsorption.

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<sup>1</sup> Nutritional medicine may overlap with nutritional therapy, but is usually based on laboratory studies of vitamin, mineral and enzyme processes and levels, techniques which are not normally available to the nutritional therapist.

A fuller discussion of these factors follows. In addition reference [18] quotes large numbers of research studies which support the justification for this approach.

#### Food allergy/intolerance

These can be defined as an idiosyncratic altered reaction to a food or foods. Both nutritional therapists and many medical practitioners [5] find in practice that food allergy and intolerance can cause diverse chronic and subacute symptoms far more commonly than is generally believed. Indicators of food intolerance may include uncharacteristic behavioural or mental disturbances [6] migraine [7], irritable bowel syndrome or colitis [8], or eczema or urticaria [9] [10] Food intolerance may also be a factor present in sufferers of more serious chronic diseases such as rheumatoid arthritis [11][12] and may manifest as some of the symptoms of the disease. The nutritional therapist and specialist medical practitioner can add many more conditions including sinusitis, multiple sclerosis and asthma to the list. The nutritional therapist is trained to recognise the possible presence of food intolerance, and to help the patient identify problem foods and minimise symptoms while eating as healthy a diet as possible.

#### Toxic overload

Research into the links between toxic overload and common chronic diseases is still in its infancy. Mankind is exposed to a cocktail of xenobiotic materials for which we may be evolutionally unprepared, from food additives to pesticides in food air and water, pharmaceutical medications, industrial pollution and heavy metal exposure (including mercury in dental amalgam, which is now known to leak from fillings and accumulate in the kidneys [13]. In the experience of nutritional therapists, indicators of a toxic overload may include chronic degenerative diseases such as osteoarthritis or cancers, asthma, myalgic encephalomyelitis (ME), multiple allergy syndrome, or skin diseases such as acne and psoriasis. The nutritional therapist is trained to combat this type of problem by reducing sources of toxicity, and using supportive measures for kidney, bowel and liver function, such as dietary measures, herbs which support liver function and drainage, antioxidant nutrients and nutrients involved in detoxification pathways such as that of cytochrome P450 oxidase.

#### Nutritional deficiencies

In the experience of nutritional therapists, indicators of nutritional deficiency are many and varied and may include any of the conditions and diseases referred to so far in this paper because nutrients are involved in immune function, detoxification, and the maintenance of healthy tissues, membranes etc. Since they are also required for the production of hormones, enzymes, prostaglandins, haemoglobin and countless other substances, on the basis of logic alone it is considered important to assess the nutritional status in patients suffering from conditions which may be linked with the deficient production of such substances. Some of the more obvious examples of these conditions are premenstrual syndrome, menstrual pain, menopausal symptoms, susceptibility to infection, birth defects, poor wound healing, fatigue, poor condition of hair, skin and fingernails, and adult-onset diabetes [14][15][16][17][18] [19]. The nutritional therapist is trained to investigate and treat the causes of nutritional deficiency (such as poor digestion, dysfunctional gut, poor diet). [See Notes page 6 for a further discussion on nutritional deficiencies].

#### Research requirements

Clearly, the diagnostic criteria used in nutritional therapy correlate poorly with those of orthodox medicine. The nutritional therapist may classify conditions such as "arthritis", "dysmenorrhoea" or "asthma" as symptoms of another disorder rather than as diagnoses in their own right, but there is no fixed relationship between a "symptom" and a diagnosis; indeed some "symptoms" can be indicators of two or more of the three broad diagnoses, or perhaps none, depending on the individual patient.

To achieve good results in a clinical trial using a nutritional therapy protocol on a group of patients with, for example, migraine, the nutritional therapist would therefore need certain criteria to be fulfilled.

1. The therapist would need to screen the trial group in advance, and exclude all those patients whose migraine he/she believes is not caused by food intolerance, toxic overload or nutrient deficits.
2. The therapist must be permitted to give each patient an individual diagnostic assessment, estimate the time period required for the treatment of each patient, and initiate a nutritional programme in the form of a therapeutic trial, exactly as the therapist would do in a genuine clinical situation.
3. The therapist must also have complete freedom to develop and fine-tune the individual treatment programmes in accordance with the patient's progress.

Standard clinical trial methodology, with its insistence that scientific rigour requires a single treatment formula for all patients with a particular western diagnosis for a finite and defined time, would clearly distort nutritional therapy beyond recognition.

Although standard trial methodology has been developed in order to eliminate bias, is that in fact possible? Blinding will be automatically broken even in the most impeccably-designed trials if the treatment studied is clearly effective or if it produces side effects. Many conventional medical procedures cannot be tested blind and this is not expected of them.

Any therapy which requires the co-operation of the patient likewise cannot be blinded. The therapy should not be penalised for this, whether it is deemed conventional or "unconventional".

### Observational studies

The complementary medicine movement as a whole has been urging research funding bodies and medical institutions to take more account of observational studies - in particular clinical audits which measure the outcomes of the therapies, and therefore enable complementary medicine to be researched as it is used, without artificial constraints. The Society for the Promotion of Nutritional Therapy wishes to add its voice to these calls, and has already carried out one such study [4].

Studies of this kind are known as "outcome studies". Patients can be selected on the basis of their western diagnosis, and they can be randomised into treatment and placebo groups. The study can also be single-blind (that is to say the patient does not know which group he/she is in but the therapist does). Outcome studies where the patients are randomised to one type of management or the other can fulfil randomisation requirements just as standard trials do, testing the overall strategy of the therapy, not the specifics.

Alternatively a group treated by a nutritional therapist could be matched with patients receiving conventional hospital treatment.

Outcome measurements can be similar to those used in orthodox research, and should include pain ratings, biochemical test results, costing of treatment as compared to conventional medication, costing of units of consulting time, and quality of life measurements.

These measurements may be direct, or diary cards, or reports by patients, families, employers or others involved. Questionnaires may contribute.

We need to recognise that sympathetic assistance and evident good will by the therapist may itself be therapeutic. Although conventional doctors may term this a placebo effect, recent writers [20] are now questioning whether the term placebo is relevant. It should no longer be allowed to dominate the acceptance or rejection of complementary therapies. Because such practitioners may give greater time and apparent sympathy is not scientifically relevant. The outcome and its cost benefit is.

### Conclusion

Like all complementary therapies, nutritional therapy works best within a holistic context. Holism is about working with individuals, not diseases; about recognising that many factors, which relate to the mind, body and spirit, are involved in health and in the complex processes which may lead to chronic ill health; about recognising that to be most effective, medicine should take into account as many of these factors as possible, depending on the patient's needs. The more serious and chronic the illness the more complex the interplay of factors undermining the patient's health is likely to be, and the more a holistic approach is needed.

To take an example, a holistic approach for a patient with a chronic disease such as rheumatoid arthritis might include a nutritional diagnosis (nutrient deficiency, food sensitivity, toxic overload), an emotional or spiritual diagnosis (what is the quality of the patient's emotional and spiritual life, is this contributing in any way to the disease process?) and a "vital force" diagnosis (assessing any distortions to the flow of electrical or life force energy to the organs). In life-limiting diseases such as cancer, where time may be in short supply, orthodox medical treatment can in many cases form a very valuable part of a holistic package. However even if the orthodox treatment is successful, complementary practitioners consider that their approaches are equally important because they seek to offer the patient a better chance of maintaining health and preventing a recurrence of the disease. The failure of orthodox medicine to do this is undisputed.

It has sometimes been said that patients are attracted to complementary medicine because it offers a soft option and more time and attention from the practitioner. Implicit in these views is a reluctance to confront the possibility that patients consult complementary practitioners because they are dissatisfied with palliative medicine. Also implicit in this attitude is the belief (without proof of any kind) that complementary therapies are essentially placebo treatments. It is only too unfortunate that the constraints to which complementary research has often been subjected might lead to results which seem to bear out this assumption.

The Society for the Promotion of Nutritional Therapy believes that it is the failure of orthodox treatment systems to make a truly significant impact on chronic disease, and the unwillingness of conventional practitioners to recognise this failure, which drives people to seek alternatives. Complementary practitioners are becoming increasingly intolerant of research constraints which do not allow them to demonstrate the true value of their therapies.

Linda Lazarides

## Notes

### 1. Nutritional therapy versus dietetics

Nutrition is the study of fats, carbohydrates, protein and other nutrients, and the theoretical needs of the human or animal body. There is nothing individual about this.

"Nutritional therapy", on the other hand, is a process whereby a knowledgeable practitioner will work together with an individual patient or client to find out how to get the best performance out of that person's body using the nutritional techniques they have learned. It is a process of exploration. Much psychology will be involved; keeping someone on a diet long enough for them to receive benefits that might seem a long time coming is a complex skill. Communications skills are also vital. A good practitioner does not simply hand out a diet or vitamin pills and send the patient away, but gives extensive back-up, help with recipes and cookery problems, and supervision to ensure the patient is coping well and not making mistakes with the instructions. A good practitioner is also available to answer questions, knows what to do if the patient is worried about any reaction to the programme, or if the programme does not seem to be producing the expected results, knows how to fine-tune the therapy in order to keep down the cost to the patient, and so on. Another important role is to find out where the patient's perceptions about lifestyle and the workings of the body may be deficient and work much education into the therapy sessions, in order to help the patient maintain control over his health in years to come.

Knowledge of how other therapies may complement (or adversely affect) nutritional therapy is also important, since the origins of poor health are often complex.

The nutritional therapist is also trained in safety aspects, drug-nutrient interactions and in dealing with patients who have difficulty following diets. Nutritional therapy is about helping a patient to understand better the workings of his body, how these connect with food and lifestyle, and how to maintain health once it is regained. He or she is trained to recommend that all patients should maintain contact with their GP while consulting the nutritional therapist.

Further details of the nutritional therapist's training are given in Appendix I: Nutritional Therapy Practitioner Competences.

### 2. Concepts which govern therapeutic decisions

#### (a) Biodiversity

Individuals will vary in their need for and ability to utilise any given nutrient. A clear example is obesity. The weight gained from a given intake of food varies between individuals to such an extent that one may lose weight on a dietary intake that is excessive for another. The bodily status of humans is in part a genetically programmed evolution to adapt to their environment. For example the native Inuit has a totally different conformation and very different metabolic requirements from the Somali. With contemporary population mobility many patients will be in an environment for which they are genetically maladapted, and what applies at a gross level will apply also at the level of micronutrients. Further, while an individual in health may cope with a sub-optimal intake of a nutrient, when ill there may be an enhanced need for this substance, and decompensation follows. Hence increasing the intake of this compound will contribute to recovery.

#### (b) Malabsorption

Much chronic disease follows occasions when a bowel upset is followed by continuing increased gut permeability. Whilst this causes an increased uptake of macromolecules, and will be made worse if digestive function is diminished, as it often is, it is accompanied by an absorptive failure of common micronutrients. The nutritional therapist is trained to evaluate and modulate these varying nutritional requirements.

### 3. Nutritional deficiency

Most medical practitioners in the developed world assume that their patients are adequately nourished. Even when clinical trial results show, for example, that vitamin B6 or GLA supplements can relieve premenstrual syndrome in a proportion of women, doctors assume that these substances act purely as drugs. They may select at random either of these "drugs" to prescribe for PMS, or indeed may prefer to prescribe oral contraceptives, for similar reasons.

Nutritional therapists on the other hand, retain the apparently somewhat heretical belief (actually soundly based on biochemistry) that supplements of vitamin B6 - or indeed any nutrient - work not as drugs but by correcting a biochemical deficiency, thus allowing repairs to damaged functions to take place. In fact they consider that a clinical trial giving all people with a particular syndrome the same nutrient is as logical as giving the same new spare part to all broken down television sets. Those sets in which that particular component was in some way deficient will "recover", and the rest will not. The same applies to people. Vitamin B6 is after all a component of the human body.

#### Assessment methods

The nutritional therapist will generally assess nutrient deficiencies by a detailed symptom analysis, consisting of a lengthy questionnaire on symptoms, medical history, diet and lifestyle, and 30 minutes interview with the patient, confirmed by therapeutic trials of dietary adjustment and supplementation. Some practitioners will send patients for blood tests, but this is often considered an unnecessary expense for the patient because blood nutrient levels are homeostatically controlled and will rarely show subclinical or localised deficits. More sophisticated, more expensive tests are really required, which are not available from routine laboratories.

## Causes

In the experience of nutritional therapists, deficiency is often related to poor diet, but equally often to poor digestion and assimilation. Deficiency symptoms are found to occur frequently in people who eat an excellent diet, therefore measures to enhance assimilation are considered essential.

The nutritional therapist will approach this task by looking for and dealing with causative factors which may be involved in impaired digestion or loss of gut wall integrity (such as deficient gastric acid production, chronic intestinal dysbiosis, or chronic allergic inflammation) and will then use a variety of diets, enzymes, herbs, and nutrients to encourage improved digestion, integrity, and repair of absorption mechanisms. These measures are particularly important in food intolerance sufferers since it is thought that food intolerance symptoms are most likely to occur when improperly digested food (which in a healthy individual should never come into contact with the bloodstream) "leaks" through a gut wall whose integrity is impaired.

## 4. Therapeutic Tools

The nutritional therapist's tools are a variety of diagnostic and therapeutic diets such as hypoallergenic, rotation, semi-macrobiotic or alkalising diets, as well as dietary supplements and herbs. Some practitioners will incorporate the principles of oriental diet therapy and its diagnostic criteria into their work. All diets are based on foods with minimal processing where possible.

Dietary supplements are:

- 1) Preparations of vitamins, minerals, amino acids, essential fatty acids, enzymes, fibre and other factors which fulfil a useful or necessary physiological function and are found in food or synthesised within the body from food. These preparations may be chemically synthesised or natural extracts.
- 2) Concentrated plant- or animal-source preparations such as fish oils, yeast, probiotics, algae and plant or herb extracts, used to supplement the diet with the nutrients they contain, or for their health-giving properties.<sup>2</sup>

Nutritional therapists use herbs as temporary health aids which form part of a wider treatment package. For instance celery seed extract may be given temporarily to help reduce the tissue acidity and fluid retention which (among other factors) can promote arthritic pain, but is considered an adjunct to nutritional techniques that deal with the toxic overload or other primary contributors to the arthritic process in that individual. Ginkgo biloba may be given to patients with Alzheimer's disease, but in fact merely forms part of a broad approach to improving the blood circulation, which may include reducing blood cholesterol levels with vitamin C and the amino acid lysine, the use of fish oils for their anticoagulant effect, antioxidants to minimise free radical damage, and a hypoallergenic diet.

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<sup>2</sup> Definition given by the Society for the Promotion of Nutritional Therapy in its response to the European Commission's discussion paper "Diet Integrators", December 1991.

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#### About the SPNT

The Society for the Promotion of Nutritional Therapy was founded in 1991 by Linda Lazarides, to unify the nutritional therapy movement and to support its practitioners. The society has played an important role in increasing awareness and understanding of the therapy, and in providing a sound postgraduate environment for its therapists and for other practitioners who wish to learn more about nutritional therapy. Its practising members are bound by a code of ethics and conduct, and it is developing good practice guidelines for all therapists who seek to give nutritional advice. It seeks to enforce its code of ethics and guidelines by encouraging the public, through its extensive public relations work, to contact the society when seeking a practitioner. In this way patients have a contact point to make complaints, which can, if necessary, be assessed by a disciplinary panel. (No formal complaints have ever been received).

SPNT's members include 600 doctors, nurses, clinical scientists, acupuncturists, homoeopaths, osteopaths and many other natural therapists as well as nutritional therapists. It welcomes all those who are interested in its work. A separate application must be made to join the society's directory of practitioners, and acceptance is subject to appropriate qualifications.

The society publishes a quarterly magazine, a newsletter and a set of informative factsheets, all of which are available to members. It holds regular seminars.

*(This organisation came to the end of its lifespan in 2000 as it "gave birth" to the British Association for Nutritional Therapy)*