

Randomised controlled trial of therapeutic massage in the management of stress

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SUMMARY

Background: Many patients presenting in general practice are suffering from stress. Approaches using complementary therapies are gaining popularity but have not been systematically evaluated.

Aim: To compare the effect of six sessions of therapeutic massage with the use of a relaxation tape on stress, as measured by The General Health Questionnaire (GHQ-30).

Design of study: Randomised controlled trial.

Setting: A stress reduction clinic in general practice.

Method: There were three treatment groups. Patients in the first group received six sessions of therapeutic massage, which was carried out by a nurse trained in this technique. Patients in the second group were given six sessions using a relaxation tape in the surgery and those in the third group were given a relaxation tape to use at home. The main outcome measures were: the GHQ-30, the Adapted Well Being Index (AWBI); a sleep scale; general practitioner (GP) consultations for any reason in the six weeks before treatment, during treatment, and the six weeks following treatment; and patient satisfaction.

Results: Sixty-nine patients completed the treatment. There were significant improvements across all four outcome measures and all three treatment groups. Following treatment the majority of patients felt far less emotional disturbance, were sleeping better, and consulting their GP less.

Conclusion: Despite very strong patient preference for therapeutic massage, it did not show any benefits over either a relaxation tape used in the surgery or a relaxation tape used at home.

Keywords: stress; massage; relaxation; primary care.

Introduction

THERAPEUTIC massage is a complementary medical approach, not normally available within mainstream health care. Alternative or complementary therapies appear to be gaining acceptance within mainstream health care and one source suggests that 20% of doctors practise such therapies, and over 70% have referred patients for them.¹ However, few alternative or complementary therapies have been rigorously evaluated.²

Stress has been defined as any demand (physical or psychological) that signals a disparity between what is optimal and what actually exists.³ Although stress is an essential part of life,⁴ most people would recognise some events as being unusually stressful.⁵ Stressful life events are associated with high levels of mental and physical illness.^{5,6} However, stressful events do not always lead to illness and factors such as low self esteem have been associated with an inability to cope with adverse life events.⁷

It may be difficult to remove stressors from an individual's life, but it is possible to influence how an individual copes with stress. A number of stress management techniques have been described, including lifestyle changes and relaxation techniques.⁸ The use of therapeutic massage as a relaxation technique was of interest in this study. Although there is anecdotal evidence about the effectiveness of therapeutic massage in this context,⁹⁻¹¹ the few controlled trials that have been done have had varied results. One trial indicated that massage was more effective than other relaxation techniques in treating anxiety in behaviourally disturbed children and adolescents.¹² Another found no differences between the effect of massage and a period of undisturbed rest for patients in intensive care.¹³

The aim of this study was to compare the effect of six sessions of therapeutic massage provided in the context of a stress reduction clinic in general practice, with the use of a relaxation tape. The null hypothesis was that there would be no difference between the treatments.

The massage would be carried out in the surgery by a nurse trained in this technique. Relaxation tapes were already used locally by a number of general practitioners (GPs), to help patients cope with stress (although not necessarily by GPs taking part in this study) and also in community-based cardiac rehabilitation programmes.

Method

The two treatments being compared were normally administered in different environments, with relaxation tapes being given to patients to use at home as required, but therapeutic massage being administered at a central point (in this case the surgery). Potentially, any observed difference in outcomes may be owing to the effect of surgery attendance

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HOW THIS FITS IN*What do we know?*

There have previously been few systematic evaluations of complementary or alternative therapies for patients suffering from stress.

What does this paper add?

Although therapeutic massage showed no benefits over the more commonly used relaxation tapes, the overall results of the study were positive. The majority of patients showed improvement on all outcome measures over the six-week period, even with a minimal intervention of a relaxation tape to use at home and two short follow-up visits to complete questionnaires.



and contact with the nurse. Therefore this trial was designed with three groups. One would receive a relaxation tape to use at home over six weeks, one would receive six sessions of therapeutic massage in the surgery at weekly intervals, and the third group would receive six sessions of the relaxation tape in the surgery at weekly intervals. The relaxation tape would be administered in the same surroundings as therapeutic massage and the nurse would be in attendance.

The researchers were aware that, without a non-treated control group, it would not be possible to determine to what extent any improvement was owing to treatment or spontaneous recovery, and there was extensive local discussion about this. The consensus was that it would not be acceptable to gain informed consent from people who had identified themselves as being distressed and were fully aware of the treatments being offered, and then randomise some to a non-treatment control group. A non-treatment control group was therefore not included.

The outcome measures used in the study were:

- The General Health Questionnaire (GHQ-30)¹⁴ scored using the 0011 system, which was recommended for repeat testing;
- The Adapted Well Being Index (AWBI),¹⁵ included because of criticisms that the GHQ-30 only focused on feelings of distress and did not take into account feelings of wellbeing;
- The Sleep Index;¹⁶ and
- GP consultations for any reason in the six weeks before treatment, during treatment, and the six weeks following treatment.

A patient satisfaction questionnaire was sent to the patients six weeks after completing treatment.

A stress reduction clinic was set up within the practice to run one day a week over two years. Inclusion criteria for the study were being aged 16 years or over and suffering from stress, as measured by a GHQ-30 score of five points or more. Individuals could be referred to the stress reduction clinic by doctors and nurses within the practice, or could self-refer. Doctors and nurses had supplies of patient information leaflets and posters and information leaflets were

also displayed at reception.

Patients were invited to a screening interview with a nurse where the study was explained and written informed consent obtained. They were screened for suitability using their case notes and an interview and asked to complete the GHQ-30.¹⁴ They were excluded from further participation if they had acute medical problems, had a skin rash, were drug or alcohol dependent or had a diagnosis of psychotic disorder, or scored less than five points on the GHQ-30 at the initial interview. This is below the recommended threshold for identifying individuals suffering from emotional distress.¹⁴

Patients not included in the study were given advice and written information on recognising and coping with stress and, if appropriate, referred back to their GP.

Those who were included completed the other baseline measures and were given an appointment to attend for randomisation and treatment. This was carried out by a second nurse who was trained in therapeutic massage and who did not have access to the completed outcome measures or preparation of the randomisation materials. Patients were randomised by picking one of three opaque sealed envelopes, inside each of which was a paper naming a different treatment group.

The three outcome measures were completed again at the start of treatment sessions 3 and 6. Patients using the relaxation tape at home were asked to attend the surgery for this. The satisfaction questionnaire was sent to them at home six weeks after treatment was completed. They were given a return envelope addressed to a researcher at a different address.

Individuals were withdrawn from the study and referred to their GP if they developed a concurrent physical illness, or if at any time they said anything to suggest that they might harm themselves or others, or that they were suffering from a delusional state.

The main outcome measure for this study was the GHQ-30. However, there were no data available on a similar group of patients to inform a power calculation, either based on a likely reduction in GHQ-30 scores or the likely proportion of patients whose GHQ scores would reduce to below the 'caseness' threshold of five points. A power calculation was performed based on detecting the mean difference between the therapeutic massage group and those using a relaxation tape at home, of eight points on the final GHQ-30 score with a standard deviation of 12 points. With α set at 0.05 and power at 0.8, the required number of patients would be 40 in each group. The aim was therefore to recruit 120 patients, which would be feasible in terms of treatment in the two-year funding period for this study, but this was a new service and the researchers had little idea of the rate at which patients would be referred. Approval was gained from the Lothian Research Ethics Committee before the study started.

Results

One hundred and sixteen patients attended the initial screening interview. Nineteen were excluded at this point: ten because their GHQ-30 was less than five points; three fulfilled one of the other exclusion criteria; five could not attend the surgery between 9.00 am and 4.30 pm; and one refused the randomisation procedure. Ninety-seven patients

were recruited but only 79 attended the randomisation and initial treatment session, of whom 69 completed the treatment course. Two patients were withdrawn by the nurse because they developed acute medical or psychiatric problems, three withdrew because they wanted massage but were randomised to other groups, and five stopped attending (Figure 1).

The results are based on the 69 patients who completed treatment. Twenty-three patients (29%) had been referred to the project by their GP, 18 (23%) by one of the nurses within the practice, and 38 (48%) self-referred; only 12 (15%) were male. Ages ranged from 25 to 75 years with a mean of 43 years (SD = 13) (Table 1).

Figure 2 shows box and whisker plots of the main

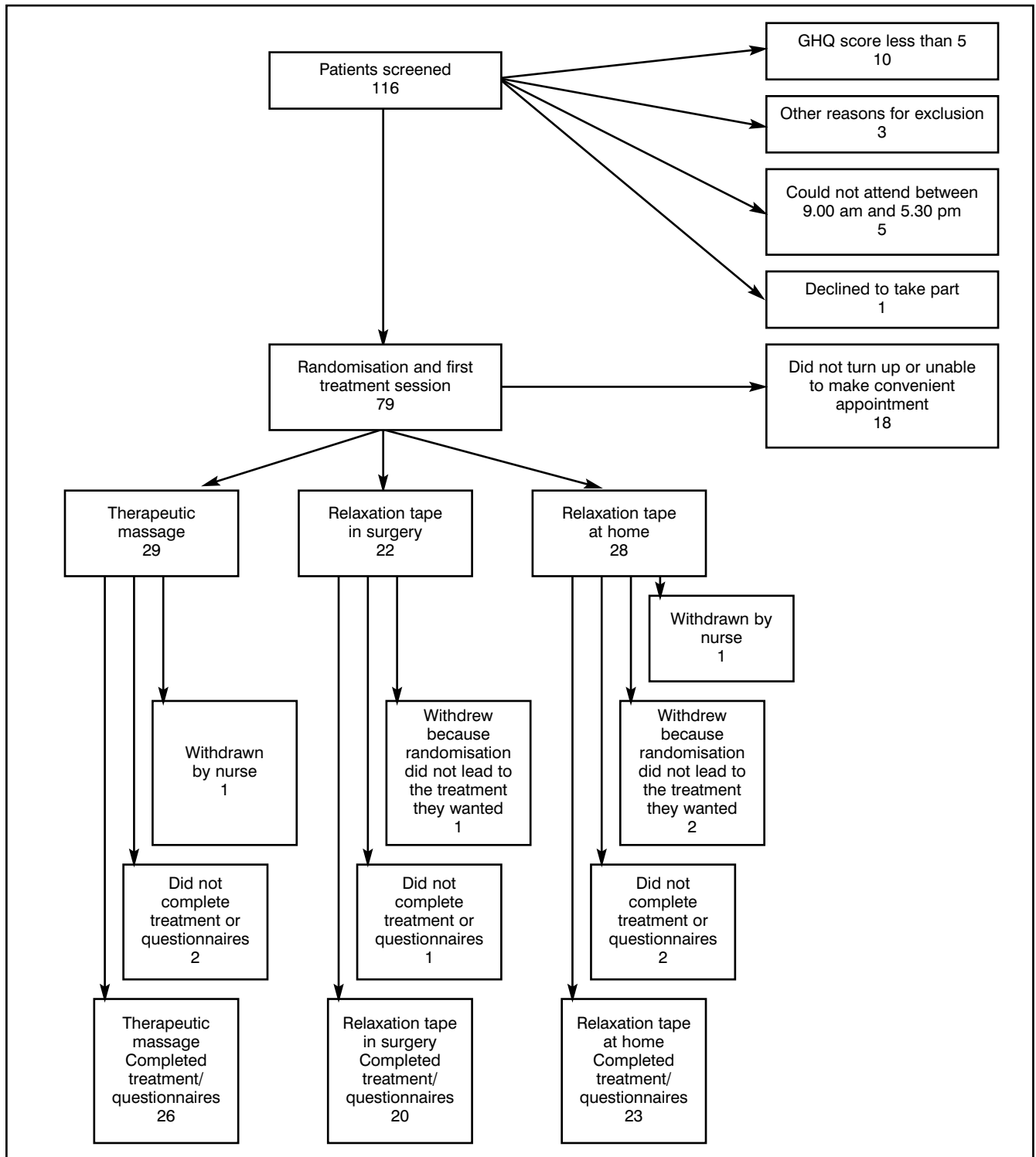


Figure 1. Recruitment and progress through study (patient numbers).

Table 1. Recovery to below the 'caseness' threshold of a GHQ-30 score of less than five points, by group.

	Therapeutic massage (n = 26)	Relaxation tape in surgery (n = 20)	Relaxation tape at home (n = 22)	Total (n = 68)
Final GHQ-30 score <5, n (%)	16 (62)	14 (70)	11 (50)	41 (60)

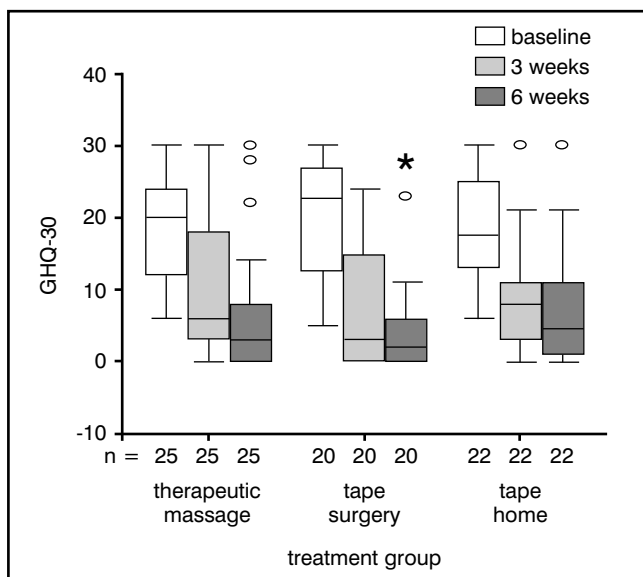


Figure 2(a). Main outcome measures, by treatment group: GHQ-30.

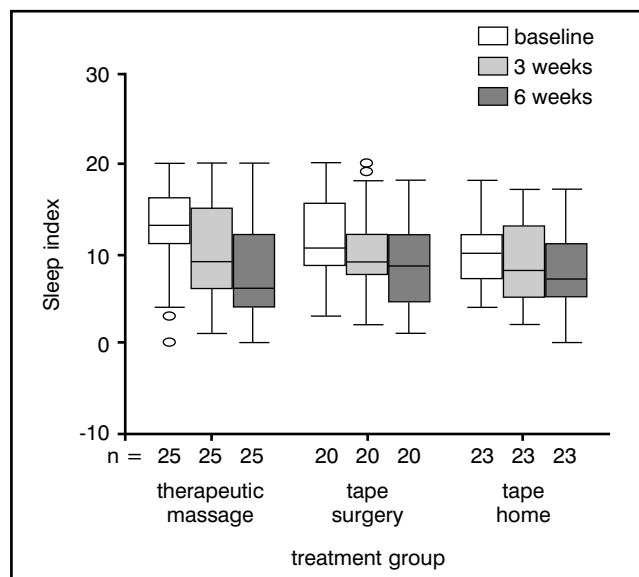


Figure 2(c). Main outcome measures, by treatment group: Sleep Index.

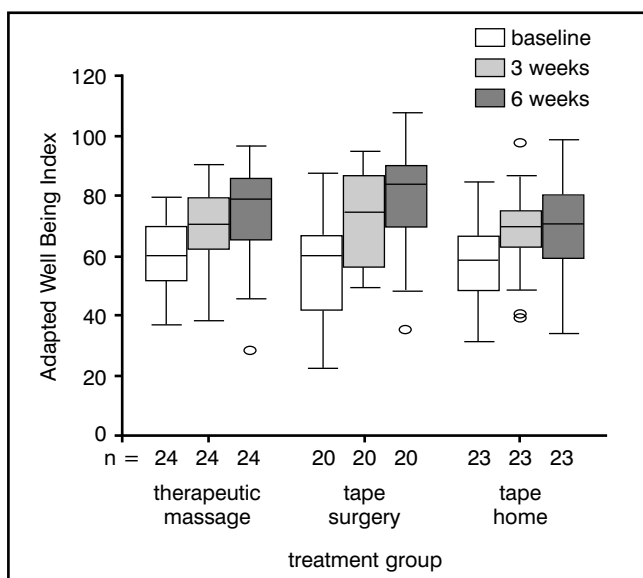


Figure 2(b). Main outcome measures, by treatment group: Adapted Well Being Index.

outcome measures (GHQ-30, ABWI, and Sleep Index). There is some missing data because questionnaires were not completed or could not be scored because questions were missed. The plots show large improvements in all measures consistent across the three treatment groups. A general linear model showed that the improvements in the outcome measures were significant ($F = 76.54, P < 0.001$; $F = 47.79, P < 0.001$; $F = 13.47, P < 0.001$, respectively) and the differences between groups were not ($F = 0.141, P = 0.87$; $F = 0.536, P = 0.59$; $F = 0.372, P = 0.69$, respectively). GP

consultations fell from a mean of 1.4 (SD = 1.2) per patient in the six weeks before the intervention to 0.75 (SD = 1.1) per patient in the six weeks following the conclusion of the intervention (paired samples $t = 3.67, P = 0.001$).

In this study a GHQ-30 score of five points or more was chosen as a threshold for identifying 'caseness' or the likely existence of emotional disorder.¹⁴ All of those admitted to the trial had an initial GHQ-30 score of five points or more. At the end of treatment overall, 60% of patients had a GHQ-30 score below this threshold. This varied between groups as shown in Table 1, but the differences were not significant (χ^2 with two degrees of freedom = 1.778, $P = 0.41$). However, the proportion of patients who were below the 'caseness' threshold following treatment was associated with the source of referral. Following treatment, 42% of patients referred by nurses and doctors scored less than five points on the GHQ-30, compared with 81% of those who self-referred ($\chi^2 = 11.088, P = 0.001$), despite there being no significant difference between the groups in mean GHQ-30 scores at the start of treatment ($t = 0.886, P = 0.38$). There was no association between the other outcome measures and source of referral.

At the start of treatment, 21 (36%) of the 60 patients who completed a follow-up questionnaire were taking medication for their stress-related problem. Six weeks after treatment, two had increased their medication, four had decreased or stopped their medication, and none had started it. There was therefore little change in the use of medication to alleviate stress. No association was found between medication use and GHQ-30 scores at the start or end of treatment.

The responses to the patient satisfaction questionnaire are summarised in Table 2. The treatments were generally

Table 2. Patient satisfaction.

	Therapeutic massage (n = 23)	Tape in surgery (n = 18)	Tape at home (n = 19)	Total (n = 60)
Preferred treatment, n (%)				
Therapeutic massage	21 (91)	11 (61)	13 (68)	45 (75)
Tape in surgery		4 (22)		4 (7)
Tape at home			1 (5)	1 (1)
Not sure	2 (9)	3 (17)	5 (26)	10 (17)
Felt benefit from treatment, n (%)				
Yes	21 (91)	16 (89)	16 (84)	53 (88)
No	1 (4.5)		2 (11)	3 (5)
Not sure	1 (4.5)	2 (11)	1 (5)	4 (7)
Would have the same treatment again, n (%)				
Yes	23 (100)	15 (83)	12 (63)	50 (83)
No		1 (6)	6 (32)	7 (12)
Not sure		2 (11)	1 (5)	3 (5)

well received. Most patients said that they felt benefit from the treatment and 83% said they would have the same treatment again (100% of the therapeutic massage group). The preferred treatment for 75% of the responders would be therapeutic massage.

Discussion

A similar pattern of improvement was seen across all four outcome measures and all three treatment groups. Despite strong patient preference for therapeutic massage, it did not show any benefits over either a relaxation tape used in the surgery or a relaxation tape used at home.

The observed improvements were significant and, following treatment, the majority of patients felt less emotional disturbance, were sleeping better and were consulting their GP less. Both massage and relaxation tapes had previously been shown to have an immediate effect in reducing anxiety,^{17,18} but no sustained or cumulative effect had been demonstrated.¹⁹ The most positive message from this study is that patients can be reassured that, with the use of an intervention to promote relaxation, they are likely to feel less stressed within a few weeks. Relaxation tapes used at home are inexpensive and effective when, as in this study, the patient knows they are going to be followed up (in this case by returning to the surgery to complete the outcome measures). It is not clear whether simply offering a relaxation tape with no planned follow-up would produce similar results.

The outcomes observed in this study could be owing to both treatments being equally effective — the study being underpowered to detect differences between the treatments — or the results could be mainly owing to spontaneous recovery. It is also possible that completing the outcome measures had a therapeutic effect.

In this study, 62% of patients who had therapeutic massage recovered to below the GHQ-30 caseness threshold of five points, compared with 50% of those who were using the tape at home (Table 1), giving the study a power of only 13% to detect a significant difference with α set at 0.05. The number of patients required to give 80% power to detect such a difference would be 268 in each group. However, given the large difference in cost between the two treatments, the dif-

ference in outcomes would have to be much greater to make the use of therapeutic massage cost-effective.

There remains the possibility that most of the improvements seen in this study were owing to spontaneous recovery. As described earlier, there was no untreated control group because it was considered unacceptable not to treat distressed individuals who would be aware that other patients were treated. The results of the study were presented to the local Primary Care Research Network and it was suggested that an observational study over a short period (six weeks) of patients presenting with stress without any treatment intervention would provide valuable information. However, none of the practices were willing to take part in such a study because a relaxation tape was a cheap and simple intervention, which they did not want to withhold.

Although the outcomes of this study were generally positive, 40% of patients continued to have a GHQ-30 score of five points or more following treatment, and some did not improve at all. A higher proportion of those who had self-referred recovered, compared with those referred by healthcare professionals. Although both groups had similar mean GHQ scores at baseline, those who had come to the attention of healthcare professionals clearly tended to have more persistent problems. In retrospect it may have been useful to ask the patient how long they thought they had been suffering from stress, although it would have been a difficult question to answer accurately.

Finally, although the use of a relaxation tape was effective, 75% of patients would have chosen therapeutic massage. The procedure for informed consent may have attracted those who wanted massage, but relaxation tapes were given equal prominence in the information leaflet. Patients did not seem to find the tapes as attractive as therapeutic massage. Qualitative research has shown that massage has significant positive meaning to individuals²⁰ and this social meaning may explain increasing evidence that massage makes people feel that their health is improved,^{21,22} although there is little associated evidence of physiological change.^{21,22}

The results of this study do not justify the use of therapeutic massage, which is a relatively expensive intervention, in stress management programmes in primary care. Relaxation tapes are inexpensive and equally effective in promoting relaxation.

There may be other indications for the use of therapeutic massage (for example in managing musculoskeletal problems, such as low back pain²³), but these will also need to be investigated.

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