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# Motivation and the placebo response : predicting non-specific therapeutic benefits from the concordance of therapeutic rituals with high-level goals

Whalley, Benjamin Jon

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University of Plymouth

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Motivation & the placebo response:  
Predicting non-specific therapeutic benefits  
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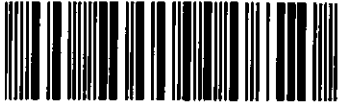


Benjamin Jon Whalley  
School of Psychology  
University of Plymouth

A thesis submitted to the University of Plymouth in  
partial fulfilment of the requirements for the degree of  
*Doctor of Philosophy*

1<sup>st</sup> September 2008

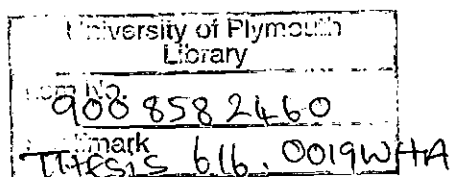
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*For Sophie & Bean*

## ABSTRACT

### MOTIVATION AND THE PLACEBO RESPONSE BENJAMIN JON WHALLEY

Predicting individual differences in placebo responding has proved hard. Predictions from dispositional or personality variables are unreliable for two reasons: first, because dispositional predictions fail to account for situational variability, and second, because the dimensions identified in popular dispositional models are *inter*-individual variables, and may not map on to *intra*-individual structures and processes involved in placebo effects. This thesis describes a new psychological mechanism of placebo responding—motivational concordance—which links placebos with established research on human values and goal-striving. Progress towards goals, particularly goals which are self-actualising, is associated with positive emotional states. Findings presented here support the view that when ritualised behaviour associated with taking a placebo substance is concordant with high-level or self-defining goals then participants experience therapeutic benefits. Thus, goals represent enduring dispositions which may interact with features of the situation in predictable ways to produce placebo responses. This motivational account avoids a number of problems associated with alternative expectancy-based accounts, in particular the proximal causes of placebo responses in complex situations. This report presents data that support the motivational concordance account in a number of ways: Placebo responding is found to be temporally consistent but contextually specific; people respond to a placebo consistently, but only when contextual features of its presentation are held constant (Chapter 2). Motivational dispositions predict responses to a complementary therapy, replicating an earlier finding (Chapter 3). Trait predictions are found to be moderated by the motivational context of the placebo ritual (Chapter 5). Chapter 6 demonstrates that motivational-affective benefits of placebos can occur ‘at one remove’; temper tantrums in young children were reduced when carers performed a motivationally-concordant placebo ritual. Finally, data from Chapter 7 suggest that motivational concordance may generalise to traits other than spirituality, and to other treatments including conventional medical therapies.

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## AUTHOR'S DECLARATION

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Several of the author's papers have been accepted for publication:

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Hyland, M.E. & Whalley, B. (in press) *Motivational Concordance Explains Change In Self-Help Therapeutic Rituals Involving Inert (Placebo) Substances*. Journal of Psychosomatic Research.

Hyland, M.E., Whalley, B., & Geraghty, A. W. A. (2007) *Dispositional predictors of placebo responding: A motivational interpretation of flower essence and gratitude therapy*. Journal of Psychosomatic Research, 62, 331-340.

Whalley, B., Jacobs, P., & Hyland, M.E. (2007) *Psychological and physical symptoms associated with chronically elevated cytokines are correlated in the general population*. Annals of Allergy, Asthma & Immunology, 99, 348-351.

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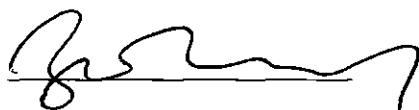
“Improving Adherence in Cardiovascular Disease”, Amsterdam, February 2008.  
Invited talk at Pfizer event: *A psychological perspective on adherence to lipid-lowering medications*

The Joint Hypnosis Conference, York, May 2007. Paper: *Consistency and inconsistency in placebo responding*

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Signed:

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Date:

1 Sept 2009

# Chapter 1

## Introduction

If scientific paradigms were to be evaluated only by their *fruitfulness*, then biomedicine in the twentieth-century must be judged extraordinarily successful (Kuhn, 1962). However the work reported here concerns a range of phenomena that have posed theoretical, practical and ethical problems for practitioners of conventional medicine: placebo effects. Placebo effects are difficult to explain within a conventional biomedical paradigm because of a background assumption of the specificity of disease aetiology. Placebo effects are characterised by equifinality, and even where specific biological mechanisms are identified, for instance the role played by endogenous opiates in placebo analgesia, the same results may be obtained by multiple methods. Red or blue pills, injections, alternative therapies, or surgery may all generate equivalent physiological responses. Only a psychological account of the mechanisms of placebo responding can provide a satisfactory explanation of these phenomena, and make predictions regarding when, why, and for whom, placebos will be effective.

## 1.1 Overview

Placebo effects are difficult to explain within a conventional biomedical paradigm because of a number of background assumptions made: that diseases may be identified by specific cellular pathologies; that scientists must identify diseases by observing and describing the relevant biochemical processes at the cellular level; and that when appropriate treatments are developed they will effect direct changes in these processes. These background assumptions have proved extremely fruitful for diseases where specific pathology exists and has been identified—most notably the treatment of infectious disease, immunization and surgery. However, to the extent that placebo effects exist and are clinically-meaningful all three of these assumptions require further specification and qualification, and this difficulty has lead many within the mainstream of scientific medicine to regard placebo phenomena as an embarrassment, to be treated with derision, contempt or outright hostility (Buckalew et al., 1981). In identifying four reasons why placebo effects are unpopular with conventional physicians, Wall notes:

...the very mention of the placebo effect is taken as a hostile questioning of the validity of the logic on which a therapy is based...we all trust our sensation as a reflection of objective reality and yet the placebo changes the sensation without affecting the objective reality. (Wall, 1992).

Epistemological concerns notwithstanding, extensive efforts have been made to identify the neural and chemical processes by which placebos have their effects on the body. It appears several physiological mechanisms are involved, including endogenous opiates, and the dopamine and immune systems (e.g. Benedetti et al. 2006; Colloca et al. 2004; Maier et al. 1994, and also see Stewart-Williams and Podd 2004). These research efforts are aimed at establishing a form of 'specificity' for placebo effects and thus

bringing them within the fold of scientific medicine. However research into these physiological processes does not presume to explain the psychological antecedents of placebo responses; although exciting this work is at best an incomplete explanation of the phenomena.

## 1.2 Changing conceptions of placebo effects

Tracing a strict chronological progression in definitions of the placebo proves remarkably difficult, in part because more sophisticated accounts often fail to transfer from interested researchers to the medical community at large. However, historical conceptions of placebos may be categorised into three primary groups: as flattery or a distraction; as an inert comparator; and more recently, as an active therapeutic manoeuvre.

### 1.2.1 Placebo as flattery

The word placebo derives from the Latin, 'I shall please', and became widely known from around the 7th century onwards as part of the 'office of the dead' ritual in the western church. The first line of Psalm 116, which was repeated by the congregation after each passage of prayer, reads 'placebo Domino in regione vivorum' or 'I will please the Lord in the land of the living'. This service was initially performed on all souls' day for those in purgatory, but was later came to be performed on other days for a particular deceased. Wealthy families might distribute both money and food to mourners immediately after the ceremony, and over time *placebo* became the term for a professional mourner with no connection to or genuine concern for the deceased. Alluding to this earlier meaning, later authors used the word to denote a flatterer or sycophant: In Chaucer's *The Merchant's Tale*, Placebo and Justinus are brothers of the knight January,

a 'senex amans' or 'amorous old man'. When January decides to marry the teenage girl May, Justinus advises caution. However January only hears Placebo's flattery, is struck blind soon after the marriage, and is later cuckolded by May and Damyan.

This early definition of placebo as a flatterer seems to have directed the later use in relation to medicine. The 1811 revision of Quincy's *Lexicon-Medicum* (cited in de Craen et al., 1999) defines placebo as 'an epithet given to any medicine adapted more to please than to benefit the patient' and this concords with the Oxford dictionary's definition from the late 18th century as 'a pill, medicine, procedure, etc., prescribed more for the psychological benefit to the patient of being given a prescription than for any physiological effect' (Oxford, 1993). The use of placebos as a comfort to patients survived well into the twentieth century (Shapiro, 1959). As an example, Richard Cabot, the eminent professor of Medicine at Harvard, describes being:

brought up, as I suppose every physician is, to use placebo, bread pills, water subcutaneously, and other devices... How frequently such methods are used varies a great deal I suppose with individual practitioners, but I doubt if there is a physician in this room who has not used them and used them pretty often...I used to give them by the bushels" (cited in Kaptchuk, 1998, p. 1722).

Ironically, although a large proportion of medications and medical interventions in this period may in fact have been placebos (in the sense that they were psychologically mediated and did not have directly-therapeutic physiological effects), doctors of the period were clear that while placebos may be of comfort to patients, they had no further *therapeutic* benefits (Kaptchuk, 1998). Few writers before the 1940s identified that placebos could actually have curative properties, although many physicians found that placebos were a useful diagnostic tool to identify malingering or false reporting of

symptoms, a role they may have retained to recent times (Nitzan and Lichtenberg, 2004). As a consequence, the 'placebo' is not paired with a 'placebo effect' until the development of controlled trials which, although it had roots with pioneers in the nineteenth century, gathered pace in the wake of the second world war.

### 1.2.2 Inert but powerful! Placebos as methodological controls

As the logic of the RCT was developed through the 1940s and 1950s, more researchers became aware of the placebo effect as an empirical and statistical fact. It became common for counterfeit medicines, typically pills indistinguishable from the genuine pharmaceutical but without biologically active ingredients, to be used as a control for the effect of simply being treated. These placebos were, by definition, inert. Early proponents of comparative medicine described *placebo effects*, that is the responses observed in patients receiving these fake pills or injections, as substantial, and this became an important argument for the use of RCTs, rather than clinical judgement, to determine the efficacy of medical interventions. Efficacious treatments were now defined as those which could be statistically distinguished from counterfeit treatment. Thus, proponents of the new comparative medicine faced a dilemma in defining the placebo. Placebo effects had to be substantial to justify the expense and complexity of controlled trials where clinical judgement had previously sufficed, but the logic of the controlled trial resulted in a narrow and seemingly contradictory definition as, for example in an American medical dictionary from 1951 as:

An inactive substance or preparation, formerly given to please or gratify a patient, now also used in controlled studies to determine the efficacy of medicinal substances. (Dorland, 1951)



Henry Beecher's paper *The Powerful Placebo* (1955) was highly influential in establishing the clinical significance of placebo effects. The paper employed informal meta-analytic methods to estimate the proportion of patients who benefited from placebo in 15 controlled trials, along with the magnitude of the placebo effects observed. These estimates may have understated the variability in responding, and overstated the size of the placebo effects observed (de Craen et al., 1999), but the paper was widely read and provided an impetus for further basic research, including the search for the *placebo responder*—a person for whom placebos would be consistently effective.

Although the existence of placebo effects provided a justification for the use of controlled trials, large placebo responses made the task of identifying statistically significant differences between verum and placebo treatments more difficult. Although many contextual variables responsible for variation in group-level placebo effect sizes were identified (for instance the colour or number of placebo pills, or the improved effects of injections compared to orally-administered placebos), identification of a 'placebo-responding type' proved elusive (Lieberman, 1967) a failure that was frustrating to both trial organisers seeking to minimise placebo response rates and clinicians who might have practical uses for this information.

In addition to these frustrations, the 1960s and 70s saw an increasing regard for ethical issues, specifically the requirement for informed consent and the active participation of patients in treatment decisions. The paternalism which had characterised earlier doctor-patient relationships became increasingly unacceptable. Taken together, these factors appear to explain the increasingly pejorative characterisations of placebos amongst medical professionals: not only were placebos a nuisance in clinical trials, they were deceptive, unethical, and therefore inadmissible, in clinical practice (Wall, 1992).

During the 1990s, re-analysis of data from clinical trials prompted a new critique of the placebo, with some researchers claiming that placebo effects may be entirely illusory, and the straightforward result of methodological biases. In reappraising Beecher's original study (1955), Kienle and Kiene (1997) argued that none of the 15 studies used provided direct evidence for placebo effects, and that 'spontaneous improvement, fluctuation of symptoms, regression to the mean, additional treatment, conditional switching of placebo treatment, scaling bias, irrelevant response variables, answers of politeness, experimental subordination, conditioned answers, neurotic or psychotic misjudgment, psychosomatic phenomena, [and] misquotation' could account for the pattern of results (p. 1311). Asbjørn Hrobjartsson and colleagues (2001 and 2004) presented meta-analyses which estimated the average effect sizes observed for placebo groups in RCTs. The authors found 'little evidence in general that placebos had powerful clinical effects'; that there were 'no significant effects on objective or binary outcomes'; and that 'outside the setting of clinical trials, there is no justification for the use of placebos' (Hrobjartsson and Gotzsche, 2001, p. 1594). Although the authors have been criticised for ignoring the potential for variation in effect sizes between conditions (Kirsch and Scoboria, 2002), the conclusions stand as a recent example of the conception of placebo as 'inert substance'.

Finally, it should be noted that the conception of placebos as an inert comparator—akin to the 'chemists' blank' (Shapiro, 1959)—has not been confined to the field of medicine. As psychotherapeutic research adopted quantitative methods the terms 'specific' and 'non-specific' came into common use, with the implication that psychotherapies, like pharmaceuticals, had both active and placebo components (Caspi, 2002). This logic is inherent in 'dismantling' or 'component' studies of psychotherapies (e.g. Jacobson et al., 1996). Although the use of the term 'non-specific' as a synonym for

placebo is common, the example of psychotherapy neatly highlights the theoretical weaknesses inherent in the characterisation of placebos as ‘inert’ (Kirsch, 1985a, 1986). ‘Non-specific’ components of treatment in psychotherapy are held to be those which are not deemed *necessary* by a particular psychotherapeutic approach—for instance the role of ‘unconditional positive regard’ from the therapist in Cognitive Behaviour Therapy. However other theoretical approaches may deem these components to be central to the treatment process (Rogers, 1946, 1951; Frank and Frank, 1991). In the absence of consensus among theorists, it is impossible to term any component of a therapy which has beneficial effects as ‘non-specific’, or a placebo (Kirsch, 2005).

### 1.2.3 Meaningful: a therapeutic ritual

In parallel with the disinterested medical use of placebos as a form of methodological control, some researchers have actively engaged in research on placebos in their own right. In the course of documenting a wide variety of effects that could be generated by manipulating the context in which a therapy was presented, researchers developed increasingly sophisticated conceptions of placebo effects. An important first step towards this more nuanced position was a critique of some of the background assumptions held by biomedical researchers. Writing in 1949, Stewart Wolf argued that research into drug effects often lacked ecological validity:

The effect of administration of a drug or other chemical agent on a bit of muscle suspended in a standard solution is predictable and reproducible because it depends only on the pharmacologic action of the agent administered. The effect of administration of the same agent on an intact organism, however, is not necessarily predictable or reproducible . . . Despite

this...drugs are often dealt with as if the intact organism were comparable to the water bath and little interest has been manifest in factors other than their pharmacologic action (Wolf, 1950, p. 100)

Importantly, Wolf's definition of placebo effects does not require 'inert' substances. Psychological effects are one of many influences on the 'end state of the organ', and it is the researchers' task to study and explain the complex interactions of these influences. In reviewing historical and contemporary definitions of the placebo, Liberman (1962) offers one of the first definitions to consider the psychological complexity inherent in placebo effects:

The effects of a placebo may be quite physical and objective, like the action of the adrenal gland or the secretion of gastric juice; however, these effects are mediated by the brain and are dependent upon the individual's ability to comprehend the cultural symbols (such as pills, hospitals, injections, and so forth) which give meaning to the doctor-patient relationship. The modern placebo is an inert substance that does not affect the physiology or chemistry of the body directly. A lactose tablet or an injection of water or saline usually serves this purpose. But the placebo is no modern invention and its frequency of use is not limited to lactose tablets and saline-filled syringes. (Liberman, 1962, p. 761)

This definition contains several important elements: First, placebo effects may have objective, specific effects on physiological functioning. Second, the placebo need not be inert, although it should not *directly* affect the physiological function of interest. Third, the effect of the placebo is psychologically-mediated, and depends upon the *meaning* of the substance or procedure used. Later writers, drawing on anthropological

and cultural-historical perspectives, similarly emphasise the importance of meaning in placebo situations (Kaptchuk, 2002; Moerman, 2002). In these accounts rituals are at the heart of all human activity and may have a rich array of meanings for those performing them; the term placebo effect denotes the beneficial consequences that are solely attributable to the performance of a particular ritual. Thus placebo effects are in fact meaning responses (Moerman and Jonas, 2002), and the placebo itself is merely an object or procedure included in the ritual—in theatrical terms, a prop. Defining placebos as props within meaningful rituals avoids the logical inconsistency inherent in ‘inert’ definitions. Additionally, this new definition places placebos in a longer and richer historical tradition of patient-practitioner interactions, and encourages researchers to consider the full gamut of placebo phenomena, and not simply the improvements noted in the control groups of RCTs.

### 1.3 Psychological mechanisms of placebo responding

A variety of potential psychological mechanisms have been proposed to explain placebo responding, for example attribution effects (Heatherton et al., 1989; Storms and Nisbett, 1970) or responsiveness to internal states (Lieberman, 1962; Beecher et al., 1953). However only two theories have developed systematic or programmatic research, and yielded reliable, replicated results; they are conditioning, and response-expectancy theory.

#### 1.3.1 Conditioning

In a series of early studies investigating habituation effects, Glaser and Whittow (1953; 1954) found that when subjects were given a drug with unpleasant side effects, subsequent administration of an indistinguishable placebo also produced a large number of

side-effects. The authors offered little discussion and no explanation of this finding, but this may have been the first demonstration of a conditioned placebo response. Building on a model and predictions outlined by Wickramasekera (1980), Voudouris et al (1989; 1985) demonstrated that both analgesic and algescic (pain-increasing) responses could be generated using placebo creams. These studies used a highly controllable pain stimulus<sup>1</sup> and stimulus intensity was manipulated in concert with the administration of the placebo to give the impression of pain reduction or increase in a series of learning trials. In later trials, at full stimulus intensity, conditioned participants experienced increased response, either positive or negative, to the placebo. In the early 1990s, this type of evidence was used to argue that classical conditioning might be responsible for phenomena, including placebo effects, which had previously been considered the domain of cognitive psychology (Turkkan, 1991).

A number of other examples of conditioned placebos can be found in the literature, although as noted elsewhere they are relatively rare in humans (Kirsch, 2004). Examples include Flaten et al. (1997) in which a muscle relaxant was used to attenuate eyeblink startle responses to a loud tone. After 3 learning trials, participants did experience a conditioned placebo response in a fourth trial, although the direction of the drug effect was reversed, a result more commonly observed in animal studies. Colloca and Benedetti (2006) reviews evidence that patients exhibit a conditioned response to the hidden administration of opiates, finding that respiratory suppression in response to placebo is exhibited, outside of conscious awareness, after sufficient doses of morphine have been administered. Along with a small number of other studies, this evidence led

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<sup>1</sup>Unusually, these studies used an Iontophoretic pain stimulus. Iontophoresis, involves the repulsion of positive potassium ions from the positive pole of an electric (DC) current, and drives these ions into the skin. This causes a prickling sensation at lower levels of stimulation, and a cramping sensation at higher levels. The degree of noxious stimulation is dependent on the amount of current and the duration of administration and is independent of skin resistance (Voudouris, 1989).

The literature suggests that classical conditioning procedures are one shaping factor but that verbal information can also shape placebo effects. The literature also suggests that conditioning procedures and other sources of information sometimes shape conscious expectancies and that these expectancies mediate some placebo effects; however, in other cases conditioning procedures appear to shape placebo effects that are not mediated by conscious cognition. (Stewart-Williams and Podd, 2004)

In a short response, Kirsch (2004) argued that, although broadly correct, the authors may have overstated the role of purely-conditioned placebos in humans, i.e. those found in the absence of expectancies. Although a purely-conditioned response may exist, for Kirsch ‘the adaptive advantage of cognition is increased response flexibility’ and ‘for it to convey that benefit... it must be capable of overriding the influence of simpler automatic processes’.

Furthermore, conditioning and cognitive accounts of placebo responses need not be conceived as mutually-exclusive—conditioning may be thought of as one, perhaps powerful, way in which expectancies can be generated (Kirsch, 2004). Although Montgomery and Kirsch (1997) found that verbal expectancies could reverse conditioning effects, a recent paper (Klinger et al., 2007) found that neutral verbal instructions did not override a previous conditioning procedure, and that the combination produced longer-lasting effects than expectancy alone. Whalley et al. (2008, also reported here in Chapter 2) found that experiencing a placebo effect strongly influenced subsequent response-expectancies, suggesting that, where it is effective, administering a placebo might itself constitute a conditioning procedure. Establishing when and how automatic and conscious processes interact is a topic of interest to many researchers, and theories

developed elsewhere may be an aid to placebo researchers (for a review of current theory in this area see Toates, 1997; Smith and Decoster, 2000).

### 1.3.2 Response expectancy

Response expectancy places placebos within the broader explanatory framework of social and cognitive psychology. Kirsch (1985b; 1997) defines a response expectancy as the “anticipation of automatic, subjective, and behavioural responses to particular situational cues” (Kirsch, 1997, p. 69). *Response expectancies* are distinguished from *stimulus expectancies*—the expected occurrence of external events. Unlike stimulus expectancies, response expectancies are held to be “directly self confirming” (p. 69), and are not, for instance, mediated by other psychological processes such as a reduction in anxiety. The response expectancy takes, therefore, the form of a self-fulfilling prophecy. Although the concept of response expectancies is applied in a number of fields (for example hypnosis and suggestion) response expectancy theory has become the dominant explanatory framework for placebo effects (c.f. Kirsch, 1999). Importantly, response expectancies are conceived as *immediate* and *unmediated* causes of placebo effects (or other changes in experience). So, although the psycho-physiological details of the effect of expectancies is unspecified, no further psychological variables are required to explain behaviour.

As noted above, Kirsch (2004) and colleagues (Kirsch and Lynn, 1999) note that conditioned responses may occur outside of consciousness and therefore independently of expectancies, although they point to the relatively scarce evidence for this phenomena in humans. Importantly, they argue that conditioning should, in most cases, be conceived within a response-expectancy framework, and that conditioning may prove



an important source of information for individuals in *generating* expectancies. Although evidence from other researchers is equivocal regarding the links and interactions of automatic and conscious processes, it seems likely that the two systems are linked in some form in human placebo responding. Theoretical niceties aside, extensive evidence has demonstrated that consciously accessible response-expectancies (i.e. self-reports of expectancy) are predictive of a wide range of placebo and related phenomena, for example hypnosis or therapeutic benefits obtained via psychotherapy (for a review see Kirsch 1997 and Kirsch 1999).

#### 1.4 What remains unexplained?

Despite limited success in identifying contextual manipulations that modulate the size of placebo effects, placebo researchers are still unable to answer many basic questions regarding the phenomenon. For psychologists, two issues are particularly pressing. First, despite extensive efforts, researchers are still unable to make reliable predictions of individual differences in placebo responding. Second, although extensive evidence suggests that expectancies for therapeutic benefit are associated with greater placebo effects, it does not necessarily follow that expectancies *cause* placebo responses in all cases. Although the data provide a good fit with response-expectancy theory, in many cases it is possible for two theories to explain the same results. Furthermore, there remain instances when expectancies do not appear to predict placebo responses, and researchers should remain open to the possibility that other psychological mechanisms

may be responsible for placebo effects, at least under some circumstances.

#### 1.4.1 Identifying a placebo responder: 'slippery results'

There are two questions here: do placebo responders exist, and if so what characteristics do they have? Neither has been satisfactorily answered.

Lieberman (1962) noted that several studies (i.e. Wolf's) had investigated consistency of responses to the same placebo, but that no study had investigated cross-situational consistency, and goes on to make an important distinction between 'bound' and 'unbound' characteristics of individuals that might contribute to placebo responding. By 'bound' and 'unbound' Lieberman refers to characteristics which are either context-specific, and relate to features of a particular placebo, or are context-independent, and apply to responses to all possible placebos. He notes:

A true consistent placebo reactor would be expected to be affected by placebos as an experimental subject and as a patient. He should respond to a placebo regardless of where he was or who was administering it. This extreme type is unlikely to be numerous, if existent at all...No study has tested the placebo reactivity of a group of patients or subjects over a wide variety of clinical and laboratory situations. Hence, the distinction between bound and unbound predispositions is wholly obscured in the literature.

(Lieberman, 1962, p. 772)

A wide variety of traits have been identified by researchers over the past 50 years as potentially related to placebo responding. However, despite positive results in individual studies, the overall pattern of findings in this area has been inconclusive. Inconsistent

findings have led several reviewers to conclude that there may be 'no such thing as a placebo responder' (Trouton, 1957; Brody, 2000; Kaptchuk et al., 2008).

The problems of conducting research in this area are typified by an early study by Knowles and Lucas (1960), who reported a mixed pattern of correlations between symptom reporting following the administration of a placebo and the personality variables of neuroticism and extraversion. In a series of studies, participants were introduced to the placebo either individually or in groups of 3, with the following instructions:

The drug to be administered is a substance which is being tested experimentally in the Research Department. Many effects have been reported following its administration and it will help us greatly to have the benefit of your personal experience.

Interestingly, when participants responded alone, positive symptoms predominated, whereas in group situations the majority of symptoms were negative. In group situations there was a strong correlation between symptoms and neuroticism,  $r(12) = .74$ , but no significant correlation with extraversion,  $r(12) = .20$ . However, under individual conditions, neuroticism did not correlate:  $r(46) = .17$ . The correlation with extraversion was again non-significant, and this time in the opposite direction,  $r(46) = -.39$ . These results are typical of the field—the authors conclude that “it is possible . . . that personality factors operate against a background of knowledge and experience, and that where this is different, responses that are apparently contradictory in their relation to personality dimensions may occur.” However their explanations for the inconsistencies in their own results are post-hoc and not replicated in further studies.

Although inconsistencies such as these might be attributed to small sample sizes<sup>2</sup>, other more recent findings suggest that an interaction is taking place between characteristics of the person and characteristics of the situation (the placebo). Geers et al. (2005a) found that optimists showed greater placebo, as opposed to nocebo responses, and that the relationship was reversed for pessimists. Optimism, as indexed by the Life Orientation Test, is closely related to negative affectivity and symptom reporting (Andersson, 1996). Because symptoms reported in Knowles' group condition were mostly negative, but were mostly positive in the individual condition, the correlation observed for neuroticism may have been mediated by what Geers has termed 'valence-enhancement'—in essence, a form of attentional bias. Thus, even high level traits such as neuroticism may, in Liberman's terms, be *bound* or contextually dependent predictors of placebo responding.

If predictors of response must be bound to the context in which the placebo is delivered, the challenge for researchers is to identify suitable pairings of traits and context-attributes. Only traits which had broad relevance to a wide variety of placebo situations could be expected to correlate with responses with any degree of consistency. In their extensive survey of the placebo-personality literature, Fisher and Greenberg (1997) note Acquiescence as the only trait with empirical credibility in this regard. A series of studies, most dating from the 1960s and 1970s, are cited with positive correlations found for placebo responses to various placebos including: a pill to induce unspecified symptoms among undergraduate psychologists, medical students, and clinicians; placebo diazepam prescribed to patients with 'functional psycho-neurotic complaints'; placebo chlordiazepoxide for female psychiatric patients; placebo anxiolytics and antidepressants

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<sup>2</sup>Assuming a sample of 12 and an effect of  $r = .4$ , a study would only have a power of .25, way below conventionally-accepted levels today

for depressed patients; and finally ‘energising’ and ‘tranquillising’ placebos given to college students. Some null results are reported, and researchers should always be mindful of publication bias; this is particularly the case, as here, when a null result will result in an almost unpublishable paper—there are an almost infinite number of traits which *could* predict placebo responses, and editors may be especially unwilling to give space to this type of null finding. However, this sequence of studies represents the clearest evidence for a trait that might predict a broad-spectrum of placebo responses.

#### 1.4.2 Non-expectancy mediated placebo effects

The concept of response-expectancies (and of expectancies in general) has been hugely influential in the study of placebo effects; where authors list determinants of the placebo response, expectancies are at or near the top. Kirsch’s original response-expectancy paper (1985b) has been cited over 240 times; and a recent review of the psychological literature describing placebo mechanisms (Stewart-Williams and Podd, 2004) noted that “expectancy construct has largely replaced related mentalist constructs in the placebo field, such as faith and hope” (p. 328).

However, there remains an important objection to concluding that response-expectancy theory provides a satisfactory psychological account of placebo responding. Response expectancy theory posits that expectancies are (mostly) unmediated causes of changes in subjective experience. However, as noted above, the data supporting this claim is sourced mostly from short-term laboratory based studies. Where effects are longer in duration or more complex—for instance multidimensional therapeutic responses to psychological interventions—it is less clear whether response-expectancies are unmediated predictors of outcome (Stewart-Williams and Podd, 2004) and other mechanisms, for example

anxiety reduction, may need to be invoked.

In practice it is relatively common for expectancy to fail to predict effects in real-world, relatively long-duration studies. The examples given below do not all fall, strictly, within a conventional 'placebo paradigms', but do represent a challenge to the completeness of response-expectancy theory. Meta-analyses of double-blind placebo-controlled trials of homeopathy show large placebo effects, which add a methodological challenge to the demonstration of any additional specific effect (Shang et al., 2005). Because of size of this placebo component, response-expectancy should predict outcomes for homeopathy, but a large ( $N = 202$ ) double blind, randomised, controlled trial of a homeopathic preparation for asthma (Lewith et al., 2002) failed to find any correlation between a surrogate measure of expectancy—attitude to complementary and alternative medicine (CAM)—and the improvements in physiological or psychological outcome. Similarly, meta-analyses of sham versus real acupuncture suggest a large placebo effect when participants are treated for back pain, (Ernst and White, 1998; Ernst et al., 2002; van Tulder et al., 2005), but a large ( $N = 239$ ) open study found that there was a non-significantly better outcome amongst those who did not believe in acupuncture (Thomas et al., 2005). In these examples, expectancies were not the primary focus of investigation, but more direct evidence is provided by studies systematically reviewed in Delsignore and Schnyder (2007). The authors identified studies ( $N = 35$ ) that had focussed on the relationship between patient expectancies and psychotherapy outcome; only modest relationships were found between global outcome expectancies and actual outcomes, although relationships for specific-expectancies were stronger.

In sum, it appears that response-expectancy theory is successful in explaining short-term effects, and for outcomes where the effect of expectancies can be unmediated (e.g. for changes in perception). Although the data are limited, in more complex situations

additional mediating variables may be needed to explain the relationship of expectancies to outcomes, and it is possible that other non-expectancy mediated mechanisms are also in effect.

## 1.5 How and where should we conduct placebo research?

Early work on placebo effects was conducted in a wide range of experimental settings, including many studies in clinical populations (e.g. Lasagna et al., 1954; Dimond, 1960; Liberman, 1964). Wolf (1950) recorded acid secretion and other physiological variables in response to both active and placebo agents, and in a later paper reported the frequency of vomiting after participants received first an emetic and then a placebo to reduce the ensuing nausea (Wolf et al., 1957). Other experimenters required participants to swallow magnets, enabling them to demonstrate the effects of placebo instructions on stomach motility (Bternbach, 1964), or recorded symptoms reported after participants took placebo LSD (Abramson et al., 1955).

More recently, ethical concerns over invasive intervention and measurement, the (lack of) reliability of earlier experimental stimuli and measurements, and increased interest in the statistical power of studies, has lead researchers to conduct basic placebo research in more controlled settings (Shapiro, 1979). Often this has involved using healthy participants in research laboratories. Some basic research has continued with particular patient populations, for instance using placebo bronchoconstrictors with asthmatics (Luparello et al., 1968; Mcfadden et al., 1969; Spector et al., 1976; Isenberg et al., 1992; Leigh et al., 2003). However the majority of data relating to psychological—as opposed to physiological—mechanisms of placebo responding comes from laboratory studies of placebo analgesia, and these tend to use ischemic, heat, or pressure-pain stimuli

(see Stewart-Williams and Podd, 2004).

This focus on placebo analgesia is driven in part by convenience—pain stimuli and participant reports are easy to administer and collect—but also by the larger-than-average placebo effects observed for trials of analgesics. Placebo analgesic effects are robust, are corroborated by physiological measurements, and researchers have been encouraged by the identification of some of the relevant opiate-mediated mechanisms (Levine et al., 1978; Benedetti et al., 1999). There may also have been an aesthetic consideration in the choice of methodology (Feyerabend, 1981)—In the face of strong scepticism regarding the importance of placebo effects, using pain stimuli and placebo analgesics may have helped to bolster placebo research as ‘real science’, especially where studies required expensive equipment to deliver heat-pain or laser pinpricks (e.g. Watson et al., 2006). Additionally, doctors often use placebo analgesia in the face of repeated and ‘inappropriate’ requests for drugs from patients (Nitzan and Lichtenberg, 2004; Lichtenberg et al., 2004) and this may have spurred interest in this particular type of placebo<sup>3</sup>.

Whatever the reason for the focus on analgesia, the effects of placebos are both substantial and reliable when administered for many other conditions, both in and outside of the laboratory. Furthermore, responses appear to be quite sensitive to differences in the context of administration. For example, it is known that responses differ with double blind vs. deceptive instructions (Kirsch and Weixel, 1988), with larger responses observed when no mention of the possibility of receiving a placebo is made. This may have important consequences for generalisations made from experimental

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<sup>3</sup>It is worth noting the often negative attitudes of conventional physicians towards both placebos and placebo responders. Goodwin et al. (1979) found that doctors underestimated the effect of placebos and used them on disliked or mistrusted patients, often with the intention of identifying malingering or over-reporting of symptoms.



understanding to clinical practice. If placebos are conceptualised as ‘meaning effects’ (Moerman, 2002) then it is important to study the full range of meanings placebo substances have for individuals, and demonstrate that the generalisations from current theoretical explanations (both psychological and physiological) are warranted. In short, researchers should pay attention to placebos which are in widespread use, effective, and which are meaningful for patients.

### 1.5.1 Complementary medicine and placebo effects

Complementary and Alternative Medicine (CAM) is a term ascribed to a wide variety of therapeutic approaches which, either for historical or theoretical reasons, fall outside the scope of conventional medical practice. CAM therapies are hugely popular, and in western countries represent a significant proportion of non-governmental spending on healthcare—in the USA expenditure has been estimated in excess of \$30 billion per annum, and this surpasses all non-insured expenditure on conventional physicians, including non-insured hospital admissions (Eisenberg et al., 1998; MacLennan, 1996). CAM therapies are used by a wide cross section of the population, including military personnel (Smith et al., 2007),

However, despite its increasing prevalence, the evidence base for the majority of CAM therapies is surprisingly weak. In a few instances, traditional herbal remedies have been found to be as effective as more modern pharmaceuticals (Kirsch, 2003, e.g.), however in many other cases this has not proved to be the case (for a broad survey of the evidence base for CAM see Singh and Ernst, 2008). Some authors have even suggested that the resurgence in traditional or CAM therapies may be the result of the difficulty of administering placebos within conventional medicine, and that

for conditions with relatively large psychological components and low pharmaceutical efficacy they may have much to recommend them (Vozeh, 2003). In practice, use of CAM seem immune to both academic debates and the ethical niceties of the medical profession. Reporting a qualitative study, Cartwright and Torr (2005) argues: “patient-practitioner relationship and explanatory frameworks provided by CAM [are] perceived as important components of the therapeutic process, irrespective of treatment efficacy” (p. 559).

As such, CAM therapies with no demonstrated advantage over placebo provide a useful context in which to conduct placebo research. Even if ‘specific’ effects of these therapies are found in future studies (which in many cases appears unlikely), existing evidence strongly suggests that these remedies induce large psychologically-mediated effects, and these are of interest to placebo researchers. Bach flower remedies or essences are a good example of this type of CAM treatment. The remedies are manufactured by placing a small quantity of flowers in a crystal bowl in full sunlight, a process which is said to capture the ‘essence’ of the flower (Bach, 1987). This source essence is then diluted many times (perhaps hundreds), and is preserved in bottles with a quantity of brandy (approximately 60%). Commercially-available Bach essences are extremely popular, but are indistinguishable from a brandy/water solution. Proponents believe that the therapeutic effects of flower essences are spiritual in nature, but controlled trials indicate no advantage over placebo (Ernst, 2002).

Bach essences are used in a number of the studies reported below (Chapters 3, 5, and 6) because they represent an ecologically-valid placebo which may be given over longer periods (e.g. weeks) without the ethical concerns raised by deceiving participants: flower essences are effective even when participants are told their use is controversial, and that scientists have no evidence for their efficacy (Hyland et al., 2006).

## 1.6 Summary

Placebo effects are complex and, because of the historical connection between placebos and RCTs, many working definitions of placebos have been overly simplistic despite the fact that a more sophisticated understanding was developing amongst the placebo research community. Two main theories—conditioning and response expectancy—have been proposed to explain placebo effects. Response expectancy theorists have been particularly active, and have developed an extensive and programmatic range of findings. Conditioning effects appear less common in humans, and it is possible to explain conditioned placebo responses within a response expectancy framework. These successes notwithstanding, the question of whether placebo responders can be identified by personality traits remains, and some real-world placebo effects don't appear to fit the response-expectancy model. Furthermore, theoretical placebo research has become too focussed on placebo analgesics administered in laboratory settings to relieve experimental pain stimuli—other paradigms are available and may have greater ecological validity, generalisability, and may help to reveal additional psychological mechanisms of placebo responding. It is to these questions that the following work is addressed.

## Chapter 2

# Is placebo responding stable over time and between contexts?

Despite extensive research efforts from the 1950s to the 1980s, reliable trait predictors of the placebo response have not been found. This study examines whether the failure to find correlates of placebo responding is due to an inherent lack of reliability in placebo responding, and whether contextual variation in the presentation of a placebo decreases reliability of responses. Results are discussed with reference to the probability of finding either cross-situational or context-specific trait predictors of placebo responding<sup>1</sup>.

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<sup>1</sup>This data has previously been reported in Whalley et al. 2008

## 2.1 Introduction

Attempts to identify ‘placebo responders’ make two important assumptions with little or no supporting data. The first assumption is that placebo responding is a temporally-consistent trait of individuals. This is to say, if a person responds to a placebo on one occasion then they will also respond on subsequent occasions. The second assumption is that responses to placebos are not context-specific. That is, if a person responds to one placebo, they will also be more likely to respond to other placebos, even when those placebos are presented differently. Where previous research (described in 1.4.1) has attempted to identify generic trait predictors of placebo responding, both assumptions are made. Pragmatic attempts to identify ‘responders’ by observation (for example in the ‘washout’<sup>2</sup> phase of clinical trials), and interactionist perspectives, which consider context-specific predictors of response, require only the assumption of *temporal* stability.

In this study, both assumptions—that there will be temporal consistency in response to a single placebo, and that placebo responding will be a generic characteristic of the person—are tested. To facilitate this task, the study was designed to optimise the likelihood of finding consistency. Specifically, responses to identical placebo treatments were assessed on two separate occasions because if consistency cannot be found with all other factors held constant it is unlikely to be found at all. Second, the study tested the additional assumption of the generic hypothesis: that an individual’s response to placebo should show consistency between contexts. To this end responses to two placebos were measured, which differed only in name. If consistency can be disrupted by a

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<sup>2</sup>Washout phases are used in clinical trials in an attempt to exclude individuals who respond to placebos, and thus to increase the observed drug/placebo difference. Typically, a washout phase will involve all patients receiving placebos for the first 10-14 days of a trial, after which those patient whose symptoms improve will be excluded.

simple change in name then the discovery of a generic 'placebo responder' would seem unlikely. Finally, the study assessed the extent to which contextual variables (response expectancy), and generic traits that had previously been implicated as potential personality correlates of placebo responding (acquiescence and absorption), were predictive of actual placebo responses.

## 2.2 Methods

**Generating placebo responses** Determining the consistency of placebo responses over time requires a repeatable and reliable experimental or clinical setting. The only previous investigation of temporal stability of response, in addition to being limited by a small sample ( $N = 21$ ), used a relatively insensitive measure of placebo outcome: Participants were taking part in a trial of various agents (an unspecified number) intended to reduce nausea following the administration of an emetic. Analysis was made of a further series of 7 responses with placebo versions of these agents. Placebo response was operationalised as the absence of nausea and/or vomiting if this had been experienced after an earlier administration of the emetic. This outcome variable was dichotomous and partial alleviation of symptoms was not recorded. The size of placebo effects is also known to be dependent on the size of the effect of the active drug the placebo replaces (Evans, 1974), and if participants believed they were receiving different drugs on each occasion this may explain some variability in placebo responses recorded, making reliability harder to establish.

In contrast, recent work on placebo analgesia has successfully employed a combination of placebo creams with a painful stimulus to the fingers (Montgomery and Kirsch, 1996), and this was the approach adopted here.

Figure 2.1: The original Forgione-Barber pain stimulator



**Pain stimuli** Two identical Forgione-Barber Strain Gauge Pain Stimulators were used (the original device is depicted in Figure 2.1 and a new version, used in this study, in Figure 2.2). The device consists of a weight (900g) at the end of a movable bar (231g) that pivots vertically from a stand at one end. The subject's index finger is placed in a grooved notch on the top of a 50 mm stand, so that the bar can be lowered gently onto the finger. The bar tapers to the point of contact which is 2mm wide. The pain stimulator delivers approximately 2041 grams of force to a finger. Two sets of the apparatus were used simultaneously, and were adjusted for the right or left hand so that the remaining three fingers could rest on the platform between the stand and the bar attachment (see Figure 2.2).

**The placebo creams** Every effort was made to ensure the creams used in the study were plausible analgesic agents because contextual factors including packaging and drug colour have previously been shown to effect placebo effectiveness (Nagao et al., 1968). Two names were selected for the creams: The first, 'Ibuprofen', was intended to be recognisable as an over-the-counter painkiller and participants were reminded it was the



Figure 2.2: Pain stimulator created for this study—both hands were tested simultaneously



active ingredient of remedies including ‘Nurofen’ and ‘Advil’; all of the participants had heard of Ibuprofen. The second name, ‘Trivaricaine’, was invented by Irving Kirsch and had been used to describe placebos in previous studies. Trivaricaine was described as a ‘well-used and effective drug, most often given in hospitals’. Both drugs were described as ‘safe, well tested, and effective’. It was indicated that any effects of the creams would wear off within an hour or two. The creams were constituted from Aqueous cream bought from a local chemist. Labels were provided by the chemist; these listed the drug name, a fictitious potency (.05% BP<sup>3</sup>), and the caption ‘FOR RESEARCH PURPOSES ONLY’, and are shown in Figure 2.3.

**Pain intensity and response expectancy ratings** Measurements of pain and pain expectancy were taken on 11-point scales, with separate ratings taken for each hand. Endpoints were marked 0: *no pain at all* and 10: *the worst pain you can imagine*. For pain ratings participants were asked: ‘How intensely did the lever hurt [with/without] the cream?’ and for expectancy measurements participants were asked: ‘How intensely

<sup>3</sup>The photograph in Figure 2.3 shows a replica of the packaging used and a mistake is visible: The labels for both creams in fact read: “30g DRUGNAME .05% CREAM”



Figure 2.3: The placebo packaging



do you think the lever will hurt [with/without] the cream?’

**Trait measures** As discussed in the introduction (see 1.4.1, page 16), many researchers have attempted to identify stable personality correlates of placebo responding. However this literature contains many conflicting or unreplicated reports, and only two trait measures been associated with placebo responding with any degree of reliability: acquiescence (Fisher and Greenberg, 1997) and absorption.

**Acquiescence** was measured with the Bass Acquiescence scale (Bass, 1956, see A.2 on page 212 for individual items), in its original 56-item form. Valid responses to each item are *yes*, *no*, and *uncertain*. Bass scale scores are calculated by summing yes responses. However, for a reliability analysis we assigned the following scores: *yes* = 2, *uncertain* = 1, *no* = 0, ( $\alpha = .80$ ). Although many of the items now appear rather dated or parochial, for instance “Who does not love the opposite sex remains a fool the whole life long” and “Success against the odds is the greatest of American ideals”, it was felt that creating new items, or updating those which appear dated, would not be of significant benefit. The

scale measures the tendency to agree with statements posed, and the content of such statements is presumed irrelevant. Consequently, amending items that appear strange to contemporary readers should not affect the ability of the instrument to measure the concept of acquiescence.

**Absorption** was measured with the 34-item Tellegen absorption scale (Tellegen and Atkinson, 1974, see A.3 on page 215 for individual items). Valid responses are 1: *yes* or 0: *no*. Absorption scores in this sample ( $M = 19.1, \sigma = 5.9$ ) were near-identical to previous college-based samples (Glisky et al., 1991). Internal reliability was good ( $\alpha = .87$ ).

**Procedure** Students and staff at the University of Plymouth volunteered for the study<sup>4</sup> and some of the students received partial course credit in return for participation. During the consent procedure participants were told that the experiment was to compare the reliability of the two analgesic creams, as described above. To administer the creams the experimenter donned surgical gloves. Expectancy ratings were taken after the cream was applied, but before the pain stimulus. The study was conducted over two identical experimental sessions, between one and eight days apart ( $M = 2.5$  days,  $\sigma = 2.0$ ). Each session consisted of two trials: on each trial, participants simultaneously received two pain stimuli, each to a finger of a different hand. One finger was treated with a placebo analgesic cream; the other finger was left untreated. For one trial, the placebo was labelled “Trivaricaine”; for the other, it was labelled “Ibuprofen”, and order of presentation was balanced across the sample. Different fingers were used for each trial within a session (see Figure 2.4). For half the trials, placebo was administered to a finger on the right

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<sup>4</sup>A portion of this dataset (30 participants) was previously reported in a dissertation for partial fulfilment of an M.Sc. (Psychological Research Methods) at the University of Plymouth. The complete dataset has been reported in Whalley et al. (2008).

Table 2.1: Balancing of drug and finger order

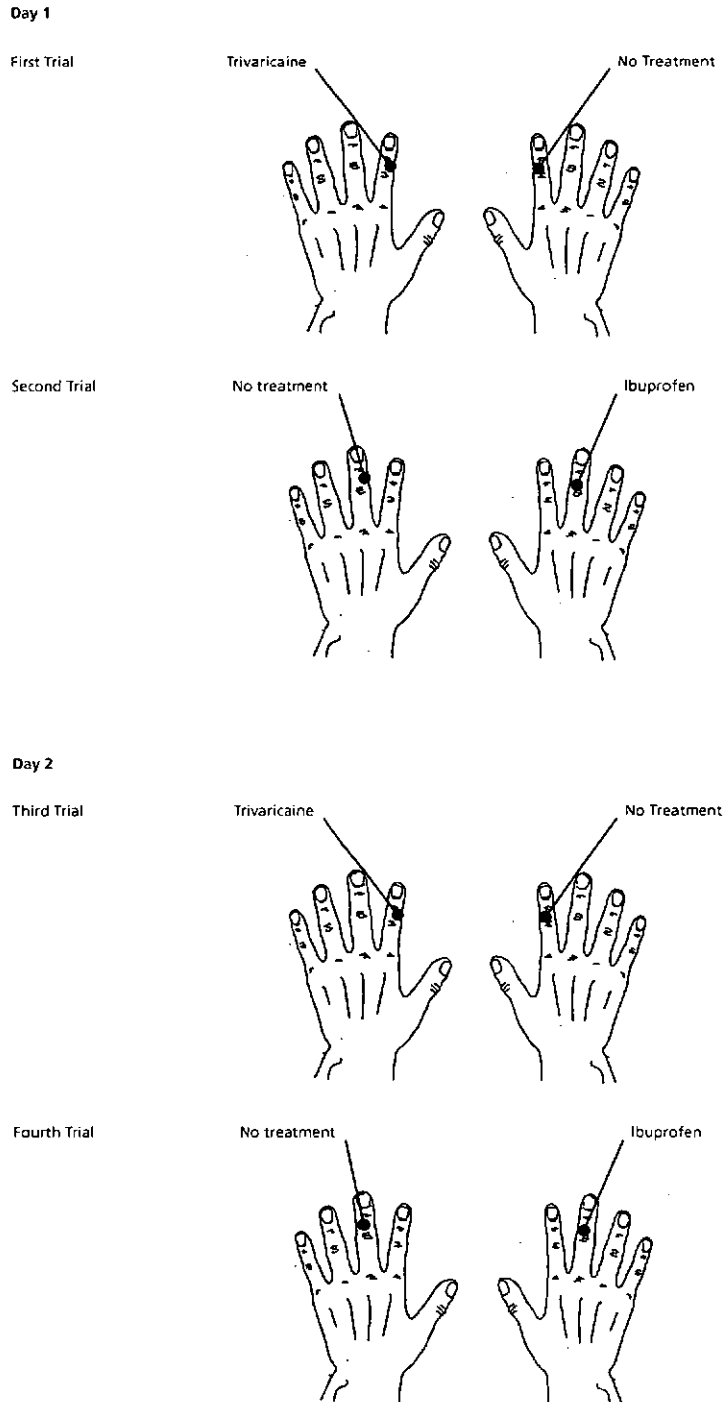
Drug (trials)	Trial 1/3 Finger (treated)	Trial 2/4 Finger (treated)
Ibuprofen (1/3); Trivaricaine (2/4)	Left Index	Right Middle
	Right Index	Left Middle
	Left Middle	Right Ring
	Right Middle	Left Ring
Trivaricaine (1/3); Ibuprofen (2/4)	Left Index	Right Middle
	Right Index	Left Middle
	Left Middle	Right Ring
	Right Middle	Left Ring

hand and for half to a finger on the left hand. Table 2.1 illustrates the groups created by crossing finger and drug order in this way. After the pain stimulus was applied pain intensity was recorded. At the end of their final session participants completed the two personality measures and were thanked and debriefed.

**Research ethics** The study, as described above, was approved by the University of Plymouth Human Sciences Research Ethics panel; specific permission was required for the deceptive instructions necessary to generate placebo effects. Participants were provided with written briefing materials (see A.1, on page 209, and once they had read the brief were asked if they had any further questions. If participants asked questions about the creams the experimenter restated information provided in the briefing sheet, and did not volunteer any further information. Only one participant asked directly whether the creams were placebos, and was told that they were not. However, this participant did not return for the second test session and is not included in the analyses below.

Because deceptive instructions had been used additional time was allowed at the end of the final test session for debriefing. Participants were given the debriefing sheet (see A.1 on page 210) and asked to read it before leaving the laboratory. No participants

Figure 2.4: Example of order of administration of creams and pain stimuli for one participant



appeared upset and many requested to be sent details of the research findings. Although a funnel debriefing procedure was not used the experimenter made informal inquiries to determine participants' perceptions of the study: the majority expressed surprise that the creams were not genuine.

## 2.3 Results

Seventy-eight participants were recruited for the study. Of these, 75 completed both test sessions and are included in the analysis which follows. The sample was predominantly female (66%) and young (mean age = 21 years,  $\sigma = 4.9$ ). Multiple one-way analyses of variance showed no significant effects for gender on any of the raw or difference-score variables (i.e. placebo or expectancy scores, see below), and male and female responses are combined in the analysis below.

**Computing placebo scores** In order to obtain estimates of the placebo effect observed (a) on each trial in order and (b) for each drug label in a given session (day), two types of placebo score were calculated. This was necessary because the analysis below seeks to identify both consistency of response over time (i.e. between sessions) and within a given context (i.e. for one or the other of the drug labels). In both cases this was achieved by subtracting reported pain scores for the treated hand from scores for the untreated hand<sup>5</sup>; high scores indicate greater placebo response on a given trial, or for a given drug in session 1 or 2. This approach was repeated for expectancy scores, again indexing either label or order, by subtracting the expected pain score from the treated hand from the expected pain score from the untreated hand.

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<sup>5</sup>A more sophisticated analysis using multiple regression and residualized change produced an identical pattern of responses, and for clarity the analysis based on difference scores is presented here.

Consequently, the variables Trivaricaine<sup>1</sup>, Trivaricaine<sup>2</sup>, Ibuprofen<sup>1</sup> and Ibuprofen<sup>2</sup> denote placebo responses in session 1 or 2. The variables Trivaricaine<sup>Expectancy1/2</sup> and Ibuprofen<sup>Expectancy1/2</sup> indicate scores for expectancies for response in session 1 or 2.

To index order rather than label, difference scores were created for each of the trials, in the order the participant experienced them. This ignores the drug label applied in each trial. For the variables Placebo<sup>1-4</sup>, and Expectancy<sup>1-4</sup>, superscripts indicate the order of participants' placebo responses and expectancies for response. Thus, Placebo<sup>1</sup> is the first response in the first session, and Placebo<sup>4</sup> is the second response in the second session, although for individual participants the drug labels used in these trials will have varied.

**Did the creams generate a placebo effect?** Mean pain ratings, with and without the placebo cream, are presented in Table 2.2 for each trial. To test for effects of the creams, a repeated-measures ANOVA (drug label, session, and treatment) was performed. A significant main effect was found for placebo treatment,  $F(1, 70) = 43.61$ ,  $p < .001$ ,  $\eta^2 = .38$ , S.M.D. = .60, indicating that the placebo creams had a moderate beneficial effect when compared with no cream. However, no effect was found for drug label indicating that effects of Trivaricaine and Ibuprofen were equivalent. No other significant main effects or interactions were found. This analysis was repeated with inter-session interval as a covariate and this indicated that the length of the delay between test sessions did not affect the reliability of placebo responses.

**Were responses temporally consistent?** First, a test was performed to determine whether a person who responded to a placebo in Session 1 was more likely to respond to the same placebo in Session 2. Large correlations between Trivaricaine<sup>1</sup> and Trivaricaine<sup>2</sup>,  $r(69) = .60$ ,  $p < .001$ , and also between Ibuprofen<sup>1</sup> and Ibuprofen<sup>2</sup>,

Table 2.2: Means (and  $\sigma$ ) for pain intensity scores ( $N=71$ )

Placebo Name	Time 1		Time 2	
	Untreated	Treated	Untreated	Treated
Trivaricaine	6.56 (1.80)	5.32 (1.89)	6.83 (1.78)	5.46 (1.95)
Ibuprofen	6.61 (1.75)	5.69 (1.86)	6.68 (1.73)	5.78 (2.03)

$r(69) = .77$ ,  $p < .001$ , indicate a strong relationship between responses to the same placebo on different occasions.

**Were responses consistent across contexts?** Correlations were used to test whether a person who responded to one placebo would be more likely to respond to a second, differently-labelled placebo. Because correlations between Trivaricaine<sup>1</sup>/ Trivaricaine<sup>2</sup> and Ibuprofen<sup>1</sup>/ Ibuprofen<sup>2</sup> were large, scores were combined for each cream creating a mean Trivaricaine placebo score and a mean Ibuprofen placebo score. There was no significant relationship between mean scores for the two placebos:  $r(73) = .05$ ,  $p = .64$ . An analysis using individual scores from each trial produced near-identical results.

**Did personality measures correlate with the placebo effect?** Correlations between the personality variables, placebo responses and expectancy responses are shown in Table 2.3. No significant correlations were found with placebo responses, although one significant correlation was found between Trivaricaine<sup>Expectancy1</sup> and Absorption. No further correlations were found with placebo or expectancy scores when collapsing across drug (i.e. mean of Trivaricaine<sup>1</sup> and Trivaricaine<sup>2</sup>); session (i.e. mean of Placebo<sup>1</sup> and Placebo<sup>2</sup>); with any of the placebo scores for occasions of administration (i.e. Placebo<sup>1-4</sup>); or finally, with the maximum placebo response exhibited in any of the trials (i.e. the largest value of Placebo<sup>1-4</sup>).

Table 2.3: Correlations of personality, placebo, and expectancy scores

	Absorption	Acquiescence <sup>a</sup>
<i>Placebo responses</i>		
Trivaricaine Session 1	.06	-.05
Trivaricaine Session 2	.02	.02
Ibuprofen Session 1	-.06	-.02
Ibuprofen Session 2	-.06	-.04
<i>Expectancy scores</i>		
Trivaricaine Session 1	.28*	.13
Trivaricaine Session 2	.10	.10
Ibuprofen Session 1	.03	.07
Ibuprofen Session 2	.01	.01

\* $p < .05$   
<sup>a</sup> Inter-correlation between the scales was .44\*\*\*

Previous work on reliability of placebo responses had suggested that groups of patients who respond either positively or negatively to a placebo may have more in common with each other than with those who do not respond at all (Shapiro, 1979). To examine this possibility, a follow-up analysis was performed including only participants who exhibited a placebo or a nocebo response (i.e. those participants who did not have a placebo difference score of zero). For participants who scored  $> 0$  on Trivaricaine<sup>l</sup>, the correlation of Trivaricaine<sup>l</sup> with Acquiescence was  $r(40) = .41$ ,  $p < .01$ ; and for absorption  $r(41) = .30$ ,  $p = .06$ . For participants scoring  $< 0$  on Trivaricaine<sup>l</sup> the correlations were: Acquiescence  $r(9) = -.59$ ,  $p = .10$ ; absorption  $r(9) = .20$ ,  $p = .61$ . This analysis was repeated for Ibuprofen scores, but none of the correlations approached significance (all  $r$ 's = 0,  $\pm .05$ ). This suggests that, for those people who did show a placebo response to Trivaricaine, then the strength of the placebo effect was greater if



Table 2.4: Correlations of placebo and expectancy scores on each trial

	Expectancy <sup>1</sup>	Expectancy <sup>2</sup>	Expectancy <sup>3</sup>	Expectancy <sup>4</sup>
Placebo <sup>1</sup>	.33**	.43***	.57***	.24*
Placebo <sup>2</sup>	.25*	.19	.30*	.60***
Placebo <sup>3</sup>	.10	.28*	.42***	.65***
Placebo <sup>4</sup>	.18	.21	.45***	.59***

\* $p < .05$ ; \*\* $p < .01$ ; \*\*\* $p < .001$ ; Placebo<sup>1-4</sup> = placebo scores on successive occasions; Expectancy<sup>1-4</sup> = expectancy scores on successive occasions.

they were high in Acquiescence and Absorption.

**Did response-expectancy predict the placebo effect?** Correlations between expectancy and the placebo effect on each trial are reported in Table 2.4. Initial response expectancies prior to any experience with either placebo cream (Expectancy<sup>1</sup>), were significantly correlated with Placebo<sup>1</sup>, and they were also significantly correlated with Placebo<sup>2</sup> (in which the placebo had a different name). Trial one expectancies (Expectancy<sup>1</sup>) did not significantly predict Placebo<sup>3</sup> or Placebo<sup>4</sup>. In all cases, expectancies were significantly associated with the size of earlier placebo effects, suggesting that participants' response expectancies were altered by experience. However, mean expectancies did not change between session 1 and 2 for either Trivaricaine,  $t(70) = 1.10$ , ns, or Ibuprofen,  $t(70) = -.07$ , ns.

**Did response-expectancies mediate the consistency of placebo responses?** To test the mediating effect of expectancy when the drug label remained the same, expectancy scores (e.g. Expectancy<sup>3</sup> or Expectancy<sup>4</sup>) were regressed on placebo scores (e.g. Placebo<sup>3</sup> or Placebo<sup>4</sup>) with the previously-experienced placebo response for the same drug label controlled (e.g. Placebo<sup>1</sup> or Placebo<sup>2</sup>). Because there were substantial correlations

between the expectancy ratings and prior (same name) placebo effects included in these analyses (ranging from  $r = .30$  to  $r = .65$ ), these regressions should be interpreted as conservative tests, although assessments of multicollinearity did not reveal excessive cause for concern (maximum *VIF* in any regression = 1.57). Then the analysis was repeated, this time controlling for earlier placebo responses to the differently-labelled drug (e.g. regressing Expectancy<sup>3</sup> and Placebo<sup>2</sup> on Placebo<sup>3</sup>). The results of all the analyses are displayed in Table 2.5. For same-placebo prediction, response expectancy was a significant partial mediator of the consistency between Placebo<sup>2</sup> and Placebo<sup>4</sup>, but not between Placebo<sup>1</sup> and Placebo<sup>4</sup>. For all three different-placebo models, prior placebo responses to different drugs predicted negatively or not at all, and expectancy was a significant predictor of the placebo response. Thus, expectancy was a significant predictor of responses, but where data for previous responses to the same cream were available expectancy did not completely mediate the consistency of responses.

**Multicollinearity** Because there were substantial correlations between the expectancy ratings and prior (same name) placebo effects included in these analyses (ranging from  $r = .30$  to  $r = .65$ ), these regressions should be interpreted as conservative tests (Kirsch, personal communication). However, as David Kenny has observed, ‘multicollinearity is to be expected in a mediational analysis and it cannot be avoided’ (2003). Kenny estimates that the effective sample size for highly collinear regressions is  $N(1 - r^2)$  where  $r$  is the correlation between the distal independent variable and the mediating independent variable. An effective sample size for these analyses is therefore between 45 and 48, and the study is sufficiently powered for this analysis.

Table 2.5: Regression Analyses of Placebo Effects Predicted by Expectancy and Prior Experience

DV	Same-placebo predicting		Different-placebo predicting	
	IV's	$\beta$	IV's	$\beta$
Placebo 2 <sup>a</sup>	-	-	Placebo <sup>1</sup>	-.27*
	-	-	Expectancy <sup>2</sup>	.31*
Placebo 3 <sup>b</sup>	Placebo <sup>1</sup>	.50***	Placebo <sup>2</sup>	.13
	Expectancy <sup>3</sup>	.14	Expectancy <sup>3</sup>	.39**
Placebo 4 <sup>c</sup>	Placebo <sup>2</sup>	.61***	Placebo <sup>3</sup>	-.12
	Expectancy <sup>4</sup>	.22*	Expectancy <sup>4</sup>	.67***

<sup>a</sup>  $R^2$  adj. = .069  
<sup>b</sup>  $R^2$  adj. = .330 and .169  
<sup>c</sup>  $R^2$  adj. = .570 and .333  
\* $p < .05$ ; \*\* $p < .01$ ; \*\*\* $p < .001$

Placebo 1 = first response, irrespective of label  
Expectancy 1 = expectancy for first response, irrespective of label

## 2.4 Discussion

**Placebo responding appears to be temporally consistent but contextually dependent** With contextual factors held constant responses to a single placebo were highly reliable; under these circumstances there is temporal stability in placebo responding. However, participants' responses to the different placebos used in this study were not consistent, indicating that even very small changes in the context of presentation can affect individual differences in the placebo response. These data suggest that the search for a generic placebo responder—one who responds consistently to placebo across different situations—may never be successful. For that reason the failure to find an association between placebo responses and generic personality measures (i.e. measures that are not paired with the context in which the placebo is presented) is unsurprising. If reliable prediction of a placebo response by a trait-like characteristic is possible, it will only be by selecting predictors that are consistent with the context in which the placebo is presented (Geers et al., 2005b,a; Hyland et al., 2006).

**Response expectancies were only modest predictors of placebo response** Because response expectancies are context-specific, they are better predictors of placebo response than the generic trait measures included in this study. The cleanest measure of this effect is the correlation between initial expectancies and the initial response to placebo (see Table 2.4). However, this reveals only a modest association, suggesting that, at best, expectancy only partially explains the placebo responses observed in this study. This finding is consistent with recent work on placebo, hypnotic, and suggestive analgesia (Price et al., 1999), in which expectancy only partially mediated the effect of the type of treatment on outcome (pain intensity).

Placebo effects were strongly associated with subsequent expectancies, suggesting that the experience of placebo effects altered participants' expectations for future responding. This may account for larger correlations observed between expectancies and placebo responses in later trials. When controlling for prior response to the same-named placebo, analysis revealed that expectancy weakly and inconsistently mediated the effect of a response to one placebo on later responses to that same placebo. There are a number of possible explanations for the unexpectedly modest results obtained for expectancy in the mediation analysis above. One possibility is that there is little change to account for. The high correlations between trials of the same placebo could be interpreted as the test-retest reliability of this measure of the placebo effect. If this were the case, differences in response from one trial to the next would be error variance, which could not be predicted reliably by any variable. However, the problem remains that, even using the cleanest measure of expectancy (the correlation of Expectancy<sup>1</sup> and Placebo<sup>1</sup>), around 90% of the variance is unexplained. It may be that other context-specific characteristics of the person determine the response to a placebo, a possibility explored in more detail in later chapters. It may also be that the measurement of expectancy was at fault—either because it is unreliable (in future, multiple items could be used to reduce measurement error), or because they do not capture the full range of expectancies for benefit which participants may have. For example, if response to placebo were due to implicit as well as explicit response expectancies, the fact that only measurements of explicit expectancies were taken might have attenuated the level of mediation observed. Work in other fields has alerted researchers to the extent to which non-conscious processing can influence behaviour without provoking verbal reports (Bargh and Chartrand, 1999; Cleeremans et al., 1998). It follows that verbal reports of expectancies may not exhaustively measure the extent to which a people are processing and responding to features of a given placebo

setting.

It is worthy of note that no significant gender differences were found in this study; neither placebo and expectancy scores nor raw pain scores differed for males and females. Laboratory studies generally show greater pain sensitivity and lower pain thresholds for women than for men (Keogh, 2006) and, although variations exist between different methodologies, pressure pain normally produces medium to large effect sizes for gender on pain threshold and tolerance (Riley 3rd et al., 1998). It may be that visual analogue scale ratings of pain are less sensitive to gender differences, or that taking simultaneous ratings of treated and untreated fingers caused participants to use the scales in an atypical manner.

**Practical implications for clinical trials** A practical implication of these data is that initial response to a placebo, as might be obtained during the run-in phase of a clinical trial, may be the best way of identifying placebo responders. However, some caveats are in order. First, designers of clinical trials should pay close attention to the transition between the 'washout' phase and the main part of the trial. Data from this study have demonstrated sensitivity to even relatively minor contextual cues. If the experience of patients differs between these two phases then patients who did not respond to the 'washout placebo' may still exhibit placebo responses when taking the (presumed) active agent. Relevant cues might include hints from physicians, a change in drug packaging, or even side effects experienced by patients—an 'active placebo effect' (Thomson, 1982). If such cues do alter the subset of patients who exhibit placebo responses then this may account for the relatively limited success of placebo washout phases when used in clinical trials (Posternak et al., 2002; Trivedi and Rush, 1994).

Second, unlike the present study, placebo controlled clinical trials contain double

blind instructions such that participants are aware that they *might* receive a placebo. In contrast, the instructions in this study were deceptive—participants were told that they *would* receive an active substance, and in this respect was similar to a comparative drug study without a placebo. Double-blind instructions have been shown to produce smaller placebo effects than do deceptive instructions, where no mention is made of the possibility that participants may receive a placebo, in previous laboratory studies (Kirsch and Weixel, 1988; Geers et al., 2006). Third, the experiment itself was not double blind; although the experimenter took care to record pain scores without sight of previous scores, it is possible that participants were responding to implicit demands of the situation (i.e. to be consistent). Fourth, a funnel debriefing procedure was not employed, and the data collected do not speak to participants impressions of or beliefs about the study. One explanation for the weak correlations between responses to the different drugs is that participants believed that only *one* of the creams was genuine, and that the other was a placebo control. Anecdotally, none of the participants expressed this view, but it is possible that participants' background knowledge of placebo-controlled trials (which often compare verum with a placebo) informed responses in this study. Fourth, this study employed an experimental pain stimulus in the lab, and it is impossible to know whether these results will generalize to clinical contexts. Finally, data on placebo analgesics might not generalize to other types of placebos. For this reason, tests of consistency of placebo responding should also be conducted with other types of placebos.

## Conclusion

The search for predictors of placebo responses is realistic, but close attention must be paid to the meanings ascribed by participants to the specific placebos used. The search

for a generic placebo-prone personality is unlikely to be successful. However, these data suggest that a context-specific approach may bear fruit.



## Chapter 3

# Contextual identification of responders for a placebo complementary therapy

Most placebo research is conducted within a response-expectancy framework, and studies often employ experimental pain stimuli and placebo analgesics. However, real-world placebos are taken in a wide range of contexts, and results are sometimes hard to explain without reference to other mechanisms of placebo action. Hyland et al. (2006) reported that dispositional spirituality predicted response to a popular but biologically inert complementary therapy, and this study is replicated and extended. Additional measures of outcome and proxy measures of expectancy are included; this provides a more conservative test of the hypothesis that the relationship between disposition (spirituality) and placebo responding is unmediated by expectancy. A working hypothesis—that motivational factors may be involved in longer-term therapeutic response—is examined by including a motivational priming task<sup>1</sup>.

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<sup>1</sup>This data has previously been reported in Hyland et al. 2007

### 3.1 Introduction

The results of study 1 suggest that generic trait predictors of placebo responding are unlikely to be found. Nonetheless, responding was consistent when the name of the placebo—the context—was held constant. This confirms that it may be possible to identify predictors of placebo responses where the predictor is related to the context of treatment.

**Dispositional predictions of placebo responses.** In a previous study, Hyland et al. (2006) identified that a dispositional variable, the motive for spirituality, predicted the degree of therapeutic benefit experienced when participants took a a very distinctive type of placebo: a Bach flower remedy. The authors performed a mediation analysis and found that this prediction was not due to increased expectancies for benefit held by those participants who scored highly on the spirituality scale. This finding is novel because, although expectancy has failed to predict outcome in other studies, the identification of a dispositional predictor of outcome that is not mediated by expectancy indicates that there may be additional psychological mechanisms at work.

Hyland et al. (2006) avoided premature explanation of the spirituality—outcome correlation. However they noted that the effect might be explained by greater optimism in spiritual participants. Optimism (Scheier et al., 1994) and spirituality (Saroglou, 2002) both correlate negatively with neuroticism, and optimism correlates with a number of spirituality scales (Salsman et al., 2005); this shared variance might explain the benefits observed for spiritual participants.

**Replicating Hyland et al. (2006)** In order to both replicate and extend the results of Hyland et al. (2006), this study employs a similar methodology, but includes additional

measures of outcome and dispositions, and allows for a more conservative test of the hypotheses that the relationship between disposition and response is independent from expectancy. Finally, a goal-priming task was included with the intention of exploring the role of goal activation in therapeutic response to flower essences.

**Additional outcome measures** Both practitioners and users of complementary therapies report benefits of treatment that extend beyond the symptoms for which assistance was originally sought. A qualitative analysis of patient reports lead Cartwright and Torr (2005) to conclude that 'CAM serves a variety of functions beyond the explicit relief of symptoms'. Users describe these benefits as both physical---enhancing relaxation, increasing energy etc.---and emotional---facilitating coping, enhancing self-other awareness.

Homeopathic practitioners explicitly recognize and value the 'multidimensional' nature of patient responses to treatment (Oberbaum et al., 2005). Oberbaum et al. claim that a homeopath's patients are hindered by lack of appropriate language when describing therapeutic changes, concluding that, in this regard, it is an 'imperfect conduit for expressing the full gamut of human experience'.

However, they note that practitioners often report benefits for patients that are additional to the reduction of the symptoms for which they were treated. Such benefits include amnesia of secondary complaints; holistic improvements in functioning, beyond those which could be expected by 'mere physical amelioration' of the primary complaint; and altered perceptions of environmental factors—for example that significant others may appear calmer, kinder, or more appreciative. In an attempt to capture this broader sense of benefit, this study includes additional outcome measures, which are not directly related to the intended treatment: a rating of general wellbeing, and a short measure

of Antonovsky's Sense of Coherence scale (SOC; Antonovsky, 1993; Schumann et al., 2003).

**Additional dispositional predictors** Although Hyland et al. (2006) used a validated measure of spirituality, the Spiritual Involvement and Beliefs Scale-Revised (SIBS-R, Hatch et al., 1998), includes some items relating to organised religion or spirituality of a particular denomination (e.g. 'I have experienced healing after prayer'). In this study, a new measure of spirituality was included to eliminate this potential bias.

Because shared variance between spirituality, optimism and neuroticism had been suggested as an explanation for the relationship between spirituality and outcome, a measure of optimism was also included in the questionnaire battery. Geers et al. (2003, 2005b) had found that optimism predicted placebo responding *where positive expectancies for change were induced*, and that where negative expectations were induced then optimism protected against nocebo effects. Although flower essence therapy is longer in duration and used to create more varied therapeutic effects than the therapy used in Geers' studies, the materials used to advertise and explain the study included phrases such as: 'Many people find flower essences to be helpful', and are therefore likely to have induced positive expectancies for change among participants. Including a measure of optimism enables the identification of any mediation of the spirituality—outcome correlation.

**Context manipulation/motivational priming task** Complex social behaviours can be triggered non-consciously, and even very subtle manipulations appear to activate behavioural concepts sufficiently to alter subsequent behaviour (Bargh, 2004). Primes, in the form of words, pictures or social situations, may engage stereotypes of social groups

or categories, or may facilitate focus on social or interpersonal goals. For example, when words related to the goals of achievement or co-operation are embedded along with other goal-irrelevant words in a puzzle, these words serve to activate goals and guide behaviour, sometimes over extended periods of time. Participants primed with achievement-related words perform better than controls; whereas those primed with cooperation-related words cooperate more on a commons dilemma type game (Chartrand and Bargh, 2002). Such a priming technique might have an effect on therapeutic response to flower essences in one of two ways:

First, it may be that spirituality—or the desire to be a spiritual person—is an interpersonal goal in the sense described above. Because dispositional spirituality predicts response to a flower-essence placebo, activating the concept of spirituality through a spiritual prime might increase placebo responses by making this aspect of a participant's value system more salient as they begin the therapy. In this instance, the expectation would be that the average outcome would improve, as the construct of spirituality would have greater salience for all participants.

Second, an alternative explanation is that priming with words such as 'spirituality', 'love' and 'compassion' might strengthen associations between the concept of spirituality and the therapy presented, 'contextualizing' it as a more or less spiritual therapy, and thus making it more motivationally appealing to participants who are high in dispositional spirituality. If this were the case, a spiritual prime should increase the correlation between spirituality and outcome, but without creating an improvement in mean responses to the treatment.

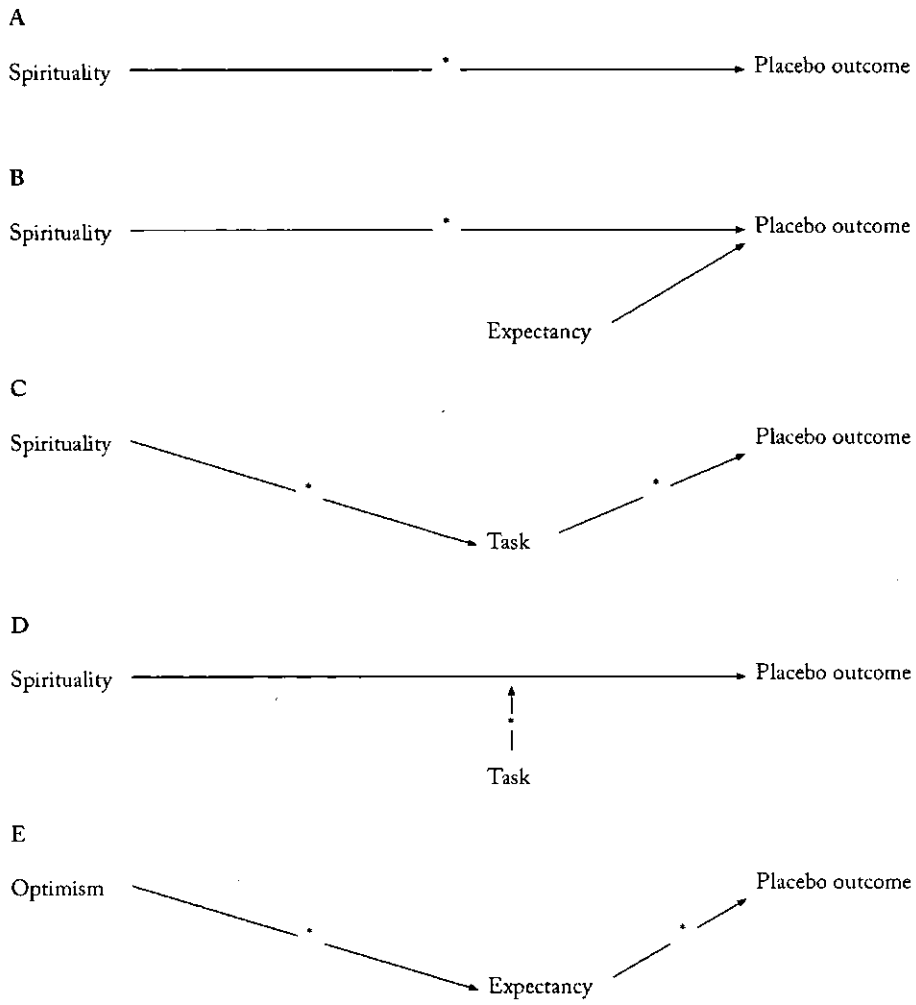
### 3.1.1 Hypotheses

Five hypotheses were proposed (see Figure 3.1). First, that the original prediction of placebo responses from dispositional spirituality would be replicated (A), and that the new measure of spirituality would be more sensitive than the previously used measure. Because adherence is associated with improvements to both true pharmacological treatments and placebos (Horwitz et al., 1990; Horwitz and Horwitz, 1993), adherence was also expected to predict outcome in this study. Second, that mediation analysis would indicate that the dispositional variable predicted variance in outcome independently of both expectancy measures (B). Third, that the goal-priming task would serve to either (C) increase response rates amongst spiritually-primed participants, or (D) increase dispositional correlations (with spirituality) amongst those exposed to the spiritual prime. Fourth, if evidence for optimism—outcome correlations is found, then expectancy should mediate this relationship (E). And finally, it was also of interest to identify evidence of broader therapeutic benefits in response to flower essences, indicating changes that were not restricted to the symptoms for which the essence was originally prescribed.

## 3.2 Methods

**Overview** Participants were recruited for an open trial of a Bach flower remedy for minor psychological symptoms. On entry, participants chose the essence they judged best-suited their symptoms, and completed a questionnaire battery that included measures of dispositions, baseline measures of symptoms and well-being, and expectancy for benefit. Participants were also randomised to one of two motivational priming conditions before receiving their chosen essence and initiating treatment. Follow-up measures were made

Figure 3.1: Study hypotheses



after three weeks via email.

**Recruitment** Undergraduate students and members of staff at the University of Plymouth with minor psychological complaints (e.g. anxiety, depressed mood) were invited to take part in an open trial of Bach flower remedies. Posters were displayed, and flyers were widely distributed around the University campus by the experimenter and several research assistants (third-year undergraduate students). Participants were not paid and did not receive course credit. Exclusion criteria were: use of flower essences in the previous six months; age of less than 18 years; currently receiving psychiatric treatment; history of alcohol abuse<sup>2</sup>; participants were required to confirm that they did not meet these criteria when providing consent.

### **Predictor Questionnaire Assessments**

**The Spiritual Involvement and Beliefs Scale–Revised (SIBS–R)** The 22-item SIBS–R was the first of two spirituality scales used (Hatch, personal communication, 2001)<sup>3</sup>. The SIBS–R is a revised version of an earlier 39-item scale (Hatch et al., 1998) that purports to measure spirituality in contrast to religiosity, although some items do refer to activities of organised religion (e.g. ‘I have experienced healing after prayer’) or to values emphasised within particular religious traditions (e.g. ‘When I help others, I expect nothing in return’). Participants respond to each item on a 7-point scale, and high scores indicate greater spirituality. Although there are more positive than negative items, the authors report that the scale is uncorrelated with social desirability (Hatch, personal

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<sup>2</sup>Because the essences are primarily composed of Brandy this was considered a sensible precaution

<sup>3</sup>Scale items listed in Table A.6 on page 222



communication, 2006). We included this scale because it had been used in the earlier study, before the development of the Spiritual Connection Questionnaire (see below).

**The Spiritual Connection Questionnaire** The second spirituality measure, the 48-item Spiritual Connection Questionnaire (SCQ-48<sup>4</sup>), was designed especially for this study, and was intended to (a) provide a scale which contained only items relating to spirituality and not, for instance, religiosity, (b) to contain equal numbers of positively and negatively worded items, mitigating against a response bias, and (c) to be culture fair, in the sense that items do not presuppose a particular conception of spirituality (i.e. Christian, Buddhist, Secular etc). The scale was based on Hunglemann's (Hunglemann et al., 1985) definition of spirituality as a "sense of interconnectedness between self, others, nature and Ultimate which exists throughout and beyond time and space" (p. 152). Scale items cover the experience of a "sense of connection" in the following domains: with the universe, e.g., "I do not feel connected to the universe in any spiritual way"; with people, "There is something of the cosmos that binds all people together"; with nature, "I never feel any special connection with a part of nature such as a flower"; and with places, "I sometimes experience joy just from being in a beautiful place". Thus, the SCQ-48 is a scale measuring the experience of spirituality as it relates to a sense of connection.

Participants respond to each item on a 7-point scale indicating agreement with the item. After correction (reversing scores), scores are summed and high scores indicate greater spirituality. The scale is uni-dimensional, with the first factor accounting for 48% of the total variance Wheeler and Hyland (2008). Additionally, the scale fails to correlate ( $r = .03$ ) with the Marlow-Crowne scale of social desirability (Crowne and Marlowe,

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<sup>4</sup>scale items are listed in A.4

1960).

The SCQ-14, which is used in later chapters, was developed as a short form-version of the Spiritual Connection Questionnaire, suitable for use in online studies, and in situations where there is a large questionnaire burden. Scale items were selected by factor analysis, with 7 positive and 7 negatively-worded items chosen. All scale items loaded  $> .6$  on the first factor of the SCQ-48 in a large public sample (Hyland, personal communication).

**Optimism** Optimism was measured using the 10-item Life Orientation Test-Revised (LOT-R<sup>5</sup>; Scheier et al., 1994), which contains 6 scored items (3 positively worded, 3 negatively worded) and 4 filler items. Participants respond to each item on a 5-point scale and higher scores indicate greater optimism. The LOT-R has been found to correlate with neuroticism (e.g. Smith et al., 1989).

**Holistic Health Beliefs** In order to provide a more conservative test of the hypothesis that the relationship between spirituality and outcome is not mediated by expectancy, we included an additional surrogate expectancy measure: the 11-item Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ; Hyland et al., 2003). The HCAMQ includes separate, validated sub-scales for 'holistic health beliefs' (HHB) and 'attitude to complementary medicine' (ACM). Although HCAMQ questions do not ask directly about expectancies for response to a flower remedy, they do indicate a general positive regard for alternative and complementary therapies; in the previous study both sub-scales were strongly correlated with expectancy for a flower essence therapy (Hyland et al., 2006). Therefore, the HCAMQ may capture additional

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<sup>5</sup>Items are listed in A.5 on 221.

variance related to positive expectancies for flower essences that was not accounted for by a standard, single-item measure of expectancy. Participants respond to HCAMQ items on a 7-point scale, and high scores on the sub-scales indicates greater positivity towards complementary medicine, or more 'holistic' health-beliefs.

**Outcome and expectancy measures** Whereas Hyland et al (2006) used only perceived change as an outcome measure, in this study we measured symptoms before and after treatment, and also took self report measures of general well-being. For all measures of outcome, measurements of expectancy were made at baseline using adapted versions of the outcome assessment question (as recommended by Kirsch, 2006 personal communication).

**Perceived change** Perceived change following treatment ( $\text{Change}^{\text{perceived}}$ ) was assessed by e-mail at the end of the study. The e-mail stated: "Thank you for taking part in our experiment. You chose: [*name of essence*] for [*symptoms reported*]. Below, you will see a perceived change scale. Please make a note of the number on the scale that you think best illustrates how you perceive you have changed after taking the flower essences". Responses were made on a 7-point Likert-type scale ranging from -3: *Feel worse* to +3: *Feel better*.

To measure expectancy for perceived change ( $\text{Expectancy}^{\text{perceived}}$ ), participants were asked "At this point in time, do you expect the flower essence will help you?" before commencing the therapy. Responses were given on an eight-point scale ranging from 8: *Yes, I definitely think it will help*, to 1: *I think it very unlikely it will help me*.

**Symptom change** At baseline participants rated up to two symptoms for which they had selected the flower essence using two, seven-point scales. The end-points were

labelled 0: *no problem*, and 6: *as bad as it could be*. Participants also provided ratings for how they expected symptoms to be after three weeks of treatment with flower essences (with the first rating in sight). After three weeks, they were asked, via e-mail, to rate their symptoms again, but without sight of the original ratings. Baseline (Symptoms<sup>baseline</sup>) and final symptom scores (Symptoms<sup>final</sup>) were obtained by taking a mean value for the symptom scores at baseline and final assessment respectively.

**Sense of coherence** Sense of Coherence (SOC) was developed in the late 1970's to measure the general tendency to perceive the world as comprehensible, manageable and meaningful (Antonovsky, 1979), with the belief that such an outlook was health promoting or *salutogenic*. Sense of coherence correlates with measures of general health, symptom reporting, and pain, for example the General Health Questionnaire, the Hopkins Symptom Checklist, and the Oswestry Low Back Pain Questionnaire; and is negatively correlated with measures of anxiety and depression—for example, the Hospital Anxiety and Depression Scale, and the Beck Anxiety Inventory (Eriksson and Lindstrom, 2005). Although initially conceived as a relatively stable measure, SOC has been found to change in response to both negative life events (Schnydera et al., 2000) and homeopathic treatments (Hyland, personal communication, 2001). On this basis it was selected as a measure of the broader benefits a CAM therapy such as a flower essences might offer. Sense of coherence was assessed using the Brief Assessment of Sense of Coherence (BASOC, abbreviated to SOC below), in which each item is rated on a five-point (0-4) scale (Schumann et al., 2003). The questions included in the BASOC are as follows:

1. Do you have the feeling you are in an unfamiliar situation and don't know what to do? 4: *very often*, 0: *very seldomly*

2. When you think about your life you very often: 4: *feel how good it is to be alive*, 0: *ask yourself why you exist at all*
3. Do you have very mixed up feelings and ideas? 4: *very often*, 0: *very seldomly*

Baseline (SOC<sup>baseline</sup>) and final (SOC<sup>final</sup>) scores were the sum of the three items at baseline and final assessment respectively; higher scores indicate greater sense of coherence. To allow a measurement of expectancy for SOC at baseline (SOC<sup>expectancy</sup>), the 3 SOC questions were repeated, and participants asked to answer indicating 'how they expected to feel at the end of the study'.

**Well-being** In addition to SOC, general well-being was included as a measure of broader improvements in psychological function. At baseline participants were asked to "Rate your general feeling of well-being during the last week". Responses were taken on a scale which ranged from: 6: *as good as it could be*, to 0: *as bad as it could be*. Participants rated where they expected to be after three weeks of treatment using the same scale. Final well-being was measured (via email) using the same scale at three weeks.

**Adherence** Adherence is associated with improvements to both true pharmacological treatments and placebos (Horwitz et al., 1990; Horwitz and Horwitz, 1993), and in this study adherence with the therapy was measured with a single item. Participants were asked to indicate which statement best applied to them: 4: *I took the flower essence regularly*, 3: *I missed doses one or two days per week*, 2: *I missed doses three or four days per week*, 1: *I missed most of the doses*, or 0: *I did not take the flower essence*.

**Email follow up** Outcome assessment emails were sent 21 days after the test session for all participants. Participants who did not reply to the follow-up were sent reminder

e-mails one week later. During the test session a small minority of participants had asked to give their replies via the telephone, and the principal investigator made these calls—instead of sending emails—on the appropriate days. The follow-up and reminder e-mails requested ratings of perceived change, the two symptoms, well-being, the three sense of coherence items, and a response to the adherence question.

**Priming task** In a task ostensibly unrelated to the main study participants were asked to circle every instance of the letter 'e' in one of two texts, designated as *spiritual* or *neutral*. No time limit was set and participants were requested to be thorough. The spiritual text was an excerpt from the Dalai Lama's essay 'Love, compassion and tolerance' (1997); the material text was an excerpt from George Orwell's 'The Moon Under Water' (1946)<sup>6</sup>

**Scale reliabilities** Internal reliability scores (Cronbach's alpha) were computed for each scale: LOT-R  $\alpha = .83$ , SCQ-48  $\alpha = .96$ , SIBS-R  $\alpha = .92$ , ACM  $\alpha = .69$ , HHB  $\alpha = .52$ , SOC  $\alpha = .60$ . In all cases, except for holistic health beliefs, reliability was good.

## Procedure

**Recruitment** Participants were recruited using advertisements posted throughout the university and at a neighbouring art college. The advertisements offered a free bottle of flower essence in return for questionnaire completion. To provide additional background information, if required, the advertisements informed participants of a commercial website on flower essences. Participants were told that the flower essences were purported to have a therapeutic effect, that this claim was controversial, and that the

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<sup>6</sup>both texts are included in the Appendix on pages 224 and 227.

researchers were investigating flower essences. Participants were not paid nor received course credit for taking part.

**The test session** On arrival at the advertised drop-in session participants gave written informed consent, and were presented with the list of 38 Bach flower essences and descriptions of the conditions for which each essence is indicated for use. Participants were told they could choose up to two essences. In addition to indicating their choice of essence, they completed the questionnaire pack (SCQ-48, SIBS-R, LOT-R, HCAMQ). Participants were then asked to provide baseline outcome ratings (symptoms, well-being, and sense of coherence), and also to provide ratings on the same scales for how they expected to feel after the flower essence treatment (these were used to calculate expectancy scores). During the period in which each participant's essence was being bottled (the solution was diluted from stock essences provided by the manufacturer) participants completed the priming task, randomized to either the spiritual or the material condition. Following the prime, participants were given their chosen essences, made by placing two drops of stock essence in a 10ml bottle of brandy (60%) and spring water (40%) solution. This is the standard procedure for administering flower essences, and no deception was involved. Participants were thanked and reminded to expect the e-mail follow-up in approximately three weeks time.

**Research ethics** The study, as described above, was approved by the University of Plymouth Human Sciences Research Ethics panel. No special permissions were required, as the study did not involve deceptive instructions (participants were informed of the essences' ingredients, and that their efficacy was controversial).

**Statistical analysis of causation** Relationships between variables of interest and a dependent variable may not be linear or orthogonal, and researchers often need to test the alternative models of causation in their data. In their influential paper, Baron and Kenny (1986) clarify two models of causation—mediation and moderation—commonly employed by social psychologists and others, and describe statistical methods to identify them.

**Mediation** When two independent variables predict variance in a dependent variable, a mediation analysis may be able to determine which of the independents is the proximal cause of changes in the dependent variable. If one independent variable A is seen to be fully or partially mediated by another mediator variable B, then it may be interpreted as a distal cause of the dependent C. In this case B is the active mechanism by which the dependent C is influenced by A. For example, if lateness in waking and throttle position in a car are correlated, and both correlate with fuel consumption, then the relationships between lateness and fuel consumption may be fully mediated by throttle position, but lateness remains a distal cause of fuel consumption. In other scenarios, A may be found to be epiphenomenal to the relationship between B and C, and considered to fall outside of the causal chain: For example, if height and weight are correlated, both may also correlate with incidence of minor head injury from low doorways. If the relationship between weight and injury were fully mediated by height, only height (and not weight) would be considered a cause of injury. Unfortunately these distinctions cannot be made statistically and must arise from a theoretical understanding of the variables in play.

Operationally, mediation is identified using three regression equations (see Figure 3.2). First, to avoid problems of multicollinearity, the independent variable must be found



to predict the dependent variable (see a); second, the mediator must be found to predict the dependent variable (see b); and third, the mediator must predict the dependent in a regression in which the dependent variable is regressed on both the independent and mediator variables (see c). Mediation is assessed as the extent to which the previously significant relationship between independent and dependent (a) is attenuated when the mediator is held constant (c). Where both the independent and the variable labelled as a mediator are significant predictors in this third regression they may be said to predict the dependent independently, and that the effect of A is *partially mediated* by B. Two important assumptions of this method of estimating mediation are that (a) the mediator is measured without error and (b) that the dependent variable not cause the mediator. More formally, the Sobel-Goodman tests may be used to establish, statistically, the degree to which mediation occurs (Preacher and Hayes, 2004). Bootstrapping (running the analysis many thousands of times using resampling with replacement) is typically used to quantify potential bias in both estimates and standard errors.

**Moderation/interaction** Where the direction and strength of the relationship between two variables is affected by the level of a third variable, this third variable may be termed a moderator, and the independent and the moderator may be said to interact (see Figure 3.3a). Operationally, where the moderator is continuous, moderation may be established by regressing the dependent variable on the independent and the moderator, along with a third variable comprising the product of the independent and the moderator:  $\hat{y} = \beta_0 + \beta_1x_1 + \beta_2x_2 + \beta_3(x_1x_2)$ . Moderation is said to occur where the product (or interaction) term,  $\beta_3$  is a significant predictor (also see Figure 3.3).

Figure 3.2: Three steps required for a mediation analysis

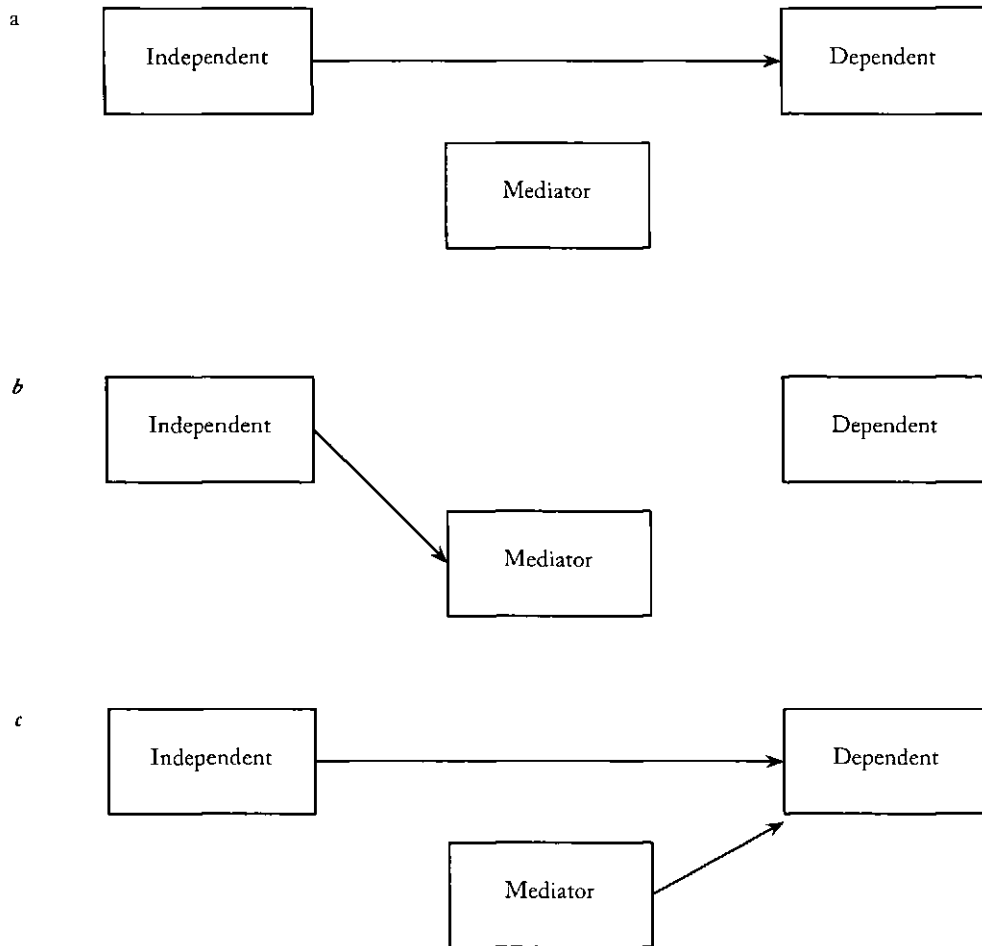
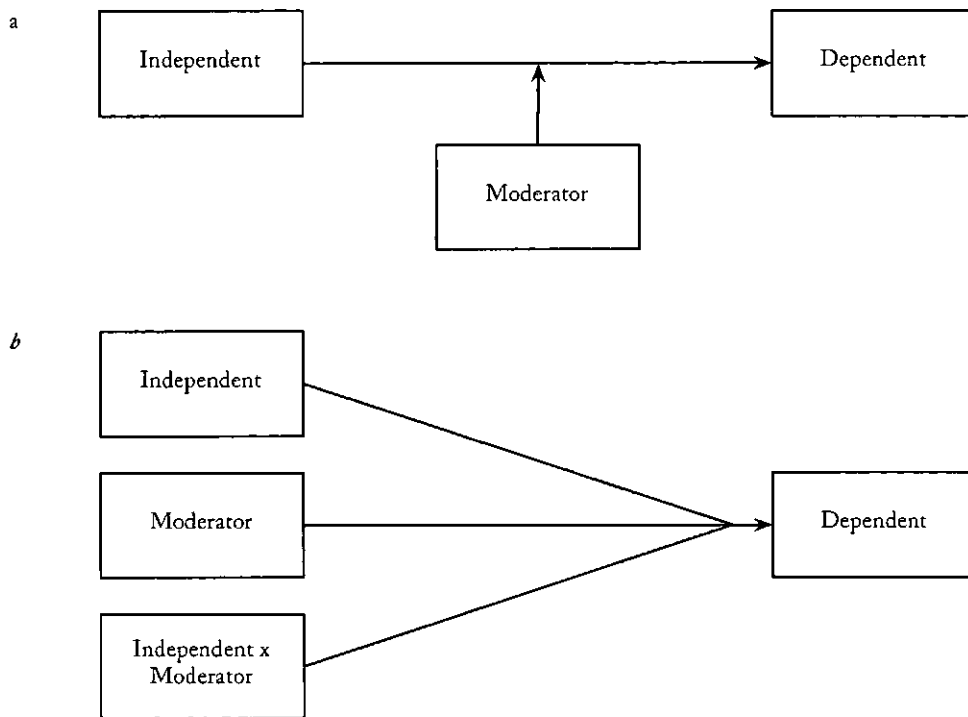


Figure 3.3: Conceptual (a) and operational (b) models of moderation



### 3.3 Results

**Sample characteristics and baseline scores** Two hundred and forty three participants from the university and art college took part in the first part of the study, of whom 167 completed follow-up assessments. One person completed the follow-up assessment but indicated that they did not take the essence (because they spilt the bottle) and was excluded from the analysis. There were no significance differences between completers and non-completers on any of the questionnaire assessments, nor the expectancy measures, nor gender or age. The following analysis is based on those 166 people who completed assessments, of whom two did not complete the ratings of expectancy<sup>perceived</sup> and expectancy<sup>soc</sup>, one did not complete an expectancy<sup>well-being</sup> rating, and one did not complete a rating of change<sup>perceived</sup> (details of the calculation of change scores is below, see page 68). There were 34 males and 132 females and mean age was 26.4 (range: 19 to 58). A series of one-way ANOVA's were performed to test for gender differences on baseline variables (all the expectancy measures, the two spirituality scales, and optimism). Women rated themselves as significantly more spiritual on both measures, SCQ-48:  $F(1, 165) = 7.06, p = .01, \eta^2 = .029$ ; and also tended to be more optimistic  $F(1, 165) = 3.63, p = .06, \eta^2 = .015$ . No other significant gender differences were found. To check that there were no baseline differences between the prime groups (spiritual/material), an additional one-way ANOVA was performed for each of the baseline measures by group. No significant differences were found between the two prime groups for any baseline variable (all  $p$ 's  $> .19$ ).

**Calculation of change scores** To facilitate the analyses below, change scores were computed for all expectancy and outcome variables except for perceived change, which

was measured with single items at baseline and followup as described above. Expectancy scores were calculated by subtracting final outcome scores from the relevant expectancy score taken at baseline, and these variables are denoted  $\text{expectancy}^{[\text{variable}]}$ . Change scores were calculated by subtracting final scores from the relevant baseline scores, and these variables are denoted  $\text{change}^{[\text{variable}]}$ . Raw baseline and follow-up scores are denoted  $\text{Baseline}^{[\text{variable}]}$  and  $\text{Final}^{[\text{variable}]}$  respectively.

### The therapy

**Did participants expect flower essence therapy to work?** Participants had volunteered for a study for which there was a suggestion that flower essences would be beneficial, and for which they received neither money nor course credit; it was therefore reasonable to expect that participants would have positive expectancies for flower essence treatment. Table 3.1 presents descriptive statistics for all expectancy measures, outcome measures at baseline, outcome change scores, and dispositional predictors of outcome.

Figure 3.5 shows the frequency of participants expecting improvement, no change, or deterioration, for each of the expectancy measures at baseline. For all outcomes, most participants expected the essences would be effective, although there was sufficient variation within the population to test the effect of expectancy on outcome.

**Was flower essence therapy effective?** Consistent with other studies of flower essences without placebo control groups, the remedy was effective for the majority of participants on each of the four outcome measures (see Figure 3.6). More than 50% of participants had improved scores for  $\text{change}^{\text{perceived}}$  and  $\text{change}^{\text{well-being}}$ , 63% had improved SOC scores, and over 80% experienced a reduction in symptoms. Although there was no control group for comparison—and change may therefore be due to natural history—it

Table 3.1: Descriptive statistics for Baseline, change and personality measurements

	<i>n</i>	mean	$\sigma$	min.	max
Expectancy <sup>perceived</sup>	236	4.8	1.8	1.0	8.0
Expectancy <sup>symptom</sup>	240	1.5	1.1	-2.0	5.0
Expectancy <sup>soc</sup>	235	1.9	1.8	-1.0	8.0
Expectancy <sup>wellbeing</sup>	235	1.0	1.3	-2.0	5.0
Baseline <sup>symptoms</sup>	240	4.1	0.97	0.5	6.0
Baseline <sup>soc</sup>	240	2.9	0.77	1.0	4.7
Baseline <sup>well-being</sup>	240	3.9	1.4	1.0	7.0
Final <sup>symptoms</sup>	168	2.8	1.1	0.0	5.5
Final <sup>soc</sup>	168	3.3	0.76	1.3	5.0
Final <sup>well-being</sup>	168	4.5	1.4	1.0	7.0
Change <sup>perceived</sup>	167	4.7	0.94	1.0	7.0
Change <sup>symptom</sup>	166	2.7	2.4	-3.0	11.0
Change <sup>soc</sup>	167	0.4	0.77	-1.7	3.0
Change <sup>well-being</sup>	167	0.6	1.7	-4.0	5.0
SCQ-48 <sup>a</sup>	233	225.0	49.0	87.0	328.0
ACM <sup>b</sup>	239	0.3	0.76	-1.8	2.3
HHB <sup>c</sup>	238	1.8	0.48	0.1	2.5
LOT-R <sup>d</sup>	239	15.0	5.0	6.0	30.0
Adherence	167	2.9	0.93	1.0	4.0

Note: some participants did not complete all of the baseline or follow up measures and *N*'s vary accordingly.

<sup>a</sup> Spirituality; <sup>b</sup> Attitude to CAM and <sup>c</sup> Holistic Health Beliefs sub-scales of HCAMQ; <sup>d</sup> Optimism.

Figure 3.4: Adherence scores (percent)

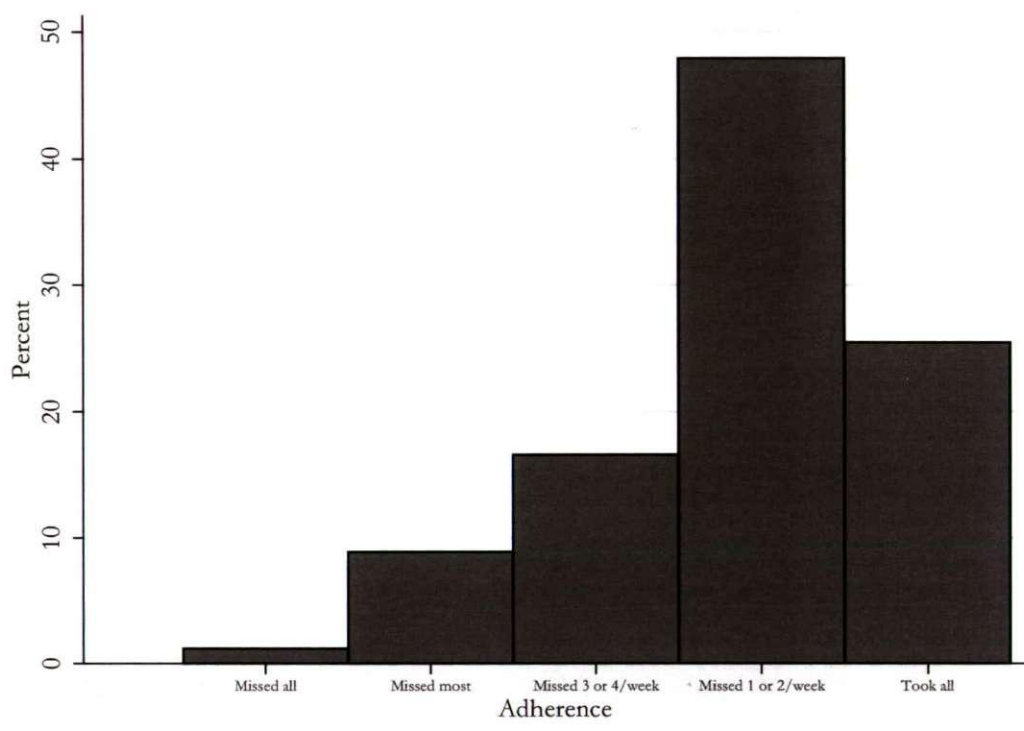


Figure 3.5: Categorized scores for expectancy (percent)

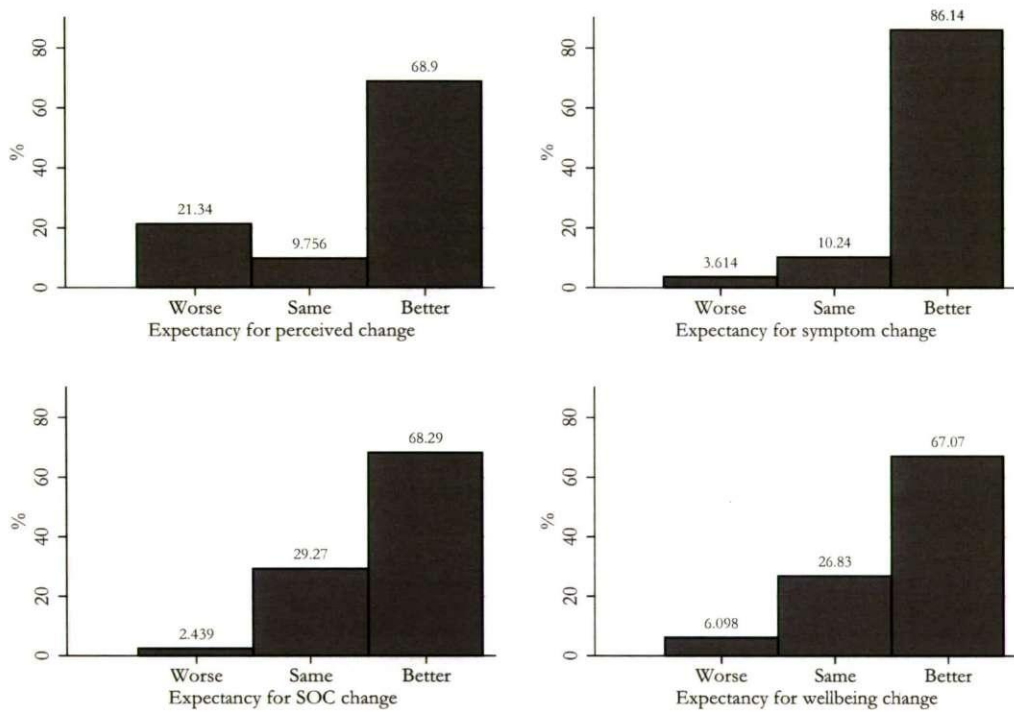
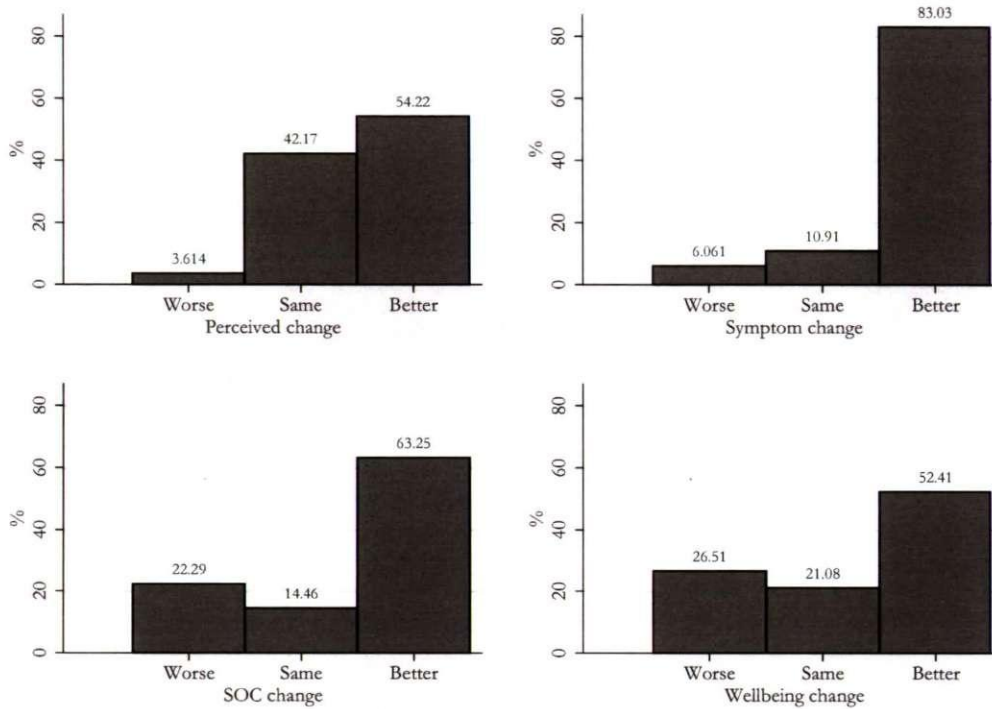




Figure 3.6: Categorized scores for outcome (percent)



is clear from these results why participants may *experience* flower essences and other complementary therapies as effective.

#### Hypothesis 1: Did spirituality predict improved response to flower essence therapy?

Correlations were computed between baseline measures of expectancy, values and attitudes, and with the four outcome measures (Change<sup>perceived</sup>, change<sup>symptom</sup>, change<sup>soc</sup>, and change<sup>well-being</sup>). These correlations are displayed in Table 3.3. Spirituality (both the SCQ-48 and the SIBS-R) correlated with perceived change, although not with change in symptoms, SOC or well-being. As predicted, the SCQ-48 was slightly more sensitive when predicting change than the SIBS-R ( $r = .25$  vs.  $.19$ ). Expectancy mea-

Table 3.2: Correlations between baseline scores and follow up scores and dispositional variables

	Baseline scores			Final scores		
	<i>symptoms</i>	<i>soc</i>	<i>well-being</i>	<i>symptoms</i>	<i>soc</i>	<i>well-being</i>
SCQ-48 <sup>a</sup>	0.07	0.06	-0.01	-0.08	0.04	0.07
SIBS-R <sup>a</sup>	-0.02	0.15	0.04	-0.11	0.16*	0.12
ACM <sup>b</sup>	-0.24**	0.01	0.02	0.06	-0.07	-0.03
HHB <sup>c</sup>	-0.09	-0.02	0.03	-0.08	0.09	0.05
LOT-R <sup>d</sup>	0.20*	-0.53**	-0.37**	0.12	-0.33**	-0.22**

\* $p < .05$ ; \*\* $p < .01$ ; <sup>a-b</sup> Spirituality; <sup>b</sup> Attitude to CAM and <sup>c</sup> Holistic Health Beliefs sub-scales of HCAMQ; <sup>d</sup> Optimism.

sures predicted change on both matched outcome measures (e.g. expectancy<sup>perceived</sup> — change<sup>perceived</sup>), and also predicted change on other outcome measures (e.g. expectancy<sup>perceived</sup> — change<sup>symptom</sup>).

Table 3.3: Correlations between outcome measures and predictors

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.
1. Change <sup>perceived</sup>	1.00											
2. Change <sup>symptom</sup>	0.33**	1.00										
3. Change <sup>soc</sup>	0.14	0.33**	1.00									
4. Change <sup>well-being</sup>	0.21**	0.45**	0.33**	1.00								
5. Expectancy <sup>perceived</sup>	0.22**	0.23**	0.06	0.05	1.00							
6. Expectancy <sup>symptom</sup>	0.15	0.36**	0.17*	0.13	0.31**	1.00						
7. Expectancy <sup>soc</sup>	0.30**	0.27**	0.35**	0.20*	0.31**	0.39**	1.00					
8. Expectancy <sup>well-being</sup>	0.16*	0.17*	0.22**	0.45**	0.18**	0.44**	0.34**	1.00				
9. SCQ-48 <sup>a</sup>	0.25**	0.12	-0.03	0.06	0.34**	0.19**	0.17*	0.08	1.00			
10. SIBS-R <sup>a</sup>	0.19*	0.07	0.00	0.07	0.21**	0.03	0.07	0.00	0.78**	1.00		
11. ACM <sup>b</sup>	-0.20**	-0.24**	-0.08	-0.04	-0.30**	-0.23**	-0.20**	-0.06	-0.37**	-0.25**	1.00	
12. HHB <sup>c</sup>	0.00	-0.02	0.11	0.02	-0.14*	-0.12	-0.03	0.04	-0.28**	-0.26**	0.14*	1.00
13. LOT-R <sup>d</sup>	0.01	0.05	0.20**	0.11	-0.21**	0.05	0.15*	0.08	-0.28**	-0.35**	0.14*	0.15*

\* $p < .05$ ; \*\* $p < .01$ <sup>a</sup> Spirituality; <sup>b</sup> Attitude to CAM and <sup>c</sup> Holistic Health Beliefs sub-scales of HCAMQ; <sup>d</sup> Optimism.

**Was the relationship due to correlations with baseline scores?** One possible explanation for the correlations between change and the dispositional and expectancy variables is that these variables are correlated with baseline scores. If this were the case, then the relationship with change scores might be due to correlations between dispositions and symptom reporting, rather than with real changes.

Table 3.2 shows the correlations between personality measures and raw baseline and follow-up scores. Optimism correlated with all baseline outcome measures and many final outcome measures, and this is consistent with a reporting bias mediated via negative affect (LOT-R is known to correlate with neuroticism, Smith et al., 1989). However, of the other variables, only attitudes to complementary medicine predicted any of the baseline scores (symptoms), indicating that the correlations between dispositional measures and change were not simply due to symptom reporting.

**Was adherence associated with better outcomes?** Descriptive statistics for adherence are presented in Table 3.1 and Figure 3.4. Adherence was not associated with better outcomes for the single-item measure of perceived change,  $r(165) = .11$ , ns. For variables with baseline and follow-up scores (Symptoms, SOC and Wellbeing), regression analysis was performed predicting the follow-up score from adherence, while controlling for baseline score. Adherence did predict changes in sense of coherence,  $\beta = .19$ ,  $p < .001$ ; but was not associated with changes in symptoms,  $\beta = -.09$ , ns, or wellbeing  $\beta = .03$ , ns.

**Hypothesis 2: Was the prediction of outcome (from spirituality) independent from expectancy?** To establish that spirituality predicts variance in outcome independently from expectancy three steps are required. First, spirituality must be correlated with

Table 3.4: Standardised regression weights from multiple regression models testing mediation hypothesis: dependent variable is Change<sup>perceived</sup>

Model	1	2	3	4	5
Spirituality	0.21*	0.18*	0.16	0.18*	0.23*
Expectancy <sup>perceived</sup>	0.12				
Expectancy <sup>combined</sup>		0.22**	0.22**	0.23**	
Attitudes to CAM			-0.09		
Holistic Health Beliefs			0.09		
Spirituality × Ex. <sup>combined</sup>				-0.05	
SpiritualPrime					-0.10
Spirituality × SpiritualPrime					0.04
Model $R^{2adj.}$	0.08	0.11	0.13	0.11	0.08

\* $p < .05$ ; \*\* $p < .01$ ; Variables in each model were entered as a single block.

outcome; as shown in Table 3.3, both measures of spirituality (the SCQ-48 and the SIBS-R) were correlated with change<sup>perceived</sup>, although not with change on other outcome variables. Because the correlation with outcome was higher for the SCQ-48 than for the SIBS-R this measure was used in the analyses which follow. Second, expectancy must be correlated with outcome; again, Table 3.3 indicates that is the case. Finally, spirituality must remain a significant predictor of outcome while expectancy is held constant. To this end change<sup>perceived</sup> was regressed on expectancy<sup>perceived</sup> and SCQ-48; results are presented as Model 1 of Table 3.4. Controlling for expectancy, spirituality was still a significant predictor of variance in outcome.

Two additional multiple regressions were performed to provide a more conservative test of the independence of spirituality by including additional measures of expectancy. First, all four expectancy measures were combined (expectancy<sup>perceived</sup>, expectancy<sup>symptom</sup>, expectancy<sup>soc</sup>, expectancy<sup>well-being</sup>) to form a composite measure: expectancy<sup>combined</sup>. Reliability for the four items was good:  $\alpha = .65$ . A second regression model was computed replacing the expectancy<sup>perceived</sup> with expectancy<sup>combined</sup>, and results are shown

in Table 3.4, Model 2. Because the models were not nested, a J-test (Davidson and MacKinnon, 1981) was used in place of the normal  $F$ -test for change in  $R^2$ . This confirmed that Model 2 was a significant improvement on Model 1,  $t(155) = 2.23$ ,  $p = .03$ . Even when this combined and thus more reliable measure of expectancy was included, spirituality remained a significant independent predictor of outcome. A Sobel test was performed for Model 2 (Preacher and Hayes, 2004). Mediation was significant ( $p = .02$ ) but partial, with only 30% of the total effect of spirituality on outcome mediated via expectancy.

Next, the ACM and HHB sub-scales of the HCAMQ were added to Model 2. The results of this combined model is shown in Table 3.4, Model 3. However, Model 3 was not a significant improvement on Model 2,  $\Delta R^2 = .015$ ,  $F(2, 153) = 1.159$ ,  $p = .32$ , indicating that these measures did not explain significant additional variance in outcomes. When these additional measures were included, spirituality narrowly missed significance as a predictor of outcome ( $p = .06$ ).

An additional multiple regression (see Table 3.4, Model 4) was computed to test for an interaction between spirituality and expectancy when predicting perceived change. Scores on the SCQ-48 and for expectancy<sup>combined</sup> were centred, and the product term calculated. The two centred scores and the interaction term were entered in a model predicting perceived change but no evidence for an interaction was found.

In sum, the effect of spirituality on perceived change is independent of expectancy and related variables, and spirituality does not interact with expectancy.

**Hypothesis 3: Did goal priming have an effect?** In assessing the impact of the prime, two related questions were asked: first, did the prime create differences in mean outcome scores, and second, did the pattern of correlations between dispositional variables and

Table 3.5: Mean differences (and F test) between outcome measures by priming condition

	<i>N</i>	Mean	$\sigma$	<i>F</i>	<i>p</i>
<i>Change<sup>perceived</sup></i>					
Neutral prime	84	4.67	0.88	0.01	.93
Spiritual prime	81	4.68	1.01		
<i>Change<sup>symptom</sup></i>					
Neutral prime	84	2.83	2.33	0.61	.44
Spiritual prime	81	2.54	2.45		
<i>Change<sup>soc</sup></i>					
Neutral prime	84	0.47	0.76	0.61	.44
Spiritual prime	82	0.38	0.79		
<i>Change<sup>well-being</sup></i>					
Neutral prime	84	0.74	1.76	1.65	.20
Spiritual prime	82	0.39	1.73		

outcome measures differ between the two prime groups?

**Did priming affect mean outcomes?** To test whether the priming task affected mean outcome scores we computed 4 one-way analyses of variance (see Table 3.5). Prime condition was not associated with mean differences for any of the outcome measures, indicating that—at a group level—the primes did not differ in effectiveness.

**Did the prime moderate relationships with dispositional variables?** Although the primes were not found to be different in terms of their effect on outcome, the possibility remained that spiritual participants may have gained additional benefit from the spiritual prime, or that non-spiritual participants benefited from the material prime. To test for this moderation effect, a multiple regression analysis was performed. In this analysis *change<sup>perceived</sup>* was regressed onto scores for spirituality, and a dummy variable for membership of the spiritual group, *SpiritualPrime* (coded 0/1). Results are shown

in Table 3.4, Model 5: there was no evidence of an interaction between group and spirituality.

**Hypothesis 4: Did optimism predict outcomes?** Correlations between optimism (LOT-R) and the Change, expectancy and dispositional variables are shown in Table 3.3. Optimism did not correlate with any of the change measures, apart from  $\text{change}^{\text{soc}}$ . However, when examined further, this relationship appears to be due to a strong correlation between optimism and sense of coherence at baseline,  $r(166) = -.53$ ,  $p < .001$ . To test whether this was the case,  $\text{SOC}^{\text{final}}$  was regressed on  $\text{SOC}^{\text{baseline}}$  and optimism.  $\text{SOC}^{\text{baseline}}$  was a significant predictor of  $\text{SOC}^{\text{final}}$ ,  $\beta = .44$ ,  $p < .001$ ; however optimism did not predict when controlling for baseline scores,  $\beta = -.09$ , ns.

**Did flower essences provide broader therapeutic benefits?** Although a definitive answer to this question would require a natural history control group, results suggest that, participants experience benefit on all outcome measures and not just for perceived changes in symptoms, or change scores based on symptom reports. Figure 3.6 shows frequencies of participants reporting change on each outcome measure; changes on SOC and well-being are comparable with the changes in symptoms, and fit the same pattern as that of  $\text{change}^{\text{perceived}}$ .

### 3.4 Discussion

These data replicate an earlier finding (Hyland et al., 2006) that spirituality predicts perceived change in symptoms following flower essence treatment. Using a new spirituality scale with equal number of positive and negative items (the SCQ-48) makes it less likely that this correlation is due to an acquiescence bias, or to social desirability



(the SCQ-48 is unrelated to social desirability; Wheeler and Hyland, 2008). Although positive expectancies for change were induced, there was no evidence for the relationship between optimism and improved outcomes reported by Geers et al. (2003). Optimism failed to predict change—though it did predict baseline symptoms and other variables. These baseline correlations are to be expected as the LOT-R is highly correlated with trait neuroticism (Deci and Ryan, 1985), and trait affectivity affects symptom reporting (Davis et al., 1995).

Consistent with practitioner reports, sense of coherence and reports of well-being increased during the flower essence treatment, and symptoms were reduced. However these changes—unlike retrospective perceptions of Change—were unrelated to spirituality. There are several possible reasons for the failure to find a correlation with spirituality. One important factor is that the use of ‘pre-post’ measures (as opposed to retrospective measurements of perceived change) doubles the error variance associated with outcome scores. Because the correlations involved are relatively small such a reduction in signal-to-noise ratio may attenuate them beyond detection. In a study designed to compare repeated and retrospective measurements of clinical outcome Fischer et al (1999) found that where effects were large then retrospective and serial (repeated) measurements correlate satisfactorily with change scores, but that when effects are smaller the two measures correlate poorly. The authors draw no firm conclusions as to the independence of the two measurements, but it appears likely that multiplication of error in repeated measurements explains the pattern of results. In both cases (large and small effects), retrospective measures were more sensitive to change, and correlated more strongly with both patient satisfaction and physical and biological indicators than did serial (change score) measures; the authors recommend the inclusion of perceived change measures whenever the results are to be applied in clinical practice. In this study, perceived change

scores did correlate with change scores from repeated measurements for symptoms and well-being, although the correlation with SOC change scores was weaker (see Table 3.3).

The mediation analysis above (see page 76) included multiple measures of expectancy, as well as measures likely to be correlated with higher expectancies (e.g. more holistic health beliefs), and so provided a relatively conservative test of the relationship between dispositional spirituality and outcome. This is important because, as Baron and Kenny (1986) note, error in the measurement of mediating variables will lead to underestimates of mediation. Expectancy was only a partial mediator of the effect of spirituality and, even when a more reliable measure of expectancy was included (see Table 3.4 Model 2) spirituality remained a significant predictor. When the measurements of attitudes to complementary medicine and holistic health beliefs were included, spirituality marginally missed significance ( $p = .06$ ), but the inclusion of these variables did not improve the overall model ( $\Delta R^2 = .02$ ), and should therefore be interpreted with caution.

**Shortcomings** First, the study did not include an untreated control group. However, it is unlikely that the correlations with ritual-congruent dimensions would have occurred as part of regression to the mean or natural history because the prediction from disposition to outcome was specific to the type of therapy (i.e. spirituality, or gratitude in Study 2 of Hyland et al. 2007). Natural variation and regression must occur, but this variation will reduce the size of correlations between outcome and predictors and does not pose a threat to the validity of this study.

Second, correlations with dispositions were only found for perceived change, and not for before/after measures. As noted, this may be due to additional error variance

in before-after measures. However, although they are correlated, perceived change and symptom change measures may index different components of variation in outcomes; it may be that perceived change is more sensitive to motivational effects (i.e. benefits of performing a congruent ritual) because it is more dependent on state-affect.

Third, it is not clear how the disposition of spirituality improves outcomes for flower essence therapy. A motivational explanation for this link is proposed in the following chapter, but alternative possibilities include a greater focusing on positive symptoms; a tendency to ignore a failure to benefit; or greater positivity, which translates into therapeutic benefit. Because correlations were only found between spirituality and change<sup>perceived</sup>, and not for other outcome measures, the possibility remains that the effect is only on symptom perception rather than a genuine reduction in symptoms (although see discussion later, on page 196).

An additional weakness was the homogeneity of the sample, and the heterogeneity of psychological and physical problems for which they took flower essences. Recruits were primarily female students and staff from the University of Plymouth who self-selected for a complementary therapy. Although this was not a clinical sample in the sense that participants met the criteria for a particular physical or psychological disorder, and a great variety of symptoms were reported, qualitative feedback from participants indicated that these symptoms caused significant distress in a large number of cases.

## Conclusion

This study replicates earlier work (Hyland et al., 2006, 2007) demonstrating dispositional predictions of particular types of placebo—namely, that dispositional spirituality predicts response to Bach remedies, a spiritually-contextualised complementary therapy.

## Chapter 4

# The motivational concordance hypothesis

Evidence from Chapters 2 and 3, and from Hyland et al. 2006 and Hyland et al. 2007, suggests that placebo responding appears to be a good exemplar of the person–situation paradox: Responses of individuals are temporally reliable but vary according to situational features. A psychological explanation of placebo effects must account for this variation, and for the correlations found between enduring characteristics of people (e.g. trait spirituality) and responses to particular types of placebo (e.g. Bach remedies). The motivational concordance hypothesis, presented below, derives from established theories of personality and motivation. It is proposed that placebo rituals that encourage people to perform self-actualising behaviours will yield therapeutic benefits. The basis of the theory is described, along with several predictions to be tested.

## 4.1 Variance and invariance in people

The goal of the personality psychologist is to identify and understand the ‘structure’ of the person – the regularities that shape behaviours in consistent, predictable ways across disparate situations (and also to know when consistency will not be observed).

**Comparative structures: Traits in personality psychology** A dominant heuristic within personality psychology has been to use factor analytic methods to find reliable inter-individual differences in response to scale items, and to label the factors which emerge as abstract traits of people. This approach has been remarkably successful and there exists noteworthy agreement between many researchers over many years, who have often tackled the same questions from different perspectives, that there are approximately 5 such abstract traits to be recovered from this type of data (Digman, 1990).

However, the statistical consensus around ‘big five’ factor models has obscured a terminological and theoretical confusion. Early in the history of personality psychology calls were made to go beyond simply to *describing* traits, and instead to *explain* the causes of behaviour—for example, to understand *why* an individual is conscientious as well as noting that they are tidy (Allport and Allport, 1921). However big-five style personality psychology fails to fulfil the requirements of a ‘dynamic psychology’ of this kind (Allport, 1937). Factor analysis identifies statistically reliable patterns of response but does not explain how either regularities, nor exceptions to regularity, come to be. Reliably identifying variables which describe the structure of inter-individual differences

does not logically support the conclusion that we are identifying structures *within* the individual. Cervone writes:

A Linnaean taxonomy differentiates plants from animals; vertebrate animals from invertebrates; mammals from reptiles, etc. But when one gets down to individual cases, one will not find that the classificatory variables exist as unitary entities within the individual, such that they may combine intra-individually. There won't be any synergistic admixture of vertebrateness, mammalness, and primateness in Harre's chimp. (Cervone, 2005, p. 427)

This critique is not new, and has been made repeatedly over the past 70 years (e.g. Allport, 1937; Epstein, 1994; Cervone, 2005). In essence, a distinction is made between abstract traits which describe the data, and hypothetical constructs which both explain existing data and make new predictions (MacCorquodale and Meehl, 1948), what Lewin termed an Aristotelian as opposed to a Galilean explanatory strategy. Behaviour is explained with reference to the essential nature of the object, rather than via dynamic interactions of object and environment (Lewin, 1935). In a charming analogy, Epstein describes the process by which a researcher might use factor analysis to develop this kind of top down theory:

Once upon a time, there was a psychologist, Sam, who decided to study cars rather than people ...because they are more controllable and easier to understand than people. ...Sam set about establishing the fundamental attributes of cars. With the aid of factor analysis, he uncovered five orthogonal attributes—color, type, size, maximum speed, and robustness (as operationally determined by service record) ... One day his car broke down. Unfortunately, he hadn't the foggiest idea of what to do about it. He knew

nothing about how the car functioned ... What he had ... was all kinds of research findings about how the basic attributes of his car correlated with breakdown ... Robustness was obviously a relevant variable, and, to be sure, it predicted future breakdowns better than chance. So now he understood why his car had broken down—it was low on robustness. However, his car, not sharing his enthusiasm over this insight, budged not an inch. (Epstein, 1994, p. 120-1)

Thus the failure to adequately link *structural variables* (Openness, Neuroticism etc.) to *psychological processes* is regarded as a failure of the overall theoretical approach. This absence of explanatory (as opposed to descriptive) power is presumed to explain the oft-reported lack of cross-situational stability in the prediction of behaviour from trait (Mischel, 1968), and if big five type traits do not map onto fundamental processes involved in placebo responses, then no reliable trait predictor for placebo responding may ever be found.

**Explanatory structures: Values and goals** Like traits, the overlapping motivational constructs of goals and values (and antecedent concepts such as learned needs, Murray, 1938), are conceived as enduring psychological structures that can organise perception and guide behaviour over long periods. Crucially however, goals are defined as internal representations of desired states and the relation of goals to behaviour is therefore less problematic. Many theories specify how goals may be arranged hierarchically, perhaps as a form of control system in which error (the disparity between actual and desired states) is minimised (e.g. Hyland, 1988). At the highest level of such a hierarchy goals may appear to share many characteristics of traits: high level goals may endure over long periods and coordinate information processing and behaviour across many domains (Rohan, 2000).

Although attempts to create taxonomies of goals are relatively tentative (Austin and Vancouver, 1996; Chulef et al., 2001), the relationships between motivation, affect and behaviour have been extensively researched, and motivational theories of goal striving and affect may help to link these structural concepts to behavioural outcomes—in the case of the present paper, to link motivational dispositions of individuals, such as spirituality, with placebo responses in specified contexts.

**Relation of values to goals** As Rohan notes, definitions of values vary (2000). However authors tend to conceptualise values as either goals in themselves (Schwartz, 1994; Rokeach, 1973), or as constructs required for the evaluation of other goals (Feather, 1996; Lewin, 1952). Some authors have attempted to distinguish values from goals by noting that they are trans-situational (Roccas et al., 2002), but it is not difficult to think of goals which may apply in many situations (e.g. the goal to save money). For the purposes of the discussion which follows this distinction appears relatively unimportant. If a person *values* spirituality, and as a consequence positively evaluates spiritually-oriented goals (and sub-goals corresponding to ‘spiritual behaviours’), this is functionally equivalent to describing spirituality as a goal in itself. As Rokeach argues: “terminal values [desired end states] are motivating because they represent the supergoals beyond immediate, biologically urgent goals” (Rokeach, 1973, p. 14). Such supergoals are distinguished from everyday goals, at least in part, by their stability: ‘supergoals do not seem to be periodic in nature; neither do they seem to satiate—we seem to be forever doomed to strive for these ultimate goals without ever quite reaching them’. Where goals are temporally stable in this way, it may be useful to say that a person has a *disposition* toward that motive.



**Spirituality as a high level goal (or disposition)** With reference to the preceding discussion it is clear that spirituality may be considered from the perspective of both traditional personality psychology (as a *trait*, in the five-factor sense of stable inter-individual differences in behaviour), or from the perspective of motivation theory (as a *goal*, a hypothetical construct used to explain the intra-individual structures which give rise to consistent behaviours over time). The perspective one adopts will be indicated by the instrument used to measure the construct. Personality psychologists concerned with traits would use measures of spirituality which primarily index *behaviours* assumed to be spiritual in nature. In contrast, psychologists concerned with motivation will adopt measures which largely ignore behaviour, and instead focus on the value respondents attach to spiritual events and spiritual meaning. In practice, little or no evidence has been found for spirituality as a *trait*, but spirituality is included in many reliable and cross-culturally validated models of *values* (e.g. Schwartz, 1992).

Existing spirituality scales, such as the SIBS-R, have tended to mix these two types of items. In contrast, when developing the SCQ, Hyland and Wheeler (2008) explicitly excluded items related to spiritual behaviour or practice. As such, the measure is intended to index the *value* respondents place on spirituality, and thus the extent to which spirituality may be considered a goal for that person.

## 4.2 A motivational explanation of real world placebos

How do placebos work in real life contexts? The data presented in Chapter 3 and other similar studies (Hyland et al. 2006 and Hyland et al. 2007, study 2), suggest that there may be more than one mechanism involved: The first is the well-established mechanism of response-expectancy (Kirsch, 1985b, 1997). Expectancy is regarded as

the primary psychological mechanism responsible for placebo effects (Stewart-Williams and Podd, 2004) and there is considerable empirical support for the role of response-expectancies in generating placebo responses. Indeed, in the two flower essence studies described above and the gratitude therapy study in Hyland et al. 2007, there is evidence that participants who expect to get better do, in fact, experience an improvement in symptoms. However, expectancies explained less of the variation in outcome in these studies than is typical in laboratory studies of placebo analgesia: correlations for expectancy were all lower than .25, compared with correlations in excess of .5 in a recent laboratory study (Whalley et al., 2008). In all three studies, dispositional predictors of outcome (i.e. motivational measures) remained significant even when more stringent tests of statistical independence were applied. In short, although spirituality and expectancy are correlated, expectancy does not appear to mediate the effect of spirituality on outcomes, and does not explain as much variance in outcomes as researchers might anticipate or desire.

It is proposed here that, in addition to response-expectancy, a second mechanism of placebo action is responsible for a proportion of the variance in outcomes for real-world placebos: that of *motivational concordance*. The motivational concordance hypothesis draws on established theories of motivation, and makes some specific predictions regarding the circumstances in which therapeutic benefits that are not attributable to response expectancy will be observed.

#### 4.2.1 Motivation and placebo effects

Motivation is an extremely broad psychological concept and in a straightforward sense—that of the ‘desire for benefit’—has previously been invoked to explain some placebo effects.

However motivational concordance is based on a broader conception of the motivational dynamics of placebo therapies, and the links between goal striving and affect.

**Health striving** In a simple sense, some theories relate the magnitude of placebo effects to the desire on the part of the patient to experience benefit. This may be characterised as a *health striving* hypothesis: patients who are motivated to get better are likely to improve, whereas unmotivated patients may not improve. Examples include situations where patients receive secondary benefits from an illness and are thus motivated to experience symptoms and delay recovery (Parsons, 1964). There is some experimental evidence that motivation, in this straightforward sense does influence placebo responding. Totman (1975) found that participants paid to participate in an experiment in which they received a placebo analgesic were less likely to experience placebo analgesia than participants who were not paid. Totman interpreted this finding as consistent with cognitive dissonance theory (Festinger, 1957): Unpaid participants had a greater motivation to experience analgesia to justify the discomfort of participating in the study, and in turn experienced greater pain relief. However no direct check was made that this manipulation (payment) did in fact increase motivation to experience analgesia. Jensen and Karoly (1991) directly manipulated both motivation and expectancy. They found that motivation did enhance responses to a placebo sedative and that this was independent of the manipulation of expectancy. It is possible that participants in flower-essence studies, who are given a choice regarding the remedy they use, have an investment in their choice and thus experience a form of cognitive dissonance favouring larger placebo effects.

In a separate series of studies Geers et al. (2005b) found that participants who were primed with the goal for 'co-operation' experienced larger placebo effects (e.g. improved sleep in response to a positive psychology-type manipulation). This state-like

concept—of the current level of desire to experience benefit—is also predominant in the psychotherapeutic literature. Termed *treatment motivation*, it is often operationalised as the degree of willingness to initiate or engage fully with treatment activities (Drieschner, 2004).

**Goal achievement and affect** However, from the perspective of social-cognitive theories of motivation, motivation-related benefits of treatments need not be limited to goals corresponding to engagement with and maintenance of therapy. Frijda (1988) notes, in defining his emotional ‘law of concern’, that “Emotions arise in response to events that are important to the individual’s goals, motives, or concerns” (p 351). This idea—that emotions are *necessarily* linked to the appraisal of goals—is widely shared (e.g. Stein et al., 1993; Kuhl, 2000; Carver and Scheier, 1990). Completing (Srull and Wyer, 1986), progressing towards (Carver and Scheier, 1990), or anticipating the completion of (Bandura, 1989) goal-directed tasks, may generate emotionally-positive experiences. Performing goal directed activities may, in itself, be experienced as pleasurable (Csíkszentmihályi, 1990), and cross-sectional studies that estimate the congruence between (i) a person’s self-reported motives and (ii) implicit measures of motivation or values, find that congruence is related to subjective well-being and positive emotional experiences (Sheldon and Kasser, 1995; Hofer and Chasiotis, 2003; Hofer et al., 2006). Activities that are consistent with important or self-defining goals are both more likely to motivate behaviour and more likely to result in subjective well-being or positive affect (Emmons, 1991; Sheldon and Elliot, 1999; Sheldon and Kasser, 1995; Oishi et al., 1999). Additionally, motive-congruence has been found to mediate the development of psychosomatic complaints in a clinical population (Baumann et al., 2005).

In sum, where engaging in a therapy may be construed as a meaningful activity that

is consistent with higher level goals, then both theory and evidence suggest that positive emotions and subjective well-being will result. This, in turn, might be responsible for the non-expectancy-mediated benefits of 'real world' placebos, *if these placebos are meaningful for participants.*

**Treatments may include self-actualising behaviour** As noted above, the majority of basic placebo research is performed in a laboratory setting and uses placebos which purport to be conventional medical interventions (e.g. analgesic creams), but this paradigm lacks ecological validity in a number of important ways: studies may use double blind rather than 'deceptive' or unambiguous instructions, as would be the case in clinical settings (Kirsch and Weixel, 1988); trials are often of very short duration; and sample populations are commonly drawn from undergraduate psychology courses and, as a result, are relatively homogenous.

In addition, the placebos used in experimental research may lack context, and may not be particularly meaningful for participants. Names of therapeutic agents are often invented (e.g. Montgomery and Kirsch, 1997), and even in clinical trials, where the name of the active agent is known, participants may need to rely on the information provided by researchers to set their expectations for benefit and for side effects. Thus, participants may have some (often limited) *information* about the placebo they receive, but placebos are not *meaningful* in the sense that they refer to important attributes of the self or culture. This forms a sharp contrast with placebos as they are commonly used. Placebo effects have a rich and vibrant life outside of the laboratory—both the forms in which placebos are administered and the meaning they hold for patients can vary widely. Motivational characteristics of real-world placebos are also very different from those used in the lab. When placebos are used in real life settings, patients are likely to have a genuine and

strong desire for treatment to be effective. Use of placebos (in the form of CAM therapies) also implies a concern with health and well-being—placebos are explicitly disallowed within conventional medical settings and so patients must have made additional efforts to acquire them.

**Complementary therapies are meaningful for patients** As discussed in Chapter 1, many complementary and alternative medicines (CAM) are regarded by conventional medical researchers as ‘no better than a placebo’ (Singh and Ernst, 2008, <sup>1</sup>). The controversy over particular techniques such as homeopathy and acupuncture can be fierce (e.g. Shang et al. 2005, and their reply to strong criticism from practitioners: Shang et al. 2006), but it appears likely that, even if so-called specific effects are found for most CAM therapies, they will be small in comparison to the non-specific or psychologically mediated components of treatment effects. The prospects for demonstrating efficacy for the Bach remedies used in Chapters 3, 5 and 6 appear particularly poor (Armstrong and Ernst, 2001; Ernst, 2002).

Despite a lack of clearly-demonstrated efficacy CAM therapies are extremely popular (see 1.5.1, page 23). This growth is, in part, attributed to the richness of the context associated with these remedies. In the sociological jargon, CAM treatments are situated within a broader discourse that encompasses an assertion of alternative politics, environmental activism, and a ‘post-Fordist’ rejection of scientific materialism (Bakx, 1991). More prosaically, studies of attitudes among CAM users have indicated that the “patient-practitioner relationship and explanatory frameworks provided by CAM [are] perceived as important components of the therapeutic process, irrespective of treatment efficacy” (Cartwright and Torr, 2005, p. 559). Therapies must ‘feel right’ as well as

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<sup>1</sup>Although note that a psychologist may regard them as ‘every bit as good as a placebo’

working effectively, and normal evidential standards are often dismissed by proponents of CAM therapies as irrelevant or unhelpful in the evaluation of CAM therapies (e.g. Walach 2005; Walach et al. 2006<sup>2</sup>). In this context treatments, both conventional and unorthodox, may be seen as constituting rituals which have the potential to facilitate self-actualisation—at least amongst patients for whom the motivational press of the ritual is concordant with high-level and self-defining goals or values.

**Matching patients to rituals** In order for researchers and clinicians to capitalise on the motivational-concordance effects described above (i.e. improvements in affect and well-being caused by progress towards valued intrinsic goals), two pre-conditions must be met. First, researchers must measure the values of patients and second, the motivational context of therapies must be known in order to create a match.

#### 4.2.2 Measuring human goals and values

Over many years, various taxonomies and models have been proposed to describe the range of human values, or analogous concepts (e.g. Murray, 1938; Rokeach, 1973). More recently, studies employing confirmatory factor analytic methods, analogous to the work which resulted in the development of the ‘big five’ model (Digman, 1990), has taken place

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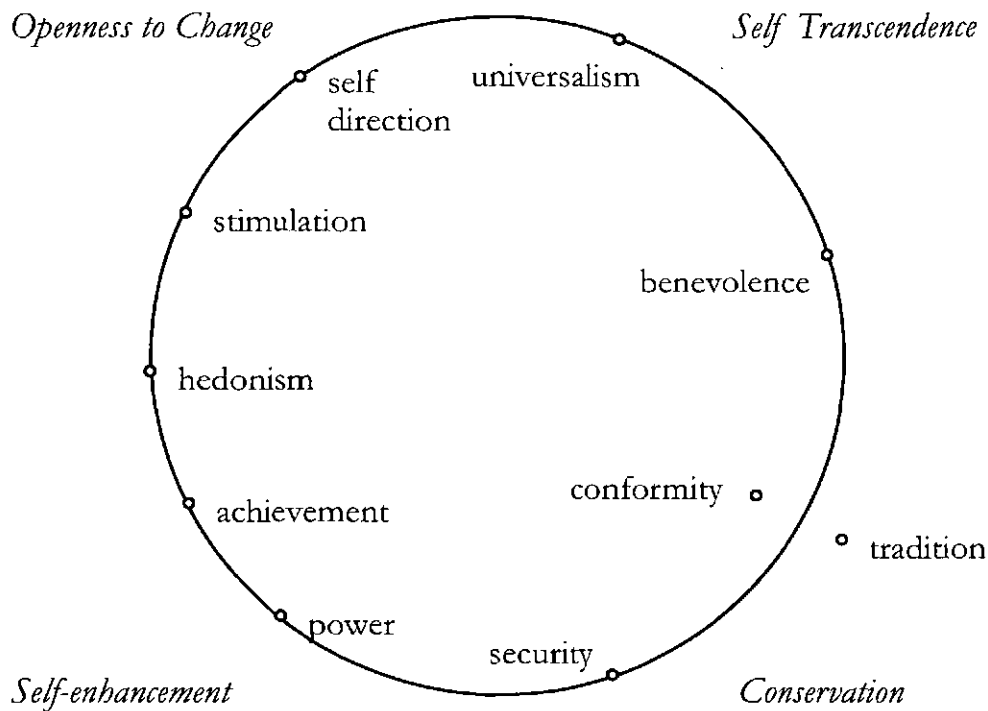
<sup>2</sup>Note that many of Walach’s arguments relate to the process of evaluating complex complementary therapies using a model developed for pharmacological agents or surgical procedures. In large measure his critique is correct: effectiveness is often overlooked because of a narrow focus on efficacy, and this is true also of evaluations of psychological interventions (ignoring, for the moment, the fact that many complementary therapies may be psychological interventions). However, Walach overlooks the ethical problems inherent in a policy which would, by design, result in governments and medical practitioners endorsing and administering remedies that, to the best of their knowledge, are psychologically active but biologically inert. Remedies which have a large psychological component may be effective in many situations, but a wide variety of non-deceptive alternatives are available—for example, counselling, a wide variety of practitioner-delivered or self-help psychotherapies, and exercise and lifestyle modification. If there is a genuine need to replace ‘tonics’, ‘cures’, ‘bitters’, ‘balsam’ (or snake oil Holbrook, 1959), a policy to provide humanistic ‘common-factors’ psychotherapy and gym membership would be this author’s preferred option.

in this field. Although details may vary between approaches, consensus has been found that (i) human values are a relatively consistent, stable and cross cultural phenomenon, (ii) there are relatively few (either 10 or 12) basic values, and (iii) that values form a circumplex structure (Schwartz, 1994; Schwartz and Boehnke, 2004; Kasser and Ryan, 1996; Grouzet et al., 2005). The circumplex model depicts values as being organised in two dimensions. Individual values have an ordered position on the circumference of a circle such that values on opposing sides of the circle will tend *not* to be jointly valued by the same individual. For example, the goal of 'security' would rarely be valued alongside 'self direction', and 'achievement' would not be valued alongside 'benevolence'. Although labels for individual values vary between models, the basic dimensions identified are conceptually similar: For the Aspiration Index, (originally developed by Kasser and Ryan 1996), Grouzet et al. (2005) labelled dimension 1 as 'Extrinsic—Intrinsic', and dimension 2 as 'Self-transcendence—Physical self'. Schwartz (1994) labels the dimensions of the Schwartz Values Scale (SVS) as 'Openness to change—Conservation' and 'Self-enhancement—Self transcendence', although other authors have suggested the relabelling these dimensions as: 'Focus on opportunity—Focus on organisation' and 'Focus on individual outcomes—Focus on social context outcomes' (Rohan, 2000). Schwartz's original model is shown in Figure 4.1. In summary, both the Aspiration Index (Grouzet et al., 2005) and the SVS appear to be suitable instruments to quantify within-subject variation in attachment to high-level goals or values.

**Spirituality as a human value** Although more recent editions of the SVS have excluded the variable *Spirituality* because of concerns over its cross-cultural universality, spirituality was included in the original circumplex model and was hypothesised to fall between Benevolence and Tradition (Schwartz, 1992). Spirituality and religiosity



Figure 4.1: Circumplex model, Schwartz, S. H. &amp; Boehner, K. (2004)



have regularly formed part of models of human values (e.g. Salvation Rokeach, 1973), but many instruments designed to measure these concepts conflate spirituality with religiosity, even when efforts are made to encompass many types of religiosity within a single instrument (Hatch et al., 1998). As discussed above (page 3.2) the Spiritual Connection Questionnaire (SCQ) was designed to measure ‘non-religious spirituality’, and was included in a previous study (Chapter 3) because it appeared to accord well with the type of new-age or non-religious spiritual values characteristic of explanations of Bach flower remedy practitioners.

**Motivational context of therapies** The task of identifying the motivational characteristics of *therapies* themselves is more problematic, and although some preliminary

work is described in Chapter 7, a general solution is not provided here. However, motivational concordance theory has developed from the need to explain a number of studies using CAM or positive-psychology type interventions which appear to have relatively well defined motivational characteristics: e.g. Bach flower remedies, and gratitude therapy (see study 2, Hyland et al., 2007). Following the theoretical principles of the inventor of Bach flower remedies, flower essence manufacturers and practitioners typically describe the remedies as spiritual in nature, and it is assumed that any prediction from measurements of trait spirituality (e.g. with the SCQ) are due to a concordance of motives. As an illustration, the following text is taken from the Green Man Essence Company website:

Green Man Essences can be used for healing, personal growth and linking with Nature. Each essence holds a particular vibration of the plant species or named energy signature so that, when used, the energy key within the essence becomes available to you to enhance your life. (Green Man Essence Company, 2008).

On subsequent pages, the functions of various Bach remedies are described. A selection of these descriptions are included below:

**Bilberry** (*Vaccinium myrtillus*) Integration of the Self. Calms and brings peace to thought processes. Communication clarified. Increases equanimity and balance in all situations, especially where there are extremes of emotion that may bring conflict. Clarity, discrimination and wisdom brought to spiritual states.

**Columbine** (*Aquilegia vulgaris*) Activates higher chakras located above the crown chakra. This greatly enhances the healing and integration of higher

faculties and functions. Aids in the rebirth and complete healing of the Self. Inspirational.

Daisy (*Bellis perennis*) Spiritualises intellect. Scattered information brought into clear focus. Understanding from an intuitive level. Stabilises those who are constantly seeking but not finding. Clarity and understanding, especially in spiritual areas. (Green Man Essence Company, 2008)

### 4.3 Complementary models of placebo responding

**Response expectancy** Kirsch (1997) defines a response expectancy as the “anticipation of automatic, subjective, and behavioral responses to particular situational cues” (p. 69). *Response expectancies* are distinguished from *stimulus expectancies*—the expected occurrence of external events. To give an example, one might have a stimulus expectancy that a analgesic cream would provide relief against a pain stimulus applied to someone else, or to oneself in the abstract; the concept of stimulus value refers to the importance attached to the expected outcome by the person—for example, in a gambling context, expectancy value might vary as a function of the stakes involved. In contrast, a response expectancy would only arise if a person had an expectancy that an analgesic cream applied to their own hand would reduce the experience of pain caused by an imminent pain stimulus. Furthermore, the concept of expectancy value is not applied to response expectancies—the presumed value of the response is independent of the effects of the expectancy on experience.

Unlike stimulus expectancies, response expectancies are held to be “directly self confirming” (p. 69). Although the concept of response expectancies are applied in a number of fields (for example hypnosis and suggestion) response expectancy theory

has become the dominant explanatory framework for placebo effects (c.f. Kirsch, 1999). Importantly, response expectancies are conceived as *immediate* and *unmediated* causes of placebo effects (or other changes in experience). So, although the psycho-physiological details of the effect of expectancies is unspecified, no further psychological variables are required to explain behaviour. Figure 4.2<sup>3</sup> illustrates this model. Consistent with Kirsch (1997), stimulus expectancies and stimulus values are linked, in a multiplicative relationship, to motivation and behaviour—in this case the taking of a placebo<sup>4</sup>.

**Motivational concordance** As described above, the motivational concordance hypothesis posits that, in addition to effects that may or may not be generated by response expectancies, placebo effects will also result from performing behaviours that are *self-concordant* and thus generate positive affect and subjective well-being. The model is illustrated in Figure 4.2.

Dispositional motives of the person and the motivational context of the situation (placebo context) are presumed to interact and generate motivation to take the placebo (perform the therapeutic ritual). If the placebo ritual is concordant with the person's values, then this performance will result in intrinsic motivation for the task, facilitate self-concordant behaviour, and generate positive emotional experiences and positive affect. The result of this change in affect is an observed placebo response; the theory does not specify the nature of the connection between positive affect and placebo responses, and in fact the nature of this connection may vary depending on the context. In some cases observed placebo responses may be purely the result of a shift in readiness to

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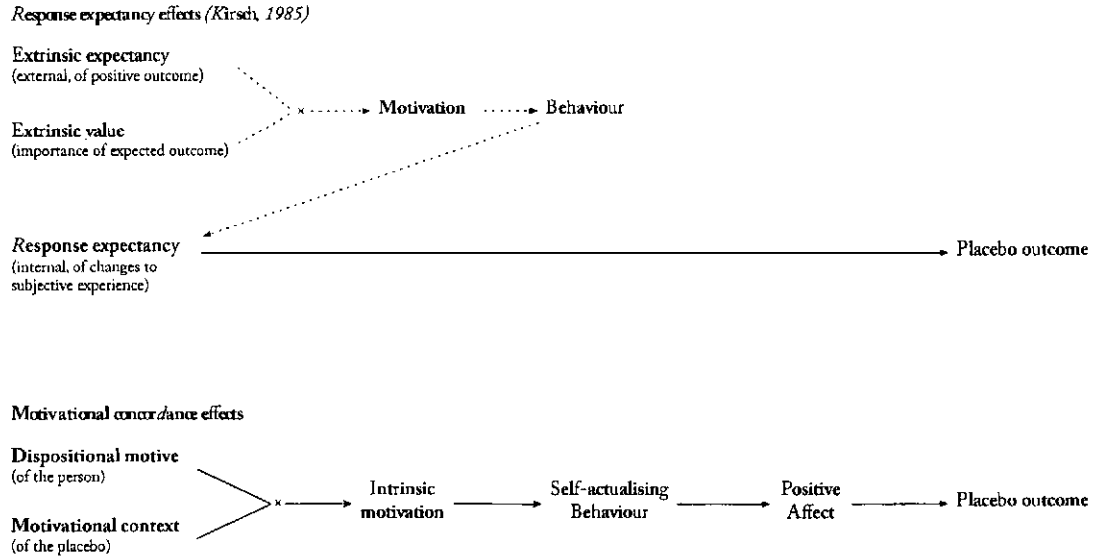
<sup>3</sup>In each model, the key pathways are indicated by solid lines, and the variables used to predict placebo outcomes are in bold face.

<sup>4</sup>Note that this part of the model (the link between stimulus expectancy, motivation, and behaviour) is not necessary to explain placebo responses in a laboratory setting, where demand characteristics of the situation will generate the required behaviour: taking the placebo.

report symptoms (Pennebaker, 1982; Rief and Isaac, 2007). In others, positive affect may generate therapeutic benefits which are biologically-mediated, for instance via a modulation of inflammatory or immune processes (Benedetti et al., 2006; Koh et al., 2008), and this is discussed further in Chapter 8.

Motivational concordance differs from response expectancy theory in a number of respects. Most crucially, motivational concordance suggests that explicit, conscious expectancies for a specific response are not necessary antecedents of placebo responses. In contrast, motivational concordance proposes that placebo effects may be non-specific, generalised, and result from a high-level compatibility between individual values and the perceived motivational characteristics of a ritual. As a consequence, a number of predictions can be made from the model:

Figure 4.2: Models of placebo responding: response expectancy and motivational concordance



## 4.4 Predictions from motivational concordance

As outlined above, the motivational concordance hypothesis generates several predictions:

1. It will be difficult/impossible to find traits which consistently predict responses to all placebo effects.
2. Therapies which are meaningful for participants will generate benefits which are not mediated by expectancy.
3. Benefit will only occur where the values/goals of the person and the context of the therapy are congruent.
4. Benefit will only occur where the person perceives themselves to have satisfactorily performed or engaged with the ritual. This engagement is subjective and not synonymous with compliance or adherence in the conventional medical sense, although compliance may correlate with subjective engagement.

The studies reported below attempt to explore and provide evidence for these predictions, and the discussion which follows addresses a number of weaknesses and limitations of both the theory and the evidence available to date.

## Chapter 5

# Manipulating the meaning of rituals: using instruction sets to determine dispositional correlations with placebo outcomes

To date, studies identifying dispositional predictors of placebo response make an assumption that participants interpret the context in which a therapy is delivered as having particular value characteristics, and that it is the concordance of these values with the participant's values which predicts the therapeutic benefit. In this chapter, context is manipulated experimentally with instruction sets that either emphasise or de-emphasise the spiritual nature of the therapy. Prediction from dispositional spirituality is hypothesised to occur only where the therapy can be presented as spiritual in nature. Results are discussed with reference to response-expectancy and motivational concordance theories<sup>1</sup>.

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<sup>1</sup>This data has previously been reported in (Hyland and Whalley, in press a)



## 5.1 Introduction

In Chapter 3, and in similar previous studies (Hyland et al., 2006), the disposition of spirituality was found to predict outcomes for a placebo complementary therapy: Bach flower remedies. These data were interpreted as indicating that, independently of expectancy, a concordance between the motivational dispositions of participants, and the motivational context or 'press' of the therapy, produced therapeutic benefits.

A weakness of these earlier studies was that the spiritual nature of the therapy was inferred rather than manipulated. Although the second study in Hyland et al. (2007) found that dispositional predictors appeared to be specific to the therapeutic intervention administered (i.e. that dispositional gratitude predicted response to a gratitude therapy, but dispositional spirituality did not), a more stringent test of the concordance hypothesis requires that the concordance of the participant and the therapy is manipulated.

**Approach** Dispositions are not, by definition, readily manipulated. In this study the motivational context of the intervention is altered and dispositional correlations compared under these different conditions. Participants are recruited for an open trial of Bach flower remedies for minor psychological and physical complaints, and randomised to three groups in which flower essences are contextualised as either a spiritual or 'positive' therapy, or are given no additional instructions. Because optimism has been found to correlate with placebo responding when participants hold positive expectancies for outcome (Geers et al., 2003), a measure of optimism was again included as a predictor of outcome. Repeated measurements of outcome were made, and independent variables used to predict rates of therapeutic change over time using multilevel growth-curve modelling.

### Hypotheses

1. That spirituality will predict variance in outcome, but only where the motivational press of the therapy is manipulated to be concordant with a spiritual motive.
2. That where spirituality predicts variance in outcome it will do so independently from expectancy.
3. That optimism may predict outcome, particularly when the flower essences are characterised as a 'positive' therapy.

Theories of motivation suggest that therapies which are concordant with self-defining goals may be easier to perform than non-concordant rituals, in addition to creating positive affect 4.2.1. For this reason two additional hypotheses are made:

4. That adherence (with instructions to take the essence regularly) will predict outcome.
5. That the degree to which participants are able to engage with the ritual will predict outcomes.

Finally, if the benefits observed among participants high in dispositional spirituality are due to motivational concordance (rather than, for example, response expectancy), then only those participants who actually complete the spiritual ritual should obtain these benefits. This leads to the hypothesis that:

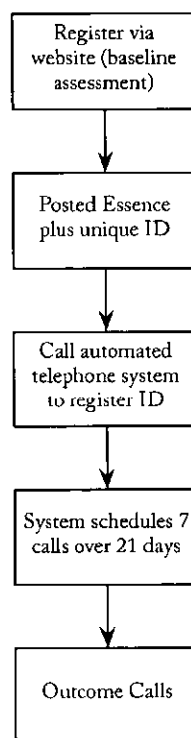
6. Adherence will moderate the relationship between spirituality and outcome — benefit due to motivational concordance will only be observed for participants who adhere to the therapy.

## 5.2 Methods

**Overview** Participants were recruited and completed baseline assessments online, and chose a flower essence remedy to suit their symptoms. Their chosen essence was posted to them, along with a unique study ID which they used to register on an online telephone system. An automated system made outcome assessments by telephone over the next 21 days. The overall progression of participants through the study is shown in Figure 5.1. This figure (and figures 5.3 and 5.2 below) follow the conventions described in Jesse James Garrett's *Elements of User Experience* (2003); these conventions are widely used in industry for specifying this type of system.

**Recruitment** Members of the general public with minor psychological complaints were invited to take part in an open trial of Bach flower remedies. Advertisements, alongside press, radio and television coverage orchestrated by the University of Plymouth press office, offered a free sample of flower essence in return for questionnaire completion and response to outcome assessments via a mobile telephone. Participants were not paid and did not receive course credit. Exclusion criteria were: use of flower essences in the

Figure 5.1: Participant flow through the study



previous six months; age of less than 18 years; currently receiving psychiatric treatment; history of alcohol abuse<sup>2</sup>.

**Procedure** Participants were instructed to log-on to a web page where they (a) were provided with information about flower essences and the study, (b) gave consent, (c) confirmed that they did not meet the exclusion criteria, (d) completed baseline questionnaire assessments (SCQ-14 and Expectancy), (e) selected any one of the 38 Bach flower essences, with essence descriptions and picture of the flower taken from a commercial website, and (f) gave a telephone number and time of day for follow-up contact. The flower essences (genuine commercially-produced essences with a standard label) were then posted to the participants.

Participants were randomised to one of three treatment groups (spiritual, positive and neutral) using a random number list as they consented to the web study. All participants received a brief introduction to flower essences on the website, and were told that, although they are biologically inert, practitioners and users make controversial claims that they work through a spiritual mechanism not yet understood by science. However, no reference was made to mechanisms of action proposed by practitioners (for example, spiritual or vibrational healing). Participants were sent their flower essence with an instruction to take three drops twice per day, and at this point in time the ritual was extended for the spiritual and positive groups. The spiritual group received the written information:

‘Flower essences work best if, while you are taking them, you imagine the essence connecting you to a universal pool of healing and love’. In the positive group participants received the written information: ‘Flower essences work best if, while you are taking

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<sup>2</sup>Because the essences are primarily composed of Brandy this was considered a sensible precaution

them, you imagine them helping you to solve your problem? Neutral group participants were not provided with additional information. These extensions to the ritual are consistent with instructions sometimes found in complementary medicine (where auto-suggestion is called 'affirmation').

When participants received their essence they were instructed to call an automated telephone line, and register their entry into the study with a unique identification code provided. This telephone registration initiated a series of calls by an automatic telephone system; calls were made on days 1, 2, 3, 4, 7, 14 and 21 after registration, at the time of day preferred by the participant (unanswered calls were followed-up 30 minutes later, with up to 5 attempts made within the time period specified by the participant). During each call, participants were asked to provide an assessment of outcome and adherence by entering numbers on the telephone keypad. At the end of the call, the written instructions for the spiritual and positive groups were repeated as part of the ritual extension. All participants were reminded to take the essence twice daily, but those in the spiritual and positive groups heard additionally: "Remember, flower essences work best if, while you are taking them, you imagine..." Finally, on day 21, the spiritual and positive groups received a question about how easy the ritual was to practice.

**Automated telephone system** The automated telephone system used to collect outcome data was programmed by the author using the Envoy 6 package and Microsoft Access. The system works by playing pre-recorded messages to the participant, and listening for user-input made via the telephone keypad. The system is fully programmable, and was able to respond to incoming data from participants. Calls were scheduled when participants registered their unique study ID code, and a call list generated in the database. The system polled this call list at regular intervals to determine when calls to

participants should be made.

Flow diagrams indicating participants' progression through the system (both incoming and outgoing calls) are shown in Figures 5.2 and 5.3. The full text of the recorded speech used for the telephone calls is given in A.10 on page 235.

**Study website** The study website was built using open source software (PHP and MySQL), and a library of functions to generate online questionnaires which were written by the author. These functions convert questionnaires in spreadsheet format to a series of HTML pages, and securely record user inputs. This approach was preferred over commercially available questionnaire software for several reasons, particularly that the system could be easily customised to meet the needs of successive studies; that it handled multi-page forms, and could programatically alter the forms displayed to participants based on data they entered; and that data from participant questionnaire responses (e.g. for baseline measures) could be stored separately from identifying information (e.g. name and address) used for study administration. Additional description of the system and examples of its use are shown in A.9 on 230.

**Data security** In accordance with recommendations of professional and ethical bodies (Kraut et al., 2004), numerous steps were taken to ensure that privacy and anonymity were preserved. These included: (i) Design of systems to minimise risks of data loss/exposure. Specifically, systems were designed not to present *any* user-entered data at any time, reducing the risk of accidental or malicious access of participant data; (ii) Use of up-to-date software (including all patches) on research web servers and telephone systems; and (iii) Regular inspection of access logs etc.

Figure 5.2: Flow diagram for calls in, indicating participant progression through the automated telephone system for registration

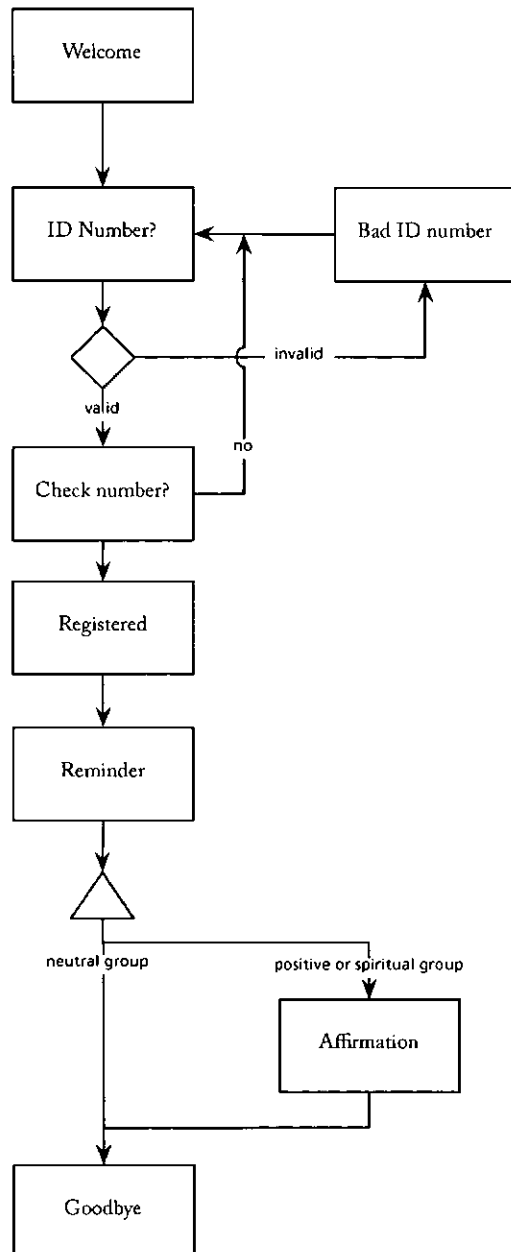
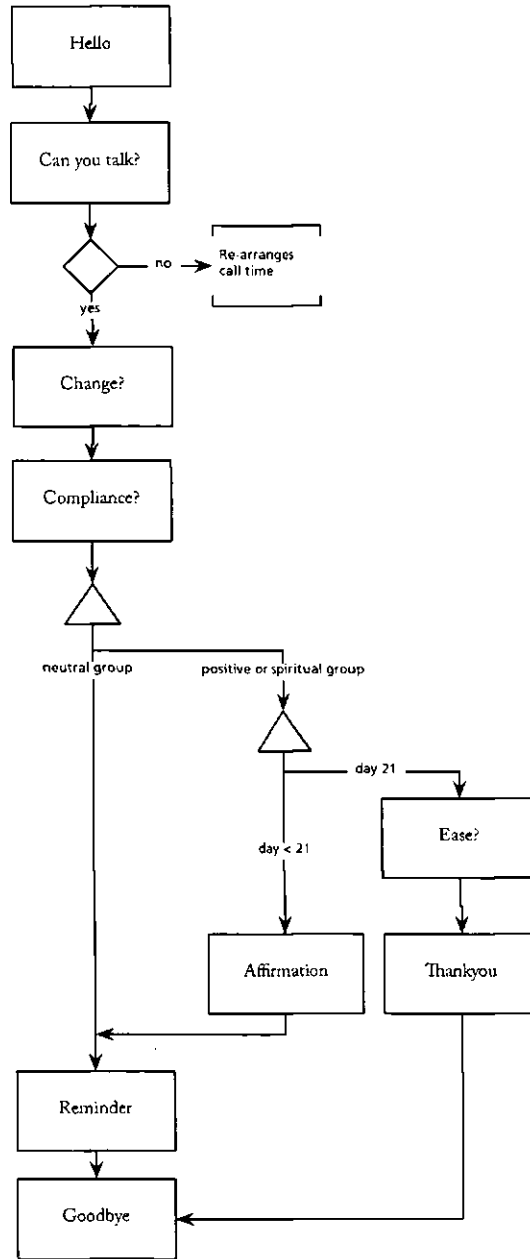




Figure 5.3: Flow diagram for calls out, indicating participant progression through the automated telephone system for repeated data collection



**Research ethics** The study, as described above, was approved by the University of Plymouth Human Sciences Research Ethics panel. No special permissions were required, as the study did not involve deceptive instructions (participants were informed of the essences' ingredients, and that their efficacy was controversial). Particular attention was paid to ensuring that informed consent was given. Briefing information was written in clear and straightforward English, and care taken to omit any psychological jargon. To successfully register on the online system participants were required to 'tick' an html checkbox, indicating that they understood the briefing information and agreed to take part in the study.

### **Baseline assessments**

**Spirituality** Spirituality was assessed with the SCQ-14, a short-form version of the original SCQ-48 used in Study 2 (see page 57). The scale consists of 7 positively worded and 7 negatively worded items, each scored on a seven-point scale, from unlike me (-3) to like me (+3). During the development of the SCQ-14 one of the criteria for item inclusion was longitudinal correlation with outcome for a flower essences therapy, and data from Study 2 were used to select items. A more detailed description of the development of the SCQ-48 and SCQ-14 can be found in Wheeler and Hyland (2008). Scale items are included in A.4 on page 218.

**Expectancy** Expectancy was measured by a single 7-point scale where participants were asked to rate "At this point in time do you expect the flower essence will help you?"; the endpoints of the scale were marked unlikely it will help (-3) and definitely think it will help (+3).

**Optimism** Optimism was measured using the 10-item Life Orientation Test (LOT-R; Scheier et al., 1994, <sup>3</sup>), which contains 6 scored items (3 positively worded, 3 negatively worded) and 4 filler items. Participants respond to each item on a 5-point scale and higher scores indicate greater optimism.

**Outcome** To assess outcome, participants heard the following message ‘How much better do you feel from taking the flower essence? Press a number from 1 to 9, where 1 means you feel much worse, 5 means you feel the same, and 9 means you feel much better.’ In the analysis below, outcome scores for calls on days 1, 2, 3, 4, 7, 14 and 21 are denoted  $outcome^{1...21}$ . Responses were recoded such that zero became the midpoint (i.e. no change).

**Adherence** Adherence was measured by the question: “Did you take the flower essence this morning? Press 1 for yes, 0 for no, or 9 if you can’t remember”. *Don’t know* responses were re-coded as 0, and the variables  $adherence^{1...21}$  indicate mean responses for individual calls.  $Adherence^{mean}$  denotes the participant’s mean score for all adherence assessments.

**Ease of the ritual** We wished to measure the extent to which participants in the spiritual and positive groups found it easy to follow the additional instructions. Ease of ritual was assessed by a single question in the final automated telephone call, which corresponded with the ritual extension in the spiritual and positive groups. In the spiritual group, this question was “How easy was it to imagine the flower essence connecting you to a universal pool of healing and love?” In the positive group, the question was: “How easy was it to imagine the flower essence helping you solve your problem?”. Both groups were

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<sup>3</sup>Items are listed in A.5 on 221.

requested to “Give your answer on the telephone keypad, where 9 means it was very easy and 1 means it was very difficult”. Ease of ritual was not assessed for the neutral group because no additional instructions to perform a ritual when taking the essence were given.

**Multilevel (growth curve) analysis** Outcome data was collected at multiple time points for each participant, and analyses must take account of this nested structure or observations within individuals. Multilevel growth-curve modelling allows researchers to estimate intra-individual changes which occur over time, whilst respecting inter-individual differences (Hox, 2002, page 73). Additionally, models may contain fixed components, and covariates may be entered at all levels of the model (e.g. observations and participants). For example, in the context of this study, outcome scores at each time point can be adjusted to take account of adherence; and change for individual participants can be adjusted to take account of group or dispositional spirituality scores. Multilevel analyses reported here were performed with the `xtmixed` component of Stata 10 (see Rabe-Hesketh and Skrondal, 2008, chapter 5). For ease of interpretation, and to facilitate model convergence, all continuous variables were standardised before being entered into a model (Hox, 2002).

**Missing data in multilevel analyses** One advantage of the multilevel approach is tolerance for missing outcome data. In this study most participants did not complete all of the outcome assessments, and some completed as few as 2 or 1 assessments. Using traditional methods (e.g. standard regression) in which scores are aggregated to before/after measures, or to change scores, would mean that information from these participants is lost. However in the multilevel approach, even participants with only one

data point are included in the analysis—although their data cannot be used to estimate variance in slopes, a single data point can be used to estimate variation in intercepts (effectively, mean levels of response) between participants. Although the approach assumes data are ‘missing at random’, this assumption is in fact less demanding than that of traditional approaches which employ listwise deletion of cases with missing data, and is less susceptible to bias. According to Rabe-Hesketh and Skrondal (2008), the probability of data being missed on a given occasion may be correlated with covariates in the model, and also with prior or future data points. However ‘Missing at random’ does mean that the probability of data being missing must not correlate with the value that *would have been observed* (page 207). Although this is somewhat problematic in a therapy-outcome study, because participants may decline assessments on the basis of their condition, the multilevel approach is recommended over traditional before/after comparisons (Rabe-Hesketh and Skrondal, 2008), and other techniques—for example structural equation modelling for longitudinal data—suffer from similar shortcomings.

### 5.3 Results

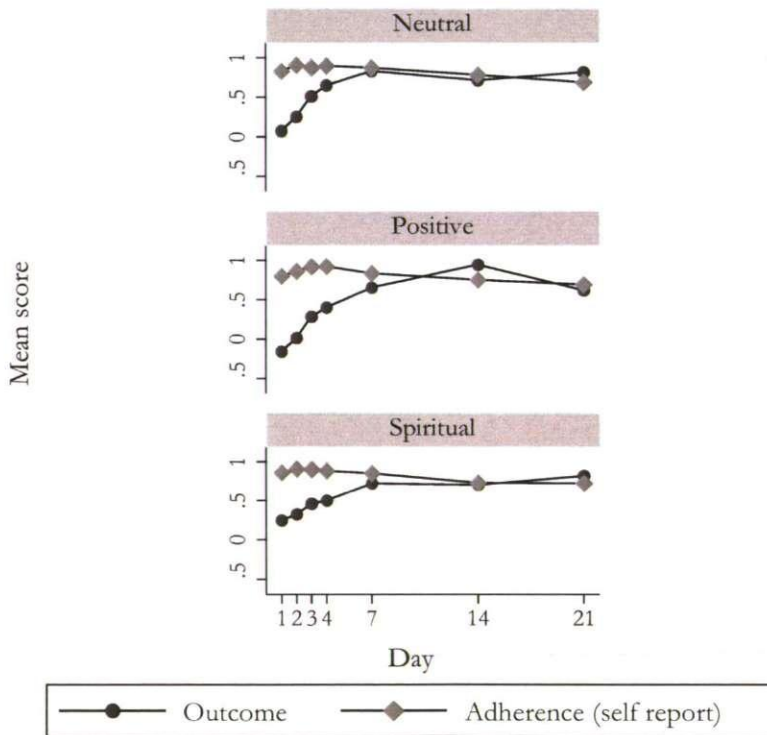
**Sample characteristics, drop-outs and response rates** Three hundred and fifty six people responded to advertisements and registered on the web site, and Table 5.1 displays the numbers of participants retained within each group at various stages of the trial. Of those participants who registered on the telephone system and responded to one of the final 3 assessments (and are therefore included in the main analyses below), 42 were male, 207 female and 2 did not state their gender. The mean age of participants was 37 years,  $\sigma = 11.9$ , range = 18 to 66 years.

Table 5.1: Participants entered and retained at various stages of the trial, by group

	Entered study online	Registered via telephone <sup>a</sup>	> 1 response, days 7-21 <sup>b</sup>	Response on day 21 <sup>b</sup>
Spiritual	118	94 (79.7)	87 (92.6)	73 (77.7)
Suggestion	117	85 (71.8)	75 (89.3)	70 (83.3)
Neutral	121	99 (81.8)	89 (89.9)	78 (78.8)
Total	356	277 (77.8)	251 (90.6)	221 (79.8)

<sup>a</sup> N and (%) of original entrants online  
<sup>b</sup> N and (%) of those registered via telephone

Figure 5.4: Outcome and adherence scores at each time point, by Group



**Did participants find flower essences effective?** Figure 5.4 presents scores for outcome<sup>1</sup> ...outcome<sup>21</sup> and adherence<sup>1</sup> ...adherence<sup>21</sup>. Scores are standardised to aid comparison; raw outcome scores are shown in Table 5.2, and adherence rates are shown in Table 5.3.

Table 5.2: Mean outcome scores (standard deviations in row below) in the three groups

Group	Assessment day						
	1	2	3	4	7	14	21
Neutral	0.08	0.25	0.52	0.65	0.83	0.72	0.82
	1.07	0.91	0.80	1.35	1.15	1.46	1.63
Positive	-0.16	0.02	0.29	0.40	0.66	0.95	0.62
	1.04	1.10	1.04	1.07	1.25	1.49	1.47
Spiritual	0.25	0.32	0.46	0.50	0.72	0.71	0.82
	0.98	1.15	1.18	1.28	1.15	1.42	1.48

Table 5.3: Adherence rates (%) in the three groups

Group	Assessment day						
	1	2	3	4	7	14	21
Neutral	83	91	88	90	88	79	69
Positive	80	86	92	92	84	75	70
Spiritual	86	91	90	88	85	73	73

To determine whether participants experienced an improvement over time outcome scores were entered into a growth curve model in which observations on days 1...21 were nested within participants. To examine whether or not rate of change was linear over the days of observation, both day of observation (days: 1, 2, ... 14, 21) and the quadratic term for days (days<sup>2</sup>) were entered into Model 1; results are shown in Table 5.4. Coefficients for both days and days<sup>2</sup> were significant, indicating that participants improved over time, but that the rate of improvement slowed over time; this mirrors the pattern observed in Figure 5.4.

Table 5.4: Growth curve models for outcomes over days 1 to 21

Model	Variable	Coef.	Std.Error	p
1	days	0.116	0.017	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
[log likelihood = -2087, N = 267, observations = 1373]				
2	days	0.116	0.017	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	positive	-0.205	0.118	.083
	spiritual	-0.065	0.113	.569
[log likelihood = -2086, N = 267, observations = 1373]				
3	days	0.116	0.017	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	spirituality	0.132	0.048	.006
[log likelihood = -2086, N = 267, observations = 1373]				

continued...



Continued...

Model	Variable	Coef.	Std.Error	p
4	days	0.116	0.017	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	neutral	0.156	0.116	.179
	spiritual	0.142	0.115	.217
	spirituality <sup>4</sup>	-0.134	0.100	.182
	neutral × spirituality	0.295	0.129	.022
	spiritual × spirituality	0.374	0.123	.002
[log likelihood = -2078, N = 267, observations = 1373]				
5	days	0.115	0.017	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	spirituality	0.118	0.048	.014
	adherence	0.129	0.032	<.001
[log likelihood = -2052, N = 267, observations = 1367]				
6	days	0.124	0.022	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	spirituality	0.069	0.066	.291
	ease	.155	0.065	.026
[log likelihood = -1276, N = 150, observations = 836]				
7	days	0.124	0.021	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	spirituality	0.063	0.065	0.334
	ease	0.159	0.065	.015
	adherence	0.105	0.043	.015

continued...

<sup>4</sup>Represents the coefficient for spirituality in the positive group, because this group is acting as the reference category: dummy variables for the other two groups are included in the model

Continued...

Model	Variable	Coef.	Std.Error	p
[log likelihood = -1252, N = 150, observations = 832]				
8	days	0.115	0.016	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	expectancy	0.125	0.048	.009
[log likelihood = -2084, N = 267, observations = 1373]				
9	days	0.116	0.017	<.001
	days <sup>2</sup>	-0.004	0.001	<.001
	expectancy	0.088	0.052	.090
	spirituality	0.097	0.052	.063
[log likelihood = -2082, N = 267, observations = 1373]				
10	days	0.070	0.020	.007
	days <sup>2</sup>	-0.002	0.001	.065
	expectancy	0.088	0.087	.315
	spirituality	0.218	0.080	.007
[log likelihood = -700, N = 92, observations = 475]				
* The positive group is the reference category to which this coefficient refers				

**Did benefit vary between groups?** In order to account for different levels of change in different groups, dummy variables were created for group, coded 0/1 to indicate group membership. As for standard multiple regression, where more than 2 values ( $k > 2$ ) must be dummy coded then dummy variables representing  $k - 1$  values are entered into the model. The dummy value not represented in the model represents the baseline from which comparisons are made. In Model 2, dummy variables for membership of the

positive and spiritual groups were added to Model 1, and neutral group membership therefore represents the baseline from which comparisons are made. Results of Model 2 are shown in 5.4. Contrasts revealed no significant differences between any of the groups, although there was a non-significant trend ( $p = .08$ ) for positive group participants to fare worse than those in the neutral group.

#### **Did spirituality correlate with outcome, and was there a moderating effect of context?**

In previous studies (see Chapter 3 and Hyland et al. 2006) dispositional spirituality predicted outcome in response to flower essences. However, in this study the context in which flower essences were administered was experimentally manipulated, and it was hypothesised that the relationship between spirituality and outcome would vary as a function of context: specifically, that spirituality should correlate with outcome for participants in the spiritual group, but not for participants in the positive group. To test this prediction two additional models were computed. First, standardised scores on the SCQ-14 (spirituality<sub>z</sub>) were added to predictors from Model 1; results of Model 3 are displayed in Table 5.4. For the whole sample, including all three groups, spirituality did predict outcome ( $coef = .132$ ,  $p .006$ ), but this relationship was weaker than in previous studies.

To test whether prediction varied by group, Model 4 included spirituality<sub>z</sub>, along with interaction terms for spirituality and the dummy coded groups. To facilitate comparison of the spiritual and positive groups, the positive group was selected as the reference group, and dummy variables for the neutral and spiritual groups were entered. As with multiple regression, interaction terms for growth curve models are simply the product of the two variables: in this case, neutral  $\times$  spirituality<sub>z</sub> and spiritual  $\times$  spirituality<sub>z</sub>. Results are displayed in Table 5.4. The likelihood ratio test indicated that Model 4 was a significantly

better fit than was Model 3 ( $p < .001$ ). Coefficients for the interaction terms indicate that outcome slopes in both the neutral and spiritual groups were significantly different from slopes in the positive group. Using the positive group as a baseline, spirituality negatively predicted outcome ( $-.133$ ), but there was a large interaction between membership of the spiritual group and spirituality ( $.37, p = .002$ ), and was thus comparable with previous findings (Hyland et al., 2006, 2007).

**Did optimism predict outcomes?** Although optimism did not predict outcomes in Chapter 3, in this study flower essences were contextualised as a 'positive' therapy for one of the groups. To test whether optimism predicted outcomes additional growth curve models were computed: first, for the whole sample, and second for positive group only. Models included time and the quadratic term for time, and also included standardised scores on the LOT-R. For the entire sample optimism did not predict outcomes ( $-.08, ns$ ). However, for the positive group only, there was a trend for more optimistic participants to have *worse* outcomes, ( $-.156, p = .064$ ; in an additional model, the coefficient for the neutral group was very similar).

**Were adherence and ease of the ritual associated with outcome?** It was predicted that spiritual people would become more involved with spiritual instructions, as indicated by the variables ease of ritual (ease) and adherence. For the spiritual group, spirituality and ease were correlated,  $r(69) = .37, p < .01$ , but they were not correlated for the positive group  $r(65) = .15, p = .23$ . Mean adherence rates did not correlate with ease  $r(137) = .09, p = .28$ , suggesting that adherence and ease of ritual measure different types of involvement with the ritual. There were no significant correlations between spirituality and adherence in any of the groups.

To establish whether adherence or ease predicted variance in outcome (i.e., slopes for participants in the growth curve models) three additional models were built. As before, outcomes on days 1...21 were nested within participants, and covariates for the day of the observation (days) and the quadratic term (days<sup>2</sup>) were included, along with standardised SCQ-14 scores. Next, either standardised adherence scores, or standardised ease scores were entered (Models 5 and 6). Note that the sample for Model 6 is smaller ( $N = 150$ ) because ease was not measured for the neutral group. Finally, Model 7 included both ease and adherence (again, excluding participants from the neutral group). All results are shown in Table 5.4 on page 121. Likelihood ratio tests indicated that all three models fitted better than Model 3, and that Model 7 was a significantly better fit than was Model 5 ( $p < .001$ )

Both adherence ( $coef = .13$ ,  $p .001$ ), and 'ease' ( $coef = .16$ ,  $p .002$ ), predicted variance in outcomes when entered in separate models (5 and 6), and also predicted independently when entered together in Model 7.

To test whether ease and adherence interacted with spirituality to produce improved outcomes, additional models were computed in which the product terms for  $ease_z \times spirituality_z$  and  $adherence \times spirituality_z$  were entered (Models 11 and 12; these models were computed separately for the spiritual group only). There was no evidence for an interaction between  $ease_z$  and  $spirituality_z$ ,  $coef = .037$ ,  $p .656$ , but adherence was a significant moderator of the effect of spirituality on outcome,  $coef = .239$ ,  $p .032$ , indicating that participants who were both high in dispositional spirituality *and* who took the spiritually-contextualised essence regularly gained additional benefit.

**Did expectancy predict outcome, and were spirituality and expectancy independent predictors of outcome?** Expectancy for outcomes was measured at baseline, and, as in

previous samples, expectancy and spirituality scores correlated,  $r(355) = .43, p < .001$ . It was hypothesised that, as before, both expectancy and spirituality would independently predict variance in outcomes. To test this hypothesis, a further series of growth curve models were calculated, following the pattern of a mediation analysis described in Chapter 3 (page 64). For all models, observations were grouped by participants, and time and a quadratic term for time were included.

First, for the whole sample, a model in which standardised expectancy score was the only independent variable was built (see Model 8, Table 5.4). In this model expectancy did predict variance in outcomes ( $coef = .13, p .009$ ). Second, because it had already been established that spirituality predicted variance in outcomes, a model with standardised scores for both expectancy and SCQ-14 was computed (see Model 9). In this model neither expectancy nor spirituality were significant predictors. However, in this study the presentation of the flower essence had been experimentally manipulated, and it was correctly hypothesised that spirituality would predict outcome in the spiritual group, but not in the positive group. For this reason Model 9 was repeated, including only those participants who had received spiritual instructions. Results are shown in Model 10. In this model, spirituality ( $coef = .22, p .007$ ), but not expectancy ( $coef = .08, p .315$ ) predicted outcome. A similar pattern was observed when both the spiritual and neutral group participants were included. This implies that although spirituality and expectancy are correlated, for participants in the spiritual group expectancy scores were epiphenomenal in the sense that, controlling for dispositional spirituality, higher expectancies did not result in improved outcome.

## 5.4 Discussion

This study builds on earlier work, and again replicates the finding that a motivational disposition predicts outcome for a placebo complementary therapy. It also provides a more stringent test of the motivational concordance hypothesis; spirituality only predicted outcomes when the therapy was contextualised in a manner congruent with this motivational disposition, and only for participants who engaged with the ritual and complied with instructions to take the essence each day.

**No group differences** There was no evidence for group-level differences in outcome, despite the widely varying instructions provided to participants in the neutral, spiritual and positive groups. In part this may reflect the wealth of background knowledge and expectation participants bring to studies of ‘real-world’ placebo effects. Unlike laboratory analogue studies, particularly those using placebo analgesics for artificially induced pain stimuli, participants in this study often had prior knowledge of Bach flower remedies. Anecdotally, it appears that this knowledge is very often inaccurate<sup>5</sup>, but prior knowledge and experience may have made it harder to manipulate participants’ expectations sufficient to identify group differences. However, the fact that the relationship between dispositional variables and outcome was reversed for the two groups suggests that a true patient-treatment interaction took place. Patient treatment interaction research is reviewed more fully in Chapter 7, but historically it has proved difficult to identify reliable methods of selecting the ‘right therapy’ for a given patient and thus maximising therapeutic benefit. This area of research has been particularly

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<sup>5</sup>in the course of 4 experiments using Bach flower remedies the author has found numerous participants to be surprised to discover that the only known ingredients of the remedies are water and brandy. Typically, people equate Bach essences with other active herbal remedies and expect them to contain pharmacologically active plant extracts.

hampered by the lack of a theoretical basis on which to select interventions (Dance and Neufeld, 1988), and it may be that motivational concordance provides a framework for future studies in this area.

Although the lack of group-level differences in outcome was somewhat surprising in this context, this finding is consistent with meta-analytic work on psychotherapy outcomes. Although controversial, meta-analyses have consistently found that therapist-delivered psychological interventions produce equivalent outcomes (Wampold, 2001), even where the theoretical orientations of treatments and researchers diverge widely (Benish et al., in press).

**Motivational congruence, adherence, and performance of the ritual** Consistent with motivational concordance theory, spirituality—outcome correlations were only found when the motivational context of the Bach remedy was congruent with that disposition, and negative correlations were found when the remedy was given an incongruent context. Although participants in the neutral group received no additional instructions contextualising the essence as a spiritual therapy, in the absence of explicit instructions it is likely that these participants relied upon prior knowledge of the remedies, which like other complementary therapies are typically conceived-of as both outside of conventional medicine and compatible with holistic or new-age beliefs (Cartwright and Torr, 2005). This evidence provides additional support for motivational concordance theory, and demonstrates more clearly that it is the motivational context of a placebo therapy—rather than characteristics of the therapy itself—that produces the observed correlation.

The pattern of correlations suggests that the enhanced rituals (positive and spiritual groups) may have provided greater opportunity for engagement, but also for discomfort



when the therapeutic ritual was discordant. Neutral instructions may allow for greater flexibility in interpretation, but reduce the maximum benefits which may be gained for highly spiritual individuals.

Adherence was not correlated with spirituality. However, amongst the spiritual group spirituality and adherence interacted: Highly spiritual people who also took the essence regularly gained additional benefits. This is consistent with motivational concordance theory which posits that it is the *performance* of a self-actualising ritual that will generate changes in affect and consequent therapeutic benefits. Thus, although adherence was a moderate predictor for the sample as a whole, it was particularly relevant for those participants who were assigned to congruent instructions.

In this study, an additional measure of 'ease' of performing the ritual was made, and self-reported identification with the ritual significantly predicted variance in outcome, and predicted variance independently of the conventional measure of adherence. This measure was retrospective, and it is possible that ease or adherence is confounded with outcome. However, taken together with the evidence that adherence moderated outcome for spiritual participants in the spiritual group, this provides some additional support for the contention from motivational concordance theory that is the performance of a meaningful, self-actualising ritual that is responsible for therapeutic outcomes.

**Optimism and expectancy** In an earlier study, Geers et al. (2005a) had suggested that where positive expectancies were generated for a placebo response, then dispositional optimism may predict outcomes. In this study, as for previous studies using Bach flower essences (see Chapter 3), positive expectancies were generated for outcomes but optimism did not predict outcome. The repetition of this null finding in two large samples ( $N = 167 - 267$ ) suggests that the relationship between optimism and outcomes

may be due to an unidentified component of the intervention context—perhaps contact with a more cheerful experimenter than the author.

A in previous studies, dispositional spirituality predicted outcome independently of expectancies. Furthermore, when both spirituality and expectancies were entered in the same model expectancies no longer predicted independent variance in outcomes. This is consistent with previous studies in which expectancy only weakly predicted outcome when spirituality and expectancy were included in the same model (see Hyland et al. 2006 and Chapter 3), and provides further evidence for the existence of motivational concordance as an additional mechanism of placebo change.

### Conclusion

The finding that dispositions can predict placebo responses was replicated in a large sample of the general public. Additionally, a manipulation of the motivational context of the therapy demonstrated that it is context, rather than specific characteristics of the therapy itself, which is responsible for this relationship between dispositions and outcomes. Expectancy was a weak predictor of outcomes and did not predict variance independently from dispositional spirituality. In sum, these data support the motivational interpretation provided in Chapter 4.

## Chapter 6

### Placebo substances and placebo effects: parental dispositions predict child response to a placebo complementary therapy

The hypothesis that responses to long-term therapeutic placebo may be mediated by the motivational concordance of the therapy was further examined. Parents or caregivers of children aged between 2 and 5 were recruited for a trial of a complementary (placebo) therapy for temper tantrums; baseline data were collected via a website, and repeated measures of outcome were collected using a programmable telephone system. Motivational characteristics of parents at baseline predicted the responsiveness of children to therapy, and these findings are discussed with reference to the role of adherence in placebo response, the role of response expectancy as an unmediated mechanism of placebo change, and the motivational concordance hypothesis<sup>1</sup>

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<sup>1</sup>This data has been submitted for publication in a manuscript entitled: *Reduction in Temper Tantrums in Young Children by a Vicarious, Behaviourally Mediated Placebo Ritual*, and is now under review.

## 6.1 Introduction

When placebos are used in experimental or clinical research, measurements of outcome are taken from the person receiving the placebo. However, as several authors note, placebo effects cannot logically be defined as the effects of inert substances without contradiction (Moerman, 2002). Inert substances are, by definition, inert, and we must identify the psychological context rather than the physical properties of an experimental situation to understand how placebo effects are generated. It follows then, that placebo effects need not be restricted to those who ingest placebo substances. Inert substances may generate *vicarious placebo effects*, defined as the effect that the administration of a placebo to one person has on a second person. Vicarious placebo effects may be distinguished from *behaviourally mediated placebo effects*, in which the behaviour of a person is altered by the change in behaviour of a second person to whom a placebo has been administered (or who is affected by a vicarious placebo effect). In this chapter, data are presented from an open trial of a placebo complementary remedy for temper tantrums in young children. The intervention appears to generate vicarious placebo effects in the caregiver, and behaviourally-mediated placebo effects in the child.

**Emotional and behavioural problems in pre-school children** Diagnosis and treatment of emotional and behavioural problems in pre-school children is an immature discipline, and one fraught with cultural as well as methodological difficulties. Rapid physical, cognitive, emotional and behavioural changes in preschool children mean that identification and classification of clusters of symptoms is problematic, although not intractable (Potegal et al., 2003). However, the belief that problematic behaviour in young children is not located ‘in the child’ but in their environment—particularly the

behaviour of their caregivers—adds to the reluctance to label children with a psychiatric disorder prematurely. It is clear that, like adolescents and adults, pre-school children can be vulnerable to psychiatric disorders that both predispose them to future harm and may be treated with psychological and pharmacological treatments; in cases where such treatments are successful it appears likely that the illness is ‘in the child’. However it is unlikely that psychiatric disorders account for the majority of ‘problematic’ behaviour in pre-school children. In many cases environmental variables—particularly the behaviour of caregivers—are likely to remain an important determinant of outcome.

‘Temper tantrums’ are a normal component of the pre-school child’s behaviour, but are nonetheless a cause for concern among parents who experience them. Although temper tantrums are largely ‘sub-clinical’, in the sense that no conventional medical or psychological therapy is deemed necessary or offered for them, they are associated with recurrent low-level illness in children, poor sleep, and with maternal stress (Hart et al., 1984). A sample of 502 English mothers of 3-year old children also highlighted links between tantrums, maternal stress and child health (Needlman et al., 1991). Tantrums were reported for approximately 7% of children, of whom 52% exhibited multiple behavioural problems. Variables independently associated with tantrums were: maternal depression and irritability, low education, use of corporal punishment, manual social class, marital stress, child care provided exclusively by the mother, and poor child health.

From a straightforward learning-theory perspective, it would seem somewhat paradoxical to expect an intervention, like flower essence therapy, in which parents are encouraged to administer a sugar pillule to children would reduce problem behaviours. Such an intervention appears to provide positive reinforcement for problem behaviours through both attention and the (desirable) pill. However the broader attribute of ‘responsiveness’ is associated with secure maternal attachment and a reduction in problem

behaviour (Strand, 2000), and on this basis a placebo intervention that boosts positive affect among parents may also increase responsiveness and positive engagement with children, thereby improving behaviour. Four mechanisms could explain how flower essences work, should they be shown to reduce reported tantrums in young children:

**Expectancy/real change:** parents may expect the tantrums to reduce in response to therapy and communicate this expectation to their child. The child actually reduces tantrums in response to this suggestion. This first mechanism fits a standard response–expectancy placebo paradigm, but with the caregiver rather than an experimenter providing the suggestion.

**Expectancy/perceived change:** caregivers may expect a reduction in tantrums and consequently perceive a reduction even though there is no real reduction in tantrums; this would constitute a vicarious placebo effect on the perceptions of symptoms.

**Concordance/perceived change:** This constitutes another example of a vicarious placebo affecting perceptions of symptoms. According to the motivational concordance hypothesis, flower essences are contextualised as a spiritual ritual and engaging in this therapeutic ritual is self-actualising for spiritual people, which leads to positive affect. This positive affect could lead to a perceived reduction in tantrums via a reporting bias, even though there is no real reduction in problem behaviour.

**Concordance/real change:** This final mechanism involves both a vicarious placebo effect and a behaviourally mediated effect: It is proposed that the behaviour of caregivers is altered by performing a motivationally concordant ritual. This change in behaviour influences the child, and results in a real reduction in temper tantrums. In the case of

this fourth mechanism, the ritual of taking the flower essence does not affect the child directly, but does so via the unintended behaviour of another person who is taking part in the ritual.

On the basis of each of these four mechanisms, it is possible to predict which baseline variables should correlate with outcome (i.e., reduced reported tantrums). For the two expectancy-related mechanisms, baseline expectancy should predict outcome. For mechanisms involving motivational concordance, spirituality should predict outcome, so long as the therapy is contextualised as a spiritually therapy (Hyland and Whalley, in press); furthermore, spirituality should predict outcome independently of expectancy. If the therapeutic outcome is mediated via parental mood (i.e., change in perceived but not real tantrums), then change in parental mood should correlate with outcome. Tests of predictors of change will therefore provide insight into the different mechanisms of tantrum reduction, should such a reduction be found. For practical reasons, and because objective measurement tends to be obtrusive, measures of temper tantrums normally rely on reports from parents, and reports from parents were used to measure outcome in this study. This makes it difficult to distinguish whether reported reductions in tantrums are real or only perceived. However, a measure of tantrum frequency was included, and this is less likely to be affected by a reporting bias than are evaluative judgements of tantrum severity. To reduce recall-based error we asked parents to report on the child's tantrums and their own mood in the previous 24 hours, and we took repeated measurements before and after treatment. Other variables relevant to the theoretical predictions above (i.e., expectancy and spirituality) were measured at baseline. The results allow us to examine whether reported tantrums reduce after placebo treatment compared with before treatment, and identify the factors associated with that reduction should it occur.

## 6.2 Methods

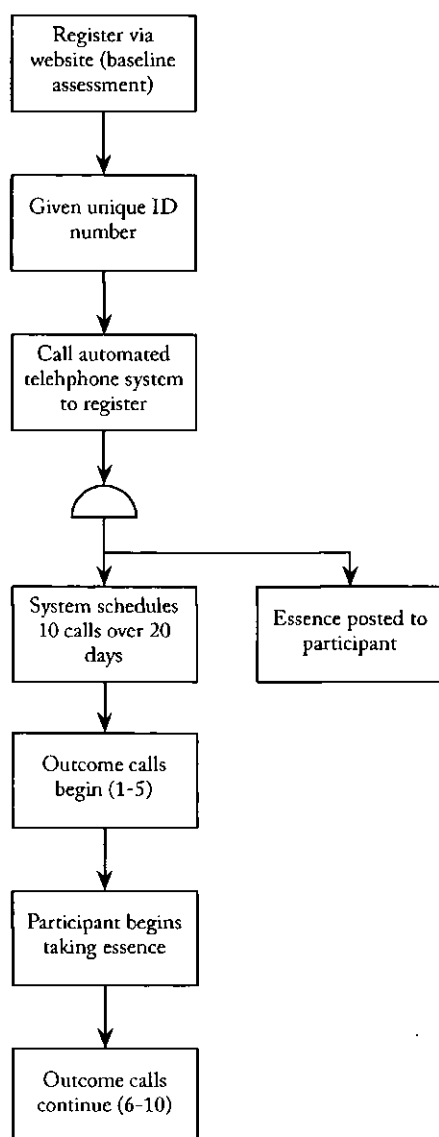
**Overview** Participants were recruited, and registered, provided informed consent, and completed baseline measures via a specially designed study website. Assessments of reported tantrums began immediately and continued for ten days. During this period, flower essences and instructions were sent to participants. Flower essence treatment began, and continued with assessments for a further 10 days. After assessments were complete a follow-up question was sent via email. Excluding technical support there was no human contact with participants who provided outcome data using an automated telephone system. The overall flow of participants through the study is shown in Figure 6.1. This figure (and figures 6.3 and 6.2 below) follow the conventions described in Jesse James Garrett's *Elements of User Experience* (2003).

**Study website** The study website was built using open source software (PHP and MySQL), and a library of functions to generate online questionnaires which were written by the author for a previous study (see page 112). These functions convert questionnaires in spreadsheet format to a series of HTML pages, and securely record user inputs.

**Automated telephone system** The automated telephone system used to collect outcome data was programmed by the author using the Envoy 6 package and Microsoft Access. The system works by playing pre-recorded messages to the, and listening for user-input made via the telephone keypad. The system is fully programmable, and was able to respond to incoming data from participants; for example, when participants indicated no tantrum had occurred in the previous 24 hours, questions relating to tantrum severity were omitted. Calls were scheduled when participants registered for the study, and a



Figure 6.1: Participant flow through the study



call list generated in the database. The system polled this call list at regular intervals to determine when calls to participants should be made.

Flow diagrams indicating participants' progression through the system (both incoming and outgoing calls) is shown in Figures 6.2 and 6.3. The full text of the recorded speech used for the telephone calls is given in A.11 on page 237.

**Data security** As in Chapter 5, numerous techniques were employed to secure user data and ensure anonymity. Crucially, all systems were programmed such that user responses were not recorded with identifying information such as names and addresses—this information was stored with the participant ID number as a key, and could only be retrieved via manual intervention on the part of the investigator. Furthermore, both the web and telephone systems did not contain functions which could display user information; once data was entered into the system then public facing web pages or call scripts did not have access to this data, significantly reducing the possibility of a security breach.

**Recruitment** A number of techniques were employed to recruit suitable participants over a 6 month period.

*Broadcast media:* The study was featured, and the investigators interviewed, on several television and radio channels, including BBC Radio Scotland, BBC Radio Devon, Outlook Southwest (BBC 1 local news programme), and each appearance coincided with increased participant recruitment in the geographical area covered by the programme.

*Local/national press:* In addition, a press release was issued and followed up with telephone calls, securing brief coverage in the Telegraph magazine, and the Daily Express. A larger feature on the study in the Plymouth Herald was accompanied by photos of one

Figure 6.2: Flow diagram for calls in, indicating participant progression through the automated telephone system for registration

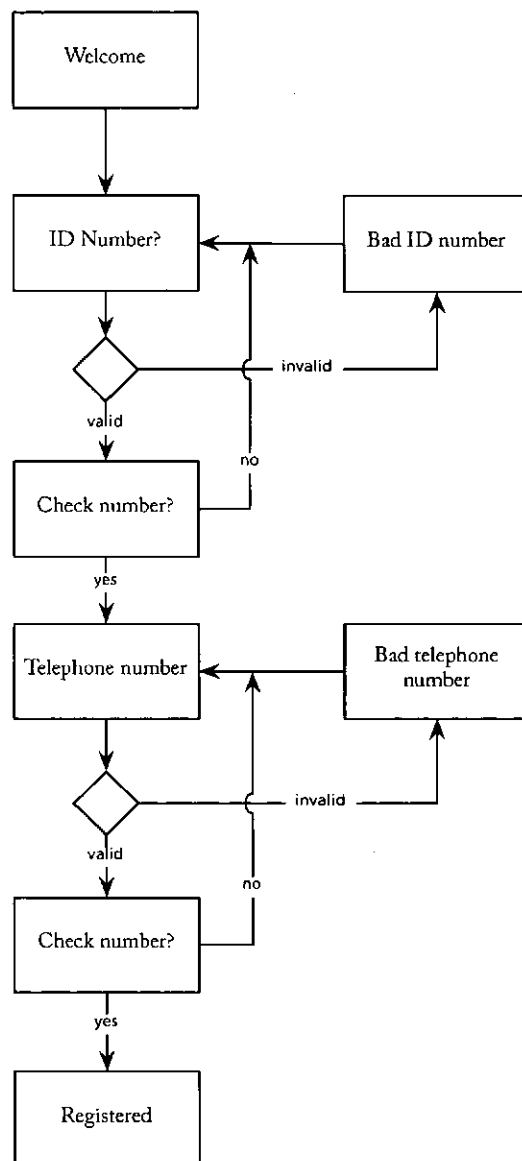
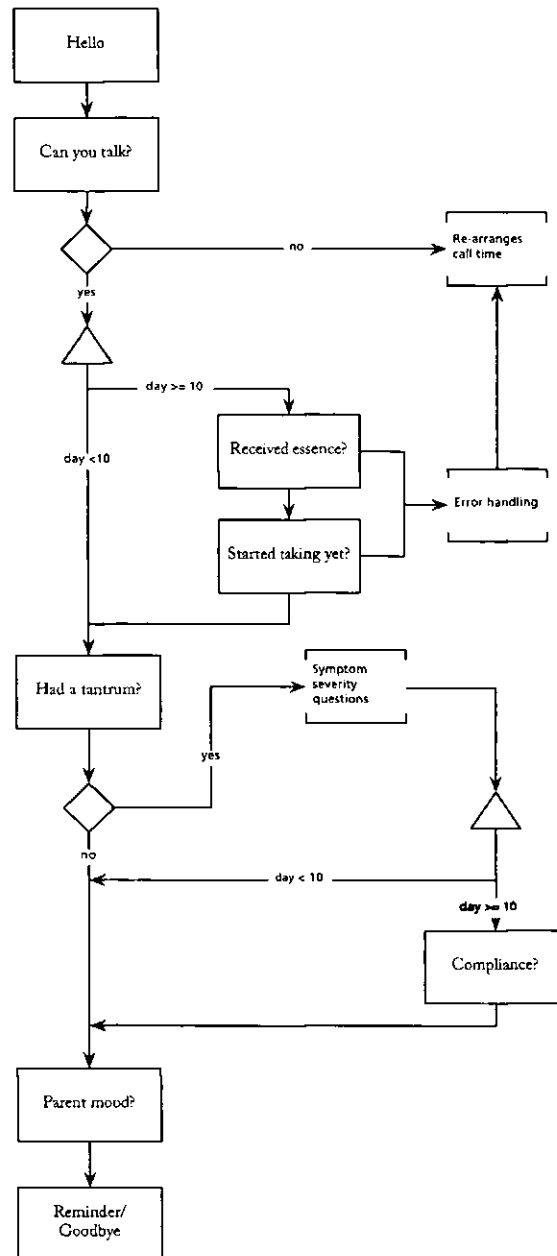


Figure 6.3: Flow diagram for calls out, indicating participant progression through the automated telephone system for repeated data collection



of the first volunteer parents and her child.

*Posters and information sheets:* The lead author contacted the head-teacher or manager of over 100 schools and day-care centres, and arranged for leaflets to be sent to around 1500 potential parents of young children (leaflets were sent home with children aged up to 6 in nursery, reception, and year 1 classes). A further 3000 information sheets and 300 posters were sent, by arrangement, to toy retailers and child entertainment venues (e.g. safari or amusement parks).

*Online:* Finally, the study was advertised online in a number of places. First, the study was promoted via the university staff portal, and on the 'Plymouth University' network on the Facebook website. Second, messages were placed on around 30 appropriate message boards and discussion forums—for example boards related to child behaviour, parenting skill, or complementary and alternative medicine. Third, a budget of £60 was allocated for online advertising. This was used to place keyword-based, text-only advertisements on the Google search network. These advertisements resulted in approximately 3,800 'click-throughs', and around 25 'conversions' (participant's recruited).

Volunteers were offered a free bottle of flower essence in return for questionnaire completion and evaluation. Volunteers were required to: be the primary caregiver of a child aged over 2; have a child who suffered from moderate to severe tantrums (defined as 1 or more tantrums lasting at least 5 minutes per day); and to own a mobile phone. Exclusion criteria were: non-UK residence and use of flower essences within the past 6 months.

**Flower essence remedies used** Complementary practitioners have added to, and made 'special' combinations of, the original Bach flower essence remedies, and many hundreds

of products are now sold purporting to treat specific conditions. In this study we used an essence combination specifically designed to help reduce tantrums in young children (named TUTS1) made by the Green Man Essence Company. We used marketing materials from the firm as the basis for information about flower essences given to participants. In this study flower essences were purposefully contextualised as a spiritual therapy: instruction booklets emphasised the role of the 'vibrational essence' of the flower and, at the end of the assessment calls, participants were told that: "Flower essences work best if, while giving them to your child, you imagine the spirit of the flower connecting you and your child to a pool of universal healing and love". These instructions are consistent with the practice of many complementary therapists, have been shown to increase the effectiveness of flower essences for spiritual patients, and to increase prediction from measurements of motivational disposition (i.e. dispositional spirituality Hyland and Whalley, in press).

**Baseline measurements** Spirituality was measured with the 14-item version of the Spiritual Connection Questionnaire (SCQ14) described previously. Two measurements relating to expectancy were made. First, participants responded to the question "How much better or worse do you expect your child's tantrums will be after taking the flower essence?"; valid responses ranged from much worse (-3) to much better (+3). Second, participants gave a response to the question: "If you think the flower will help, how soon after beginning to take the flower essence do you think it will help?". Valid responses were: 1 or 2 days (1), 3 or 4 days (2), 5 or 6 days (3), A week or longer (4). The gender and age of child and caregiver were recorded, as well as the relationship of parent to the child.

**Outcome assessments** Assessments were made via an automated telephone system every 2 days during the study period, with 10 calls made in total. Compliance was measured in the final 5 calls when flower essences were being taken.

**Tantrum frequency:** Caregivers were asked “How many tantrums has your child had within the past 24 hours?” Responses were made using the telephone keypad.

Provided the child had experienced at least one tantrum, caregivers were asked the following questions about the severity and additional characteristics of the worst tantrum in the past 24 hours.

**Tantrum severity:** Caregivers were asked: “On a scale of 1 to 9, how bad was the tantrum?” Responses were made using the keypad, where 1 was not bad at all, 5 was about average, and 9 was very bad.

**Tantrum characteristics:** Six additional characteristics of the worst tantrum reported were assessed. Single questions measured the incidence of screaming, whining, kicking and hitting, and crying. Ratings were given from not at all (1) to a great deal (9). Two further characteristics were measured with 2 or 3-item scales. Caregivers were asked: “Did your child hold their breath?” responding No (0), or Yes (1); and then “Did your child get down on the floor?” responding No (0), Crouching down (1), or Lying on the floor (2). These symptom measures correspond to the key characteristics of problematic tantrums in young children (Potegal et al., 2003).

**Mood ratings:** Caregiver mood ratings were measured with an individual item in each call: “How happy are you today?” Caregivers responded on a scale ranging from

much more unhappy than normal (-4), about normal (0), to much happier than normal (4).

**Compliance:** Caregivers were asked: “How many times did your child take the essence yesterday?” and responded not at all (0), once (1), or twice (2).

**Follow up question** A follow up email asked participants to endorse one of the following statements: I told my child that the remedy would reduce his or her tantrums (1), I can’t remember whether I told my child that the remedy would reduce his or her tantrums (0), or I did NOT tell my child that the remedy would reduce his or her tantrums (-1).

**Procedure** An outline of the study flow is shown in figure 6.1. After recruitment, participants provided consent via the study website, and completed baseline measures (demographic information, spirituality, and expectancy). Following submission of baseline measures, participants were provided with a unique identity code and asked to call an automated telephone line to complete the signup process by entering their unique ID code and the mobile telephone number at which the participant wished to receive assessment calls. After hanging up, the automated system dialled the participants’ number to complete the first assessment call (day zero).

Assessment calls continued for the period before treatment—in total 5 calls on days 0, 2, 4, 6 and 8. During this time a sample of the essence and an instruction pack was posted to participants, timed to arrive no earlier than day 8, and with a note that the essence was not to be used until day 9. Assessments continued on days 10, 12, 14, 16 and 18. For the assessment on day 10, the automated system inserted additional questions to check that (a) the essence had been received and (b) treatment had begun. If either



of these conditions were not met, all further assessment calls were delayed by 1 day; the maximum delay for any participant was 3 days.

Assessments before treatment (days 0 to 8) included measures of tantrum frequency and parent mood. If a tantrum had occurred then severity and the other characteristics of the tantrum were also measured. Assessments after treatment began (days 10 to 18) were the same, but also included the measure of compliance, a reminder to take the essence in accordance with the instructions, and the message contextualising the essence as a spiritual therapy. Follow-up emails were sent following collection of all data, arriving between 3 and 22 weeks after the final outcome measure.

**Research ethics** The study, as described above, was approved by the University of Plymouth Human Sciences Research Ethics panel. At the suggestion of the panel, sugar pillules (approx 2mm diameter) were used in place of the brandy/water solution used in Chapters 3 and 5. Two independent physicians (a Emergency Medicine specialist and a Psychiatrist) were consulted to verify that the pillules posed no risk to the participant population. No special ethical permissions were required as the study did not involve deceptive instructions (participants were informed of the essences' ingredients, and that their efficacy was controversial). However, particular attention was paid to ensuring that informed consent was given. Briefing information was written in clear and straightforward English, and care taken to omit any psychological jargon. To successfully register on the online system participants were required to 'tick' an html checkbox, indicating that they understood the briefing information and agreed to take part in the study.

## 6.3 Results

### Sample characteristics

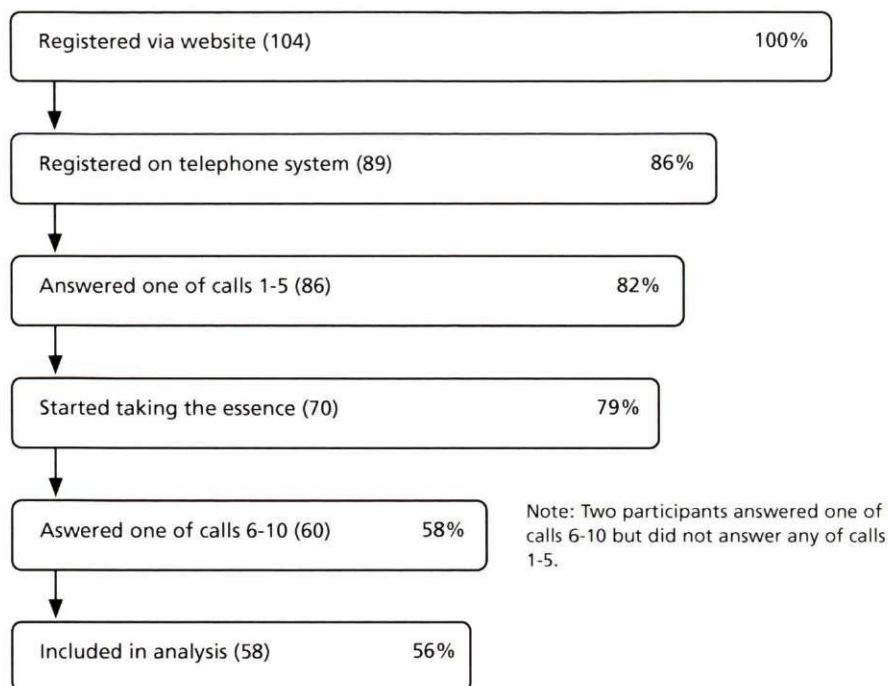
Figure 6.4 shows the numbers of participants at various stages of the study; only participants who completed at least one outcome measure prior to taking the flower essence, and another measure after taking the essence were included in the final analysis. From the 58 parent-child dyads, 48 parents (89%) and 18 children (35%) were female; 41 parents (71%) completed at least 2 calls before and after treatment (i.e., responded to at least 4 calls), and 23 (40%) completed at least 3 before and 3 after. Descriptive statistics for baseline variables are shown in Table 18. Completers and non-completers were compared with one-way analyses of variance for baseline measures (spirituality, expectancy, child gender, child age, parent gender, parent age). No significant differences were found between completers and non-completers, except for child age: Parents of older children were more likely to have completed the study than younger children,  $F(1, 100) = 5.6$ ,  $p = .02$ ; the mean difference was 6.4 months.

Table 6.1: Descriptive statistics for baseline variables

	mean	$\sigma$
Expectancy <sup>amount</sup>	5.7	0.79
Expectancy <sup>speed</sup>	2.6	1.2
Expectancy <sup>combined</sup>	8.3	1.2
Spirituality <sup>*</sup>	4.5	1.0
Parent age <sup>†</sup>	34.0	8.0
Child age <sup>‡</sup>	-41.0	14.0

\* SCQ-14; † years; ‡ months

Figure 6.4: Participant attrition



**Expectancy ratings** Participants were generally positive about the flower essences, although sufficient variability in expectancy was found to test for expectancy effects. Reliability for the two expectancy items was  $\alpha = .47$ , and for the main analysis the items were combined into a single measure of expectancy. The pattern of analyses below remained unchanged if the single item expectancy measure was used in place of the combined score.

**Compliance** Overall, compliance was relatively high. Tables 6.2 and 6.3 show the number of parents initiating treatment at each time point, along with the mean number of doses administered. Figure 6.5 shows the frequencies for participants administering 0, 1 or 2 doses at each time point.

Figure 6.5: Frequency of doses administered at each time point

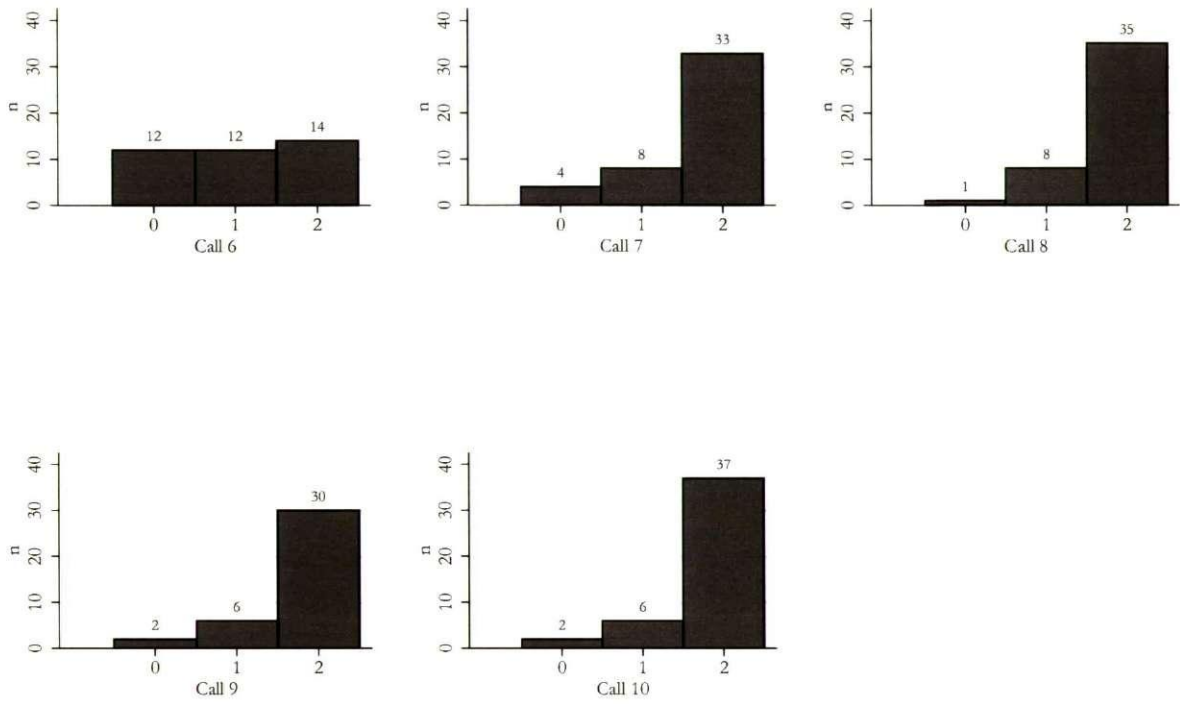


Table 6.2: Percentage of participants initiating treatment at each time point

Day	%
10	66
12	86
14	95
16	97
18	100

Table 6.3: Mean number of doses administered at each time point

Day	Mean	$\sigma$
10	1.1	0.83
12	1.8	0.52
14	1.9	0.45
16	1.6	0.59
18	1.8	0.52

### Changes in response to treatment

**Multilevel approach** In this study, multiple measurements of outcome were taken, both before and after treatment. If enough data were available, a growth curve modelling approach such as that used in Chapter 5 should be able to determine the change in individual trajectories that is attributable to treatment, and also the proportion of this change attributable to other independent variables. This would make it possible to determine which proportion of the change in a child's trajectory was due to being treated, to their parent's dispositional spirituality, and to the interaction between treatment and parent's spirituality—that is, the effect of motivational concordance. However, the number of missing data points for outcome makes it hard to justify growth curve modelling in this instance; too few data points remain to reliably model curves for before and during treatment (in many cases, only one 'before' and one 'during' measurement is available). Nonetheless, a simpler multilevel approach may still be used to model a 'main effect' of treatment and account for predictors of change.

In the analysis which follows measurements of outcome are nested within participants; no further nesting (i.e. use of a three-level model) is required because no separate measurements were taken from children. A dummy variable at level-1 is used

to indicate whether an observation was taken before or during treatment with flower essences (*treated*, 1/0) and estimates for the effect of *treated* are allowed to vary randomly between participants; thus the model allows for children to vary in their response to treatment. Additional independent variables such as spirituality, expectancy, parental mood, are then entered at level 1 or level 2 as appropriate. This approach is similar to a repeated measures analysis of variance, except that level-1 predictors may be included where available, for example using compliance or parental mood to predict outcomes on individual measurement occasions.

**Were reported tantrums reduced when taking flower essences?** This was an open trial with no natural history control. As such, it is impossible to be sure what proportion of any benefit observed should be attributed to the flower essence treatment; other factors, particularly a regression to the mean, may account for a proportion of benefit normally attributed to a placebo, as other authors have noted (Hrobjartsson and Gotzsche, 2001, 2004). However, as was also the case for the studies reported above (see Chapters 3 and 5), estimating the efficacy or effectiveness of a Bach flower (i.e. placebo) treatment was not a design goal. Nonetheless, to ensure that changes in symptoms had occurred—and therefore that there was an improvement in symptoms which might be predicted by dispositional variables—a model was developed to predict standardised combined tantrum scores ( $\text{tantrums}_z^{\text{combined}}$ ) from a level 1 variable of *treatment* (coded 0/1 to indicate whether an observation had been made before or during treatment). Coefficients for treatment were allowed to vary randomly between participants. Results are displayed in Model 1 in Table 6.4. Treatment accounted for approximately half of one standard deviation in outcome scores, indicating that children's behaviour improved significantly during the study ( $p < .001$ ).

Table 6.4: Models predicting combined tantrum ratings ( $\text{tantrums}_z^{\text{combined}}$ ) before and after treatment

Model	Variable	Coef.	Std. Error	p
1	<i>treatment</i>	-0.495	.066	<.001
	[log likelihood = -406, N = 58, observations = 397]			
2	<i>treatment</i>	-0.255	.099	.010
	<i>parentalmood</i> <sup>-1</sup> <sub>z</sub>	-0.092	.040	<.001
	[log likelihood = -256, N = 54, observations = 257]			
3	<i>treatment</i>	-0.261	.091	.004
	<i>parentalmood</i> <sup>-1</sup> <sub>z</sub>	-0.082	.044	.064
	<i>spirituality</i> <sub>z</sub>	0.209	.096	.029
	<i>spirituality</i> <sub>z</sub> × <i>treatment</i>	-0.218	.091	.017
	[log likelihood = -253, N = 54, observations = 257]			
4	<i>treatment</i>	-0.217	.099	.029
	<i>parentalmood</i> <sup>-1</sup> <sub>z</sub>	-0.095	.045	.034
	<i>spirituality</i> <sub>z</sub>	0.251	.114	.028
	<i>spirituality</i> <sub>z</sub> × <i>treatment</i>	-0.228	.114	.046
	<i>expectancy</i> <sup>combined</sup> <sub>z</sub>	0.083	.099	.400
	<i>expectancy</i> <sup>combined</sup> <sub>z</sub> × <i>treatment</i>	0.040	.101	.691
	[log likelihood = -237, N = 52, observations = 242]			

**Was change in reported tantrums predicted by parental mood?** It was hypothesised that parental affect, or mood, would predict changes in reported tantrums among our sample of children. Although 'mood' may often be conceived as a short-term summary report of affective state, autocorrelations exist within time series data of mood states spanning multiple days (Huba et al., 1976). In this dataset, significant autocorrelation was found for parental mood,  $F(1, 42) = 8.37$ ,  $p = .006$  (Drukker, 2003), and it was, therefore, possible that parental mood might predict tantrums over subsequent days. To test whether this was the case, a lagged level-1 variable of standardised parental mood was created,  $parentalmood^{-1}_z$ . This variable comprised the parental response measured at the *previous* time point. A lagged variable was used to ensure that responses could not be influenced by the tantrum symptoms which were themselves to be predicted. Model 1 was repeated with  $parentalmood^{-1}_z$  included at level-1, and results are displayed as Model 2 in Table 6.4. Parental mood was a significant predictor of reported tantrums at the subsequent point of measurement ( $p < .001$ ).

**Did dispositional spirituality amongst parents predict a reduction in reported tantrums with treatment?** Adapting the multilevel analysis used in Chapter 5 (see page 117), growth curve models were developed to predict whether children of highly spiritual participants responded more positively to treatment than did children of non-spiritual parents. Because measurements of outcome were taken both before and during treatment, to test the hypotheses it was necessary to establish whether *treatment* interacted with spirituality scores. For Model 3 (see Table 6.4) parameters from Model 2 were reprised, with two new terms added: standardised scores on the SCQ-14,  $spirituality_z$ ,



and the product term for spirituality and treatment,  $spirituality_z \times treatment$ . Inspection of the coefficient for the product term indicates that spiritual participants were significantly more responsive to treatment ( $p .017$ ). However the coefficient for  $spirituality_z$  indicates that spiritual participants were also more likely to report more tantrums *before* treatment ( $p .029$ ). Because of the method of analysis employed (i.e. examining interactions between treatment responses and dispositions within the individual), it is unlikely that these higher baseline scores account for the greater treatment responses among spiritual participants. Although it is possible that a scaling effect is occurring, whereby spiritual participants have greater room for improvement in symptoms, in previous studies (e.g. Hyland and Whalley, in press) spirituality was found to predict outcome without also predicting higher baseline symptoms.

#### **Did expectancy predict outcomes, or mediate the effect of spirituality on outcomes?**

Scores for the two expectancy questions were averaged to create a more reliable composite measure of expectancy:  $expectancy^{combined}$ ;  $\alpha$  for the two items was  $.47^2$ . This new variable was standardised,  $expectancy^{combined}_z$ , and entered alongside the product term for  $expectancy^{combined}_z \times treatment$  into Model 4; results are shown in Table 6.4. The interaction of expectancy and treatment was not significant ( $coef = .04$ ,  $p .69$ ), indicating that expectancies of parents did not account for changes in tantrum behaviour in response to treatment. Parental expectancies did not predict higher overall levels of reported tantrums (as did spirituality).

**Did telling a child the purpose of the essence (i.e. generating expectancies) increase treatment effects?** To test whether affirmative responses to the follow-up question

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<sup>2</sup>Repeating the analysis below with separate scores produced almost identical results

(*toldchild*), indicating that parents told their children that the essence would help their tantrums, would predict larger treatment effects, an additional model was computed. This followed the pattern established above: combined outcome scores were predicted by the variables: *treatment*, *toldchild*, and the product of *treatment*  $\times$  *toldchild*; this product term was not a significant predictor (*coef*=  $-.12$ , *p* .23 ) indicating that children who were told the essence would help experienced no greater benefit than children who were not told.

**Did compliance with treatment predict a reduction in tantrums?** To test whether compliance predicted variance in outcome, a conventional growth-curve model was computed predicting tantrum scores during the treatment phase only (i.e. *tantrums<sub>z</sub><sup>combined</sup>*, but excluding assessments made before treatment began). As in Chapter 5, trajectories over the days of assessment were allowed to vary randomly for individual participants, and compliance scores were entered as a level-1 predictor. In this model, compliance did not predict tantrum scores (*coef*=  $-.009$ , *p* .921 ). However, compliance scores may have lacked sufficient variation to predict outcomes in this way (see above, and discussion).

## 6.4 Discussion

This study shows that placebo or 'meaning responses' are possible in young children when caregivers deliver the therapy to the child. Carer's responses indicated that there was a reduction in both the frequency and severity of reported tantrums. Seventy six percent of those who completed the study reported a drop in tantrum frequency, and about a third of the sample experienced a reduction in frequency of reported tantrums to less than

50% of their original value. Consistent with previous research on adult use of FEs (see Chapters 3 and 5, and Hyland et al. 2006), spirituality correlated with positive outcome, but caregivers' expectancies did not predict change.

Of four possible explanations for the reduction in tantrums, two are inconsistent with these data. It is unlikely that the reduction is due to either (i) parents expecting benefit, communicating this to children, and eliciting a response expectancy in the child, or (ii) parents expecting benefit and so perceiving an improvement in the absence of real change. In both cases expectancy should predict outcome and should mediate the relationship between dispositions and outcome; this was not the case in this study.

It appears more likely that either (iii) parental mood improved because of motivational concordance with the flower essence therapy, and so caused parents to perceive an improvement in their child's behaviour, without real change having taken place, or (iv) that motivational concordance improved parents' mood, and subsequently altered their behaviour to create a real reduction in tantrums. Dispositional spirituality of parents predicted reported responses of children, and as in previous studies this relationship was not mediated by expectancy.

Because changes in parent behaviour were not measured directly and measures of tantrums were subjective, these data do not directly help distinguish between hypotheses 3 and 4. However there are a number of reasons to believe that the change in tantrums was real rather than simply perceived, and stemmed from changes in parental behaviour. Reductions were observed for all measures of tantrums, including reports of tantrum frequency, which are less likely to be biased than subjective ratings of severity. Furthermore, these measures were made on repeated occasions and required participants to recall the incidence of tantrums over a relatively short period of time (24 hours); it is known that retrospective judgements are subject to recall biases (Kahneman et al., 1982;

Redelmeier et al., 2003), and that more frequent sampling may partially alleviate these problems (Scollon et al., 2003).

Children are sensitive to parental cues of distress or dissatisfaction (McDonald et al., 2007). If child rearing is found to be non self-actualising, then parents may emit cues that elicit tantrums. Spirituality is generally considered a psychologically healthy disposition; it is correlated with better mental health (Ellison and Levin, 1998; Siegel et al., 2001) and addressing spiritual needs may hasten physical recovery (Mueller et al., 2001). However in this study high pre-treatment spirituality correlated positively with tantrum frequency. Although spiritual people might systematically differ from non-spiritual people on other attributes, this finding is consistent with a hypothesis that the everyday experience of child rearing may fail to enable self-actualisation for spiritual people. The instruction to “imagine the flower connecting the child to a universal pool of healing and love” provides spiritual people with the opportunity to re-conceive child-caring as a spiritual, and thus self actualising, activity. This may alter the affective tone between the caregiver and the child, and thereby reduce tantrum-inducing cues. Many parents sent emails after the study to say how effective the treatment was, and that the change in the child was instantaneous—consistent with the hypothesis of cue elimination rather than a change in reinforcement schedule; a selection of qualitative feedback recorded during the study is included in A.12 on page 239.

A limitation of this study was that no wait-list or no-treatment control was included. It is therefore possible that changes were due to natural history, regression to the mean or other artefacts confused with placebo effects (McDonald et al., 1983; Kienle and Kiene, 1997). However dispositional spirituality, as in previous studies, predicted the degree of therapeutic benefit; because of the analyses employed, it is unlikely that this relationship is the result of statistical artefacts; natural variation and regression must

occur, but this variation will tend to reduce the size of correlations between outcome and predictors and does not pose a threat to the validity of this study. Nonetheless, to estimate the true size of the effects observed, future studies would benefit from both a control group and objective measures of child behaviour—perhaps via ambulatory recording of physiological variables associated with arousal.

Additionally, the attrition rate for this study was relatively high when compared to the previous studies. Although high attrition rates are normal in studies of self help therapy, some caution is required when interpreting coefficients when data for such a large number of participants is unavailable.

### Conclusion

This study provides limited evidence for the existence of a ‘vicarious placebo effect’. As in previous studies, concordance between the motivational context of a placebo and the high-level goals of participants seemed to be responsible for the therapeutic benefits observed, lending additional credence to motivational concordance theory.

## Chapter 7

### Choosing the right therapy: are expectancies for therapy outcome determined by values?

An attempt is made to broaden the range of pairings between motivational dispositions (or values) and outcome for specific therapies. Studies to date have found relationships between dispositional spirituality and response to a flower essence therapy, and between dispositional gratitude and response to gratitude therapy. However, generalising predictions from the motivational concordance hypothesis requires that the value-contexts of therapies are identified. This would allow therapists—for instance eclectic psychotherapists—to select therapies uniquely suited to their patients. Here, multidimensional scaling is used to relate validated scales of dispositional values to the perceived efficacy of a range of therapies for depression. Data are presented which should facilitate identification of contextually-specific dispositions for the therapies studied<sup>1</sup>.

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<sup>1</sup>This data is reported in: Whalley and Hyland (in press b)

## 7.1 Introduction

Half a century ago, Lee Cronbach suggested that the important question in psychotherapy was not whether therapy was effective, but rather which therapy and for whom (Cronbach, 1953). This suggestion was based on the observation that patients are not uniform and so may respond differently to different therapies (Kiesler, 1966). The continuing popularity of eclecticism in clinical practice (Norcross et al., 2002), as compared with the manualised therapies that are subjected to randomised trials, rests on an assumption that treatment should be tailored to the patient. However, this commonsense notion—that one size will not fit all—has not been matched by unambiguous evidence upon which researchers and clinicians could recommend individual treatment decisions.

**Patient-treatment interactions** Part of the problem is that patient-matching—selecting the appropriate treatment for any individual patient—can be considered in different ways. First, different types of therapy may be appropriate depending on the state of the patient in the disease/treatment process, for example, the patient's stage of change (Prochaska and Norcross, 2002) or the phase of psychotherapeutic treatment (Beitman, 1987). Second, matching based on traits of patients might be used to aid practitioners when selecting techniques within a therapeutic orientation. Particular techniques might be considered more suited to one patient than another, irrespective of the stage of disease or treatment (Hollon and Beck, 1986). Third, therapists can adopt a 'technical eclecticism' in which patients' trait characteristics determine the selection of effective techniques, irrespective of theoretical orientation (Lazarus, 1981), and both trait and state characteristics may be combined (Beutler et al., 2000). In this paper, we examine the extent to which dispositional characteristics can be used to inform choice between

theoretically diverse therapies.

**Previous patient-treatment interaction research** Some interactions have been found between stable patient characteristics<sup>2</sup> and types of therapy. In a study of individual treatment for major depression, Ogrodniczuk et al. (2001) found a large sex-by-treatment interaction: Men experienced greater improvement in interpretative as opposed to supportive therapy, and this pattern was reversed among female patients. In a second study of group therapies for depression (Ogrodniczuk et al., 2004), there was no interaction but instead a main effect of gender, with women experiencing much larger gains than men in group therapy. Reanalysing RCT data, Blatt and Shahar (2004) found that pre-treatment patient characteristics differentially predicted response to psychoanalytic and supportive/expressive treatments. Patients were classified according to clinical case reports, and “dependent and affectively labile” patients showed greater improvement with supportive treatment than with psychoanalytic treatment. However, psychoanalytic treatment was more effective for “independent and self critical” patients, for whom supportive therapy induced a slight worsening in symptoms. In a comparison of cognitive, experiential, and supportive therapies, Beutler et al (1991) found that externalising and non-defensive patients improved most in response to cognitive therapy, whereas internalising and defensive patients responded best to experiential or supportive therapy. Miller (1991) claims, on the basis of clinical experience, that individuals low in openness may prefer directive therapies whereas those high in openness may benefit from more imaginative approaches, and also that extraverts may respond more positively to treatment if the therapist speaks quickly and avoids long introductory sessions. Interventions for smoking cessation also appear sensitive to baseline characteristics of

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<sup>2</sup>Note: patient-treatment interaction research based on the severity or type of dysfunction a patient is suffering is not discussed here, although the picture is similarly unclear.



clients (Hall et al., 1998; Jacobs et al., 1971; Ogrodniczuk et al., 2003; Canuto et al., 2007).

**Empirical and theoretical problems with patient-treatment interaction research** Despite these interesting findings, reviewers note that research has been patchy, and hampered by the lack of a theoretical framework for predicting interactions (Dance and Neufeld, 1988). Additionally, several high profile studies have failed to match patients with treatments. Project MATCH, a large RCT for alcohol treatments (Project MATCH Research Group, 1993), was specifically designed to facilitate the identification of patient-treatment interactions. The failure to match patients to therapies in this study, and also in similar UK studies (Heather et al., 2008), has led some researchers to call into question the whole endeavour of attempting to match patients to alternative treatments (Allen et al., 1998). There are a number of explanations for the difficulty in identifying interactions between types of patients and different therapies. First, identifying individual differences in clinical settings is fraught with methodological problems and costs (Shoham-Salomon, 1991). In particular, large samples are required to demonstrate patient/treatment interactions. Secondly, recognising that different patients will respond to different treatments has appeared philosophically at odds with the recent drive to demonstrate the efficacy of 'specific' psychological treatments and techniques and gain institutional support for their dissemination. Thirdly, and perhaps most importantly, researchers interested in common factors, or eclectic clinicians delivering a variety of techniques, have lacked a broad theoretical rationale (beyond the observation that their patients differ) for individual differences in response to different therapeutic approaches (Dance and Neufeld, 1988). Here we propose that motivation theory—in particular the relationship between self-actualising behaviours and positive affect—may explain at least part of the variance in individual responses to psychological treatments.

**An alternative approach: common factors and human values** It is possible that researchers have simply been testing the wrong matching hypotheses. The interactions that are tested have often been based on matching hypothesised 'specific' components of therapies studied and relevant dispositional characteristics of the patient. However, there is considerable evidence that specific factors play only a small role in psychotherapy outcomes compared with contextual factors (Wampold, 2001). If contextual factors play an important role in outcome, it may be more productive to predict interactions from clients' perceptions of therapies rather than from researchers' theoretical understanding of the therapeutic process.

**Using motivational concordance to identify interactions** Motivational concordance, as described in Chapter 4, may be helpful in the attempt to predict patient-treatment interactions. In previous flower-essence studies, a dispositional measure of values (spirituality) was related to both expectancies for positive outcome and outcome (where the therapy was concordant with the disposition measured).

These effects are explained with reference to theories of motivation: self help therapies constitute a ritual which enables the expression and fulfilment of self-defining goals, and this goal-achievement leads to subjective well-being. It follows, that the 'non-specific' benefits of motivational concordance will be experienced in addition to any 'specific' benefits a therapy has (e.g. the psychological benefits of taking an antidepressant medication will be experienced in addition to the pharmacological action of the drug). Therefore, in order to maximise contextual benefits of a therapy, researchers or practitioners should select therapies that are concordant with their clients' motivational dispositions (or the therapies re-contextualised in such a way as to maximise congruence).

Unfortunately, in real-life contexts the motivational characteristics of therapies are unknown and without this information it is impossible to select motivationally concordant therapies. The priority, therefore, is to identify the motivational characteristics of real-world therapies, after which new pairings of dispositions and therapies may be identified in studies of real therapy outcomes.

**Structure of human values** As discussed above (see page 86), 10 (or 12) human values may be thought of as high-level goals towards which people may express varying degrees of commitment. Results from large-scale, cross-cultural studies suggest that human values form a circular two-dimensional structure, most likely a circumplex (Schwartz, 1994; Grouzet et al., 2005).

This larger structure provides a useful starting point for our task of attempting to describe the motivational characteristics of therapies for depression. In the motivational concordance studies, congruent dispositions (spirituality, gratitude) were correlated with expectancy for benefit, but values predicted variance in outcomes independently of expectancy. That is to say, where patients have values that are congruent with a therapy then they will have positive expectancies for it, but that the relationship between congruence and positive outcomes does not depend on these expectancies.

For the purposes of this study, it is assumed that this pattern continues for other dispositions. If the assumption proves to be correct, it may be possible to identify pairings of relevant motives and therapies by, in the first instance, mapping the relations between values and the *perceived efficacy* of various therapies, and later directly testing the independence of the relationship between congruence and outcome.

## Aim

Do a person's values predict their perceptions of effectiveness for different therapies? A questionnaire was designed to answer this question, and samples collected from two populations: undergraduate psychologists and members of the general public. Because of the exploratory nature of this research, it was not appropriate to conduct it in a therapeutic context at this stage, for instance by observing correlations between motivational variables and real therapy outcomes. Instead, a laboratory analogue is used to gain preliminary data. Perceived effectiveness, or expectancy of benefit from a therapy, was measured, rather than an outcome for a real therapeutic intervention. Therefore, this is not a direct test of the hypothesis that therapies that are concordant with a patient's values will improve therapeutic outcomes. Nevertheless, the data presented provide a starting point from which to establish such a relationship in future studies. The approach is to (a) describe various therapies for a common psychological complaint (depression), (b) elicit ratings of perceived effectiveness of those therapies, (c) measure dispositional values and (d) perform multidimensional scaling (MDS) to identify similarities between dispositional values and the perceived effectiveness of therapies. For comparison with previous studies, a description of a therapy (Bach flower essences) for which dispositional values (dispositional spirituality) are known to predict therapeutic outcome, was included.

## 7.2 Methods

**Recruitment and procedure** Sample 1 comprised undergraduates at the University of Plymouth who volunteered in return for partial course credit. For sample 2 members of the public volunteered to complete questionnaires, and were entered into a prize draw

for £100. The study was publicised via the university intranet, internet message boards, and with keyword and location-specific advertising. Online advertising appeared on the Google search network. In both cases, inclusion criteria were UK residence and age 18+. Exclusion criteria were a current diagnosis for a serious psychological condition or current receipt of psychological treatment for depression. Participants consented to the study and completed questionnaires online. Ratings of therapies were completed first, followed by questionnaire measures.

**Study website** In common with studies presented above, the study website was built using open source software (PHP and MySQL), and a library of functions to generate online questionnaires which were written by the author (see page 112 for more details). These functions convert questionnaires in spreadsheet format to a series of HTML pages, and securely record user inputs. Procedures for informed consent, anonymity and data security were the same as those followed in Chapter 5 (see page 112).

**The therapy vignettes** Participants read a series of vignettes of 6 therapies for mild-moderate depression, and were asked to picture themselves in a situation in which they might need this type of support. The therapies were: cognitive behavioural therapy (CBT), antidepressant drug therapy (Drug), psychodynamic psychotherapy (Psychodynamic), existential psychotherapy (Existential), client centered psychotherapy (Rogerian), and flower essence therapy (Flowers). Therapies were selected on the basis that they should be perceived as distinctly as possible; flower essence therapy was included primarily as a point of comparison with previous work. The descriptions of the therapies were constructed and expressed in terms of treatment for depression. Each description stated the cause of depression presupposed by the therapy and the remedy

proposed and the type of practitioner responsible for the treatment (see Table 7.1 for summary details).

Table 7.1: Key information from the therapy vignettes

Therapy	Supposed cause of depression	Remedy and type of practitioner
Rogerian psychotherapy	Experiences that are harmful to the person, including lack of unconditional positive regard.	The counsellor avoids judging the client in any way, attempts to understand their problems fully - in the client's own terms - and offers unconditional positive regard.
CBT	Inaccurate or incorrect beliefs and thought patterns.	A clinical psychologist teaches the client exercises which help control and challenge unhelpful thoughts, and develop positive thought patterns.
Drug therapy	Chemical imbalance in the brain (lack of serotonin).	Antidepressant drugs increase levels of serotonin in the brain. After being prescribed by a medical doctor the drug is taken each day.
Existential psychotherapy	Being overwhelmed by meaninglessness of life.	The existential psychotherapist (a psychologist) will focus on present problems, ways to progress in the future, and explore with the client how they find meaning in life.
Flower Essences	Energy flow can be unbalanced by the pressures of modern life, leads to emotional and psychological problems.	Flower essences capture the energy signature of plants. This healing energy can be transmitted to the client via the essences, which are dispensed by complementary practitioners.
Psychodynamic psychotherapy	Unconscious (repressed) memories, often of early childhood experiences, brought about by psychological trauma.	The psychotherapist recovers repressed memories using dream analysis, hypnosis and word association, interprets dreams and other statements, bringing prior memories into conscious awareness and resolves them.

**Perceived effectiveness of the therapies** For each therapy participants were asked, “If you were depressed, how likely is it that this therapy would work for you?” and “Does this therapy ‘feel right’ to you?” Responses were made on 7-point scales, and the anchors were *Very likely to work for me/Very unlikely to work for me*; and *Feels right/Doesn’t feel right*. Responses to both questions were highly correlated and were combined to form a perceived effectiveness score for each therapy; Cronbach’s  $\alpha$  for item pairs ranged from .83 to .87 in sample 1, and from .85 to .92 in sample 2.

**Questionnaire measures** Participants completed the Spiritual Connection Questionnaire 14 (SCQ-14; Wheeler and Hyland, 2008) and the Schwartz Values Scale (SVS; Schwartz, 1994). The SCQ-14 consists of seven positive and seven negative items about the experience of spiritual connection with the universe and other people, and the happiness such connection brings. The SCQ-14 correlates with outcome for flower essence therapy. The SVS has 57 items, each of which is followed in parentheses by a short explanatory phrase. For instance item 1: “Equality”, is followed by the phrase: “Equal opportunity for all”. Respondents rate the importance of each value item as a guiding principle in their life on a 9-point scale from opposed to my principles (-1), through not important (0), to of supreme importance (7). Responses were scored in accordance with the author’s instructions to create ten subscales: Conformity, Tradition, Benevolence, Universalism, Self-Direction, Stimulation, Hedonism, Achievement, Power and Security. Higher scores indicate greater importance.

**Analysis** Although the comparative model fit of variants of the circumplex model is normally tested via confirmatory factor analytic models (Schwartz and Boehnke, 2004; Perrinjaquet et al., 2007), the relationships between values are best visualized with



multidimensional scaling (MDS). MDS is particularly useful for revealing unknown structures (Shepard, 1964), and when dealing with large correlation matrices (Hills, 1969), and is therefore well suited for our exploratory purposes. MDS is a set of related techniques for exploring similarities or dissimilarities in data. A matrix of dissimilarity relationships may also be constructed from the inter-correlations between responses, and here this technique is used to overlay relations between (a) scales of values and (b) ratings of perceived effectiveness of therapies for depression. If participants rate a particular pair of items in a similar manner they will be located in a multidimensional space such that the distance between them is smaller than the distance for other pairings. The resulting map indicates the relations between all items in the analysis. Correlation matrices are also provided for reference. MDS was performed using Stata 10. Dissimilarity matrixes for correlations between items were computed (Borg and Groenen, 2005), and scaled using iterative non-metric MDS. Because the relative positioning of axes within MDS plots is essentially arbitrary, plots were rotated where this aided comparisons between samples. Model fit was assessed using conventional stress indices, and with comparison to previous MDS studies of human values (Schwartz and Boehnke, 2004). In all cases two-dimensional solutions were preferred on the grounds of interpretability, and for comparability with previous data on the structure of values.

**Research ethics** Permission to administer the questionnaire battery described above to (i) undergraduate participants and (ii) members of the general public was obtained from the University of Plymouth Human Sciences Research Ethics panel. No risk of harm to participants was identified, although particular attention was paid to ensuring participants gave informed consent. Briefing information was written in clear and straightforward English, and care taken to omit any psychological jargon. To successfully

register on the online system participants were required to 'tick' an html checkbox, indicating that they understood the briefing information and agreed to take part in the study.

### 7.3 Results and Discussion

For sample 1, 126 undergraduates, of whom 111 (85%) were female, completed questionnaires; the average age was 21,  $\sigma = 6$ . For sample 2, 163 members of the public, of whom 113 (69%) were female, volunteered to complete questionnaires online. Nine responses were excluded because of missing data and the average age was 32 years,  $\sigma = 14$ .

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.
1 CBT	1															
2 Rogerian	-0.19*	1														
3 Drug	-0.13	-0.37**	1													
4 Existential	0.06	-0.13	-0.27**	1												
5 Flowers	-0.27**	-0.11	-0.37**	-0.21*	1											
6 Psychodynamic	-0.38**	-0.24**	-0.04	-0.35**	0.01	1										
7 conformity	-0.20*	-0.19*	0.16	-0.08	0.20*	0.07	1									
8 tradition	-0.26**	0.09	-0.13	-0.16	0.20*	0.26**	0.22*	1								
9 benevolence	-0.06	0.18*	0.0	0.01	-0.08	-0.06	0.09	-0.12	1							
10 universalism	0.17	-0.03	-0.29**	0.06	0.12	0.04	-0.17	-0.12	0.04	1						
11 selfdirection	0.20*	0.1	-0.14	0.19*	-0.16	-0.16	-0.35**	-0.23*	-0.09	0.02	1					
12 stimulation	0.04	0.01	-0.09	0.04	-0.02	0.05	-0.43**	-0.20*	-0.29**	-0.05	0.31**	1				
13 hedonism	0.09	-0.03	0.24**	-0.12	-0.13	-0.08	-0.34**	-0.36**	-0.07	-0.36**	0.07	0.31**	1			
14 achievement	-0.05	0.1	-0.06	0.06	-0.05	0.0	-0.1	-0.05	-0.05	-0.25**	0.22*	0.03	-0.06	1		
15 power	-0.14	-0.02	0.24**	-0.05	-0.05	-0.03	0.0	0.0	-0.30**	-0.46**	-0.21*	-0.01	0.26**	0.1	1	
16 security	-0.01	-0.17	0.32**	-0.1	-0.06	-0.02	0.12	0.05	-0.16	-0.33**	-0.42**	-0.26**	0.13	-0.20*	0.26**	1
17 Spirituality	-0.23*	0.18*	-0.29**	-0.04	0.23**	0.16	-0.01	0.1	0.13	0.18*	-0.06	-0.08	-0.24**	0.05	-0.34**	-0.26**

\*p < .05; \*\*p < .01

Table 7.2: Correlation matrix of expectancy and value variables in sample 1

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.
1 CBT	1															
2 Rogerian	-0.16*	1														
3 Drug	-0.09	-0.32**	1													
4 Existential	0.03	0.04	-0.25**	1												
5 Flowers	-0.31**	-0.24**	-0.28**	-0.36**	1											
6 Psychodynamic	-0.39**	-0.20**	-0.17*	-0.30**	0.04	1										
7 conformity	-0.04	0.15	-0.11	0.07	-0.10	0.06	1									
8 tradition	-0.18*	0.03	0.010	-0.17*	0.13	0.14	0.40**	1								
9 benevolence	0.18*	-0.02	-0.03	0.12	-0.20*	-0.01	0.08	-0.05	1							
10 universalism	0.07	0.09	-0.22**	0.04	0.09	-0.05	-0.30**	-0.22**	0.12	1						
11 selfdirection	0.09	0.01	0.02	0.03	0.04	-0.18*	-0.49**	-0.51**	0.01	0.34**	1					
12 stimulation	0.05	0.10	0.02	0.0	-0.06	-0.10	-0.42**	-0.34**	-0.22**	-0.01	0.38**	1				
13 hedonism	0.1	-0.14	0.19*	-0.11	-0.14	0.08	-0.24**	-0.31**	-0.14	-0.38**	-0.05	0.31**	1			
14 achievement	-0.01	-0.05	0.10	-0.07	-0.08	0.11	0.04	-0.12	-0.41**	-0.44**	-0.03	0.24**	0.20*	1		
15 power	-0.17*	-0.08	0.17*	-0.07	-0.10	0.01	0.22**	0.18*	-0.44**	-0.60**	-0.38**	0.00	0.22**	0.38**	1	
16 security	-0.06	0.00	0.010	0.0	-0.02	0.07	0.41**	0.15	-0.10	-0.32**	-0.47**	-0.50**	-0.05	-0.04	0.26**	1
17 Spirituality	-0.19*	0.10	-0.37**	0.04	0.42**	-0.02	-0.11	0.14	-0.01	0.29**	0.18*	-0.06	-0.42**	-0.17*	-0.25**	-0.27**

\*p < .05; \*\*p < .01

Table 7.3: Correlation matrix of expectancy and value variables in sample 2

Correlation matrices of all variables for samples 1 and 2 are shown in Table 7.2 and Table 7.3. Results of the MDS analysis are presented in Figure 7.1 and Figure 7.2. Figure 7.1 shows MDS solutions including only the value scales (SVS subscales and the SCQ-14). For both samples, the relative positions of SVS subscales are comparable with previous work on the SVS (Schwartz and Boehnke, 2004; Perrinjaquet et al., 2007), although in the student sample, the position of Achievement was somewhat displaced. For samples 1 and 2 the position of Tradition and Conformity varied, and was found either on the same polar angle, or at separate locations on the circumplex. This reflects an existing debate regarding the independence of these constructs (Perrinjaquet et al., 2007).

Figure 7.2 shows MDS solutions when both the value subscales and perceived effectiveness ratings for therapies were included. Both plots suggest that therapies are perceived and evaluated in terms of values or motives.

**Flower essences** As in previous studies, positive expectancies for Flower essence therapy was associated with Spirituality, and also with Tradition, and was opposed to Stimulation and Hedonism. Because flower essences are explicitly contextualised as a spiritual therapy they act as a form of control in this study, and provide a point of comparison with previous work in which dispositional spirituality predicted real therapeutic outcomes (Hyland et al., 2007, 2006; Hyland and Geraghty, 2008).

**CBT** Positive expectancy for CBT was consistently associated with the values of Self-Direction and Stimulation, and was opposed to Tradition, Conformity and Security. Therefore, participants with high expectancies for CBT may be broadly characterised as high in values relating to 'openness to change', and low in values relating

Figure 7.1: Two-dimensional MDS plots for SVS values and spirituality

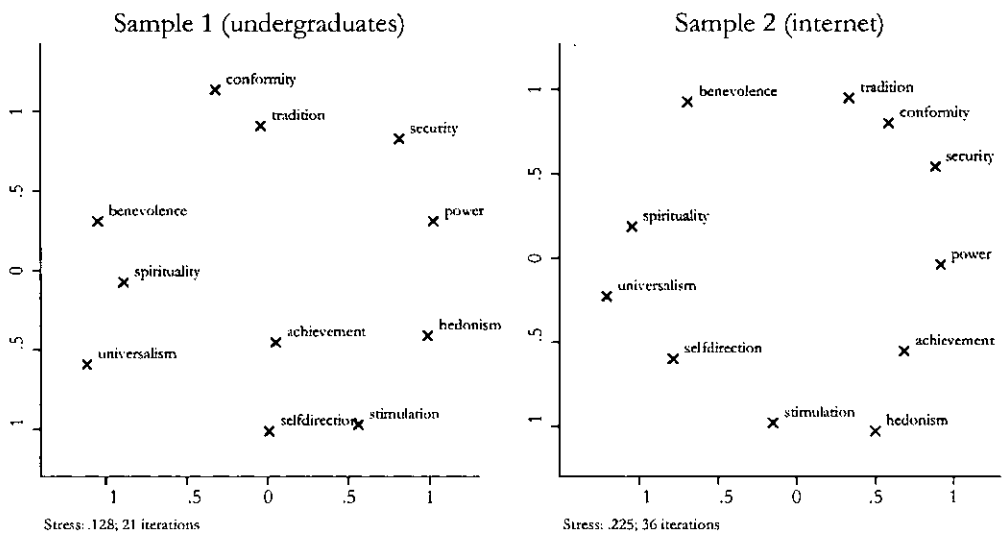
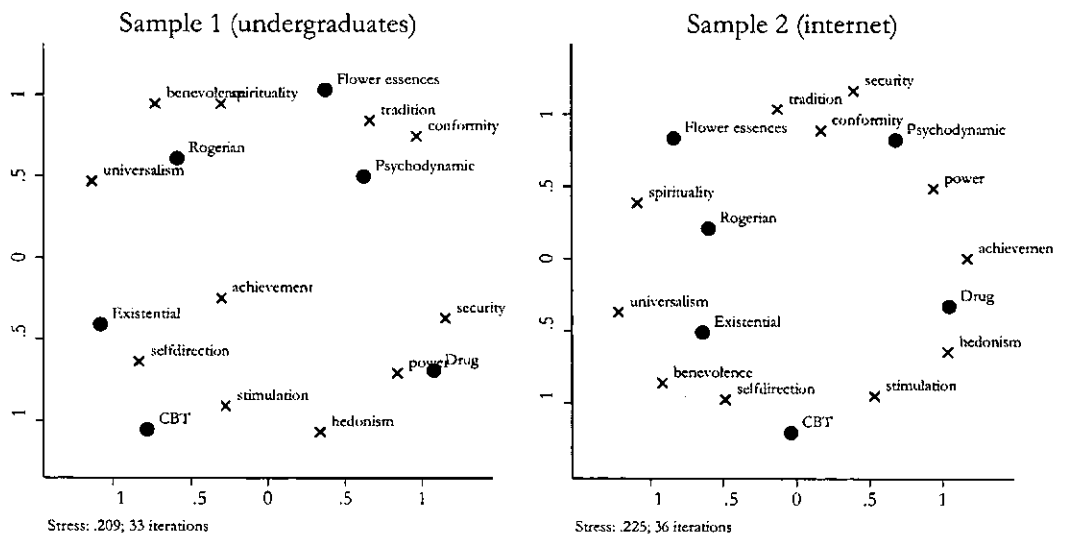


Figure 7.2: Two-dimensional MDS plots for SVS values, spirituality, and therapy effectiveness ratings



to 'conservation' (Schwartz and Boehnke, 2004) or that they focus on 'opportunity' rather than 'organisation' (Rohan, 2000). Intuitively, the relation between CBT and self-direction makes sense; CBT requires participants to undertake active problem solving, and to take a large degree of responsibility for their treatment—institutional or personal authority is not emphasised within the treatment context.

**Drug therapy** Expectancies for Drug therapy were associated with Power and Security amongst undergraduates, and with Hedonism and Achievement in the Internet sample—values that would be classified as 'self-enhancing' or related to individual opportunity. In both samples expectancies for Drug therapy were opposed to Universalism and Spirituality, and for the internet sample Drug therapy was also opposed to Benevolence.

Again, this pattern of relationships makes intuitive sense: because drug therapy does not involve extensive problem solving or talking about difficulties (as does CBT) it may be interpreted as a quicker or more efficient means of treatment, avoiding 'fuss'. Additionally, the fact that drug treatment is delivered by an authority figure within an impressive institutional setting may reassure individuals valuing power or security. As Liberman (1962) noted in a discussion of context-specific predictors of placebo responding:

Patients, especially when sick and totally dependent upon the doctor, could be expected to respond positively to physicians who are viewed as authority figures. Similarly, people who tend to possess uncritical respect for authorities in general (such as parents, employers, the church) may be susceptible to the induction of placebo effects by 'authority-type' doctors. (Liberman, 1962, p. 773)



Finally, it may be that the relation to hedonism is caused by a requirement for quick gratification (a relatively simple solution to the problem) overriding other concerns.

**Psychodynamic, Existential and Rogerian therapies** Associations with Psychodynamic, Existential and Rogerian therapies were less reliable between samples, but nonetheless revealing.

Existential psychotherapy was consistently associated with Self-Direction, but also with Benevolence in the internet sample. Psychodynamic therapy tended to be associated with self-enhancement or conservation values (e.g. tradition, security, conformity). Rogerian therapy was associated with Universalism, Spirituality and Benevolence in the undergraduate sample, but was less clearly placed in the internet sample. These relationships, while less consistent than those for the Drug and CBT therapies, retain an intuitive sense, and appear to reflect the differences between the therapies: Self-direction is emphasised in existential psychotherapy, because the therapy itself is concerned with the participant finding meaning in life. Universalism and Benevolence are clearly compatible with the general approach of Rogerian practitioners; and the direction provided by the therapist in the Psychodynamic therapy (as described in the vignette) appears to have appealed to participants who valued conservation-oriented values such as tradition and conformity.

**Agreement with bivariate correlations** With few exceptions, this pattern of results was replicated in the bi-variate correlations (see Table 7.2 and Table 7.3). Because relative positions within the MDS solutions are likely to be more stable than a correlation for any single pair of variable, these are used as the primary outcome of these studies. However, the fact that there exist moderately-sized correlations between expectancies

and values (comparable with correlations between expectancy for flower essence therapy and dispositional spirituality found in earlier studies) provides encouragement that these measurements of values may be of use when predicting real therapeutic outcomes.

**Limitations** A number of additional limitations of the study must be noted. First, the samples were drawn from healthy volunteers with no current or past diagnosis of depression or any other mental illness. Interpretations and evaluations of different therapies may change as a result of the experience of illness, although the results from both samples were comparable despite significant differences in average age.

Second, the associations revealed by the MDS models are between values and perceived effectiveness, and not real therapeutic outcomes, and perceived effectiveness was evaluated for only one condition: depression. Although expectancies may correlate with outcomes, further work is needed to establish whether dispositional values can predict real therapeutic outcomes.

Third, both value and expectancy measurements depend on self-reports, and may be subject to various presentational biases. Recent methodological developments in social psychology, including the use of reaction time tasks in which participants categorise category-relevant words may be of use in developing new measures of values (Nosek et al., 2006; Nosek and Banaji, 2001). In fact, this type of task was suggested as early as 1937; Allport noted that, during word association tasks, participants responded more quickly to stimulus words associated with their interests.

Fourth, the vignettes used in this study are not in any sense 'thick descriptions' of the therapies investigated (Geertz, 1973). Reading about a therapy is very different from experiencing it first hand, and the meanings attached to therapies in real life may differ from those elicited by the vignettes. Videotaped encounters from real

therapeutic sessions might represent an improvement over short vignettes, although suitable materials may be hard to obtain, and it is not clear how variation due to the therapist or the clients involved in the taped sessions would be controlled between therapies.

Finally, indices of stress in our MDS models were low in comparison to previous work on the SVS, but high when compared to conventional cut-off levels (e.g. stress  $< .2$ ). There are two possible sources of stress in MDS: insufficient dimensionality and a lack of reliability in measurement; both may have contributed to observed stress in our data. Although the SVS values are well described by a two-dimensional model, it seems unlikely that evaluations of therapies are constrained solely by their motivational characteristics, and this may account for the increased stress in the combined models. It may also be the case that some therapies have a greater motivational 'press' than others, or are interpreted more flexibly by participants creating a less reliable association with single value. Additionally, the SVS is a broad instrument designed to measure a wide

range of values. Each sub-scale is composed of between 2 and 9 items, and the sub-scales with small numbers of items are likely to be less reliable.

Notwithstanding, this study has, for the first time, identified a correspondence between dispositional values and perceived effectiveness of therapies, drawing on a theoretical rationale derived from motivation theory and the contextual model of therapy. Because perceived effectiveness is an important determinant of outcome in psychotherapy (Kirsch, 2005), this alone may have clinical implications, providing a theoretical rationale for clinicians to tailor the way in which any given therapy is presented. From a practical perspective, these preliminary data suggest that tailoring the presentation of standard therapies to the motivational characteristics of patient may be of therapeutic benefit. For example, if a patient is identified as highly spiritual then cognitive behavioural therapists could present standard techniques in a more spiritually oriented way—for instance using prayer or affirmation as homework—and place less emphasis on scientific validation of the treatment. Similarly, if a patient is high in Benevolence, then emphasising values of kindness or caring within the treatment may be particularly beneficial. This conclusion is in accordance with early unpublished studies, reported by Rokeach (Rokeach, 1973), in which attrition in psychotherapy was associated with concordance between the values of patient and therapist; it may be the case that the motivational context of the therapy, as perceived by the patient, is determined in part by the values of the person delivering it.

## Conclusion

Patients with mental health problems are faced with a range of therapeutic options and must choose between them on the basis of restricted empirical evidence. Similarly, the expanding array of empirically supported therapies presents eclectic psychotherapists with a dilemma—which therapy should be assigned to which patient? The results presented here indicate that a person's value system predicts which therapies they believe will be effective for them, and that it may be possible to use this value framework to predict client-treatment interactions. It is desirable therefore, if for this reason alone, to preserve variety in the provision and presentation of treatments (Soffer, 2007).

## Chapter 8

### General discussion

The preceding chapters described a new motivational mechanism responsible for real-world placebo responses—motivational concordance. This new mechanism is not incompatible with existing accounts of placebo responding, including response expectancy theory, although it does suggest that these accounts are incomplete. In contrast with previous research on dispositional prediction of placebo responding, motivational concordance moves beyond a simple description of inter-individual differences in behaviour; it provides an account of intra-individual structures involved in placebo responses, and makes several specific predictions.

Taken together, the new theory and data suggest that high-level or self-defining goals represent enduring dispositions, and that these dispositions interact with features of the situation in predictable ways to produce placebo responses. The mechanism has broader implications for all therapeutic interventions—including conventional medical therapies—where there is a psychological contribution to outcome and where patients must actively participate in treatment.

Religious man can live only in a sacred world, because it is only in such a world that he participates in being, that he has a real existence (Eliade, 1959, p. 64)

## 8.1 Summary of key findings

**Placebo responding is temporally consistent, but highly sensitive to small changes in context.** In Chapter 2 participants responded consistently to a placebo analgesic cream across a period of several days, but only when the cream retained the same label. Responses to differently labelled responses were not significantly correlated, indicating that participants were highly sensitive to this change in the context of the placebo. These findings confirmed that dispositional predictions of placebo responding are theoretically possible, but only if the disposition measured is contextually-relevant for the placebo used.

**'Real-world' placebo effects are not fully explained by response-expectancy theory.** Results presented in Chapters 3, 5 and 6 replicated other studies using a similar methodology (Hyland et al., 2006, 2007; Hyland and Geraghty, 2008), in which response expectancies did not mediate disposition–outcome correlations. Furthermore, predictions from expectancy were much lower than is common in laboratory based placebo studies. A common feature of all of these studies is that placebos are administered over longer periods of time (days or weeks) than typically is the case with laboratory studies. In addition, the placebos administered held richer contextual meanings for participants.

Tests of mediation established that, even when controlling for multiple measures of expectancy, motivational characteristics of participants continued to predict outcomes.

Additionally, in Chapters 5 and 6, evidence was found that compliance with treatment instructions, i.e., better ‘performance’ of the ritual, interacted with dispositional motivations to produce better outcomes: When the ritual was congruent with individuals’ values, then better performance of the ritual produced larger placebo effects. These findings are consistent with the motivational concordance hypothesis, and are more difficult to explain within a response-expectancy framework.

**Congruence between an individual’s values and the motivational context of a placebo ritual predict outcome.** The study reported in Chapter 5 demonstrated that the predictions of placebo responses from motivational characteristics of the person were, as predicted, dependent on concordance of these characteristics with the motivational context of the therapy.

**Placebo effects were found ‘by proxy’ in parents who administered a placebo to their young child.** Results from Chapter 6 suggested that parents benefited from a *vicarious* placebo response when they administered a motivationally-concordant therapy to their young children. In turn, children experienced *behaviourally mediated* placebo responses—tantrum severity and frequency were reduced, most likely due to changes in parental affect. Responses to a follow-up question indicated that the majority of parents did not tell their children the purpose of the flower essence remedy, and this provides additional evidence that placebo effects need not be mediated via response expectancies in all cases.

**Stimulus expectancies for various therapies for depression were systematically related to dispositional values.** Notably, expectancies for anti-depressant medications were related to the values of Power and Security, whereas expectancies for cognitive be-



behaviour therapy were related to Self-Direction and Stimulation. This suggests that value-orientations may be a useful guide to future patient-treatment interaction researchers.

## 8.2 Theoretical implications

### 8.2.1 Relationship to existing theories

**Motivation as health striving** Linking placebo responding to motivation in a straightforward sense is not new. A ‘health striving’ hypothesis (reviewed in 4.2.1) has a relatively long history (Parsons, 1964), and has been invoked to explain some laboratory-based placebo effects (e.g. Jensen and Karoly, 1991). However, although the health striving hypothesis allows for participants’ motivations to affect perceptions (of symptoms or other relevant stimuli), or enhance other placebo mechanisms, goals are not fully integrated as causal elements of the placebo response. The theory suggests that if participants desire improvement then improvement will happen, and is very similar in structure to response-expectancy theory—i.e. that what participants *expect* to happen will happen. In both cases—health striving and response expectancy—desires and expectancies are presumed to be responsible for therapeutic responses but distal causes of therapeutic response are left unspecified (except in the very general sense that expectancies and desires are learned through prior experiences).

**Proximal causes of placebo effects—weaknesses in current theories** In addition to the distal causes of placebo responding, proximal causes of therapeutic change are also neglected by health-striving hypotheses and by response expectancy theory as it applies to complex placebo contexts. As noted above, in simple contexts expectancies can have unmediated effects on outcomes, but in more complex scenarios additional psychological

variables are required to explain generalised therapeutic effects, for example in anxiety reduction in psychotherapy (Delsignore and Schnyder, 2007; Stewart-Williams and Podd, 2004). Indeed, where (placebo) complementary therapies are used to promote general well-being, rather than to treat a particular problem, it is difficult to explain the wide variety of benefits experienced (Oberbaum et al., 2005) within an expectancy framework, and outcome predictions from response expectancies are often disappointing (see 1.4.2).

In contrast, the motivational concordance hypothesis uses established theories of motivation to provide an explanation of both the distal, intermediate, and proximal causes of therapeutic benefits of placebos: Taking a placebo is conceived as a form of motivated behaviour directed towards certain goals, and extensive evidence links both progress towards goals and goal-striving with changes in affect. It is this link between behaviour (performance of the ritual) and emotional experiences that has both perceptual (Emmons, 1991) and physiological (e.g. Hoppmann and Klumb, 2006) effects, which are presumed to underpin the wide variety of therapeutic effects observed. In addition, a motivational approach allows researchers to predict individual differences in placebo responses, and may facilitate the identification of patient-treatment interactions in psychotherapy research.

**Goal congruence might facilitate expectancy effects** Over the past 30 years there has been a general trend in psychology to include 'hot' or emotional influences on information processing. Many authors conceive moods and emotions as representing information about the context in which stimuli are to be processed, alerting individuals to situational requirements (Schwartz, 2002, 1990). Well-studied examples include the counter-intuitive findings that participants perform better on analytic or numeric

problem solving tasks when in a negative mood, whereas performance on creative tasks requiring playful or divergent thinking improves during positive moods (for a review of this research area see Schwartz and Clore, 1996). Other findings that message scrutiny may be affected by mood valence are particularly relevant here: Wegener et al. (1995) found that positive moods increased scrutiny (or processing) of positive information, but reduced scrutiny of mood-threatening information. 'Hot' or emotional influences on placebo responding are ignored by response-expectancy and conditioning theories, but it may be that, in addition to the direct benefits of goal attainment and positive mood on psychological and physical state (see Chapter 4), the affective consequences of motivationally-concordant placebo rituals *also* facilitates expectancy or conditioning effects. If performing placebo rituals generates positive mood it may also facilitate processing of information intended to generate expectancies or conditioned responses; this might account for the observed correlations between dispositions and expectancies in the motivational concordance studies presented above.

### 8.2.2 Relationship to developments in personality psychology

The motivational concordance hypothesis fits neatly with a number of recent trends in personality psychology and provides an interesting test-case for new, interactive models of persons and situations. A core problem for personality psychologists, in common with researchers trying to identify a 'placebo responder', is to create models that reconcile enduring characteristics of the person with cross-situational inconsistencies, which are so often observed in practice (Mischel, 1968). Although abstract dispositions have produced disappointing results when predicting placebo responses (see 1.4.1), the concepts of goals and motivation may form the basis of a more satisfactory explanatory

framework.

**Weaknesses of dispositional research** As previously noted (4.1 page 86) dispositional research, and particularly the 'five factor' model of personality, has been successful in building consensus around an empirically-derived model (Digman, 1990). However, personality psychologists have faced greater challenges when attempting to map personality dimensions onto regularities in behaviour, and critics of big-five models point to two related problems with predictions of behaviour from this type of dimensional information, one empirical the other theoretical. First, simple predictions of behaviour from personality dimensions ignores important attributes of the situation, and cross-situational inconsistencies are likely to undermine the utility of this type of prediction (Mischel, 1968). Second, and more importantly, critics argue that factor-analytic dimensions are theoretically inadequate for the task to which they are put: Although dispositional researchers have provided a reliable account of the structural regularities *between* individuals, it is inappropriate to assume that the data on which five factor models are based also describes structures and processes that actually exist *within* individuals. To take Epstein's (1994) analogy, a factor analysis of the attributes of cars (weight, colour etc.) might provide an acceptable fit with the data, but would tell us nothing about how cars operate or how to go about fixing one.

**Motivations provide a theory-driven alternative to trait-based constructs** that are inductively derived from behavioural regularities. This allows a 'bottom-up' account of the structures and processes required to explain cross-situational consistency in placebo responding. Recent models of cross situational consistency in personality psychology emphasise the role of intentional constructs—motivations—in determination of be-

haviour. Both Mischel and Shoda (1995) and Cervone's 2005 models of personality stress the importance of motivation to create an integrated account of structures and processes. Cervone's KAPA model (Knowledge and Appraisal Personality Architecture) distinguishes Knowledge—any enduring representation of the self, others or information about the world—from appraisals—relational judgements that concern the meaning of encounters for oneself.

**Is the Spiritual connection questionnaire a pseudo-ideographic measurement?** When constructing instruments to measure aspects of personality, researchers must reconcile themselves to making one of two assumptions and decide whether they believe the construct they wish to study does or does not vary in content *between* individuals. In dispositional personality psychology researchers typically make the first assumption, adopting what is termed a nomothetic approach to measurement; when developing measurement instrument, the primary goal is to achieve construct validity, and this is done by eliminating scale items which fail to correlate with a hypothesised latent variable (see Figure 8.1a). Great care is taken to be sure that scale items are clear, unambiguous and interpreted in a consistent fashion by all participants. An alternative approach is to take construct validity for granted, making the assumption that the construct does in fact exist as a property of the individual, and allow individuals to identify which items correspond to that construct for them, and the importance they place on them (see Figure 8.1b). As can be seen from Figure 8.1, *nomothetic* measurement comes to an empirical description of the construct based on participant responses, and that the construct represents a statistical average of all participant interpretations; in this example items 2 and 4 might be rejected because only a minority of participants endorse them. In contrast, *ideographic* measurement requires a theoretical assumption that the construct

in fact exists, but that its content (indexed by various scale items) differs from individual to individual. In this example, the concept is divorced from the items (content), which may vary widely from individual to individual.

An interesting feature of the measurement of human values, for instance via the SVS or SCQ, is that this nomothetic/ideographic distinction becomes somewhat blurred. Whereas dispositional researchers tend to employ scale items that are concrete and require relatively little interpretation (e.g. 'Complete tasks successfully', 'Love large parties', 'Go on binges', 'Love to read challenging material'), measures of values use language which is more open and ambiguous. Examples from the SCQ include: 'I feel I have an inner spiritual strength', 'I will never have a spiritual bond with another person'. The key concept—spirituality—is left undefined. Similarly, other items such as 'I sometimes experience other people "shining with an inner light"' or 'I feel an inner strength from a spiritual connection with others' could be interpreted literally, but are equally likely to be interpreted metaphorically and could refer to a wide variety of subjective experiences. Thus, the SCQ appears to presume the existence of 'spirituality' or spiritual motivation as a within-person construct, but allows for considerable variation with regards the content the concept refers to.

Abstracting the concept of spirituality from specific content may be an important factor in the success of the SCQ in predicting motivational concordance effects. Although participants may differ in what they understand by the word 'spirituality', participants with divergent interpretations of the concept may still score highly on the scale. Provided these 'spiritual' participants also interpret the placebo ritual as 'spiritual' in nature, the pseudo-ideographic approach of the SCQ makes it possible to predict concordance of participants' dispositions with their evaluation of the ritual, and consequently explain variance in outcomes. In the flower essence studies presented here, the therapy was

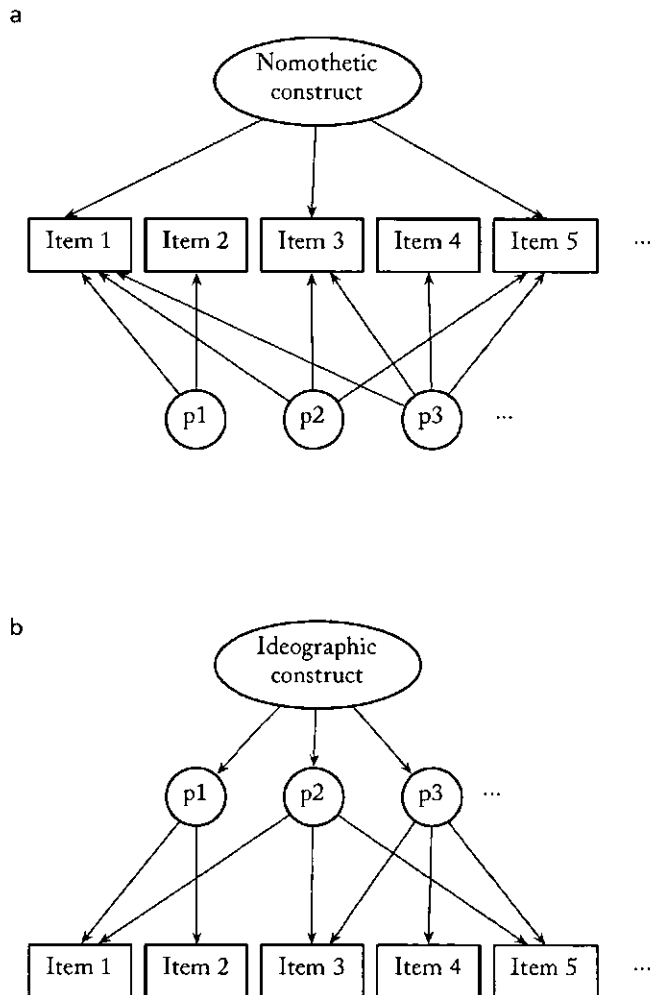
presented as generically spiritual and was not tied to any particular form of spirituality or religious tradition, and this may explain the relatively large proportion of people for whom it was effective. If the contextualising information provided had described the therapy as imbuing a person with the ‘wisdom of the Buddha’, or the ‘magical healing power of Eir’, then the range of people for whom the essences were effective is likely to have been much reduced.

### 8.3 Limitations, weaknesses and questions outstanding

**Lack of repeated measurements of response expectancies** Response-expectancies were measured only once during each study. It is possible that, as illustrated in Figure 4.2, performance of the ritual served to increase response expectancies, generating a positive feedback loop between improved and consistent performance of the ritual, improved expectancies, and changes in subjective experience. In fact, without such a feedback loop it is difficult to envisage how relatively short-duration conscious response expectancies would be able to generate the longer-term improvements in well-being demonstrated here.

**Potential for measurement error to underestimate mediation via response expectancies** A weakness of Baron & Kenny (Baron and Kenny, 1986) type mediation analyses is that error in the measurement of mediating variables (in this case response-expectancies) may result in an underestimate of the extent of mediation. Because this is a problem of measurement rather than design, no clear solution can be offered. However, if an experiment could be designed such that participants had neutral expectancies for outcome—perhaps using deceptive instructions that misled participants as to the true

Figure 8.1: Nomothetic (a) and ideographic (b) measurement models





purpose of the ritual—then this could provide additional evidence for the motivational concordance hypothesis. If participants gain benefits when performing a ritual for which they have no expectation of benefit, at least for the primary outcome measure, then this would support motivational concordance rather than response-expectancy explanations.

**Other issues relating to the measurement of response expectancies** The architect of response expectancy theory explicitly states that response expectancies are consciously accessible mental constructs and argues that the concept of an implicit response is unfalsifiable and therefore scientifically disallowed (Kirsch, 2004). However developments in social and cognitive psychology have highlighted the benefits of some types of implicit measurement when compared with explicit self-reports, and suggest possible directions for future research; these are discussed below (see page 205).

**Examining possible interactions between mood and expectancy** As noted above, some theories of emotion conceive of mood as conveying important information about the requirements of situations; as a consequence mood may affect the processing of situational information, especially where new information may have consequences for mood-maintenance (Schwartz, 2002), including expectancies for benefit or harm from placebo interventions. A future study might test this hypothesis more directly by first inducing positive and negative moods and second observing whether differential effects are observed on placebo or nocebo responses—current theory implies that a positive mood induction would boost placebo effects and protect against nocebo effects, and that negative mood would have the opposite effect.

**Were observed therapeutic changes ‘real’ or mediated by symptom reporting?** The studies presented here primarily employed measures of outcome that were based on

retrospective participant reports. This type of outcome measure is extremely convenient for researchers and is widely used in both theoretical and clinical work. Although before/after measurements of symptoms have intuitive appeal as less likely to be subject to response biases, researchers have suggested that perceived change measures are superior to change scores in some important respects. Fluckiger et al. (2007) found that although retrospective and pre-post measures were equally mood dependent, only pre-post measures were subject to regression effects. Fischer et al. (1999) also found good agreement between retrospective and pre-post measures, and noted that retrospective symptom scores correlated better with patient satisfaction ratings.

Nonetheless, demonstrating motivational concordance effects with physiological or observer-rated outcomes would be an important additional finding, and would build on the finding that congruence of daily activities and goals was predictive of decreased cortisol fluctuation (Hoppmann and Klumb, 2006).

It is unfortunate that the data reported here cannot be used to distinguish between 'real' changes in symptoms and changes that are due solely to altered symptom reporting. It is plausible that observed therapeutic benefits are caused (proximally) by changes in symptom reporting, and (distally) by improvements in affect—previous work has shown that trait negative affectivity is related to symptom reporting (Pennebaker, 1982; Rief and Isaac, 2007). Such changes should not be dismissed as trivial however; a perceived reduction in symptoms may improve overall levels of psycho-social functioning. Reducing symptom reports in this way (i.e. by reducing negative affect rather than inducing a reporting bias via the demands of the situation) is a worthy goal. However, it is also possible that motivational concordance generated 'real' changes in symptoms—that is, changes which might be identified more objectively via observer report or physiological measurement, as is the case with response-expectancy placebo effects (Kirsch, 1997).

**Estimation of an effect size for motivational concordance** The studies presented here did not use natural history (or similar) controls, and employed relatively heterogeneous samples—with the exception of Chapter 6, participants for motivational concordance studies were recruited for a variety of ‘minor psychological complaints’. Although estimation of effect sizes across heterogeneous populations is possible (e.g. Hrobjartsson and Gotzsche, 2001, 2004), it is undesirable because pooling of effects may obscure differential efficacy of the treatment for population subgroups (Wampold et al., 2007; Kirsch and Scoboria, 2002). For both of these reasons, it is impossible to gauge the true size of the effects caused by motivational concordance, nor their potential clinical significance. Additionally, none of the participants involved in these studies had a serious illness, and the clinical significance of effects observed must therefore be treated with caution. However, it should be remembered that although participants did not meet clinical diagnostic criteria they self-selected for treatment and must have perceived their problem as worth treating; reported compliance was relatively high in all three flower essences studies.

**What types of motive does motivational concordance apply to?** Like other similar work (Hyland et al., 2007; Hyland and Geraghty, 2008), the studies presented here used only therapies that were concordant with intrinsic motives. These interventions are, therefore, similar to a class of interventions grouped under the label of ‘positive psychology’ (Seligman et al., 2005). Would other types of motives produce similar therapeutic benefits?

Limited data from other fields suggest that congruence with extrinsic motives would not produce the same benefits as congruence with intrinsic motives (Hofer and Chasiotis, 2003; Hofer et al., 2006; Sheldon and Kasser, 1995), but this should be tested directly

by future studies. It is an intriguing prospect that actualising 'negative' motives—for example to harm others—might create well-being in individuals who value such goals. Researchers might be able to employ violent first-person computer games to enable self-actualisation in this area.

Additionally, there remains some theoretical debate about precisely what SVS-type values scales are measuring. It may be the case that SVS-style responses are influenced not only by the (hypothesised) value system, but also by other factors related to the availability or salience of these values in recent experiences; reported values are influenced by the degree to which values have been satiated by recent experiences. For example, Rokeach (1973) reports that the value most distinctive of prison inmates is *wisdom*. Although this finding is based on cross sectional data and cannot be used to draw strong causal inferences, it is unclear whether the prisoners believed that wisdom was an attribute they possessed or lacked (Rokeach, 1973, p. 134). Similar effects are found in the motivation literature. Gollwitzer and Wicklund (1985) reported a series of experiments showing that the extent to which a person had *fulfilled* self-defining goals (e.g. to be a musician or to be a psychologist) negatively predicted self-presentational behaviour aimed at demonstrating competence in that domain. Future work on motivational concordance should investigate the extent to which value-fulfilment predicts therapeutic benefits; the self-actualising rituals of motivationally concordant therapies may offer diminishing returns for those whose everyday behaviour is already self-actualising. However, distinguishing between satiated and non-satiated values (Murray, 1938) may be difficult in practice.

**Some values may be easier to use than others** If goals are hierarchical (Hyland, 1988), to pursue high-level values such as spirituality requires the identification of a series of

nested sub-goals, reducing in abstraction to the level of motor potentials. Within a given cultural or historical context, it may be easier to identify sub-goals of some high-level values than for others, at least with regard to health and therapy. Although arguing from a failure of imagination is a dangerous strategy, it is easier for this author to imagine a 'spiritual' remedy than one based on the values of Power or Hedonism. This may simply reflect the current popularity of CAM therapies, and the waning fortunes of traditional psychoanalytic approaches, but it might also be the case that some values are easier to reconcile with therapeutic activities than others.

## 8.4 Practical implications

### 8.4.1 Predicting placebo responding is possible and should be attempted

Work to prospectively identify placebo responders, or to predict patient-treatment interactions in psychotherapy research, has faced numerous challenges, and often results have been disappointing. Critics have focused on the lack of a theoretical rationale for identifying patient-treatment interactions (Dance and Neufeld, 1988), as well as high profile empirical failures (Project MATCH Research Group, 1993) to suggest that matching patients to treatments might be best abandoned (Heather et al., 2008).

Although at an early stage, the work presented in Chapters 2 and 5, and also Chapter 7 suggests that (a) empirically, placebo responses vary within individuals, based on relatively small changes in the context of presentation, and (b) motivation theory may be a useful organising principle in predicting these person  $\times$  situation interactions. Based on the results from Chapter 7, researchers might match patients to treatments by measuring both the values of patients and the motivational characteristics of therapies.

Replication of these findings in patient samples with clinical outcome measures would be an exciting development.

#### 8.4.2 Variety should be preserved in the choice and delivery of treatments

Preserving a variety of equivalent treatments may be of use, particularly when alternative treatments for a condition are of similar efficacy but differ in their delivery context—for example different psychological treatments of depression (Wampold, 2001; Soffer, 2007). However, the benefits of variety may also apply to the delivery of conventional medicine. A large component of the response to all therapies, even powerful analgesics, is psychologically mediated (Benedetti et al., 1998). Consequently, both doctors and policy makers should strive to maximise the psychological benefits of any therapy.

**Existing therapies could be reframed in motivationally-concordant forms for individual patients** Many existing therapies might benefit from enhancing concordance between values of patients and the motivational context of the therapy. To take one example, instructions for dosing of a conventional pharmaceutical agent might be altered, where appropriate, to reflect the motivational characteristics of patients. This might be particularly applicable in circumstances where dosing is frequent and must respond to symptoms—for example in asthma. Patients who place high value on Self-Direction could be given a maximum, but told to dose ‘as they feel is correct for them’. Patients who value Tradition or Power could be provided with details of the doses which other people used in similar circumstances, or have strict rules set which must be followed when determining a dose, in the form of a letter from an authority figure—perhaps a respected secondary care specialist. Such an approach might also improve compliance with medications, a factor that is often overlooked in the transition

from clinical trials to clinical practice (Bouchard et al., 2007). In clinical trials, adherence is associated with lower mortality for both verum and placebo arms, but adherence to medications for chronic conditions is typically poor.

In a similar fashion, cognitive behaviour therapists might reframe therapy activities in motivationally-concordant terms. Homework exercises designed to challenge negative thoughts might be described as as analogous to devotional practice for highly spiritual patients; as self-improvement activities for achievement-oriented participants; or as a time to remember connections with other people and with nature for patients who place value on Universalism or Benevolence. It is possible that the extent to which therapists can be flexible, describing interventions in terms that are accessible and motivationally-compelling to patients, will prove to be another factor in the large variability between therapists in studies of psychotherapy outcomes (Wampold and Bolt, 2007).

**Minority groups and context of health provision** Public health specialists have long been concerned with disparities in health status between particular ethnic or minority groups and the population at large. Research in this area tends to be epidemiological in nature, and focussed on identifying relatively gross disparities in disease risk due to socio-economic or genetic factors. However, in the psychotherapeutic literature concepts such as ‘micro-aggression’ have been developed to explain poor treatment outcomes amongst minority service-users (Sue et al., 2007). If treatment contexts tend to be more motivationally discordant for minority users then motivational concordance may be an additional mechanism by which disparities in outcome are maintained.

### Implications for CAM research

**Is this a scientific validation of Bach flower remedies?** Harald Walach's observation of homeopathy: "[that it] is scientifically banned, [...] for lack of a sound theoretical model to explain its purported effects" (Walach, 2005, p. 192) applies in equal measure to many other CAM therapies, including Bach flower remedies. Motivational concordance appears to supply, at least in part, a theoretical rationale for how such therapies work, and for whom they should be prescribed. As such, this undermines a perceived barrier for wider adoption of CAM therapies.

However accepting motivational concordance theory does not necessarily entail supporting the general prescription of biologically inert remedies. Alternative means of capitalising on motivational effects are available (e.g. Hyland et al., 2007; Hyland and Geraghty, 2008; Seligman et al., 2005) and should be chosen in preference to CAM therapies which, although they may be effective and have an increasingly plausible theoretical rationale, would be fundamentally deceptive if supported by governments that are otherwise committed to evidence-based policy making.

**Wider impact** Over recent years CAM research, for example on the effects of homeopathy or acupuncture, has been dominated by increasingly heated debates over estimates of efficacy—that is, the extent to which CAM therapies differ from various types of control conditions. Increasingly sophisticated meta-analyses have identified shortcomings with the reporting of trials (for example, unclear descriptions of randomisation/allocation procedures and descriptive statistics omitted), and a bias towards the publication of larger effects in smaller, underpowered studies (Shang et al., 2005). However the ensuing arguments over the validity of meta-analytic methods obscure a larger truth: Whatever the case with regards the specific effects of homeopathy, these effects are dwarfed by



the psychological components of the interventions. Motivational concordance theory may provide additional impetus to the psychological study of some CAM therapies. Empirically it explains new variance in outcome, and may be more palatable to both proponents and opponents of CAM therapies. It is at least preferable to the conclusion that CAM therapies are 'no better than placebo', a phrase which explains nothing and hides much that is interesting. A motivational concordance explanation allows researchers to view patients as engaged in a self-actualising ritual. Patients' active participation in giving meaning to a therapy is a key component in the therapeutic benefits observed. In short, psychological explanations of CAM no longer require a deceptive researcher or practitioner and a gullible patient.

## 8.5 Future directions

A number of directions for future research are suggested by the data presented here:

**Repeated or improved measurements of response expectancies** As noted, a possible alternative explanation for the findings presented here is that the mediating role of response-expectancies is underestimated because (a) expectancy measurements are subject to error and (b) expectancies may change over time.

Taking repeated measurements of expectancy throughout a study would enable the researcher to be sure that expectancies were not, for example, increased by early changes in symptoms due to natural history; such an increase in expectancies might account for subsequent therapeutic improvements. These repeated measurements would be easily incorporated as a lagged variable within a multilevel analysis, similar to that used in Chapters 5 and 6.

**Implicit measures of response expectancies and motives/dispositions** Because response-expectancy theory explicitly defines expectancies as consciously-accessible, all research into expectancy effects in placebos have relied upon verbal reports from participants. However, as Shanks and St John (1994) note, “Tests of verbal recall tend to be less sensitive to small amounts of knowledge than other behavioral measures” (p. 394). Thus, even if one accepts the premise that expectancies *must* be conscious, the goal of measuring expectancies accurately demands that additional techniques are adopted. Additionally, verbal measurements of expectancies may be subject to a number of presentational biases, depending on the situation or context of a particular placebo. Taking the example of flower essences, participants drawn from a science-based undergraduate degree (or who are speaking to a scientifically-oriented researcher) might not wish to admit that they have positive response expectancies for what they perceive to be an ‘unscientific’ treatment<sup>1</sup>. An alternative explanation for the data presented in Chapters 3, 5 and 6 follows from this—it might be the case that expectancies do mediate the effects of flower essence treatment, but that only participants high in dispositional spirituality are prepared to admit to having positive response-expectancies.

As a consequence, non-verbal (i.e. behavioural or otherwise implicit) measures of expectancy are *necessary* to test response-expectancy in many relevant circumstances, although researchers may have to tolerate doubts over the status of such measurements as conscious constructs (Baeyens et al., 1994). To achieve this it may be desirable to adapt implicit measurement methodologies from social and cognitive research to obtain implicit measurements of expectancy. Behavioural measures, such as the amount participants would be prepared to pay for a given placebo, might also capture variance in

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<sup>1</sup>A small (N = 25) pilot survey of attitudes to several therapies for depression, not presented here, indicated that Bach remedies were seen by University of Plymouth undergraduates as ‘kind’, ‘spiritual’ but not ‘scientific’.

expectations not explained by verbal reports.

Similar techniques could be employed to develop implicit measures of motives or values. Pakizeh et al. (2007) used a reaction-time task to confirm that the circumplex model of values was not dependent on semantic relatedness of SVS items, but this data did not bear directly on relationship of implicit and explicit value measures. Researchers using other types of implicit measures have begun to identify conditions under which implicit and explicit measures will correlate (Hofmann et al., 2005), and this approach may be useful in future work on values, helping to address some of the criticisms of the SVS (e.g. low discriminant validity and reliability, Perrinjaquet et al. 2007)

**Physiological outcomes** Demonstrating effects with physiological outcomes, as opposed to self report, would strengthen the claim of motivational concordance theory to be an important mechanism in real world placebo effects. To demonstrate physiological effects might be difficult in the type of studies presented here, in part because sample populations and conditions treated were so heterogeneous. Researchers might have improved success in the lab, perhaps using relatively sensitive measures such as facial EMG or startle eye-blink moderation (Wittenbrink and Schwarz, 2007) following a motivationally concordant (or non-concordant) relaxation intervention. Disease models and clinical populations (see below) may also afford useful opportunities for objective measurements of outcome.

Asthma patients are currently receiving increased attention as an interesting group with which to conduct laboratory-based placebo research (Kaptchuk et al., 2008). This interest stems from the significant psychological component involved in asthma (Lehrer et al., 2002) and the fact that accurate and objective measurements of lung function are relatively straightforward to obtain (e.g. with a cheap peak-flow device). Thus asthma

may also be suitable for further work on motivational concordance.

**Studies in other patient populations** Subject to ethical constraints, researchers might use motivationally-concordant 'positive-psychology' type interventions in real clinical populations. Suitable groups might initially include mild or early-stage patients who would otherwise be offered little to no treatment, for example mildly depressed patients who would otherwise be offered only self-help or supported self-help interventions. Patients with chronic obstructive pulmonary disease (COPD) may also be suitable for this type of research. Psychological complaints are under-treated in COPD patients, and conventional treatments such as cognitive behavioural therapy (CBT) or antidepressant medications may be poorly tolerated (Yawn, in press). Irritable Bowel Syndrome may be another good candidate because it affects a relatively large number of people (Wilson et al., 2004), is responsive to placebo effects (Vase et al., 2003), and is suited to repeated measurements of both perceived improvement in symptoms and symptom frequency—symptom counts may be less susceptible to bias than self-report ratings of severity.

Finally, a replication of the patient-treatment interaction methodology developed in Chapter 7 should also be attempted in clinical populations. Such a study might be combined with an existing RCT or open trial to compare, for example two different psychotherapies, or psychotherapy vs antidepressant medication, and would require very little additional effort to run within this setting.

## Conclusion

In conclusion, evidence from multiple sources suggests that motivational concordance is an additional psychological mechanism responsible for the real-world benefits of placebos. A motivational mechanism is compatible with earlier expectancy and conditioning accounts, but has some advantages, particularly when explaining generalised therapeutic benefits from complex interventions.

# Appendix A

## Experimental materials

### A.1 Participant information sheets from Chapter 2

#### Briefing

1. This is a study comparing the effectiveness of two different pain relieving creams.
2. These drugs have already been tested for safety in large clinical trials, and are in use in hospitals and clinics
3. The first drug is called Ibuprofen, and you may have seen it available in Chemists' stores, or advertised on television. It is widely used, and an effective pain reliever.
4. The second drug is called Trivaricaine. It is also widely used, primarily in hospitals and doctors' surgeries; it is not yet available over the counter, but has also been tested over many years and is an effective pain reliever.
5. We need to test the drugs over period of several days, since this is how they are generally used by the public
6. To provide a standardised stimulus to compare the drugs, we use a lever device, which will place pressure on one of your fingers. This produces no lasting damage, although it does hurt a moderate amount whilst the pressure is applied.
7. For each drug, we will be apply pressure to the treated finger, and an untreated finger for comparison.

8. Each trial will last 2 minutes, and you'll be asked to give a rating for how much the finger hurt immediately afterwards.
9. You are free to leave the experiment AT ANY TIME – including during one of the trials.
10. If you do wish to leave the trial please tell a member of the team and we will ensure all your data is destroyed.
11. Your data will remain anonymous at all times.
12. If you have any concerns about the procedure, or feel distressed, please tell the experimenter, or call one of the help-line numbers below.

UPSU Advice Line 01752 232281

Samaritans 08457 90 90 90

## Debriefing

Dear Participant,

At the start of this experiment I had to leave out some pieces of information. This decision was not taken lightly, and was necessary to investigate a phenomenon called the placebo effect. After reading this I hope you will understand and agree with this decision.

I'm interested in whether some people consistently respond to placebos – that is, a pill or cream that has no active ingredient, but that is suggested to be effective. At present, it appears that we all respond to suggestions of this kind to some extent, and identifying a group that consistently responds is extremely difficult.

This experiment was designed to answer that question by testing the same placebo creams over a number of days; the measure of placebo response was the difference in pain scores between your 'treated' and untreated fingers. Neither cream contained any active drug ingredients.

We hope you will understand why deception was necessary, and that you will not be embarrassed if you responded to one of the creams. The connection between mind and body is powerful, and it is to be expected that we can 'will' things to happen in this way.

If you have been upset or troubled by this experiment in any way, please do not hesitate to contact myself, my supervisor Professor Michael Hyland (01752 233144), or one of the members of the UPSU Advice Line (01752 232281).

I hope to publish the results of this study soon, and if you are interested in the results please say so (either now or by email) and I will be happy to send you a copy. If you have any other questions please also feel free to ask.

Regards, and many thanks,

Ben Whalley



## A.2 Bass Acquiescence Scale

### Instructions

Please indicate whether you agree, disagree or are uncertain about each of the statements listed below:

### Scale items

1. Success against the odds is the greatest of American ideals.
2. Love is the greatest of the Arts.
3. There is no satisfaction without a companion to share it.
4. Love of the opposite sex makes the world go round.
5. They never fail those who die in a great cause.
6. He that has many friends never fear disaster.
7. Destroyers of tyranny have contributed most to mankind.
8. You only injure yourself when you take not of despised critics.
9. The only known cure for fear is faith.
10. Our chief want in life is somebody who will make us do what we can.
11. Never trust a flatterer.
12. He who laughs last laughs longest.
13. No principle is more noble or holy than that of true obedience.
14. There is nothing which the body suffers which the soul may not profit by.
15. One false friend can do more harm than one hundred enemies.
16. No gift is more precious than good advice.
17. Obedience is the mother of success.
18. The victory always remains with those who admire rather than with those who criticise.

19. The greatest fortunes are for those who leave the common path and blaze a new trail for themselves.
20. 'Tis vain to quarrel with our destiny.
21. To be happy, always stay within the law.
22. You should give more than you want to give.
23. Pity is the touch of god in human hearts.
24. What we win through authority we lose; what we win through consideration we keep.
25. A sense of duty is the basis of character.
26. Next to love sympathy is the most divine passion of the human heart.
27. Stay away from the proud man who is ashamed to weep.
28. Sweet is the sleep of men with virtue.
29. One should feel the failures of friends as if the failures were his own.
30. Giving is always better than receiving.
31. He that loses his conscience has nothing left that is worth keeping.
32. Virtue is a struggle in which we overcome our weakness.
33. He conquers all who conquers himself.
34. It is difficult to do excellent work without great strain.
35. Only a statue's feelings are not easily hurt.
36. Happiness must be won through great effort.
37. The restless sleeper blames the couch.
38. Seeing is believing.
39. Still water runs deep.
40. Make yourself honey and the flies will eat you.
41. The grass is always greener in the other fellow's yard.
42. Most bog cows have little horns.

43. Every man is blind to his own defects.
44. Jaws are the only part of the body that like to work.
45. Those in high places are in greater danger than those in lowly ones.
46. Life is a struggle from beginning to end.
47. Wild colts make good horses.
48. Empty heads go with loud talk.
49. You can't teach an old dog new tricks.
50. Count your sheep and the wolf will eat them.
51. Sleep is loved by everyone.
52. The feeling of friendship is like that of being comfortably filled with roast beef.
53. Who does not love the opposite sex remains a fool the whole life long.
54. Better one safe way than a hundred on which you are not sure.
55. We like best that which lies beyond our reach.
56. Amusement is the medicine for worry.

### Scoring

Participants respond *agree*, *disagree* or *uncertain* to all questions, and affirmative answers are summed to provide an overall score. All items are positively scored.

## A.3 Tellegen absorption Scale

### Instructions

This questionnaire consists of questions about experiences that you may have had in your life. We are interested in how often you have these experiences. It is important, however, that your answers show how often these experiences happen to you when you are not under the influence of alcohol or drugs.

### Scale items

1. Sometimes I feel and experience things as I did when I was a child.
2. I can be greatly moved by eloquent or poetic language.
3. While watching a movie, a TV show, or a play, I may become so involved that I may forget about myself and my surroundings and experience the story as if it were real and as if I were taking part in it.
4. If I stare at a picture and then look away from it, I can sometimes “see” an image of the picture almost as if I were still looking at it.
5. Sometimes I feel as if my mind could envelop the whole world.
6. I like to watch cloud shapes change in the sky.
7. If I wish I can imagine (or daydream) some things so vividly that they hold my attention as a good movie or story does.
8. I think I really know what some people mean when they talk about mystical experiences.
9. I sometimes “step outside” my usual self and experience an entirely different state of being.
10. Textures – such as wool, sand, wood – sometimes remind me of colors or music.
11. Sometimes I experience things as if they were doubly real.
12. When I listen to music I can get so caught up in it that I don’t notice anything else.
13. If I wish I can imagine that my body is so heavy that I could not move it if I wanted to.

14. I can often somehow sense the presence of another person before I actually see or hear her/him.
15. The crackle and flames of a wood fire stimulate my imagination
16. It is sometimes possible for me to be completely immersed in nature or in art and to feel as if my whole state of consciousness has somehow been temporarily altered.
17. Different colors have distinctive and special meanings for me.
18. I am able to wander off into my thoughts while doing a routine task and actually forget that I am doing the task, and then find a few minutes later that I have completed it.
19. I can sometimes recollect certain past experiences in my life with such clarity and vividness that it is like living them again or almost so.
20. Things that might seem meaningless to others often make sense to me.
21. While acting in a play I think I could really feel the emotions of the character and “become” her/him for the time being, forgetting both myself and the audience.
22. My thoughts often don’t occur as words but as visual images.
23. I often take delight in small things (like the five-pointed star shape that appears when you cut an apple across the core or the colors in soap bubbles).
24. When listening to organ music or other powerful music I sometimes feel as if I am being lifted into the air.
25. Sometimes I can change noise into music by the way I listen to it.
26. Some of my most vivid memories are called up by scents and smells.
27. Some music reminds me of pictures or changing color patterns.
28. I often know what someone is going to say before he or she says it.
29. I often have “physical memories”; for example, after I have been swimming I may still feel as if I am in the water.
30. The sound of a voice can be so fascinating to me that I can just go on listening to it.
31. At times I somehow feel the presence of someone who is not physically there.

32. Sometimes thoughts and images come to me without the slightest effort on my part.
33. I find that different odors have different colors.
34. I can be deeply moved by a sunset.

### Scoring

Participants respond *yes* or *no* to all questions. All items are positively scored.

## A.4 The Spiritual Connection Questionnaire

### Instructions

Below is a list of statements about the experience of spirituality. Please show to what extent these statements describe you by circling the number which best correspond to your experience. For example, if the statement is very like you, then circle 3. If it is only slightly like you, then circle 1. Do not spend too long over any statement. Just give the first answer that comes into your head. There are no right or wrong answers.

### Scale items

1. Sometimes when I look at a person I feel a connection which is very special and different from usual human contact
2. For me, happiness is achieved from pleasure, not spiritual fulfilment<sup>(reversed)</sup>
3. I sometimes experience joy just from being in a beautiful place
4. I do not feel connected to the universe in any spiritual way<sup>(scq14, reversed)</sup>
5. I am very sensitive to the atmosphere of a house
6. I never feel that I am making contact with someone's soul<sup>(reversed)</sup>
7. For me, spirituality gives me a feeling of ultimate happiness
8. I never feel any special connection with a part of nature such as a flower, tree or mountain<sup>(reversed)</sup>
9. I can sometimes enter a state where I feel connected to the universe
10. For me, places do not have a special atmosphere<sup>(reversed)</sup>
11. I am drawn to spiritual people
12. Spirituality is not important to me<sup>(reversed)</sup>
13. For me, spirituality is a kind of love for everything
14. I do not have a personal relationship with some power greater than myself<sup>(scq14, reversed)</sup>
15. I sometimes experience other people 'shining with an inner light'<sup>(scq14)</sup>
16. It is not important to me to be connected with a spiritual being or force<sup>(reversed)</sup>

17. I can sometimes feel love for living or non-living parts of nature (flowers, trees, stones, animals etc)
18. The physical world as we know it is all there is<sup>(reversed)</sup>
19. There is something of the cosmos that binds all people together
20. Spirituality does not contribute to my life<sup>(reversed)</sup>
21. I feel there is a form of energy that binds all life together<sup>(scq14)</sup>
22. I feel no spiritual connection to the world around me<sup>(scq14,reversed)</sup>
23. I have a deep feeling of being connected to my family both past and future
24. I have never had a spiritual experience that has changed my life<sup>(scq14,reversed)</sup>
25. We are all participating in something larger and greater than any of us
26. I do not believe events in my life unfold according to a greater plan<sup>(reversed)</sup>
27. I can sometimes feel a connection with those who are no longer with us
28. I am not much affected by my surroundings<sup>(reversed)</sup>
29. I believe all life is connected
30. I will never have a spiritual bond with another person<sup>(scq14,reversed)</sup>
31. I feel I have an inner spiritual strength<sup>(scq14)</sup>
32. I am not touched spiritually by beauty<sup>(reversed)</sup>
33. There is a larger plan to life<sup>(scq14)</sup>
34. I find spirituality in others rather off-putting<sup>(reversed)</sup>
35. My spirituality makes life good for me<sup>(scq14)</sup>
36. I never get completely immersed in the beauty of my surroundings<sup>(reversed)</sup>
37. For me all life is connected
38. I do not feel that there is a form of energy that binds people together<sup>(reversed)</sup>
39. I have joy in my life because of my spirituality
40. The beauty of the universe fails to move me<sup>(reversed)</sup>
41. I feel an inner strength from a spiritual connection with others<sup>(scq14,)</sup>



42. The cosmos (everything that exists) has only a physical dimension, not a spiritual one<sup>(reversed)</sup>
43. My connection to something spiritual makes me happy<sup>(scq14)</sup>
44. I have no sense of awareness of those who will come after me<sup>(reversed)</sup>
45. I feel that I am always protected by an ultimate principle, force or being<sup>(scq14)</sup>
46. I have no feeling of being connected with the spirit world<sup>(reversed)</sup>
47. My feelings of a spiritual connection with the cosmos (everything that exists) are important to me
48. Spiritual connections with other people do not help me<sup>(reversed)</sup>

### Scoring

Participants respond by circling a number on a 7-point scale as follows: *Unlike me* -3 -2 -1 0 1 2 3 *Like me*. Items marked <sup>(reversed)</sup> are reverse coded. Items marked <sup>(scq14)</sup> are included in the shorted SCQ-14. In both scales, scores are averaged such that higher scores indicate greater spirituality.

## A.5 The Life Orientation Test - Revised (LOT-R)

### Instructions

Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think 'most people' would answer.

a) I agree a lot

b) I agree a little

c) I neither agree nor disagree

d) I *disagree* a little

e) I *disagree* a lot

1. In uncertain times, I usually expect the best.
2. It's easy for me to relax *(reversed)*
3. If something can go wrong for me, it will.
4. I'm always optimistic about my future.
5. I enjoy my friends a lot. *(reversed)*
6. It's important for me to keep busy. *(reversed)*
7. I hardly ever expect things to go my way.
8. I don't get upset too easily. *(reversed)*
9. I rarely count on good things happening to me.
10. Overall, I expect more good things to happen to me than bad.

### Scoring:

Items 2, 5, 6, and 8 are fillers. Responses to 'scored' items are to be coded so that high values imply optimism.

## A.6 Spiritual Involvement and Beliefs Scale – Revised (SIBS–R)

### Instructions

Participants are asked how strongly they agree with the statements in Table and circle one of the seven responses below:

1. Strongly Disagree
2. Disagree
3. Neutral Mildly Disagree
4. Mildly Agree
5. Agree
6. Strongly Agree

### Questionnaire items

1. I set aside time for meditation and /or self-reflection.
2. I can find meaning in times of hardship.
3. A person can be fulfilled without pursuing an active spiritual life. *(reversed)*
4. I find serenity by accepting things as they are.
5. I have a relationship with someone I can turn to for spiritual guidance.
6. Prayers do not really change what happens. *(reversed)*
7. In times of despair, I can find little reason to hope. *(reversed)*
8. I have a personal relationship with a power greater than myself.
9. I have had a spiritual experience that greatly changed my life.
10. When I help others , I expect nothing in return.
11. I don't take time to appreciate nature. *(reversed)*
12. I have joy in my life because of my spirituality.
13. My relationship with a higher power helps me love others more completely.

14. Spiritual writings enrich my life.
15. I have experienced healing after prayer.
16. My spiritual understanding continues to grow.
17. I focus on what needs to be changed in me, not on what needs to be changed in others.
18. In difficult times, I am still grateful.
19. I have been through a time of suffering that led to spiritual growth.
20. I solve my problems without using spiritual resources.<sup>(reversed)</sup>
21. I examine my actions to see if they reflect my values.
22. How spiritual a person do you consider yourself? (with '7' being the most spiritual)

### Scoring instructions

All negatively worded items (3, 6, 7, 11, 20) are reverse scored, i.e. strongly agree = 1, agree = 2,... strongly disagree = 7. For all other items the score is the number circled by the subject.

## A.7 Love, compassion and tolerance.

**By the Dalai Lama** The essence of all religions is love, compassion, and tolerance. Kindness is my true religion. No matter whether you are learned or not, whether you believe in the next life or not, whether you believe in God or Buddha or some other religion or not, in day-to-day life you must be a kind person. When you are motivated by kindness, it doesn't matter whether you are a practitioner, a lawyer, a politician, an administrator, a worker, or an engineer: whatever your profession or field, deep down you are a kind person. Love, compassion, and tolerance are necessities, not luxuries. Without them, humanity cannot survive. If you have a particular faith or religion, that is good. But you can survive without it if you have love, compassion, and tolerance. The dear proof of a person's love of God is if that person genuinely shows love to fellow human beings. To have strong consideration for others' happiness and welfare, we must have a special altruistic attitude in which we take upon ourselves the burden of helping others. To generate such an unusual attitude, we must have great compassion - caring about the suffering of others and wanting to do something about it. To have such a strong force of compassion, we must have a strong sense of love that, upon observing sentient beings, wishes that they have happiness - finding a pleasantness in everyone and wishing happiness for everyone, just as a mother does for her sole sweet child. To have a sense of closeness and dearness for others, use as a model a person in this lifetime who was very kind to you. Then extend this sense of gratitude to all beings. Deep down we must have real affection for each other, a dear realisation or recognition of our shared human status. At the same time, we must openly accept all ideologies and systems as a means of solving humanity's problems. One country, one nation, one ideology, one system is not sufficient. It is helpful to have a variety of different approaches on the basis of a deep feeling of the basic sameness of humanity. We can then make a joint effort to solve the problems of the whole of humankind.

Every major religion has similar ideas of love, the same goal of benefiting through spiritual practice, and the same effect of making its followers into better human beings. All religions teach moral precepts for perfecting the functions of mind, body, and speech. All teach us not to lie or steal or take others' lives, and so on. The common goal of all moral precepts laid down by the great teachers of humanity is unselfishness. Those teachers wanted to lead their followers away from the paths of negative deeds caused by

ignorance and to introduce them to paths of goodness. All religions can learn from one another; their ultimate goal is to produce better human beings who will be more tolerant, more compassionate, and less selfish.

Human beings need spiritual as well as material sustenance. Without spiritual sustenance, it is difficult to get and maintain peace of mind. The purpose of religion is not to argue which one is the best. Over the past centuries, each great teaching has served humanity, so it's much better to make friends, understand each other, and make an effort to serve humanity than to criticise or argue. Buddha, Jesus Christ, and all other great teachers created their ideas and teachings with sincere motivation, love, and kindness toward humanity, and they shared it for the benefit of humanity, I do not think those great teachers created differences to make trouble. Our human mind always likes different approaches. There is a richness in the fact that there are so many different presentations of the way. There are two ways to enter into Buddhism; one through faith and one through reasoning. Faith alone may not be sufficient, Buddha always emphasised a balance of wisdom and compassion: a good brain and a good heart should work together. Placing importance on just the intellect and ignoring the heart can create more problems and more suffering in the world. On the other hand, if we emphasise only the heart, and ignore the brain, then there is not much difference between humans and animals. These two must be developed in balance, and when they are, the result is material progress, accompanied by good spiritual development. Heart and mind working in harmony will yield a truly peaceful and friendly human family. I feel that my mission is, wherever I am, to express my feeling about the importance of kindness, compassion, and the true sense of brotherhood. I practice these things. It gives me more happiness, more success. If I practice anger or jealousy or bitterness, no doubt my smile would disappear. The real troublemakers are anger, jealousy, impatience, and hatred. With them, problems cannot be solved. Though we may have temporary success, ultimately our hatred or anger will create further difficulties. Anger makes for swift solutions. Yet, when we face problems with compassion, sincerity, and good motivation, our solutions may take longer, but ultimately they are better.

When I meet new people, in my mind there is no barrier, no curtain. As human beings you are my brothers and sisters; there is no difference in substance. I can talk with you as I would to old friends. With this feeling we can communicate without any difficulty and can make heart-to-heart contact. Based on such genuine human relations

- real feeling for each other, understanding each other - we can develop mutual trust and respect. From that, we can share other people's suffering and build harmony in human society.

## A.8 'The Moon Under Water'

By **George Orwell** My favourite public-house, the Moon Under Water, is only two minutes from a bus stop, but it is on a side-street, and drunks and rowdies never seem to find their way there, even on Saturday nights. Its clientele, though fairly large, consists mostly of "regulars" who occupy the same chair every evening and go there for conversation as much as for the beer. If you are asked why you favour a particular public-house, it would seem natural to put the beer first, but the thing that most appeals to me about the Moon Under Water is what people call its "atmosphere." To begin with, its whole architecture and fittings are uncompromisingly Victorian. It has no glass-topped tables or other modern miseries, and, on the other hand, no sham roof-beams, ingle-nooks or plastic panels masquerading as oak. The grained woodwork, the ornamental mirrors behind the bar, the cast-iron fireplaces, the florid ceiling stained dark yellow by tobacco-smoke, the stuffed bull's head over the mantelpiece—everything has the solid, comfortable ugliness of the nineteenth century. In winter there is generally a good fire burning in at least two of the bars, and the Victorian lay-out of the place gives one plenty of elbow-room. There are a public bar, a saloon bar, a ladies' bar, a bottle-and-jug for those who are too bashful to buy their supper beer publicly, and, upstairs, a dining-room. Games are only played in the public, so that in the other bars you can walk about without constantly ducking to avoid flying darts. In the Moon Under Water it is always quiet enough to talk. The house possesses neither a radio nor a piano, and even on Christmas Eve and such occasions the singing that happens is of a decorous kind. The barmaids know most of their customers by name, and take a personal interest in everyone. They are all middle-aged women—two of them have their hair dyed in quite surprising shades—and they call everyone "dear," irrespective of age or sex. ("Dear," not "Ducky": pubs where the barmaid calls you "ducky" always have a disagreeable raffish atmosphere.) Unlike most pubs, the Moon Under Water sells tobacco as well as cigarettes, and it also sells aspirins and stamps, and is obliging about letting you use the telephone. You cannot get dinner at the Moon Under Water, but there is always the snack counter where you can get liver-sausage sandwiches, mussels (a speciality of the house), cheese, pickles and those large biscuits with caraway seeds in them which only seem to exist in public-houses. Upstairs, six days a week, you can get a good, solid lunch—for example, a cut off the joint, two vegetables and boiled jam roll—for about three shillings. The special pleasure of this



lunch is that you can have draught stout with it. I doubt whether as many as 10 per cent of London pubs serve draught stout, but the Moon Under Water is one of them. It is a soft, creamy sort of stout, and it goes better in a pewter pot. They are particular about their drinking vessels at the Moon Under Water, and never, for example, make the mistake of serving a pint of beer in a handleless glass. Apart from glass and pewter mugs, they have some of those pleasant strawberry-pink china ones which are now seldom seen in London. China mugs went out about 30 years ago, because most people like their drink to be transparent, but in my opinion beer tastes better out of china. The great surprise of the Moon Under Water is its garden. You go through a narrow passage leading out of the saloon, and find yourself in a fairly large garden with plane trees, under which there are little green tables with iron chairs round them. Up at one end of the garden there are swings and a chute for the children. On summer evenings there are family parties, and you sit under the plane trees having beer or draught cider to the tune of delighted squeals from children going down the chute. The prams with the younger children are parked near the gate. Many as are the virtues of the Moon Under Water, I think that the garden is its best feature, because it allows whole families to go there instead of Mum having to stay at home and mind the baby while Dad goes out alone. And though, strictly speaking, they are only allowed in the garden, the children tend to seep into the pub and even to fetch drinks for their parents. This, I believe, is against the law, but it is a law that deserves to be broken, for it is the puritanical nonsense of excluding children—and therefore, to some extent, women—from pubs that has turned these places into mere boozing-shops instead of the family gathering-places that they ought to be. The Moon Under Water is my ideal of what a pub should be—at any rate, in the London area. (The qualities one expects of a country pub are slightly different.) But now is the time to reveal something which the discerning and disillusioned reader will probably have guessed already. There is no such place as the Moon Under Water. That is to say, there may well be a pub of that name, but I don't know of it, nor do I know any pub with just that combination of qualities. I know pubs where the beer is good but you can't get meals, others where you can get meals but which are noisy and crowded, and others which are quiet but where the beer is generally sour. As for gardens, offhand I can only think of three London pubs that possess them. But, to be fair, I do know of a few pubs that almost come up to the Moon Under Water. I have mentioned above ten qualities that the perfect pub should have and I know one pub that has eight of them. Even there, however, there is no draught

stout, and no china mugs. And if anyone knows of a pub that has draught stout, open fires, cheap meals, a garden, motherly barmaids and no radio, I should be glad to hear of it, even though its name were something as prosaic as the Red Lion or the Railway Arms.

## A.9 System used to build online questionnaires

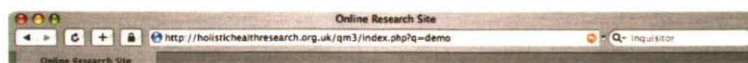
A series of scripts and functions were written in the PHP programming language to facilitate quick, reliable and secure creation of online questionnaires. A series of 'screen grabs' are included below demonstrating the key functions from the user's perspective. Security was maintained using standard open source tools and protocols. Data was stored in a flat file, and could be exported to a Stata-compatible format by requesting a specific password protected URL.

Additionally, Figure A.4 shows the current (retrieved 22nd July 2008) state of the research group website created to promote studies, provide information to potential participants, and provide an attractive 'orienting point' for users who arrived via online-advertising or from media coverage.

Figure A.1: User required to enter a pre-defined study ID number (access blocked without a valid ID)



Figure A.2: System requires user to select a checkbox (used to ensure consent given for online studies)



Online Research Site

Some checkboxes

This one is required

This one isn't

This one is pre-ticked

Continue >>



Online Research Site

Some checkboxes

You must agree with the statement, and tick this box, to proceed.

This one is required

This one isn't

This one is pre-ticked

Continue >>

Figure A.3: Various question formats allowed by the system (custom question formats or scoring systems were easily created on an ad-hoc basis)

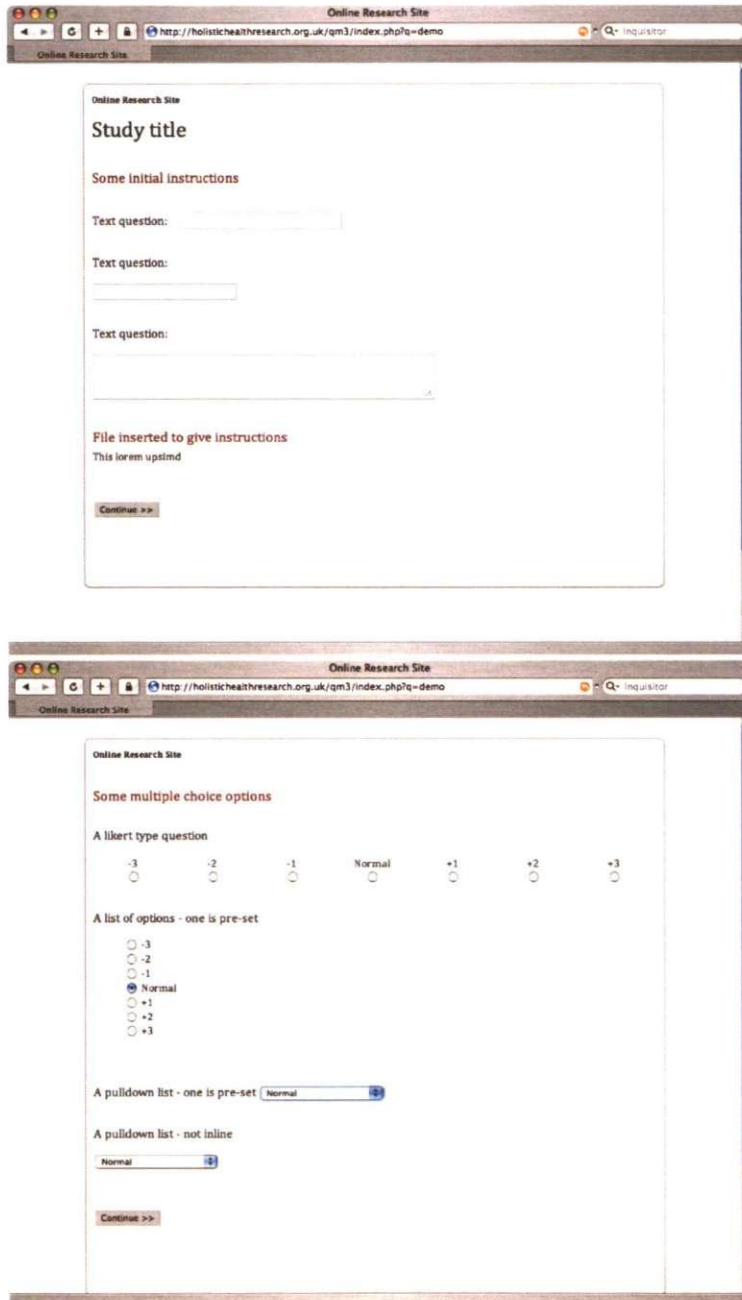
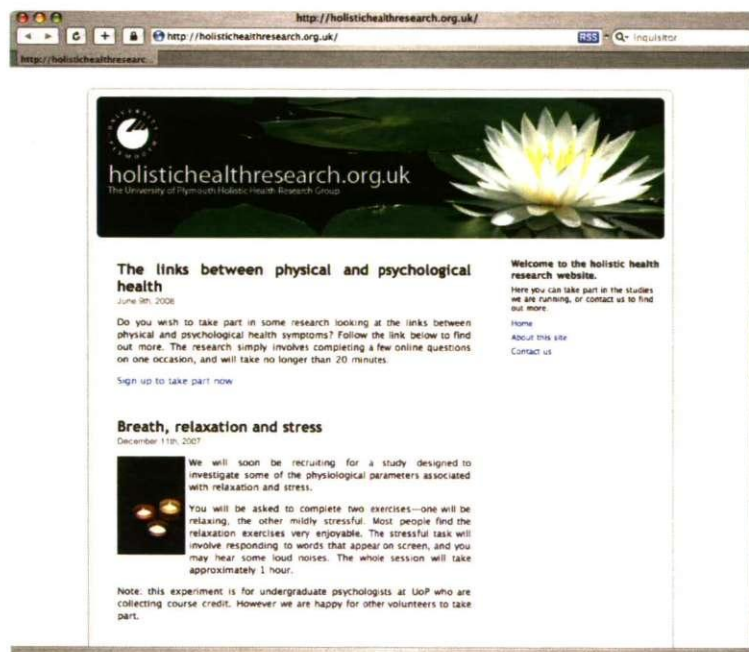


Figure A.4: Research group website used to promote studies (retrieved 22 July 2008)



## A.10 Text of automated telephone system described in Chapter 5

### *Calls in*

Note, a flow diagram indicating a participant's flow through the call system can be found on page 113.

**Welcome** Hello, this is the University of Plymouth research line.

**ID number?** Please enter the ID number which was sent to you with the flower essence pack (it should be a four digit number).

**Check number?** Was that [repeat entered number] ? Press 1 for yes or 2 for no.

**Bad ID number** That didn't seem to be a valid study ID code. Please try again

**Registered** You're now ready to start the study.

**Reminder** Remember to take 3 drops of the essence twice each day, in the morning and evening.

**Affirmation (positive/spiritual)** Flower essences work best if you picture that they are doing you good as you take them / Flower essences work best if you picture the spirit of the flower connecting you to a pool of universal healing and love.

**Goodbye** We'll call you tomorrow to find out how you are getting on. Thank you and goodbye.

### *Calls out*

Note, a flow diagram indicating a participant's flow through the call system can be found on page 114.

**Hello** Hello, this is an automatic call from the University of Plymouth to find out how you're getting on with your flower essences - this will only take around 2 minutes.

**Can you talk?** If now is a good time to answer the questions please press 1. If you would prefer us to call back later today press 2. If you don't want to be called again today press 3.



**Change?** How much better do you feel from taking the flower essence? Press a number from one to nine, where FIVE means you feel the same, ONE means you feel much worse, and NINE means you feel much better.

**Compliance?** Did you take the flower essence this morning? Press ONE for no, or NINE for yes. If you can't remember, press FIVE.

**Ease? (spiritual/positive)** When you were taking the flower essences, how easy was it to picture the spirit of the flower connecting you to a pool of universal healing and love? / When you were taking the flower essences, how easy was it to picture the flower essences helping you? Press a number from ONE to NINE, where NINE means very easy, and ONE means very difficult.

**Affirmation (spiritual/positive)** Flower essences work best if you picture the spirit of the flower connecting you to a pool of universal healing and love / Flower essences work best if you picture that they are doing you good as you take them.

**Reminder** We're finished now, but remember to take 3 drops of the essence twice a day, morning and evening.

**Goodbye** We will call again soon to find out how you are getting on. Goodbye.

**Thankyou/goodbye** Thanks for your help - we hope you have enjoyed participating in the study. If you would like any more information about our work please email Ben Whalley at ben dot whalley (that's W H A L L E Y) at plymouth dot ac dot uk. We'll hang up now, so thanks, and good-bye.

## A.11 Text of automated telephone system described in Chapter 6

### *Calls in*

Note, a flow diagram indicating a participant's flow through the call system can be found on page 141.

**Welcome** Hello, this is the University of Plymouth research line.

**ID number?** Please enter the ID number you were given on our website to register for the study.

**OK** Thanks,

**Telephone number?** ...please enter the telephone number you would like us to call you on over the next few weeks, followed by the hash key. This must be your own mobile phone number and not a landline.

**Registered** Thanks – you've now registered for the study. We'll send you a pack containing the flower essence in the post, but it is important you don't use it before the date marked on the pack. The reason is that we would like to find out about your child's tantrums before taking the essence. As soon as this call is finished, we'll call you straight back to ask you the first of the questions about your child's tantrums. Goodbye for now.

**Bad ID number** That didn't seem to be a valid study ID code. Please try again

**Bad phone number** That didn't seem to be a valid mobile phone number. UK mobile phone numbers have 11 digits, and begin with the numbers 0 and 7.

**Check number?** Was that [repeat entered number] ? Press 1 for yes or 2 for no.

**Major problem** We're sorry but this doesn't seem to be working out. Please contact Ben Whalley via the study website if you are having problems with this system.

### *Calls out*

Note, a flow diagram indicating a participant's flow through the call system can be found on page 142.

**Hello** Hello, this is an automated call from the University of Plymouth to find out how your child is getting on with the flower essence.

**Can you talk?** If you can talk now please press 1. If now is not a good time but you would like us to call back later press 2. If you don't want us to call again today please press 3.

**Call back** If you want us to call back in about 15 minutes please press 0. In about an hour, press 1. In 2 hours press 2. In three hours press 3. In four hours press 4. If you have changed your mind and don't want a call today please press 9.

**Will call back soon** Ok, we'll call back soon. Goodbye.

**Won't call again today** Don't worry. We won't call again today, but you'll receive your next call as usual in a few days. Goodbye.

**Received essence?** Have you received the flower essence yet? Press 1 for yes, 0 for no.

**No essence yet** Ok, we'll call again tomorrow – hopefully you will have received the essence by then and we can find out how you're getting on with it. Goodbye.

**Started taking yet?** Have you begun to give the essence to your child? Press 1 for yes, 0 for no.

**Please start taking** Ok, we'll call again tomorrow. Please start giving the essence to your child, either this evening or tomorrow morning. If you don't wish to give the essence to your child, please contact Ben Whalley via the study website to withdraw from the study. Goodbye.

**Had a tantrum?** Has your child had a temper tantrum in the past 24 hours? Press a number on your keypad from 0 to 9 to indicate how many, or the star key if it has been more than 9.

**Think of worst tantrum** Please think about the worst of the tantrums when answering the following questions.

**Tantrum length?** Approximately how long did the tantrum last for? Press 1 for less than a minute. Press 2 for less than 2 minutes. Press 3 for less than 3 minutes. Press 4 for less than 4 minutes. Press 5 for less than 5 minutes. Press 6 for between 5 and 10 minutes. Press 7 for 10 minutes or more.

**Extra questions** Now we'll ask a few questions to get a better picture of the tantrum.

**Tantrum severity?** On a scale of 1 to 9, how bad was the tantrum, where 1 is not bad at all, 9 is very bad, and 5 is about average.

**Whining?** During the tantrum, did your child whine? Press a number from 1, which means no whining, to 9, which means lots of whining.

**Crying?** [As for Whining above]

**Screaming?** [As for Whining above]

**Kicking or hitting?** [As for Whining above]

**Hold breath?** Did your child hold their breath? Press 0 for no. Press 1 for yes.

**On floor?** Did your child get down on the floor? Press 0 for no. Press 1 for crouching down. Press 2 for properly lying on the floor.

**Compliance?** How many times did your child take the essence yesterday. Press 1 for once, 2 for twice, or 0 for not at all.

**Parent mood?** On a scale of one to nine, how happy are you today, where 9 is much happier than normal, 5 is about normal, and 1 means much more unhappy than normal.

**Reminder** Remember to give your child the essence twice each day. The makers of this essence think that flower essence work because the essence connects your child to a universal pool of healing and love. Many people find it best to give it first thing in the morning and last thing at night.

**Goodbye**

**Start taking if you have it** If you have the essence, please start giving it to your child tomorrow.

## A.12 Qualitative feedback from Chapter 6

We didn't tell our little boy about the essences - he wasn't even 2 and a half when we started. however, fingers crossed the tantrums and hitting has reduced by about 80% so I would say a definite success for us.

~

Please feel free to use my comments i have told so many people about this and they cant wait for it to come out on the market. Please let me know where i can purchase some more 4 my son A.

A has one tablet a day now, you can tell the difference in his behavior if we have forgotton to give him one. I think this stuffis amaizing.

Note, the same mother had previously emailed to say:

Dear Ben, Thankyou my families life has changed so much since my son A has been taking his happy pill. A was told that this was his happy pill. He sleeps better, he is a different child altogether and my parents have noticed a difference too. Please please let me purchase some more i dont care what it cost.

~

The first time I gave the flower essence I caused a tantrum - he took the capsule and then asked for 'more sweetie'. When I said 'no' he had a tantrum shouting 'MORE SWEETIE'!!! He did eventually accept he was only going to get one at a time.

~

i did not tell my child, infact i told her it was a vitamin...i stopped the "viamins" about 6 weeks ago and found little tantrums coming back, not as long as before though, and mostly when shes tired.

~

I can quite honestly say that these remedies changed our life! It took two weeks. After the first 10 days or so my daughter started to have problems sleeping. She wasn't unhappy, just very awake. So i reduced the pills to just one in the morning and instantly she slept better at night.

The first remedy I gave her changed her instantly, but this only lasted for about 3/4 of an hour - but it was the first time I'd seen my daughter actually

relax - I could see it in her face, I'd never seen it before - only in her older sister who seems relaxed all the time! After that had worn off it took a couple of days for her to find out for herself how she should be, she seemed to be allowed to learn that being more placid was a happier and greater place to be.

After two weeks she didn't need them anymore. However, about 7 weeks or so later she was very ill with flu like symptoms for just over a week, and as she recovered from that she started to resort back to her old ways again of anger and frustration. I started giving her a remedy in the morning for 3 days and she settled down instantly. That was the 2nd - 3rd week of October and she hasn't needed anything since.

I'd love to know what's in them. But, whatever it was, please take it from a mother who was at her limits - they work. And you are brilliant to want to concentrate on this as part of your studies.

Well done and good luck in whatever else you choose to do.

We have been thrilled at the results the pills had on our 4 year old son James. Not sure if it was a combination of starting school along with the pills that made them especially effective but we are definitely intending to buy some more as we are now near the end of the supply!

Love these three questions, as the one comment I wanted to make was (relevant and )that the tablets seemed to help with my child's tantrums. I feel that this COULD have been purely through placebo effect as I had told him they were going to help. Or it could have been because they had an ingredient that calmed him??. Nevertheless-does this really matter too much? The desired effect is to cease or reduce the child's tantrum/s. As a parent, I don't really care too much how this is achieved if it involves an unharmed substance. I feel children ( or in any case my child) tantrum/s primarily to gain attention from their carer. If a parent taking the time to

administer a herbal tablet to the child satisfies that child's need for attention (thus ceasing the tantrum) then great. If it works because of its specially selected ingredients then great too. But it does make a difference.

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