Relaxation training as complementary therapy for mild hypertension control and the implications of evidence-based medicine

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Relaxation therapy for the treatment of hypertension presented a number of challenges, in terms of conducting and using research as well as gaining the wider acceptance of this complementary therapy in common practice in Hong Kong. Two issues were central to the current implementation of complementary therapies: the evidence-based practice movement and the management of risk during the implementation of new therapies. A major concern was how to maximize the chance of inclusion of research on complementary therapies in evidence-based practice systematic reviews. This was thought to be achievable by making the data amenable to meta-analysis when small samples may be unavoidable. The empirical work examined the effects of three relaxation therapies for the reduction of high blood pressure in nine Chinese subjects. Subjects were randomly assigned to three groups: (a) progressive muscle relaxation, (b) stretch release relaxation and (c) cognitive imagery relaxation. Systolic, diastolic blood pressure and heart rate were assessed in a baseline session, the 8th post-treatment session, and a 30-days follow-up session. Data were analyzed using ANOVA and Paired sample *t*-test. One-Sample Kolmogorov-Smirnov Tests for the normal distribution were performed among the three groups. The results verified that the normality assumption for the data had not been violated. Results revealed that in the context of the study all relaxation therapies can reduce blood pressure in Chinese subjects, but stretch release relaxation and progressive muscle relaxation therapies appeared to be more effective in lowering blood pressure compared to cognitive imagery relaxation. These data are in a form available for meta-analysis at a later date. The study also shows a degree of clinical significance and validation with respect to a Hong Kong population. It demonstrates ways in which the inclusion of research on complementary therapies in systematic reviews can be maximized.

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INTRODUCTION

This study began by considering the possibility of conducting research on the implementation of relaxation therapy in the treatment of hypertension. Relaxation therapy had been used by one of the authors in the treatment of stress. The proposed use of relaxation for the treatment of hypertension, as a complementary therapy in the context of this study, was perceived to present a number of challenges in terms of conducting and using research, as well as gaining wider acceptance in common practice. Aspects of this dilemma have been discovered in the context of nursing practice (Chadwick 1999). They are: time, lack of evidence-based practice, resistance from nursing and medical colleagues, feelings of encroachment on the physician's territory, drafting working protocols, lack of hospital policy, inadequate nursing staff levels and lethargic management (Chadwick 1999). In considering these findings, it was concluded that two issues were also central to the current implementation of relaxation therapy as a complementary therapy. They were the growing evidence-based practice paradigm and the management of risk in the implementation of new practices.

Complementary therapy and evidence-based medicine

Complementary therapies have been defined as those supportive services and 'adjunctive' regimens that are used alongside established medical treatments. They differ from alternative therapies in that they do not replace established therapy (Cassileth 1999). Arguments that the effectiveness of complementary therapies should be supported by the evidence are well established (Richardson 2000, Freshwater 1996). This is not only a matter of quality promotion in health care; it is also an issue of the increasing involvement of paramedical professions in the therapeutic process. Irrefutable evidence has also become a means of supporting the expanded role of health care professionals such as nurses (Richardson 2000). Regardless of professional needs, more health care organizations are espousing the value of evidence-based decision making. One of the earliest contributions to the evidence-based decision-making movement was made by Cochrane, who called for the preparation, maintenance and dissemination of systematic reviews in all fields of health care (Cochrane 1979, Sackett et al. 1996). There is now an increasing public and political interest in the evidence on which decisions about the effectiveness and safety of health care are based (French 2000, Goode & Piedalue 1999, Muir-Gray 1995). Muir-Gray argues that evidence-based decision-making is a process that is now thought to be essential to a publicly accountable health care system. This is expressed by an increasing tendency for health care organizations to adopt a managed care system in a competitive market environment (French 2000, Buerhaus 1998). This development has onerous implications for the introduction of complementary therapies, given that orthodox medicine is the dominant form of health care through out the world (Monte 1993). Because of this, it is now usual to anticipate that the introduction of complementary therapies by members of professions allied to medicine will be met with opposition from physicians. In the area of research, it has been observed that there now seems to be a clash between the medical profession and those working in the field of complementary therapy research about what constitutes relevant evidence (Richardson 2000). The medical profession has largely advocated randomized clinical trials, which many advocates of complementary therapies find irrelevant and reductionist (Richardson 2000).

The managed care movement, however, necessarily involves managers and funders of health care services in making decisions about 'standard' treatment regimens. It is understandable that a primary concern of physicians, managers and funding providers is the management of risk. It has been suggested that one of the main obstacles to the introduction of new interventions (therapies) in hospital settings is insecurity associated with risk management (French 2000). Indeed, one nursing study on complementary therapies concluded that monitoring the effects of treatment did not seem to exist in any structured way (Chadwick 1999).

Even where the evidence provides consistent support for a particular intervention, it is often the case that the local practitioners find it difficult to abandon existing treatment regimens for alternative treatment regimens. As such, validation in local practice is still required (French 2000, French 1999). When the evidence is not clear or unequivocal, the degree of risk is even higher, particularly in a managed care system where clinical protocols or pathways may determine funding decisions. Two approaches to risk management that are applicable to complementary therapies have been suggested: action research and replication research in the context of implementation (French 2000). One of the difficulties in managing risk by adopting structured forms of monitoring such as these is that samples are often small (French 1999). This problem, however, is not insurmountable. Robinson has suggested that in the RCT context the overemphasis on significance testing and inadequate sample sizes increases the probability of a type 2 error (Richardson 2000). Even if small samples bring this about, it has been argued that clinical significance should also be valued in the evidence-based decision making process (Richardson 2000, Sackett et al. 1991). The ethics of client choice and the availability of samples under the control of the physician indicate that often evidence-based practice or research validation will necessarily be conducted on small samples. One must still, however, accept that at this time the evident-based health care paradigm is rooted in a tradition of meta-analysis and that there is always more confidence placed on findings that are based on 'hard data' and statistical analysis (Richardson 2000, Hunt & McKibbon 1997, Robinson 1995). It has been said that the major failing of research into complementary therapies has been the lack of measurement of treatment outcomes (Freshwater 1996). It was decided that the future acceptance of complementary therapies is likely to be affected by their exclusion from systematic reviews. Their inclusion in systematic reviews is most likely if measurement of treatment outcomes is conducted and if the data are amenable to meta-analysis (Robinson 1995, Lynn 1989). Taking account of this, the current study, on

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relaxation therapy intervention for hypertension, utilized the services of one of the authors to try to solve the problem of statistical analysis of small samples. The following gives an account of the research process conducted in a context where relaxation therapy is not considered an orthodox therapy, and the system of Chinese health beliefs may determine the type of relaxation therapy that is more effective.

LITERATURE REVIEW

Relaxation therapy and hypertension

High blood pressure is one of major risk factors contributing to stroke and other cardiovascular diseases, and billions are spent yearly on treating cardiovascular disease (Crotty et al. 1999). One report given to the 9th ASEAN Congress of Cardiology used epidemiological data. It suggested that in both hypertensive and normotensive people, a lowering of 5–10 mm Hg in systolic and diastolic blood pressure could possibly reduce the number of strokes by half a million and myocardial infarction by 150,000 annually in China alone (ASEAN Congress of Cardiology Report 1992). It has also been reported that treatment using alternative therapy alone can reduce blood pressure by about 10 mm Hg (Hart 1996). Taking account of such a therapeutic objective and the reported potential of alternative therapies, it is possible to argue that non-pharmacological treatments and complementary therapy can make a significant contribution to reduction of morbidity in patients with hypertension.

Different modes of relaxation therapy have become popular amongst nurses and other health professionals during the last 30 years. They have been adopted for the reduction of pain, anxiety, tension headaches and other somatic illnesses (Benor 1996, Larsson & Carlson 1996, Hatler 1998, Szeto & Yung 1999). However, the findings of these studies were usually based on caucasian populations in eurocentric cultural contexts, and this is very much the case in blood pressure control (Aivazyan et al. 1988, Buby et al. 1990, Paran et al. 1996, Amigo et al. 1997). Cross-cultural research (USA and USSR) had been conducted on the effects of relaxation therapies on hypertension control in Caucasians. The results showed that both groups of patients had a reduction in blood pressure at post-treatment (Blanchard et al. 1988). The findings suggested that relaxation methods could be applied effectively to Caucasians. What still remains in question, however, is whether these relaxation therapies have the same variable effects on people with Chinese health beliefs. For instance, it has been found that behaviour therapy in treating obsession had to be modified for the treatment of Chinese patients (Yung 1993). In recent years, different relaxation methods have been found to produce differential effects, with muscularly-oriented relaxation therapy more effective in reducing somatic problems, and cognitively oriented relaxation therapy more effective in controlling cognitive components such as anxiety reduction (Lehrer 1996, Lehrer et al. 1994). As such, it was considered necessary to explore the effect of relaxation therapy for the treatment of hypertension in a Chinese population.

THE METHOD

The aims of this study were to test: 1) whether relaxation therapies were effective in reducing blood pressure for patients with Chinese health beliefs, and 2) to see if different types of relaxation therapy had a differential effect in lowering blood pressure for hypertensive patients holding Chinese health beliefs.

Subjects

A sample of nine volunteer Chinese subjects, four males and five females, had been diagnosed as hypertensive by a registered medical practitioner following certain criteria. These criteria were: 1) age between 30 and 60 years of age; 2) systolic blood pressure (SBP) between 145 and 160 mm Hg, or diastolic pressure (DBP) between 90 and 109 mm Hg (phase V3); 3) not suffering from any psychiatric disorder; 4) no other physical abnormalities including physical damage of muscles which would restrict their practice of relaxation techniques; and 5) were not engaged in other forms of relaxation exercise. The reason for excluding subjects who suffered from psychiatric disorder was that these subjects often have cognitive disorders that can interfere with their ability to use their imagination. In addition, muscle-oriented relaxation exercises such as progressive muscle relaxation and stretch release relaxation can further damage the muscles of those subjects who already have muscle or tissue damage. They must also be excluded. In addition, subjects who were engaging in other relaxation exercise would deliver an additional confounding variable. Subjects were also instructed to take and record their own blood pressure at home, a more natural environment, to ensure that their readings were accurate. This was thought necessary because an individual's blood pressure readings could be inflated by the white collar effect, that is, the tendency of blood pressure to rise in a person during a medical visit (Le-Pailleur et al. 1996). The subjects ages ranged from 31 to 55 years. The mean was 43 years, the mean systolic blood pressure 155.0 mm Hg, mean diastolic blood pressure 96.0 mm Hg, mean heart rate 76.8 per minute. Ethical approval was granted from the ethics sub-committee of the university before conducting the study. Written informed consent was obtained from the subjects, and their participation was voluntary. All subjects were provided with a full explanation of the study.

Measuring instrument

The Dinamap Model BP 1846 SX (Critikon Inc., USA) automated portable blood pressure monitor was used to measure the subject's systolic and diastolic blood pressure and heart rate. Prior to the conduct of the experiment, the machine was calibrated against a standard mercury sphygmomanometer with blind trials (Yung & Keltner 1994).

Design

The study schedule consisted of a 2-week baseline assessment, an 8-week treatment period and a 30-day follow-up period.

Subjects were randomly allocated to one of the three treatment conditions: progressive muscle relaxation (PMR), stretch release relaxation (SR), and cognitive imagery relaxation (COG). The PMR training in the present study was a therapeutic process guided by Jacobson (1938) which focused on the tension and relaxation of different muscle groups. The SR training was guided by the model of Stretch Relaxation developed by Carlson and Collins which focused on the stretching and relaxation of muscle groups (Carlson & Collins 1990, Carlson et al. 1990). According to muscular relaxation therapy, muscular relaxation exercise may change the equilibrium of vasodilation and vasoconstriction in the circulatory system so that the imbalance favours vasodilation. The vasodilation, in turn, decreases peripheral resistance effects in the lowering of blood pressure.

The COG training involves suggestive relaxation procedure instructing the subjects to imagine a relaxed scene without any physical exercise or movement of skeletal muscles. Imagery as a means of relaxation can create a state of parasympathetic nervous system overdrive (Crotty et al. 1999), a reduction in the activity of the sympathetic nervous system, resulting in physiological changes such as decreased blood pressure and heart rate. The following statements represent the relaxation instructions:

PMR instruction

When I say begin, I would like you to make a tight fist with your hands. Now make a tight fist with your hands, make it as tight as possible. Hold it (10 s). Now, release your hands and let your fingers rest (30 s).

SR instruction

When I say begin, I would like you to stretch the muscles of your jaw by placing the fingertips of each hand on the joints of each lower jaw. Ready? Apply the pressure upwards as you move your hand towards the temple area to stretch the jaw muscles. As you reach the cheekbones, hold the stretch (10 s). Now, release the stretch and return your hand to a resting position (30 s).

COG instruction

When I say begin, I would like you to image that the muscles of your forehead are becoming more and more relaxed, more and more relaxed (60 s).

Procedure

Other aspects of the procedure were common for all subjects in all groups and for all sessions. Subjects were seated in a recliner and treated individually. Temperature and lighting was adjusted to low levels and set constant. Prior to treatment, the experimenter demonstrated the relaxation procedure for the subjects in their respective groups until they fully understood the procedure. When they arrived at the laboratory, subjects were rested for 10 min before their blood pressures were taken. The display of the subjects' blood pressure readings was shielded from them in order to minimize the instrument feedback effect, and no conversation was held between the subject and experimenter during measurements (Le-Pailleur et al. 1996). Blood pressure was recorded on the left arm at the heart level.

All subjects received three blood pressure measurements at the pre-treatment, after the 8th treatment and at the 30 days follow-up. Studies have shown that reduction of blood pressures can be a reaction to repeated measurement (Jacob et al. 1991, Kaufmann et al. 1991). Measurements were taken by the same investigator throughout the experimental period. All subjects in all treatment sessions received individual live instructions, as previous research showed that live training may be a crucial factor of effective training (Borkovec & Sides 1979, Lehrer 1982). All treatment sessions for the three therapeutic conditions were set at 20 min duration, with the same practitioner (the first author) conducting all the sessions to ensure that the relaxation procedures were standardized. As far as possible, subjects were scheduled for treatment at the same time of day throughout the whole treatment programme. All subjects attended their treatment sessions twice a week, with at least 2 days between each treatment session. After the 8th session, they were instructed to practice once every day at home

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and to keep a record of this on a Daily Record Sheet provided by the experimenter. They were given audiotapes for this relaxation training. The audiotape instructions were an exact copy of the experimenter's live instructions given during the laboratory treatment procedures. This also contributed to the standardization of the treatment procedures.

RESULTS

The means and standard deviations for SBP, DBP and HR of the subjects among the three groups are shown in Table 1. Table 2 shows the ranking of the mean reduction in systolic, diastolic blood pressure, and heart rate for PMR, SR and COG treatment groups. All three treatment groups show a lowering of blood pressure with muscularly-oriented relaxation treatments, particularly SR, producing the greatest reduction in blood pressure and heart rate. One-Sample Kolmogorov-Smirnov Tests for the normal distribution were performed among the three groups, and the results verified that the normality assumption for the data had not been violated. Because of this, parametric tests could be applied. Analysis of variance (ANOVA) showed that there was a significant difference in systolic blood pressure ($F=[2,6]=8.80$, $p<0.01$), but not in diastolic blood pressure ($F=[2,6]=0.56$, $p=0.59$) and heart rate ($F=[2,6]=0.35$, $p=0.71$) among the three groups. Paired sample *t*-tests were used to test the significance of each treatment group's difference in blood pressure and heart rate between pre-treatment and post-treatment, pre-treatment and follow-up, and post-treatment and follow-up measures (Table 3). The results showed that the SR procedure proved superior in effect to PMR and COG procedures in lowering blood pressure. There were significant differences in SBP at the pre-treatment/follow up measure ($t=7.90$, $p<0.05$) and DBP at the pre-post treatment measure ($t=4.17$, $p<0.05$) and pre-treatment/follow-up measure ($t=6.39$, $p<0.05$) for SR group. A significant difference was also found for SBP for pre-post treatment measures for PMR group ($t=4.46$, $p<0.05$). No significant difference in blood pressure reduction occurred in the COG group, although there were reductions in SBP, DBP and HR at the follow-up period. In summary, these different methods of relaxation therapy appeared to be effective in lowering blood pressure for Chinese patients. All subjects reported that they were able to follow the training instructions for the different kinds of relaxation procedures when practiced during the 30 days follow-up period, with subjects in the COG group reporting a higher frequency of practice (mean = 24.00) than SR (mean = 6.33) and PMR (mean = 6.00).

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DISCUSSION

The findings from the present study showed that relaxation therapies, particularly the SR and PMR relaxation therapy, were effective in lowering systolic and diastolic blood pressure in Chinese hypertensive patients. The greatest reduction was found in systolic blood pressure.

Table 1 Means and standard deviations for stretch release relaxation (SR), progressive muscle relaxation (PMR) and cognitive imagery relaxation (COG) on systolic, diastolic blood pressure and heart rate

		Pre treatment Mean (SD)	Post treatment Mean (SD)	Follow-up test Mean (SD)
SR	SBP	140.00 (8.53)	128.83 (1.53)	132.67 (10.13)
	DBP	94.17 (5.69)	83.67 (2.31)	84.00 (4.44)
	HR	84.00 (26.51)	76.00 (18.00)	77.50 (21.29)
PMR	SBP	172.83 (9.71)	186.33 (41.02)	157.33 (36.82)
	DBP	100.33 (4.73)	106.17 (15.04)	91.83 (15.54)
	HR	69.17 (15.18)	65.83 (14.00)	69.67 (24.48)
COG	SBP	152.33 (10.68)	157.50 (7.26)	139.33 (6.66)
	DBP	93.50 (13.14)	91.17 (13.32)	83.50 (7.566)

Table 2 Ranking of mean reduction in pressure and heart rate for stretch release relaxation (SR), progressive muscle relaxation (PMR) and cognitive imagery relaxation (COG) treatment groups

Rank	Mean SBP reduction (mm Hg)	Mean DBP reduction (mm Hg)	Mean HR reduction (per min)
1	(PMR) 15.50	(SR) 10.20	(SR) 8.00
2	(COG) 13.30	(COG) 9.50	(COG) 0.20
3	(SR) 7.30	(PMR) 8.50	(PMR) −0.05

Table 3 Comparisons of pre-post test occasion, pre-follow-up test occasions and post-follow-up test occasion in systolic blood pressure (SBP), heart rate (HR) for stretch relaxation (SR), progressive muscle relaxation (PMR) and cognitive imagery relaxation treatment (COG) groups

		Pre-post *t*	Pre follow-up *t*	Post follow-up *t*
SR	SBP	2.64 (0.12)	7.90 (0.05)*	0.75 (0.53)
	DBP	4.17 (0.05)	6.39 (0.05)*	0.13 (0.91)
	HR	1.62 (0.25)	1.40 (0.30)	0.47(0.68)
PMR	SBPM	0.59 (0.61)	0.82 (0.50)	4.46 (0.05)*
	DBP	0.80 (0.51)	0.89 (0.47)	2.30 (0.15)
	HR	2.56 (0.13)	0.09 (0.94)	0.55 (0.64)
COG	SBP	1.79 (0.22)	2.68 (0.12)	3.67 (0.07)
	DBP	3.88 (0.06)	2.56 (0.13)	2.04 (0.18)
	HR	1.08 (0.39)	0.15 (0.89)	0.58 (0.62)

Paired *t*-tests; * $p < 0.05$.

The present findings are consistent with the cross cultural studies conducted on USA and USSR populations.

This is in keeping with the previous evidence (Surwit et al. 1982). Furthermore, the results supported the assertion that muscular-oriented relaxation procedures are more effective than cognition-oriented procedures in treating somatic problems (Lehrer 1996).

There was, however, no significant reduction in heart rate among the three treatment conditions. The findings show a slight reduction in heart rate for SR and COG treatment groups and a slight increase in heart rate for PMR group. This inconsistency is in keeping with long-standing evidence that changes in heart rate do not necessarily correspond to changes in blood pressure (Dicara & Miller 1968, Shapiro et al. 1969).

Although subjects in the COG group reported the highest frequency of home practice, the greater reductions in blood pressure were obtained among SR and PMR groups at pre-follow up and post-follow up period. The present study revealed no significant relationship between frequency of practice and the reduction in blood pressure. As the study only included a 30 days follow-up period, continuous monitoring should be further explored in future studies.

The present findings are consistent with the cross cultural studies conducted on USA and USSR populations (Blanchard et al. 1988). Chinese subjects also demonstrated a reduction in blood pressure on post-treatment measurement, although the methods of relaxation therapy were different in the Blanchard study. It also appears that blood pressure reduction was more affected by the modality-specific effects of relaxation therapy. The results of the present study are supported by previous eurocentric studies (Lehrer 1996, Lehrer et al. 1994), which indicate that muscularly oriented relaxation therapy such as progressive muscle relaxation and stretch release relaxation might work better for the somatic components of an illness.

Despite these encouraging findings, there are certain limitations in the present study. Firstly, the frequency of home practice in relaxation therapy was based on the subjective reports from each subject. Secondly, a control group was not included in the present study. Thirdly, a long-term follow-up was not been carried out. Given the clinical and statistical significance of these results, and taking account of the limitations, the use of relaxation therapy as a complementary therapy for the control of hypertension in the Chinese population is recommended and follow-up research is worth pursuing. Replication studies and larger studies should be conducted in the same context by the current and other researchers, and meta-analysis should be conducted when sufficient data are available.

CONCLUSION

In addition to the findings, this study demonstrates a number of possibilities for the implementation of complementary therapies in an evidence-based medicine environment. They are:

- That the existing evidence can be validated in practice in the form of small-scale studies in the context of implementation
- That the research process can be used as a structured form of monitoring the effects of complementary practice
- That statistical analysis can be undertaken on small samples.

These observations encourage the belief that such small-scale studies can be replicated or maintained on a long-term basis as a part of everyday practice. The data thus obtained are amenable to meta-analysis at a later date, and as such make it more likely that complementary therapies are included in the systematic reviews produced by the Cochrane Collaboration and others (e.g. Robinson 1995, Lynn 1989).

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