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Mind- Body Medicine

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Mind–body medicine

Although complementary medicine's effects are often dismissed as placebo, few clinicians would trivialise the powerful effects of the mind on the body. A range of health practitioners and educators scrape the iceberg of psychosomatic medicine and the emerging science of psychoneuroimmunology.

The CM educator

Prof Marc Cohen

While the importance of a good 'bedside manner' has long been recognised, the development of a therapeutic relationship and subsequent clinical exchange has recently begun to attract scientific interest through studies on the 'placebo effect'. In the past the placebo effect was considered a scientific distraction and the refuge of charlatans and the purveyors of snake oil. It is now recognised, however, that all therapies have a nonspecific therapeutic action in addition to any purported specific activity and that, in clinical practice, the placebo effect is continually being evoked regardless of the modality used.

The power of the placebo effect is evidenced by its ability to produce positive therapeutic outcomes in virtually every medical condition, and researchers must go to enormous efforts to counter it with the double-blinding of clinical trials and the recruiting of large numbers of patients into clinical trials in order to detect 'effect beyond placebo'.

Remembering wellness

The placebo effect has recently been termed 'remembered wellness' by Dr Herbert Benson¹, who also coined the term the 'relaxation response' in reference

to meditation. Benson describes the three essential components of remembered wellness as the belief and expectancies on the patient's part, on the doctor or caregiver's part, and that arise from the relationship between patient and caregiver.

Of these factors, it is likely that the magic of placebo is most dependent on the relationship between patient and caregiver. The therapeutic relationship is a profound and sacred one. This has been acknowledged since ancient times and is codified in the Hippocratic oath. A clinical consultation certainly has the potential to be a very intimate and meaningful exchange. If a doctor only cares to ask, people will reveal things that they would not tell anyone else in their life. This includes very personal and/or highly emotionally charged information, such as the characteristics and timing of their bodily excretions, details about their personal relationships and sex lives, the content of their dreams, as well as information about their home, work and financial pressures.

The practitioner's special place

To have people confide in you and to participate in some of people's most personally significant moments, including both the beginning and end of their life, is a great privilege.

Furthermore, practitioners' personal lives are undoubtedly enriched through intimate contact with many individuals from different walks of life. It is also likely that the more intimacy a practitioner is able to develop with their patients, the more profound effect they may have on their patients' lives.

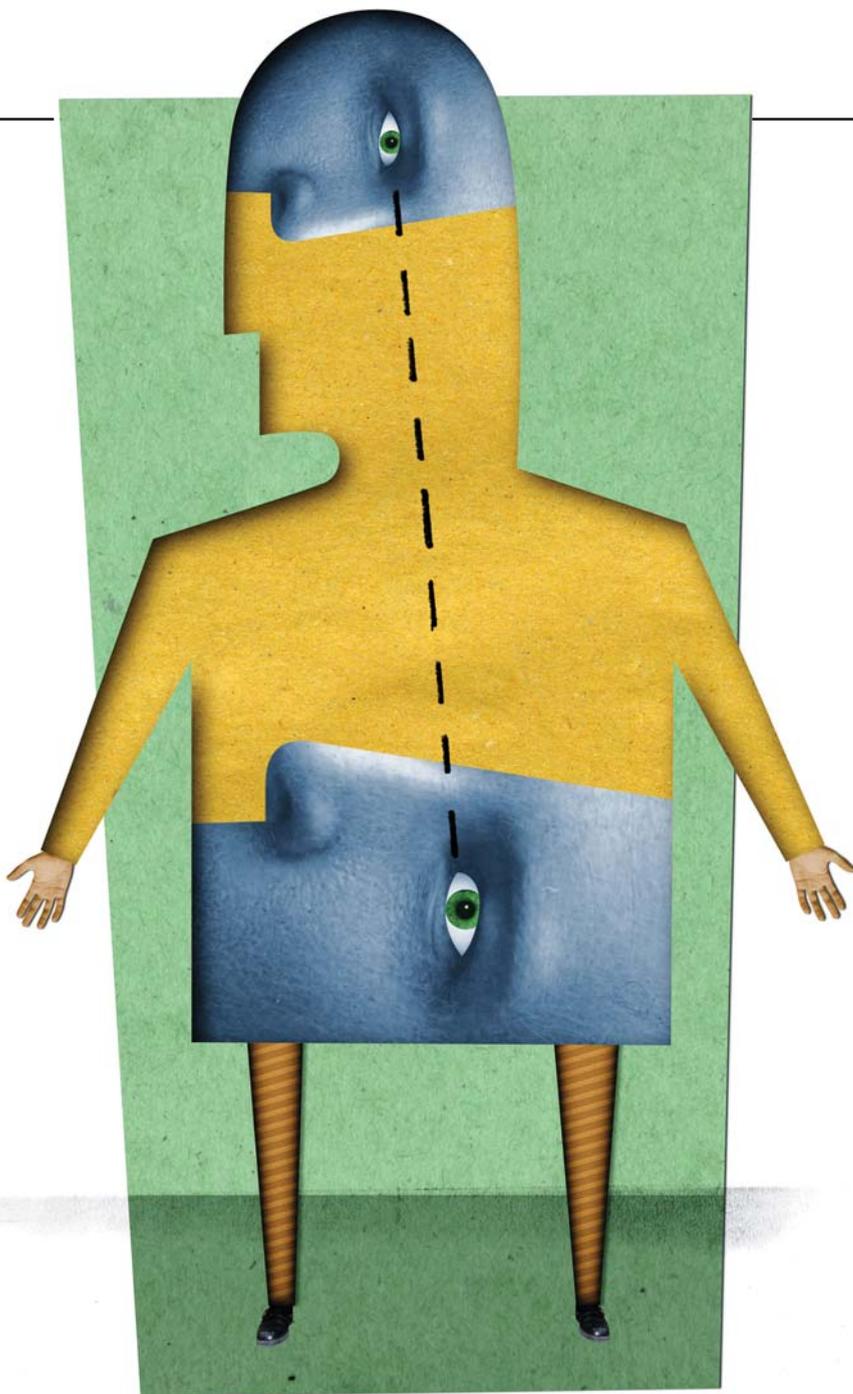
This attitude has been taken to extreme by the celebrated Dr Patch Adams, who sets a conscious intention of making every new patient a personal friend for life. This might involve an initial full-day consultation, a home visit, and asking to see the patient's private diaries. He claims that he has never been refused access to this material and, in most cases, people were delighted that someone was so interested in them.

While this may be unlikely to be adopted by most other health practitioners, it is clearly possible for practitioners to develop close and meaningful relationships with people in the clinical context. This is more likely to happen when patients are treated as functioning human beings who happen to have an illness rather than defining them by their illness [see *JCM* 2004;3(3):42–4].

Developing rapport and trust with people places practitioners in a much better position to allay their patients' fears, adequately address issues of the most concern, and help reduce the burden of stress that accompanies virtually all illness.

Talking them up

Health professionals commonly see people at their worst; when they are in pain and/or feeling sick, scared, sleep deprived and fearful of the possible implications of an illness. Rather than thinking of people in terms of their illness however, it may be more productive to think of people in terms of their highest level of functioning. Thus, perhaps the most important question a practitioner can ask a patient is, 'What makes you happy?' or,



The CM researcher

Prof Edzard Ernst

In complementary medicine (CM), we regularly encounter therapies that, in clinical trials, generate no specific therapeutic effects. The conclusion in such cases is often that the treatment is not effective. This irritates advocates of that therapy who claim, and sometimes can document, that many people have been helped by their approach. The obvious explanation is that the treatment, while devoid of specific therapeutic effects, has powerful non-specific effects [see *JCM* 2004;3(5):8].

A classic example for this scenario is acupuncture as a treatment for smoking cessation. The results of rigorous clinical trials are not entirely uniform but, overall, they show that acupuncture is not better than sham acupuncture or other interventions in helping people to stop smoking. Yet both sham and real acupuncture are associated with respectable cessation rates.¹ Depending on one's point of view, one could thus conclude that acupuncture is ineffective, i.e. not better than placebo, or acupuncture is effective, i.e. it does help in smoking cessation albeit through a placebo response.

What's wrong with a powerful placebo?

Many proponents of CM argue that the distinction between specific and non-specific effects is academic and has no importance from a pragmatic point of view: all that matters in clinical practice is to help patients. If the desired outcome, e.g. smoking cessation, is achieved, the mechanism or nature of the effect (i.e. specific or non-specific) is next to irrelevant.

At first glance, this argument is disarming and convincing. Essentially, it states that treatments are useful even if they are pure placebos, provided they

'What is it that makes you feel alive?' The answers to these questions provide a more holistic understanding of a patient's life and hence provides the basis for a more meaningful relationship. Placing a focus on the positive aspects of a patient's life is also more likely to effectively evoke remembered wellness than the answer to the question, 'What is the problem?'

The most powerful therapeutic tool available to doctors a few centuries ago was probably the therapeutic relationship and the power of placebo rather than the leeches, emetics and their other tools of trade. As we continue to delve further

into the science of placebo, it is conceivable that future doctors may look back at our times and make a similar assessment.

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generate a sizable placebo response. On closer inspection, however, the argument turns out to be seriously flawed.

Placebo effects are part and parcel of almost any therapeutic intervention; anything from acupuncture to surgery is associated with placebo effects.² They are thus only a very weak justification for promoting a treatment that does not also generate specific therapeutic effects. It can be wise to try to maximise placebo responses in clinical practice but, in order to do that, there is no need for a pure placebo therapy. In the example of smoking cessation, nicotine patches also come with a (free) placebo effect but have the additional advantage of specific effects, as demonstrated in placebo-controlled trials.³ Thus specific therapies constitute the better treatment.

The ethical dilemma

Administering pure placebos, such as acupuncture for smoking cessation, can also be associated with ethical problems. In particular, it usually means knowingly misleading the patient, i.e. prescribing a

treatment under false pretences. One might argue that this only applies if the acupuncturist is aware of the scientific evidence, i.e. when he knows the body of evidence showing that it is a placebo therapy. Thus uninformed acupuncturists would not behave unethically when administering acupuncture for smoking cessation. The obvious problem with this is that, arguably, such a therapist would not be medically competent, i.e. not informed about the best evidence related to his therapy. And this, in turn, would be even more ethically questionable.

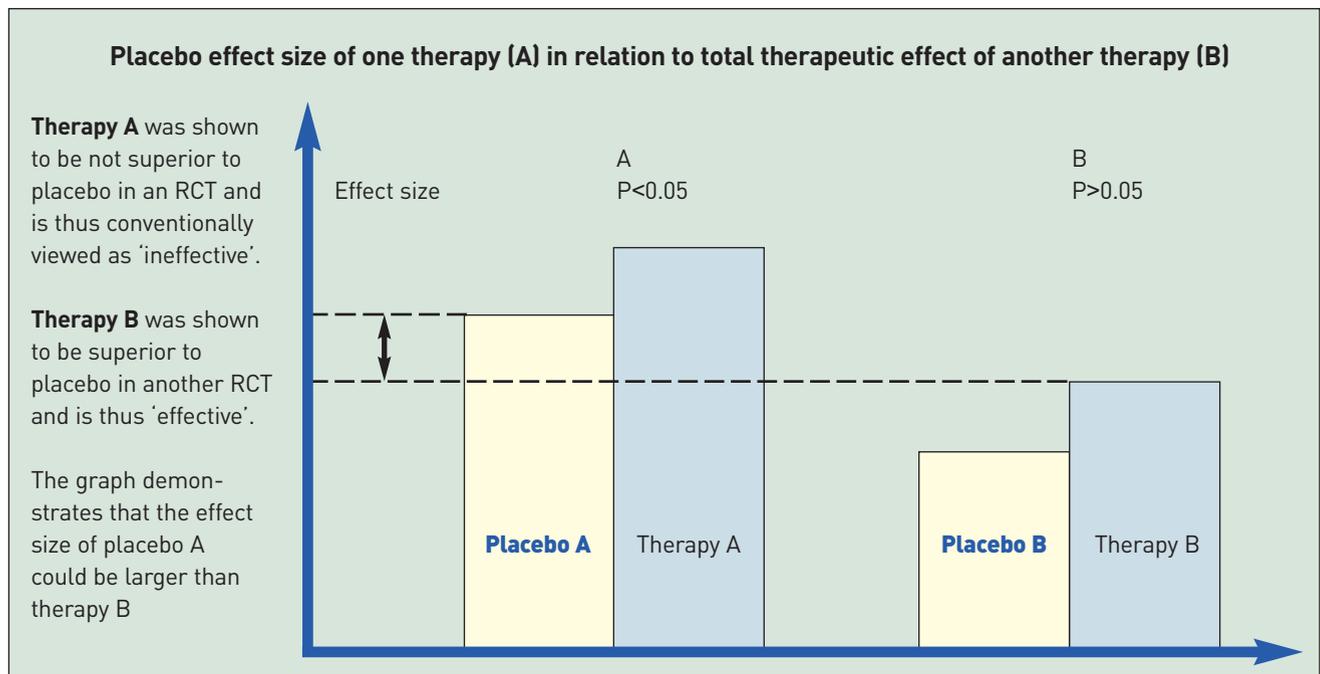
Even if administering a placebo therapy was ethically unproblematic and not less effective than prescribing the best available treatment (this could be the case if no effective treatment for smoking cessation had yet been identified), this approach would have its limitations. In judging the therapeutic value of interventions, we also need to consider their risks. Only if they do not outweigh the potential benefits, is it ever ethical to employ a given therapy. With pure placebo interventions, the benefit would

only consist of the placebo effect which is notoriously unpredictable and usually not sizeable.² In the case of acupuncture, serious risks exist but are rare⁴, and mild transient adverse effects occur in about seven per cent of all patients.⁵

The degrees of placebo effect

It has been argued that placebo effects could vary according to the type of therapy. Acupuncture, for instance, has several characteristics that could render it a 'powerful placebo': it is invasive, exotic, slightly painful, costly, often hyped up by the media, etc. One could therefore postulate that the placebo effect of such therapies is larger than the total therapeutic effect of a conventional therapy proven to be effective (better than placebo). The figure below depicts such a situation.

In this scenario, a pure placebo treatment (i.e. a therapy devoid of specific therapeutic effects) could generate a better outcome than an effective standard treatment. Could this be a situation where the use of a placebo is medically





and ethically justified? The answer is, probably not. First, the situation depicted above is purely theoretical. There does not seem to be any evidence that, in reality, it exists. Second, if we had some evidence along such lines, we might *suspect* that placebo A is superior to therapy B. Yet this would not constitute proof. The logical mistake is to compare the results of two different studies which were not designed to be compared. Faced with such a scenario we would need to conduct an equivalence trial comparing placebo A with treatment B. In all likelihood, it would not confirm the superiority of the former over the latter.

In conclusion, there is nothing wrong with a powerful placebo effect. In clinical practice, we should use it wisely to help patients and alleviate suffering. The fact that a given therapy generates a large placebo response is, however, not a sufficient justification for using it if it is devoid of specific therapeutic effects.

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The holistic GP

Dr Craig Hassed

If one field of medical research were an exemplification of the importance of the holistic approach, it would be psychoneuroimmunology (PNI). The mind, through infinitely complex interconnections between brain, hormones and neurotransmitters, communicates directly and indirectly in a twoway feedback system with the immune system. Central in the process is the brain's limbic system, involved with emotional responses, and the frontal lobes¹, associated with rationality, perception and meaning.

Having normal white-cell counts, for example, is no guarantee of normal immune function, as it is immune-cell function and modulators of immunity that are vital. With data suggesting that the stress of modern life is increasing² and that mental health issues, particularly depression, are predicted to be the major burden of disease within the next few decades³, one can only surmise that PNI will become an ever-more important issue in the future.

The mind's clinical effects on immunity:

- Conditioning of immune responses
- Altered immune markers
- Susceptibility to infections
- Severity and progression of infections
- Relapse rate of chronic and latent infections
- Immune defences to some cancers
- Activity of inflammatory illnesses
- Activation and progression of autoimmune conditions
- Response to immunisation
- Activity of allergic conditions.

Conditioning of immune responses

It had been recognised in the 19th century that one could condition immune and allergic responses. A 'paper rose', for example, can induce allergic reaction in

susceptible individuals.⁴ Later, it was found that exposure to 'symbolic non-allergenic environment' can induce asthma.^{5,6} It was not until Robert Ader, the father of PNI, performed more rigorous studies that the science came of age. He found that animals demonstrated classically conditioned immunosuppression even after a single dose of the chemotherapeutic agent, enough for them to die prematurely.⁷

Although it has a variety of clinical implications, there has been little therapeutic application of conditioning of human immune function. In animals, it has been found to help reduce drug dosage in SLE⁸, improve outcomes for rheumatoid arthritis⁹, retard the rejection of transplants, and improve survival of heart allografts.^{10,11} Cellular and humoral immunity can both be conditioned for better or for worse¹², as can inflammatory mediators, such as cytokines.¹³

Altered immune markers

Depression has been found to affect inflammation, prolong infection and delay wound healing.¹⁴ Changes in immune-cell numbers and function start to occur within five minutes of the stressful event.¹⁵ Depending on the person's perception and reaction, immunosuppression can remain for up to 72 hours afterwards.¹⁶ Those who perceive self-control in stressful situations have no negative effect on immunity whereas those who perceive they have no control, either over the event or their response to it, have a prolonged negative effect.

Early studies did not take account of the fact that individuals vary markedly in magnitude of psychological and physical response to stressful events. Differences in immune response can be predicted by individual variability in stress-induced sympathetic nervous system (SNS) activation. Those who have higher reactivity to stress (e.g., increased blood pressure, heart rate, and adrenaline) also have the greatest disturbance to immunity



and susceptibility to infection.¹⁷

Salivary IgA, a frontline defense against respiratory and GI infections, has been found to be reduced by stressful life-events, exam pressure, social isolation, grief, anxiety and the need to have power and influence others.^{18,19,20,21} Furthermore, S-IgA levels measured before and after a five-minute period of induced positive (care and compassion) or negative (anger and frustration) emotions showed corresponding increases and decreases for hours afterwards.²²

Positive emotional states have an effect upon reversing stress and upregulating immune function. Laughter, for example, is associated with increases in WCC, improved immunoglobulin levels, reductions in inflammatory hormones and increased interferon.^{23,24} Norman Cousins is a notable case study of a man who reversed the activity of a disabling inflammatory condition called ankylosing spondylitis.²⁵ Similar effects of laughter have been found for rheumatoid arthritis.²⁶ Mindfulness therapy has significant effects on helping with depression²⁷, reducing reactivity to stress and lowering cortisol²⁸, but these changes also seem to be associated with clinically important effects on immunity.^{29,30} Other studies have shown increased T-cell production of IL-4 and IFN- γ and decreased NK cell production of IL-10. These changes are consistent with a shift in immune profile from one associated with depressive symptoms to a more normal one.³¹

Susceptibility to infections

Stress increases susceptibility to the common cold in those exposed to a measured dose of respiratory viruses.³² The rates of infections increased in a dose-response manner with the degree of stress. Further research confirmed that those with high SNS and cortisol reactivity demonstrate the greatest impact upon cell numbers and function.³³ Thus our response to the event rather than the event deter-

mines our vulnerability to the risk of infections. Increased sociability is associated with a decreased probability of developing a cold independently of other social, demographic and health variables.^{34,35} Significant immunosuppression occurs during bereavement and this is associated with a sixfold higher rate of pneumonia in the year post-bereavement.^{36,37} Even more significant immunosuppression occurs during marital separation.^{38,39} Psychological interventions that can help people with stress are, if practised, associated with reduced infections.

Infection severity and progress

If one gets an infection, such as influenza, one is likely to experience more severe symptoms with high levels of stress.⁴¹

Chronic and latent infection relapse

Emotional state not only predisposes to acute infection but also significantly effects the duration and reactivation of chronic infections. Depression causes a marked decline in cellular immunity to shingles⁴², and exam pressure affects immune response to, and reactivation of, glandular fever. Studies on HIV patients have shown that for every one severe stressor per six-month study interval, the risk of early disease progression was doubled.⁴³ There are significant improvements in prognostic markers for HIV-positive men who have CBT, with reductions in depression and anxiety corresponding with reductions in stress hormones, improvements in WCC and elevation of DHEA.^{44,45}

Immunity and cancer

An outcome trial on patients with early-stage malignant melanoma showed that six weeks of stress management improved immune function over a number of months⁴⁶, and this correlated six years later with half the recurrence rate and a third the death rate compared to control patients.⁴⁷

Inflammatory illnesses

Stress has been found to have effects upon inflammatory modulators⁴⁸ and also on the progression of inflammatory diseases. Asthma, for example, has been found to have many emotional triggers.⁴⁹ Psychological and emotional factors are significantly predictive of asthma deaths in children.⁵⁰ Relaxation, psycho-education and biofeedback improve clinical outcomes⁵¹, cost-effectiveness, adjustment, compliance, and perceived self-competence but decrease the use of medical services. Yoga significantly reduces asthma attacks per week, improving scores for drug treatment and lung function.⁵² This has been confirmed in other studies that have also shown about 70 per cent of patients were able to reduce or stop their medication under supervision.⁵³ Journalling has not only been found to have significantly anti-inflammatory effects upon asthma and rheumatoid arthritis (RA),⁵⁴ but is also associated with fewer infections and quicker wound healing.⁵⁵ Reviews of psychosocial intervention for inflammatory arthritis show that they are associated with reduced pain and doctor's visits by 40 per cent.^{56,57,58} Meta-analyses of mind-body therapies and arthritis showed small but statistically significant effect sizes for pain, disability, and depression.⁵⁹

Autoimmune conditions

Emotions affect inflammation through a process called 'immune dysregulation'. In the elderly, this dysregulation may be associated with cardiovascular disease, osteoporosis, inflammatory arthritis, type-2 diabetes and certain cancers, as well as frailty and functional decline. During high-stress periods, there is a shift towards dysregulation and the 'type-2 response' associated with susceptibility to infections, latent viral expression, allergies and auto-immune conditions.⁶¹

Studies are now confirming what many patients and clinicians have

suspected for a long time; unsupportive social environments and events that a person perceives and experiences as stressful are associated with the onset and exacerbation of autoimmune diseases.^{62,63} RA, inflammatory bowel disease, type-1 diabetes, MS and SLE are increasing steeply and worsening mental health may have an important role to play in this phenomenon. For example, stress in the prior week is associated with increased inflammation, pain and disease activity in RA.⁶⁴ Grave's disease⁶⁵ and SLE are also significantly affected by life stress.⁶⁶

Self-reported stressful life events in patients with relapsing–remitting MS showed an independent relative risk of 2.2 for exacerbation in the following four weeks.⁶⁷ Over 40 per cent of life events are associated with exacerbations in the subsequent six weeks. As with other aspects of PNI, SNS reactivity predicted exacerbations and the proportion of weeks ill.⁶⁸ A recent meta-analysis confirmed that stressful life events clearly predict MS exacerbations.⁶⁹

Response to immunisation

Both flu⁷⁰ and hepatitis B⁷¹ vaccination take far less well in people with high levels of stress, anxiety, social isolation and depression, whereas changes in brain function found with meditation are associated with improved mood and

correlate with better response to immunisation.⁷²

Activity of allergic conditions

As well as asthma, allergies have also been found to be affected by modulators of emotion, such as viewing a humorous video⁷³ or listening to soothing music.⁷⁴ Many of the changes mentioned about inflammation also have implications for aggravation of allergies.⁷⁵

Conclusion

Mind clearly affects immunity for better or worse and the effects are clinically significant. Individual variation depends on how a person responds to events and not all people are at higher risk with adverse life events. Much is still to be discovered about PNI and the therapeutic potential is great, but care has to be taken with unrealistic expectations. Furthermore, psychosocial interventions are best as adjuncts to conventional medical therapies in a more holistic approach.

Despite accumulating evidence, PNI is still under-acknowledged, under-funded, under-utilised in therapy, under-researched and under-taught in medical curricula. The time may soon come when doctors could be held legally responsible for not informing their patients that psychological factors are significant determinants of health and are

important potential therapeutic modalities. Patients are clearly looking for a more holistic approach to healthcare but often perceive that they have to go outside orthodox medicine to find it.⁷⁶ If we could more completely embrace Plato's exhortation that we 'ought not to attempt to cure the body without the soul', we might be a lot closer to providing healthcare which is at once sustainable and optimally effective.

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The mind–body naturopath

Dr Nimrod Sheinman

Healing can be regarded as an equation. On one side of the equation are the forces that may generate or contribute to an illness. On the other side are the external resources of medical science together with the body's internal healing abilities. Natural medicine has developed various modalities as to how to enhance the 'healing from within', be it through nutrition, acupuncture, hydrotherapy, fasting, herbs, touch or homeopathic remedies. Mind–body medicine^{1,2} is now expanding the picture of what true holistic medicine can be like: incorporating patients' emotions, images, thoughts, awareness and beliefs as powerful agents in the healing process.

Current research

It is beyond the scope of this article to summarise the complete body of knowledge and science of psychoneuroimmunology (PNI) and mind–body research. However, some of the main themes that have influenced my own mind–body practice include:

- 1 Hans Selye's work on the stress response³ and the whole art of stress assessment and stress reduction;
- 2 Ader's⁴ discovery of conditioned immunosuppressive response and the deep significance of the mind and the immune system communicating and interacting;
- 3 Benson's research on the 'Relaxation Response'⁵, showing that we can actively evoke a healing experience to influence and enhance health;
- 4 Kiecolt Glaser's investigations⁶ of psychosocial factors and their effect on immune cells and immunocompetence;
- 5 The significant field of placebo research⁷ showing the power of the biological outcomes of belief, trust and faith;
- 6 The field of psych-oncology and the

- pioneering (albeit not always fully scientific) work of Simonton⁸, LeShan⁹, Siegel¹⁰ and Spiegel¹¹;
- 7 The role of personality, lifestyle, stress and emotions in cardiovascular disease (CVD).¹² The role of hostility and one's relationship with anger in healing the heart¹³;
 - 8 The work of Dean Ornish¹⁴ reversing CVD through holistic multilevel intervention, combining group work, stress reduction, nutrition, exercise, meditation, yoga and community;
 - 9 The new developments in positive psychology, with the publications of Kobassa¹⁵, Antonovsky¹⁶ and Seligman¹⁷ emphasising the role of commitment, control, challenge, meaning and empathy in determining health, longevity and survivability;
 - 10 The field of meditation¹⁸, mindfulness¹⁹ and guided meditations²⁰, and the profound contribution of Buddhist psychology to health psychology and to Western holistic medicine²¹;
 - 11 The power of guided imagery in clinical practice in working with illness, pain and dark emotions, and in evoking and creating health²²;
 - 12 The inspirations in numerous articles and books of holistic thinkers and doctors, such as Larry Dossey²³ or Naomi Remen.²⁴

The five phases of therapy

A relatively easy and working model for clinical practice can be used through the Five Level Star, with each pole representing one aspect of the whole: physical, emotions, cognitions, behaviour and spirituality. Each pole brings unique inquiry, assessment, therapies, teachings, advices and techniques, and the whole is always larger than the sum of its parts.

- 1 **The physical:** pathology, medications, symptoms, nutrition, supplements, relaxation/tension levels, pain picture, connectedness to one's body.
- 2 **The emotional:** stress, anger–fear–

grief, joy–love–openness–trust, expression of feelings, the experience of illness, amount of love (received/ given), satisfaction, helplessness, sense of worth, connection to others.

- 3 **The cognitive:** assessment of thoughts, memories, self-image and -assessment, inner dialogues, dreams, expectations, cognition.
- 4 **Behavioural aspects:** choices, habits, lifestyle, nutrition, exercise, compulsions and addictive behaviours, expression of one's feelings and needs, abilities to ask for help, setting boundaries.
- 5 **Spiritual aspects:** belief system, sense of meaning, god, spiritual practices and community, existential search, relationship with life and being alive.

Clinical perspectives

The new perspectives, tools, techniques and insights are presenting therapeutic challenges on various levels:

- 1 The intake: asking the 'right' questions, seeing the whole picture, making the 'right' connections.
- 2 Nature of the therapy: symptom and acute work, chronic work, prevention work, spiritual work, holistic work.
- 3 Using and integrating the techniques: meditation, empathic dialogue, guided imagery, cognitive responses, touch, breath work, etc.
- 4 The doctor as teacher: teaching skills of relaxation, meditation, positive thinking, open dialogue, creative expression of feeling and needs. Encouraging awareness, participation and responsibility as an important factor in the healing process.
- 5 Enhancing the doctor–patient relationship through presence, empathy, opening up, non-judgment, trust, unconditional presence, compassion, patience and sensitivity.
- 6 Finding the 'middle way': doing vs. being, reducing the symptom vs. 'enlarging' the patient–person, and curing vs. healing.

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The GP educators

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There are several effects a medicine can have when administered to a patient. Some effects depend directly on the medicine's pharmacological action. There exists, however, another effect that is not linked to the medicine's pharmacology, which can also appear when a pharmacologically inactive substance is administered: *the placebo effect*. This effect may involve practically any organ system in the body. Furthermore, the placebo effect is not limited to medicines but is also seen with medical procedures, physiotherapy or surgery.¹ The placebo is defined as any therapeutic procedure, or a component thereof, that is objectively without specific activity for the symptom or disease being treated. A placebo can also be defined as an intervention designed to simulate medical therapy, but not believed by the investigator or clinician to be a specific therapy for the target condition. Alternatively, it could also be a treatment that is believed to be inefficacious, though believed to be efficacious at the time of use.²

A historical context

The term 'placebo' dates back to the 116th Psalm in the Hebrew bible. The ninth verse of this psalm begins with the words *et ha lech*, meaning 'I shall walk'. This was translated into ancient Greek as *euarestiso* and then into Latin as *placere*, meaning 'I shall please'. In the 12th century, the word entered the English language as the name commonly given to evening prayers for the dead. The leading hymn began with *Placebo domine in regione vivorum*, or 'I shall please the Lord'.

The scientific study of the placebo effect is usually dated to the pioneering work of Henry Beecher that was published in 1955 as *The Powerful Placebo*. Beecher concluded that, across

the 26 studies he analysed, an average 32 per cent of patients responded to a placebo.

Currently, the power of the mind and positive thinking is not a novel notion. Some skepticism remains, however, as shown in a recent review by Hrobjartsson and Gotzsche.¹ In their review of more than 150 clinical trials that included both

placebo and no-treatment groups, the authors concluded that they found little evidence that placebos in general have powerful clinical effects. Similar findings were presented by these same authors at the NIH campus in Bethesda, Maryland on November 19–21, 2000, at a meeting entitled 'The Science of the Placebo'. Conference participants found that

placebo effects — defined as the beneficial physiological or psychological changes associated with the use of inert medications, sham procedures, or in response to therapeutic encounters and symbols, such as the white coat — can often appear to be real and significant, not make-believe.

This new legitimacy is altering and expanding the concept of the placebo from its pejorative 19th-century definition as a medical practice adapted more to please than benefit the patient, to one that encompasses many features occurring in the course of patient-provider interactions which can positively affect health and well-being and the delivery of complete healthcare. Within this framework, hope is the perception of positive expectation.

The study of placebo

It has been shown that placebos have measurable physiological effects. They tend to speed up pulse rate, increase blood pressure and improve reaction speeds e.g., as when participants are told they have taken a stimulant. Placebos have the opposite physiological effects when participants are told they have taken a sleep-inducing drug.

The placebo effect is part of the human potential to react positively to a healer. A patient's distress may be relieved by something for which there is no medical basis. A familiar example is when a band-aid put on a child's bruise makes the child feel better, although there is no medical logic as to why it should do so. Participants in clinical trials who receive a placebo may also experience negative effects. Similar to side-effects with a medication, these can include nausea, diarrhoea and constipation. This negative placebo effect has been termed 'the nocebo effect'.

Integrative medicine is composed of healing modalities that have especially potent performative efficacy. Therapeutic

characteristics that may enhance placebo effects seem especially prominent in unconventional healing practices. Although more research into this question is necessary before any such assertion can be made with confidence, an enhanced placebo effect raises complex questions about what is legitimate therapy, and who decides.³

In conclusion, epidemiological and evidence-based medicine methodologies do not cater for the no-treatment group. Perhaps it is now time to evolve this thinking to include the no-treatment arm in the traditional randomised clinical trials. This would allow for a direct measurement of the effect of placebo. The addition of a no-treatment comparative group would provide direct scientific evidence as to whether placebos really do have an effect or not. Only if it can be shown that patients with a particular condition can benefit when treated with a placebo than when not treated at all can we be sure that the placebo response really does not work for the outcome of interest.

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