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Differences in perceived risks and benefits of herbal, over-the-counter conventional, and prescribed conventional, medicines, and the implications of this for the safe and effective use of herbal products

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Summary
Objectives: To investigate people's views about the efficacy and specific risks of herbal, over-the-counter (OTC) conventional, and prescribed conventional medicines, and their likelihood of taking a second (herbal or OTC conventional) product in addition to a prescribed medicine.
Methods: Experiment 1 (1 factor within-participant design); Experiment 2 (1 factor between-participant design). Convenience samples of general population were given a hypothetical scenario and required to make a number of judgements.
Results: People believed herbal remedies to be less effective, but less risky than OTC and prescribed conventional medicines. Herbal medicines were not seen as being safer simply because of their easier availability. Participants indicated that they would be more likely to take a herbal medicine than a conventional OTC medicine in addition to a prescribed medicine, and less likely to consult their doctor in advance.
Conclusion: People believe that herbal medicines are natural and relatively safe and can be used with less caution. People need to be given clear information about the risks and benefits of herbal medicines if they are to use such products safely and effectively.

Introduction

The sale and use of herbal medicines has increased significantly over the past 20 years. Eisenberg et al.,[1] for example, reported that use of herbal medicines in the US increased from 2.5% in 1990 to

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12.1% in 1997, with a total of $ 5 billion being spent. Within the UK, Thomas et al.[2] found that over 30% of a random sample of 5010 adults were taking, or had been taking, herbal remedies. Despite this increase in usage, and the concurrent increase in the amount of information promoting usage, there are still relatively few studies that have examined people's beliefs about the risks and benefits of herbal products, particularly as a distinct medicine type (rather than asking about complementary medicines in general). Thus, the majority of studies in the area have compared experiences with, and views about, complementary as opposed to orthodox medicines.[3–6] Such general comparisons, however, make it more difficult to address a number of key questions.

For example, one reason for the increased usage of complementary, including herbal, medicines is that such products are believed to be safer than orthodox treatments,[7–10] but it is not clear from the existing studies what underlies this perception. Thus, are herbal medicines perceived to be safe because they are more readily available, or for some other reason, such as their being a more natural product? In relation to this, Tomassoni and Simone[11] proposed that the over the counter availability of herbal medicines fosters the notion that they are safe. The present study compares people's views about the risks and benefits of herbal, over-the-counter (OTC) conventional, and prescribed conventional medicines. This should provide a more thorough understanding of people's views of the relative safety of the three medicine types, as well as what might underlie any differences in perceptions.

There is also evidence that people do not inform their physicians if they are taking complementary medicines.[7,12–14] Eisenberg et al. found that of the 34% of respondents who reported using at least one complementary therapy in the past year, 72% did not inform their doctor. More recently, Bennett and Brown found that the majority of users (86%) did not discuss their use of herbal remedies with their doctor. The evidence on this is mixed, however. Klepser et al. reported that both users and non-users of herbal therapies indicated that they would disclose such information if asked by doctors and pharmacists (although the study did not assess whether such information would be volunteered spontaneously). In addition, Harnack et al.[15] reported that 89% of their sample of 376 US respondents agreed with the statement ''you should inform your physician of any herbal products you are taking''.

A related question concerns whether people would consult their doctor if they experience an adverse side effect as a result of taking a herbal product. It has been reported that many people do not associate adverse reactions with herbal products they are taking, as they believe the products are safe. As a result, many do not inform their doctors when they experience a reaction. Barnes et al.[16] found that patients were less likely to report adverse reactions resulting from use of a herbal product compared with a prescription drug.

Experiment 1 in the present study specifically compares people's views about the risks (adverse side effects, dependency, interaction with prescribed medicines) and benefits of herbal, over-the-counter (OTC) conventional, and prescribed conventional medicines in order to gain a better understanding of people's views of the relative safety of the three medicine types, as well as what might underlie any differences in perceptions. Thus, herbal medicines may be seen to differ from OTC and prescribed (conventional) medicines because they are seen as being more natural. Alternatively, herbal and OTC medicines may differ from prescribed medicines because the former two are more easily available and can be self-prescribed. Experiment 2 looks at how likely it is that people would take a herbal or OTC product in addition to a prescribed medicine, whether they would seek advice in advance of doing this (and from what source), and what action they would take if they experienced an adverse effect.

Methods

Participants

Participants (Experiment 1, $n = 77$; Experiment 2, $n = 120$) were adult members of the general population, recruited as opportunity samples in a London coach station. For Experiment 1, this took place on weekdays in October 2003 and, for Experiment 2, in December 2003. Further details of the samples are provided in the results sections.

Design

In Experiment 1, a one factor (medicine type: prescribed, OTC, herbal) within-participant design was used; that is, all participants answered questions relating to the three different medicine types. The order of the three sets of questions was varied, in a systematic way, for different participants (so that an equal number of people received each possible ordering).[17] In Experiment 2, a one factor (medicine type) between-participant design was used, with participants being allocated at random (using a random number generator program) to one of the two conditions (herbal, OTC).[17] Thus, half of

the participants received the scenario relating to herbal medicines and half received the one relating to OTC medicines.

Materials

Participants were given a (5 page in Experiment 1; 4 page in Experiment 2) booklet. Page 1 contained a scenario about suffering from persistent stomach indigestion (Experiment 1) or chronic shoulder pain (Experiment 2). In Experiment 1, the scenario asked people to imagine they were suffering from persistent stomach indigestion, and asked for their views about the first medicine type. After answering the questions, they were asked for their views in relation to the second, then third, medicine type, in both cases in relation to suffering from persistent stomach indigestion. The wording of the scenario used in Experiment 2 is shown in Appendix 1. In both experiments, the scenario was followed by a number of questions, mostly assessed using 6-point unipolar Likert rating scales (the specific questions asked are shown in Figs. 1 and 2). The final page asked for basic demographic information (age, sex, highest educational qualification, and occupation). In addition, in Experiment 1, participants were asked how many times in the past year they had been prescribed a medicine, bought an OTC medicine, and bought a herbal medicine (with four response categories; 0, 1—4, 5—9, 10+). In Experiment 2, they were asked if they had suffered from a chronic pain related condition in the past 5 years, and whether they had taken a herbal/OTC (as appropriate for condition) medicine in the past 5 years.

Procedure

Participants were approached in waiting areas of the coach station and asked if they would be willing to take part in a study assessing their views on taking medicines. All but 8 agreed to do so in Experiment 1 and all but 10 in Experiment 2. No incentive was provided. If they agreed to participate, after giving their consent, they were given a copy of the booklet and were asked to read the front page and then answer the questions on the following pages. They were told that they could re-read the first page at any point, and that they should not deliberate over their answers; we were interested in their initial responses. They were reminded that they could withdraw from the study at any point, although none did so. All completed the questionnaire within between 5 and 10 min. Ethical approval was given by the University of Reading Research and Ethics Committee.

Statistical analyses

Statistical analyses were carried out using SPSS for Windows, version 10.1. One factor (prescribed/OTC/herbal) within participant ANOVA was

1. In general, how effective do you think that prescribed medicines would be for your condition (from 1, not at all effective, to 6, very effective).
2. In general, what do you think is the overall level of risk associated with any medicines that would be prescribed for your condition (from 1, no risk at all, to 6, very high risk).
3. How likely do you think it is that such medicines would be associated with adverse side effects (from 1, not at all likely, to 6, very likely).
4. How likely do you think it is that you would become dependent on medicines that are prescribed for your condition (from 1, not at all likely, to 6 very likely)
5. How likely do you think it is that any medicine prescribed for your condition would interact with another prescribed medicine that you might be taking (from 1, not at all likely, to 6, very likely)[2]
6. In general, how likely is it that you would take a prescribed medicine for your condition (from 1, not at all likely, to 6, very likely)
7. How likely is it that you would vary the dosage of medicines prescribed for your condition from that shown on the instructions (i.e. take more or less) (from 1, not at all likely, to 6, very likely)

Figure 1 Measures used in Experiment 1.

1. How likely is it that you would take the second painkiller that has been recommended to you? (from 1, not at all likely, to 6, very likely)
2. To what extent do you think the second drug would be beneficial? (from 1, not at all beneficial, to 6, very beneficial)
3. What do you think the three main benefits would be?[4]
4. To what extent would be concerned about taking the second painkiller? (from 1, not at all concerned, to 6, very concerned)
5. What would you three main concerns be?[4]
6. In comparison to your prescribed painkiller, how potent / strong do you think the second painkiller would be? (from 1, nowhere near as strong, to 6 equally as strong)
7. How likely do you think it is that you would suffer an adverse side effect as a result of taking the second drug? (from 1, not at all likely, to 6, very likely)
8. If you did experience an adverse side effect what action would you take (please tick one) - (stop taking the second drug and wait for symptoms to clear, stop taking both medicines, consult GP immediately, stop taking second drug and visit GP immediately, ask local pharmacist, ask friend/family member, other (please specify)?
9. How likely it is you would seek advice about taking the second drug (before taking it) from the following sources (pharmacist / retailer, GP, family/friends, Internet/ books/magazines). Each of the four options was assessed with 6point Likert scales (from 1, not at all likely, to 6 very likely)
10. If you decide to take the second painkiller, during your next visit to the GP for shoulder pain, how likely is it that you would spontaneously tell the doctor about taking the second drug? (from 1, not at all likely, to 6, very likely)
11. If you were asked by your GP whether you were taking any other medicines, how likely is it that you would tell your GP that you were taking the second painkiller (from 1, not at all likely, to 6, very likely).

Figure 2 Measures used in Experiment 2.

used in Experiment 1. Bonferroni corrected post-hoc (pairwise *t*) tests were applied to the first six measures, where overall significant effects were observed. In Experiment 2, the 11 measures using the Likert rating scales were analysed with independent *t* tests.

Results

Experiment 1

Participants (30 males; 47 females) were aged between 18 and 70. They had a range of educational backgrounds (from having no formal qualifications to a higher degree) and occupations (including teachers, shop assistants, and office and manual workers, as well as some being retired and unemployed). The vast majority had English as their first language, and the remainder spoke it to a high level of proficiency. Thirty-two participants (42%) reported having used herbal medicines in the past year, 57 participants (74%) reported having taken an OTC medicine in the past year, and 55 participants (71%) reported having been prescribed a medicine in the past year.

Table 1 shows means and standard deviations, for the three different medicine types, for the seven measures, together with *F* values and significance levels.

For efficacy, likelihood of side effects and likelihood of dependency, there was a significant difference between each of the three medicine types, in that prescribed medicines were thought to be more effective, and more likely to give rise to side effects and dependency than OTC medicines. OTC medicines were thought to be more likely to be effective and lead to side effects and dependency than herbal medicines. For perceived risk, likelihood of interaction with a prescribed

Table 1 Experiment 1: mean and standard deviation ratings for the seven measures (max = 6) for the three different medicine types

Measure	Prescribed	OTC	Herbal	*F*-value and significance level
Perceived efficacy	4.53 (1.12)	3.81 (1.27)	3.03 (1.32)	$F = 33.45$; $p < 0.001$
Perceived risk	3.08 (1.24)	2.91 (1.26)	2.04 (1.06)	$F = 27.2$; $p < 0.001$
Likelihood of side effects	3.60 (1.28)	2.91 (1.19)	2.34 (1.26)	$F = 24.42$; $p < 0.001$
Likelihood of dependency	3.36 (1.53)	2.86 (1.62)	1.90 (1.05)	$F = 33.11$; $p < 0.001$
Likelihood of interactions	3.68 (1.45)	3.57 (1.28)	2.75 (1.48)	$F = 14.97$; $p < 0.001$
Likelihood of taking medicine	4.06 (1.64)	4.04 (1.60)	2.83 (1.60)	$F = 14.91$; $p < 0.001$
Likelihood of varying dosage	2.07 (1.26)	2.24 (1.48)	2.21 (1.40)	$F = 0.63$; $p > 0.1$

The right hand column shows the *F*-value and significance level for each measure.

medicine, and likelihood of taking the medicine, there was no difference between prescribed and OTC medicines, but both differed significantly from herbal medicines. There was no difference between any of the medicine types in terms of likelihood of varying the recommended dosage. Finally, there was no effect of having taken the different medicine types in the past year on any of the measures.

Experiment 2

The participants were 120 members of the general population, aged between 18 and 72 (42 males and 78 females). They had a similar range of educational backgrounds and occupations to those used in Experiment 1. The vast majority had English as their first language, and the remainder spoke it to a high level of proficiency. Thirty-four participants (28%) reported suffering from a chronic pain condition in the past 5 years, and 77 (64%) indicated that they had taken a herbal medicine in the past 5 years.

Chi-squared analyses showed that the two experimental groups did not differ in terms of age, gender, level of background education, or past medicine use, and therefore any differences between the groups were likely to be due to the different medicine types.

Table 2 shows mean and standard deviation ratings for the two groups for the 11 measures, together with *t* values and significance level. It can be seen that participants completing the questionnaire in relation to taking a herbal medicine indicated that they were significantly more likely to take the medicine, and provided significantly higher ratings for how beneficial they believed the medicine would be. They also provided significantly lower ratings for level of concern, degree of potency/strength, and likelihood of getting side effects. In addition, they provided significantly lower ratings for likelihood of seeking advice from GP, and significantly higher ratings for likelihood of seeking advice from internet/books/magazines than those completing the questionnaire in relation to taking an OTC medicine.

Participants were also asked to list what they believed would be the three main benefits of taking the second medicine and their three main concerns. Table 3 shows the four main benefits and concerns

Table 2 Experiment 2: mean ratings (max = 6), with standard deviations, for each of the 11 measures using the Likert rating scales

Measure	Herbal	OTC	*t*-Value/significance level
Likelihood of taking second drug	4.00 (1.49)	2.65 (1.58)	$t = 4.79$, $p < 0.05$
How beneficial second drug would be	3.52 (1.24)	2.97 (1.23)	$t = 2.44$, $p < 0.05$
Level of concern about taking second drug	3.00 (1.37)	4.30 (1.43)	$t = -5.07$, $p < 0.05$
How potent/strong second drug would be	2.85 (1.29)	3.55 (1.68)	$t = -2.51$, $p < 0.05$
Likelihood of suffering side effects	2.70 (1.12)	4.09 (1.42)	$t = 5.89$, $p < 0.05$
Likelihood of seeking advice from pharmacist/retailer	3.52 (1.56)	4.01 (1.71)	$t = -1.66$, $p > 0.1$
Likelihood of seeking advice from GP	3.52 (1.82)	4.53 (1.60)	$t = -3.21$, $p < 0.05$
Likelihood of seeking advice from family/friends	3.48 (1.56)	3.23 (1.53)	$t = 0.85$, $p > 0.1$
Likelihood of seeking advice from internet/books/magazines	3.47 (1.63)	2.38 (1.45)	$t = 3.84$, $p < 0.05$
Likelihood of spontaneously telling GP about second drug	4.53 (1.48)	4.31 (1.72)	$t = 0.74$, $p > 0.1$
Likelihood of telling GP if asked	4.61 (1.53)	5.04 (1.44)	$t = -1.55$, $p > 0.1$

The right hand column shows the respective *t*-value and significance level.

Table 3 Experiment 2: number and percentage of participants listing main perceived benefits and concerns from taking the second medicine, together with χ^2 values and significance levels

	Herbal	OTC	χ^2 values and significance levels
Main benefits			
Pain relief	21 (35%)	38 (63%)	$\chi^2 = 12.0$, $p < 0.05$
Natural	11 (18%)	0 (0%)	$\chi^2 = 11.33$, $p < 0.05$
Effective	5 (8%)	7 (12%)	$\chi^2 = 0.53$, $p > 0.1$
Little or no side effects	11 (18%)	1 (2%)	$\chi^2 = 11.33$, $p < 0.05$
Main concerns			
Side effects	18 (30%)	23 (38%)	$\chi^2 = 1.50$, $p > 0.1$
Little knowledge/lack of scientific testing	11 (18%)	5 (8%)	$\chi^2 = 2.16$, $p > 0.1$
Interactions	15 (25%)	19 (32%)	$\chi^2 = 1.08$, $p > 0.1$
Addictive/dependency	1 (1%)	7 (12%)	$\chi^2 = 5.23$, $p < 0.05$

listed for the two medicine types, together with χ^2 values and significance levels. Those completing the questionnaire in relation to OTC medicines were significantly more likely to list pain relief as a benefit than those completing it in relation to herbal medicines, while those in the latter group were significantly more likely to list the medicine being natural and there being little or no side effects as benefits. In terms of concerns, those completing the questionnaire in relation to OTC medicines were significantly more likely to list risk of addiction/dependency than those in other group.

Table 4 shows the most likely courses of action that participants indicated they would take if they experienced an adverse effect as a result of the second medicine. There were no significant differences in terms of responses to the two medicine types (all p's > 0.05). The most likely courses of action for both drugs were to stop taking the second drug and either wait for symptoms to clear or to visit GP immediately.

Discussion

In line with previous studies,[7,10,18] our experiments provide support for the position that herbal medicines are seen as being safer than conventional (prescribed or OTC) medicines. In particular, they are seen as being less likely to give rise to adverse side effects, to interact with other medicines, and to lead to dependency. Furthermore, our findings suggest that herbal medicines are not perceived as being safer than prescribed medicines simply because of their easier availability; rather they are perceived to be more natural. The results of Experiment 2 indicated that participants would be more likely to take a herbal than an OTC conventional medicine, in addition to a prescribed medicine, and would be significantly less likely to seek advice from their GP in advance of doing so in the case of the herbal remedy. Given this, and the fact that over 50% of the sample indicated they would not consult their GP if they experienced an adverse effect as a result of taking the second medicine, there is clear

Table 4 Experiment 2: number and percentage of respondents selecting the various courses of action if they experienced an adverse side effect from taking the second medicine

Most likely course of action	Herbal medicines no. (%) of responses	OTC medicines no. (%) of responses	Total no. (%) of responses
Stop taking medicine and wait for symptoms to clear	18 (30%)	18 (30%)	36 (30%)
Stop taking both medicines	4 (6%)	3 (5%)	7 (0.6%)
Consult GP immediately	15 (25%)	6 (10%)	21 (17.5%)
Stop taking second drug and visit GP immediately	18 (30%)	19 (32%)	37 (31%)
Ask local pharmacist	4 (6%)	6 (10%)	10 (8%)
Ask family/friend	3 (5%)	1 (2%)	4 (3%)
Other (please specify)	0	1 (2%)	1 (1%)

support for Fugh-Berman's[19] recommendation that clinicians should always ask patients about their use of herbal medicines and warn them about possible herb—drug interactions.

Interestingly, there was no effect of experience of medicine use. This lack of effect differs from that reported by Furnham and Lovatt[4] and Harnack et al.[15] Furnham and Lovatt found that complementary medicine users were more likely to agree that such medicines were effective than to agree that orthodox medicines were effective, whereas the reverse was the case for GP patients using conventional medicines. Similarly, Harnack et al.[15] found that herbal medicine users were more likely than non-users to agree with the statement that herbal medicines tend to be safer than prescribed or OTC medicines, and significantly less likely than non-users to agree with the statement that it is a good idea to visit the physician before taking herbal products. It is possible that significant differences might have been found in our experiments if the sample sizes had been larger (although our sample sizes had sufficient power to pick up medium size effects).

This study has a number of limitations. First, we used convenience samples, recruited from a coach station, rather than a representative sample of the general population. Our previous studies have shown, however, that participants recruited at such stations are broadly similar to those recruited from other public places. In addition, our demographic data shows that the sample used in the current study was fairly diverse in terms of age, educational background and occupation. It is also the case that, although we deliberately selected a sample that included users and non-users, our 'users' were not taking the medicines for the particular illness specified in the hypothetical scenario. It may be that a different pattern of results would have been obtained if we had tested users and non-users suffering from the particular condition outlined in the questionnaire. Although this potentially limits the generalisability of the current study, previous studies using similar scenarios and questionnaires have found very similar patterns of effects in analogue studies (using hypothetical scenarios and questions) and patient studies, where the participants were answering questions about medicines they were currently taking.[20,21] Nevertheless, future studies should include such comparison groups. A further limitation is that we only assessed participants' perceptions as opposed to reasons for taking the medicine. However, there may be occasions when perceptions differ from reasons for usage.

In summary, the present paper has shown that herbal medicines are seen as being a distinct medicine type, which is 'safer' than either prescribed or over-the-counter conventional medicines, primarily because they are perceived to be more 'natural'. This perception results in people indicating that they would be more likely to take a herbal product in addition to a prescribed medicine and would be less likely to consult their doctor in advance of doing so. Taken together, the findings provide support for the notion that people need to be provided with clear information about the risks and benefits of herbal medicines if they are to use such remedies safely and effectively. This information should be based on up-to-date scientific research and should specifically relate to the herbal medicine in question.

Appendix A

Wording of scenario used in Experiment 2.

''Please imagine you are in the situation below.

You have been suffering from chronic shoulder pain and have been prescribed anti-inflammatory painkillers by your GP. Although the medicine provides some relief, you still experience some pain at times. A friend recommends a herbal medicine that they have been taking for a similar condition. You consider taking this in addition to the prescribed anti-inflammatory painkiller.''

The wording of the third sentence was modified slightly for those in the OTC condition.

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