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INVOLVING INERT (PLACEBO) SUBSTANCES

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Abstract

We tested the contribution of two mechanisms, response expectancy and motivational concordance, to reported psychological benefit from a popular, biologically inactive, self-help, complementary therapy (a placebo). Flower essences were taken by 251 people for self-selected symptoms and were randomized to receive three different kinds of information. When the flower essence was presented as a spiritual therapy, then baseline spirituality ($\beta = .35$, p = .01) and expectancy ($\beta = .25$, p = .03) independently predicted outcome. When flower essences were presented as a suggestive (i.e., non-spiritual) therapy, then spirituality negatively ($\beta = -.27$, p = .03) and expectancy ($\beta = .33$, p = .01) predicted outcome. For both groups expectancy predicted outcome after controlling for spirituality and compliance, but did not after controlling for ease of task completion. Expectancy failed to predict outcome in the non-enhanced ritual group. The results suggest that motivational concordance is an important therapeutic mechanism for real-life placebos.

Keywords: Placebo, placebo responder, motivation, therapeutic ritual, psychotherapy, contextual

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model, flower essence

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Placebo or non-specific responses play a role in most therapeutic encounters, on occasions accounting for the majority of variance in outcome for both conventional medicines (1, 2) and complementary medicines (3-5). Nevertheless, the underlying mechanisms remain uncertain. There is considerable consensus that conditioning and expectancy can both play a role (6), but there is also evidence for the existence of additional mechanisms. (7-11).

All therapies involve some kind of ritual – a therapeutic ritual. By therapeutic ritual we denote the totality of meaning which is attached to the therapeutic encounter, as perceived by the person, client or patient (12). Self-help rituals are simpler than many others in that they do not involve a therapist, and so minimise therapist-mediated effects.

In this paper we show that when an inert substance is taken in a self-help therapeutic ritual the mechanisms that affect outcome, and hence the correlations between baseline and outcome variables, can be manipulated by altering characteristics of the therapeutic ritual. We focus on two mechanisms: expectancy and motivational concordance. Expectancy is a conventionally accepted placebo mechanism for which there is considerable evidence. Motivational concordance is a recently proposed mechanism (11), which may prove important when explaining long term therapeutic change.

Expectancy and the placebo responder

Therapeutic contexts have meanings related to both beliefs (i.e., cognitive meanings) and feelings (i.e., affective meanings). Expectancies are an important component of cognitive meaning. Response expectancy theory suggests that expectancies have a direct effect on physiological responses, unmediated by any other psychological variable; that is, symptoms and physiological responses tend to become consistent with the expectation, without mediation (13, 14).

The long history of research into 'the placebo responding personality' has been framed

primarily within an expectancy (i.e., cognitive) heuristic. There are two views: one is that dispositions such as suggestibility and acquiescence are predictors of placebo responding because they amount to a generic tendency to respond to suggestion (15). More recently the trait of optimism has also been found to predict placebo outcome (16, 17); optimism correlates with expectancy, with optimists expressing more positive expectations. The second and more popular view is that there is no such thing as a placebo responding personality (18, 19). Adherents of this second view point to the considerable inconsistency in the placebo-responder personality literature, and also make a theoretical point: Expectancies are determined by an evaluation of the specific aspects of the situation—in the context of the person x situation debate, they are the consequence of the situation and the person, and not just the person. For this reason one would not predict a generic placebo responding personality – only context-specific correlations between expectancies and outcomes.

Motivational concordance and the placebo responder

The theory of motivational concordance is based on the assumption that the placebo response is a reaction to the *behaviour* of the therapeutic ritual. Two well-established theories explain why the behaviour of a therapeutic ritual might affect outcome. First, several motivation theories (self determination theory, control theory, self-actualization and personal growth theory) share a common assumption that goal fulfilment is a positive experience (20-25). There is a general consensus that the attainment of self-actualizing, self-defining, or self-relevant goals leads to positive affect. Additionally, there is a well-established link between affect and immune function (26, 27), and so positive goal attainment can also create therapeutic physiological changes (28). Second, self-perception theory suggests that behaviour is a source of information about the self (29, 30), and the behaviour of the ritual could therefore provide information that affects perception of symptoms. What is common to both these theories is the idea that the therapy is effective to the extent that a person engages in the ritual.

There are two reasons why a person may engage with a therapeutic ritual. One is the

desire to get better and the expectation that the therapy will be effective – i.e., the extrinsic value of the ritual which, when coupled with expectancy, leads to motivated behaviour. A second reason is that the ritual satisfies important, self-actualising goals (i.e., the intrinsic value of the ritual) which, when coupled with the expectancy of achieving those self-actualising goals, leads to motivation to engage in the ritual. Here we focus on the second of these motivations to engage with a ritual, namely the intrinsic motivation of the ritual. Note that people may be more optimistic about self-actualising rituals because the extrinsic expectation of success can be associated with the intrinsic value of the ritual.

People have different self-actualising goals, so a ritual that is self-actualising for one person may not be so for another. For any ritual, a person whose motivations are concordant with the ritual should be more engaged and so have better outcomes (due to either of the two mechanisms of behaviourally mediated therapeutic benefit). Intrinsic motivation for the ritual depends on the fit between the person's motives and the ritual. So, according to motivational concordance theory, there should be no such thing as a generic placebo responder, but there should be context specific placebo responders, where the placebo responder characteristics depend on the therapy. The implication is that correlations between predictors and outcome should change if the motivational context of the therapy is changed.

Figure 1 provides a schematic representation of response expectancy theory and the behaviourally mediated motivational concordance theory. Classical motivation theory shows that motivation (i.e., the tendency to engage in goal-oriented behaviour) is the product of value and expectancy -i.e., expectancy x value theory (31). If response expectancy is the only mechanism (i.e., motivational concordance does not occur), then expectancy of positive outcome should correlate with outcome, and neither the intrinsic motivation for the therapy nor behaviour should add additional variance. If motivational concordance is the only mechanism (i.e., response expectancy does not occur), then expectancy of positive outcome should not add additional variance compared to intrinsic motivation for the therapy. If response expectancy and motivational concordance are both true, then expectancy of positive outcome on the one hand, and intrinsic values and behaviour on the other should both contribute variance to outcome.

Flower essences as placebos

Flower essences are a form of complementary and alternative medicine that can be purchased over the counter in pharmacies and health shops, or via the internet, as a remedy for psychological symptoms. They are widely used in Western countries: a major pharmacy in the UK reports 650,000 bottles sold annually for a cost of £3.4 million in 2006 (personal communication). Each of the 38 Bach flower essences purports to treat a different psychological symptom (including anxiety, depression, and fatigue, as well as more unusual symptoms such as impatience or over concern with others). Users select the particular flower essence using a chart that is placed near the essences in the retail outlet or on the internet and which helps users decide on the particular essence or essences they need. Like other complementary medicines, flower essences are a spiritually contextualized therapy (32), and the spiritual nature of flower essences was part of the rationale presented by their inventor, Edward Bach (33). From a biochemical perspective all 38 essences are identical (brandy 60% and water 40%) and no difference has been detected between verum and placebo (34, 35). Flower essences can be considered a self-help placebo which is used regularly for clinical purposes.

When employed in placebo research, flower essences are offered free of charge to volunteers in return for questionnaire completion (10, 11). Like double-blind placebo trials, users in flower essence placebo studies believe they are engaging in real therapy and are not paid.

Unlike clinical trials, participants believe that they are given verum (which is the case); uncertainty about group assignment in clinical trials may affect results (36). The use of flower essences in placebo research is not a laboratory analogue, and placebo mechanisms for laboratory analogue studies may not be the same as those for real life therapies. The methodology relies on an existing set of beliefs and corresponds closely to the normal ritual use of the inert substance.

Dispositional spirituality predicts response to flower essences independently of

expectancy (10) and this finding has been replicated with a more conservative test where multiple measures of expectancy were taken (11). These findings can be explained by the motivational concordance mechanism. Spirituality is one of the high-level values or goals that motivates behaviour (37). If flower essences are interpreted as a spiritually oriented therapy, then people placing high value on spirituality should be more motivated to perform the flower essence ritual, find it more satisfying, become more involved in the ritual, and gain greater benefit. The idea of a behaviourally mediated form of placebo response is consistent with anthropological data showing the beliefs are not essential for response to rituals that are acted out (38).

There are two aims of this study. The first is to show that the correlation between spirituality and outcome occurs only when flower essences are contextualized as a spiritual therapy and not when contextualized as a non-spiritual therapy. This would show that dispositional predictors depend on context, as predicted by motivational concordance.

The second aim is to test whether response expectancy alone, motivational concordance alone, or both theories together contribute to outcome. To do this was have measured expectancy and spirituality as before but have added indicators of behavioural engagement, namely compliance and a retrospective measure of ease of task completion. The latter measure could be biased by perceived outcome (i.e., people perceive the task easier only because they have had a positive outcome); the former measure is not subject to this reporting bias. For this reason, these two behavioural measures will be analysed separately. However they are, of course, only indicators of behavioural engagement, in the sense that they do not cover all variance attributable to behavioural engagement.

Method

Overview

Participants provided informed consent and completed questionnaires at baseline and were then randomized to three groups (spiritual, affirmation and neutral), each receiving different kinds of further information. They took flower essences for three weeks during which time they

provided follow-up assessments. Excluding technical support, there was no human contact with participants, who entered baseline data online and provided follow-up data using an automated telephone system.

Procedure

The study was advertised through the media. Those taking part would be given a free bottle of flower essence in return for questionnaire completion and evaluation. Exclusion criteria were: use of flower essences in the previous six months; currently receiving psychiatric treatment; history of alcohol abuse. 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 randomized to one of three treatment groups (spiritual, affirmation 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. 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 affirmation 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 affirmation group participants received the written information: 'Flower essences work best if, while you are taking 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 compliance by entering numbers on the telephone keypad. At the end of the call, the written instructions for the spiritual and affirmation 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 affirmation groups heard additionally: "Remember, flower essences work best if, while you are taking them, you imagine..." Finally, on day 21, the spiritual and affirmation groups received the question about the ease of the ritual.

Assessments

The Spiritual Connection Questionnaire 14 (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. Because it measures reported experience, the scale can be considered to measure the motive to engage in spiritual activity. A longer version of the scale predicts outcome for flower essence treatment (11). The scale is secular in content and is consistent with the kind of New Age beliefs associated with complementary medicine. High scores indicate more spirituality.

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 to help you?"; the endpoints of the scale were marked *Unlikely it will help* (-3) and *Definitely think it will help* (+3).

To assess outcome, participants heard the following message 'How much better do you feel from taking the flower essence? Press a number from one to nine, where *one* means you feel

much worse, *five* means you feel the same, and *nine* means you feel much better." A *final outcome* score was calculated from the mean of the last three outcome assessments (positive scores indicate improvement). An *initial outcome* score was calculated from the mean of the first three outcome assessments.

Compliance was measured by the question: "Did you take the flower essence this morning? Press *one* for yes or *zero* for no". *Overall compliance* was calculated as the mean of responses made (high scores indicate greater compliance). 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 affirmation 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 affirmation group, the question was: "How easy was it to imagine the flower essence helping you solve your problem?" Participants responded on a 9-point scale where 9 was defined as *very easy* and 1 as *very difficult*. Ease of ritual was not assessed for the neutral group.

Results

Three hundred and fifty six people registered on the web site, of whom 118 were randomized to the spiritual group, 117 to the affirmation group and 121 to the neutral group. Of these, 277 registered on the automated telephone system, and 251 people responded on at least one of the three final days of data collection (42 male, 201 female; mean age = 37, SD = 11.9, range = 18 to 66 years), of whom 87 were in the spiritual group, 75 in the affirmation group and 89 in the neutral group. There was no significant difference between groups in the numbers registering on the telephone system ($\chi^2 = 3.8$, p = .15; all p values reported are two-tailed), or completing one of the final assessments ($\chi^2 = 3.4$, p = .18).

We also examined outcome scores for the three instructions groups; mean scores (standard deviations in parentheses) for final outcome were: spiritual: 5.7 (1.2), affirmation: 5.7 (1.0), neutral: 5.8 (1.4). Note, the point of no-change is 5 and higher scores indicate

improvement. There was no significant difference in final outcome between the groups, F(2,248) = .04, p = .96. An equivalent comparison between initial outcome scores was also not significant F(2, 248) = 1.77, p = .17. Because the baseline scores between the three groups were not identical we examined the residualised change scores by carrying out an analysis of covariance with the final outcome as the dependent variable, week 1 scores as covariate and group as a fixed factor. There was still no significant difference between the groups. Analysis of final outcome showed that for the total sample 122 (50.7%) people had improved; 88 (39.8%) remained the same; and 21 (9.5%) deteriorated. Because group did not affect overall outcome, we combined the data for all three groups to provide a picture of improvement over time. For the total sample, Figure 2 shows the mean outcome score for each day of measurement. Improvement is gradual during the first week, but there is little further improvement after day 7. [FIG 1 ABOUT HERE]

We next investigated predictors of change. Table 1 shows the correlations between the baseline measures for the sample as a whole, and Table 2 shows correlations with baseline variables and variables that may be affected by group, namely, final outcome, ease of ritual, and compliance. The correlations with initial outcome are not shown: these are generally much lower that the correlations with final outcome.

[TABLES 1 AND 2 ABOUT HERE PLEASE]

An inspection of Table 2 suggests that correlations with outcome differ between groups. To test whether this difference was significant we performed a multiple regression analysis. We entered final outcome (converted to z scores) as the dependent variable, with spirituality (also converted to z scores), group (coded 0/1 for affirmation/spiritual groups), and the spirituality * group interaction term as predictors. There was no main effect of spirituality ($\beta = -.09$, p = .47), but the interaction term was significant ($\beta = .37$, p = .01) showing that the correlation between spirituality and outcome was significantly different between the spiritual and affirmation groups. Motivation theory predicts that spiritually motivated people would become more involved with spiritual instructions. We tested whether our measures of ease of ritual and of compliance could be considered measures of involvement by examining the correlations between spirituality, ease of ritual and compliance. For the spiritual group, spirituality and ease of ritual were correlated, r(69) = .37, p = < .01, but they were not correlated for the affirmation group r(65) = .15, p = .23. Compliance did not correlate with ease of ritual for the spiritual or affirmation groups (ease of ritual was not measured in the neutral group). These results suggest that ease of ritual can be considered a measure of involvement linked to motivation, whereas compliance is not. Compliance is an indicator of behavioural engagement with the task, but where the engagement is due to factors other than motivation-induced involvement. The psychological mechanisms leading to compliance are unclear. Compliance correlated with expectancy for the neutral group r(92) = .22, p = .04, but not the spiritual group, r(91) = .14, ns, nor the affirmation group r(80) = .04, ns,

For each of the three groups we tested (a) whether spirituality and expectancy contributed independently to outcome, and (b) whether ease of task and compliance explained significant additional variance when added to the two baseline measures. Because ease of task completion, but not compliance could be caused by outcome, we carried out the multiple regression in three steps. For each group we carried out a multiple regression where final outcome was the dependent variable; trait Spirituality and Expectancy added in the first step; Compliance added in the second step and (for spiritual and affirmation groups only) Ease of ritual were added in the third step. The results are shown in Table 3.

The first step of the analysis shows that, for the affirmation and spiritual groups, spirituality and expectancy independently predict outcome, but the negative β in the affirmation group suggests that participants who are relatively high in expectancy and low in spirituality have better outcomes whereas those low in expectancy and high in spirituality have worse outcomes. Thus, in the spiritual groups the correlations between expectancy and spirituality and

outcome are consistent with previous data, but in the affirmation group, a different pattern emerges. There were no independent predictors of outcome in the neutral group – spirituality just missed significance at p = .06.

The second step shows that for the affirmation and spiritual groups Expectancy remains significant after controlling for Spirituality and Compliance. In step 3 Expectancy is no longer significant after controlling for Spirituality, Compliance and Ease of task completion. These results show that the question of whether expectancy is mediated via behaviour depends on the behavioural measures taken. Compliance and Ease of task completion are indicators of engagement with a task, and do not necessarily capture all the variance associated with task engagement.

As a final examination of behaviour during the study, we tested whether completers differed from non-completers on baseline variables. We computed two new variables: Registered (0/1) indicating whether a participant who completed baseline data online went on to register with the automated telephone system; and Completed (0/1) indicating whether the participant answered at least 1 of the final 3 telephone calls and was thus included in the analysis above. We then ran a two separate logistic regressions, first with Registered and then with Completed as the dependent variable. Spirituality, Optimism, Expectancy and Group (dummy coded such that the neutral group was the reference category) were entered as predictors. Only Spirituality predicted study completion: for Registered b = .27, p = .02; Completed b = .23, p = .02.03. A follow-up analysis indicated there was no interaction between spirituality and instruction group. As a further test of the contribution of expectancy to completion we entered Expectancy by itself with for each of the two measures of drop out. In neither case did expectancy predict drop out; for Registered, b = -.04 and for Completed, b = .02.

We included a measure of optimism to see if we could replicate earlier findings (16, 39) that optimism predicts outcome for therapies where a positive expectancy is generated. For the sample as a whole the correlation between optimism and perceived change was -.06, ns.

[TABLE 3 HERE PLEASE]

Discussion

In this study, participants engaged in a therapeutic ritual that resembles real life purchase and use of flower essences over the internet. Our study ritual differed from the real life ritual only because participants did not pay for the essence, completed assessments, and were aware they were taking part in a study. There was a gradual improvement in outcome over the first seven days of the study. We found that the previously reported correlation between outcome and spirituality is not due to flower essences per se, but due to the way they are contextualized as a spiritual therapy. When flower essences are contextualized as a less-spiritual therapy (i.e., affirmation group), then the previously reported correlation disappears, as predicted by motivational concordance and consistent with research on gratitude therapy (11). Thus, we have achieved the first aim of the study: we have shown that the predictors of placebo outcome are context dependent, as predicted by motivational concordance. We do not know what motive is congruent with 'affirmation' therapy, however spirituality is negatively related to values such as power (37), and we found that people who were low in expectancy and high in spirituality did badly with affirmation therapy. We received informal feedback from a participant in the affirmation group that he felt he was being manipulated by the instructions. It may be that some people, particularly spiritual people, respond badly to auto-suggestive instructions.

A second aim of this study was to compare the relative contribution of response expectancy (i.e., directly mediated effect of expectancy) versus motivational concordance (i.e., values and expectancy are mediated via behaviour). First, we confirmed previous research that motivational concordance is a mechanism for placebo response. We found that spirituality, as well as two behavioural measures, predicted outcome independently of expectancy. Thus, the effect of expectancy is not *only* mediated directly – there are also effects that appear to derive from the behaviour of engaging in the ritual. The answer to the question of the relative

contribution of response expectancy versus motivational concordance is complex. We examined whether expectancy predicted additional variance for outcome when spirituality and behavioural engagement were taken into account. We used two measures of behavioural engagement, but these measures were taken at different points during the study. Compliance was measured during the treatment period, and might thus cause perceived benefit, but cannot be caused by perceived benefit. Ease of task completion was measured at the end of the study, and this could both cause or be caused by perceived benefit. First, if we assume that only compliance is a valid behavioural measure, then response expectancy appears to contribute to outcome and, based on β values, to a similar degree as motivational concordance. Expectancy predicted outcome after controlling for spirituality and compliance for both the spiritual and affirmation groups (but not the neutral group). Of course, compliance does not capture the full meaning of task engagement, so this test favours response expectancy. Second, if we assume that both compliance and ease of task completion are valid measures of behavioural engagement (i.e., ease of task completion causes outcome but not vice versa), then it would appear that only motivational concordance predicts outcome. Expectancy did not predict outcome in any of the three groups after controlling for spirituality, compliance and ease of task completion.

On the basis of the model of motivational concordance shown in Figure 1, why did
Spirituality predict independently after controlling for Compliance and Ease of Task completion?
We believe the reason is that Compliance and Ease of Task completion are not ideal indicators of engagement with a task. Because motivation is so closely linked with task engagement,
Spirituality (i.e., the measure of value) explains additional variance in behaviour and hence outcome, not covered by Compliance and Ease of Task completion.

In our study, the neutral group acted as a control condition for the enhanced rituals that were provided in the spiritual and affirmation groups. Comparison between the neutral group and other groups leads to two conclusions. First, the provision of additional information stabilizes the meaning of the ritual – the slightly lower correlation with spirituality in the neutral, as compared

with the spiritual, group suggests that not everyone interprets flower essences as a spiritual therapy. The brief initial reference to spirituality when the essence was presented online was not necessarily remembered, and we know from contacts with participants in past studies that some people associate Bach flower remedies with pharmacologically active herbal remedies such as St John's Wort or Echinacea. Second, in the neutral group there was no correlation between expectancy and outcome – in contrast to the other two groups, previous flower essence research (11), and many other studies. The lack of an expectancy correlation is surprising but adds to data suggesting that response expectancy may not be as important a mechanism for real life placebo responses as it is in laboratory analogue studies (40, 41).

A possible criticism of our previous research is that expectancy and spirituality are not equally reliable measures and so the independent effect of spirituality on outcome or the weak effect of expectancy on outcome is an artefact created by the properties of the scales. This study provided a more robust test of the motivational concordance hypothesis by examining whether the placebo effect was mediated through behaviour – i.e., whether 'doing the ritual' was more important than 'believing in the ritual.'

The correlations with expectancy and spirituality suggest that our measure 'ease of ritual' reflects involvement in the task, i.e., the extent to which people get involved in 'doing the ritual.' By contrast, compliance failed to correlate with expectancy and spirituality, suggesting that compliance measures the degree of 'doing the ritual' but without tapping into involvement. For both enhanced information groups (i.e., spiritual and affirmation) we found that compliance and ease of ritual predicted outcome; expectancy failed to explain additional variance when ease of ritual completion was included as a predictor, consistent with the prediction of motivational concordance but not of response expectancy. Thus, these data provide further evidence to suggest that 'doing the ritual' rather than 'believing the ritual' may be the important factor for long term placebo effects.

Analysis of drop out rates shows that higher spirituality at baseline improved a

participant's chances of both entering the assessment phase and completing the study. During the process of obtaining consent flower essences were briefly described as a spiritually oriented therapy for all three groups, and participants' prior knowledge of flower essences is likely to have been concordant with this spiritual orientation. Thus for all groups spirituality predicted drop out. By contrast, expectancy at baseline failed to predict drop-outs, consistent with the assumption that drop out behaviour is determined by motivational concordance. Other research has shown that participants who fail to improve in psychotherapy tend to drop out (42), so it would seem in our study that drop out and improvement are, in part, driven by the same mechanism, namely motivational concordance with the therapy.

Despite different instructions given to the three groups, there was no overall difference in mean outcome. Although the purpose of our study was to examine correlations rather than mean differences, a failure to find any difference between groups was surprising – even though there is a history of research showing that different therapies are equally effective (43, 44). Despite the absence of an overall difference the three instructions were not equally effective for individuals, suggesting that the advantage of one type of ritual for one person in a group is counterbalanced by its disadvantages for another person. Our enhanced rituals (i.e., the spiritual and affirmation groups) provided the opportunity for greater involvement, but the greater specification means that it is uncomfortable for those for whom the ritual is non-concordant. By contrast the neutral condition allows greater flexibility for people to interpret the ritual so as to be concordant with their motives. In sum, there are two possible explanations for the overall equivalence between the three groups. The first is that instructions influence the way people interpret the ritual, but without instructions people construct their own interpretation of the meaning of the ritual, and there are equal numbers of those who find any particular type of instruction congenial or noncongenial. The second explanation is that another more important therapeutic mechanism is yet to be discovered.

Although it was peripheral to the main aim of the study we measured optimism at

baseline to see whether optimism predicted outcome, as suggested in previous research (16, 39). Although flower essences generated positive expectancies we failed to find a correlation between optimism and outcome, despite a large sample size. These results are consistent with our overall conclusion that dispositional predictors of outcome depend on the context in which the placebo is taken.

There are several limitations to this study. First, participants did not have a serious illness, though they self-selected to treat a problem for which they perceived it worth engaging in the study to treat. Second, the problems treated were heterogeneous, and it is possible that the contribution of different mechanisms varies with the psychological problem being treated. Third, we have no objective monitoring of behaviour during the study, though we do have a subjective measure of compliance, and internet studies are a valid method for collecting this type of data (45). Fourth, we used a single measure of perceived change – though on several occasions – rather than a before/after measure of outcome. Fifth, measurement deficiencies of a single-item expectancy measure may be responsible for the failure of expectancy to predict independently of other variables. However, previous research (46) has shown that spirituality predicts independently of multi-item expectancy measures. Sixth, our measure of ease of ease of ritual could be biased by the participant's experience of outcome. As noted above, this leads to uncertainty in our data as to whether response expectancy makes a significant but smaller contribution to outcome, or whether it makes no contribution. Finally, it should be noted that our results may have no bearing on short term placebo effects, especially short term placebo analgesia studies, where expectancy appears to have a direct effect.

In conclusion, our data show that placebo responders can be identified, but also that, consistent with other research (47), placebo responders vary with the therapeutic context. This research also suggests that motivational concordance is the primary mechanism for long-term change in self-help therapies involving an inert substance. Whether response expectancy provides an additional contribution cannot be determined from our data. We do not know why

engaging in motivationally concordant rituals is so important – whether the behaviour of the ritual alters affect or self-perceptions (or both) was not investigated in this study. However, our data do suggest that placebos in real life cannot be understood only as a cognitive appraisal of expectancy of outcome.

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Table 1. Correlations between baseline variables ($n = 356$)					
Predictor	1	2	3		
1. Spirituality	_	.43**	.28**		
2. Expectancy		_	.04		
3. Optimism			_		
* $p = <.05$; ** $p = <.01$.					

Table 2. Correlations between predictors and final outcome (OUT); ease of ritual (EASE); and compliance (COM) in three experimental groups

	Neutral $(n = 89)$		Affirm	Affirmation $(n = 74)$		Spiritual $(n = 87)$			
	OUT	EASE	COM	OUT	EASE	COM	OUT	EASE	COM
Spirituality	.22*	_	.18	.09	.15	04	.34**	.37**	.13
Expectancy	.10	-	.21*	.24*	.35**	.14	.28*	.37**	.08
Ease of ritual	_	_	_	.34**	_	.07	.41**	_	.15
Compliance	05	_	_	.25*	.07	-	.23*	.15	_

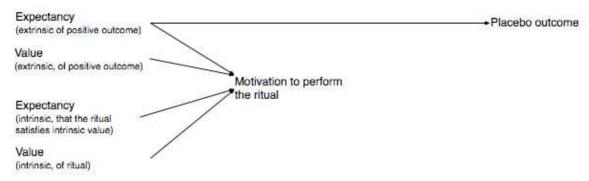
^{*} p = <.05; ** p = <.01

Table 3. Multiple regressions for final outcome shown separately for the three groups, showing $\boldsymbol{\beta}$ and p (in parentheses) values for the predictor variables entered in two steps.

Predictors:	Neutral Group	Affirmation Group	Spiritual Group
Step 1			
Spirituality	.23 (.06)	27 (.03)	.35 (.01)
Expectancy	01 (.92)	.33 (.01)	.25 (.03)
	Model R^2 adj. = .03	Model R^2 adj. = .10	Model R^2 adj. = .23
	F(2,86) = 2.2, p = .12	F(2,64) = 4.7, p = .01	F(2,68) = 11.9, p = <.01
Step 2			
Spirituality	23 (.05)	24 (.05)	.31 (.01)
Expectancy	.01 (.98)	.30 (.02)	.23 (.04)
Compliance	09 (.39)	.18 (.13)	.23 (.03)
	R^2 change. = .01	R^2 change. = .03	R^2 change. = .05
	F(1,85) = .75, p = .39	F(2,63) = 2.39, p = .02	F(1,67) = 4.64, p = .04
Step 3			
Spirituality		26 (.03)	.26 (.03)
Expectancy		.20 (.10)	.17 (.12)
Compliance		.17 (.13)	.21 (.05)
Ease of ritual		.30 (.01)	.22 (.05)
		R^2 change. = .08	R^2 change. = .04
		F(2,62) = 6.42, p = .01	F(2,66) = 3.90, p = .06

Figure 1. Two different placebo mechanisms

Response expectancy theory



Motivational concordance theory

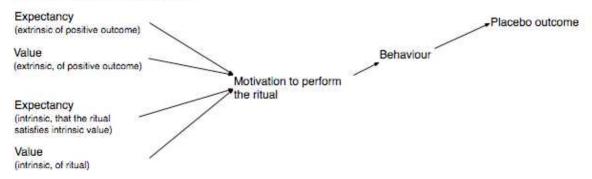
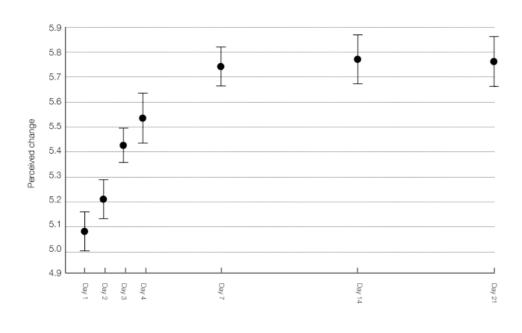


Figure 2. Mean symptom change (with 95% confidence interval) on days 1 through 21 †



Authors' note

We thank Ainsworths Ltd. for providing us with flower essences free of charge and without precondition.

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