HYPNOTHERAPY FOR RELIEF OF PAIN AND OTHER SYMPTOMS IN PALLIATIVE CARE PATIENTS: A PILOT STUDY

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ABSTRACT

There is limited understanding of the role, scope, practicality and evidence for the value of hypnotherapy in palliative care. This was a pilot study to test the feasibility of researching hypnotherapy in palliative care and to begin to explore issues such as recruitment, effect sizes and appropriate symptoms to address. The study design was a randomized eight-week crossover study of four treatments of hypnotherapy with waiting list controls using MYMOP2 questionnaires. The participants, 32 adult patients, in-patient and out-patient, with life limiting illness, were referred over two years. 23 (72%) patients entered the study, 11 (34%) completed. 11 (34%) died between referral and completion. There were some improvements in symptoms which did not reach statistical significance. This study suggests that hypnotherapy may have a place in the management of symptoms in palliative care patients and suggests ways to research this further including study design and power calculations.

Keywords: hypnotherapy, palliative care, pain, symptoms.

INTRODUCTION

Complementary therapies are widely used by palliative care patients (Rees et al., 2000). Palliative care includes attention to the whole person and those close to them (World Health Organization, 2002) including psychological and spiritual needs. There are many symptoms experienced by patients with life-limiting illness, both cancer and non-cancer diagnoses: prevalence of pain – the most feared consequence of cancer (Grond et al., 1994) – being 67%, as well as fatigue, anorexia, nausea, insomnia and many other symptoms (Kirkova et al., 2010). Recent work has also demonstrated the prevalence of psychological distress in the carers as well as the patients with life-limiting illness (Galfin et al., 2010), and government initiatives have emphasized improving end-of-life care (NHS, 2010). Hypnotherapy has been suggested to improve symptoms beyond usual care in these patients (Rajeskaren et al., 2005).

If hypnotherapy could be shown to be effective, acceptable and safe in the management of symptoms in palliative care that would be important; but an effective research programme in this area can seem dauntingly difficult to implement. However, pragmatic randomized controlled trials of a new treatment method can demonstrate whether there is any practical value, above usual care, without necessarily using a placebo condition. Moreover, clinically

meaningful outcomes can be assessed without knowing the precise mechanism of action (Roland and Torgerson, 1998).

HYPNOTHERAPY

Hypnosis can be described as a state of mental concentration leading to progressive relaxation. Sometimes a state of increased alertness, with an enhanced ability to concentrate on a single idea to visualize overcoming difficulties, may be induced which may be helpful.

If the subconscious mind is where deep-seated beliefs are held, then it may be adjusted to bring about helpful changes. A hypnotherapist can suggest beneficial ideas to help relieve the subject's symptoms. The specific mechanisms are incompletely understood but hypnotherapy is widely used in the UK.

Hypnotherapy is accepted as legitimate medical treatment and is represented by the British Association of Medical Hypnosis (British Association of Medical Hypnosis, 2010). A retrospective study showed that hypnotherapy was safe, pleasant and generally helpful but followed up only 16% of those treated (Finlay and Jones, 1996).

Hypnotherapy has been used in irritable bowel syndrome (Harvey et al., 1989) although a Cochrane review only cautiously supported its efficacy (Webb et al. 2007). Hypnotherapy has also been used for cancer symptoms (British Association of Medical Hypnosis, 2010), for pain as well as nausea and vomiting (Savitz, 1983; Mansky and Wallerstedt, 2006). Hypnotherapy has been used in asthma, dentistry and obstetrics (Vickers and Zollman, 1999), it has also been discussed descriptively in general terms in palliative care (Rajeskaren et al., 2005; Marcus et al., 2003a, 2003b; Peintinger and Hartman, 2008) but there is little evidence about its use for pain in this context (Thornberry et al., 2007).

METHODS

RESEARCH QUESTION

Primary question: Among a population of adult patients already known to a palliative care service and receiving usual care, does hypnotherapy produce a significant improvement in pain?

Secondary question: In this population does hypnotherapy produce an improvement in the symptom (other than pain) that is most distressing to the patient?

Further aims of this pilot study were to examine:

1. referral and recruitment of patients receiving palliative care with pain;
2. acceptability of hypnotherapy as an intervention in this patient group;
3. the feasibility of providing hypnotherapy as an intervention for symptoms in addition to normal care in this patient group and this setting;
4. other important symptoms that patients in this group have and to assess if these might be amenable to hypnotherapy;
5. the size of any change in symptoms to perform power calculations to inform the design of future studies.

SETTING/PARTICIPANTS

Thirty-two patients were recruited from existing caseload (approximately 600 receiving care from the service at any one time) of Hospiscare; both in-patient and out-patient services were included. This recruitment rate was as predicted from earlier work with this patient group (Galfin et al., 2012).

Exclusion criteria

A life expectancy of three months or less, a history of psychosis or delirium, inability to concentrate well enough to participate or give informed consent, communication difficulties too great to allow participation both in hypnotherapy and with the study material, hypnotherapy within one month, too frail to tolerate burden of participation, previous adverse effect from, or concern about, hypnotherapy.

Inclusion criteria

Significant pain, despite standard analgesia. The therapist made individual clinical decisions about inclusion or exclusion of particular patients for other symptoms in exactly the same way that they would in any other setting.

CONSENT

Patients were approached by their usual clinical staff during the course of their routine care, and were given an initial information sheet (Appendix 1). If they were interested then the hypnotherapist arranged to meet them and gave further information (Appendix 2). If they wished to participate they were asked to sign a consent form and to select an envelope containing either letter A or letter B – randomly pre-allocated by someone unconnected with the study.

PROCEDURE

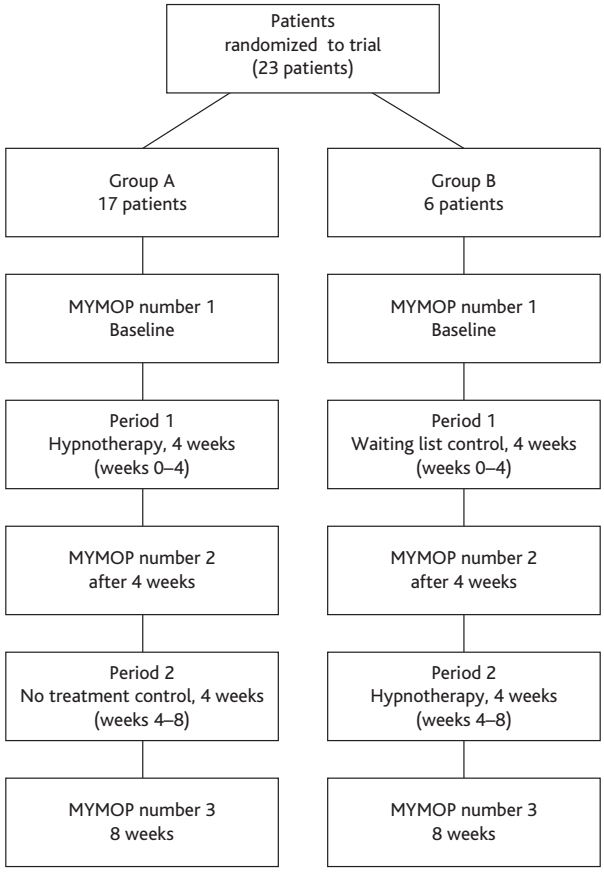
If group A, participants filled in a MYMOP2 questionnaire and proceeded with the first of four weekly hypnotherapy treatments.

If group B participants also completed the questionnaire, but were then asked to return for the first of their treatments in four weeks time.

All patients were seen again at four weeks, a further MYMOP2 performed and then group B started four weekly treatment sessions while group A reverted to usual treatment alone. All patients were seen after a further four weeks to repeat the MYMOP2.

All patients continued with all of their usual treatment for their condition during the study. They were able to change, initiate or stop any of their usual treatment in any way as normal. It became clear that pain was less common than other symptoms as a primary symptom ('Symptom 1'); of the 23 patients entering the trial just eight (35%) had pain as Symptom 1. Of the remaining fifteen (65%) the most common symptom was anxiety, with eight (35%) citing this as their major issue. Insomnia, depression, headache and desire to stop smoking were the remaining issues identified as Symptom 1.

Figure 1. Flow chart of trial design



INTERVENTION

Four sessions of hypnotherapy were delivered by a single qualified hypnotherapist already known to Hospiscare and delivering other complementary therapies. Sessions lasted approximately 60 minutes, and hypnotherapy was tailored to the individual participant, addressing pain or other important symptom and a specific second symptom. Participants were encouraged to attend one of the three day-centres for treatment, although, as with other complementary therapies at Hospiscare, the hypnotherapist was able to see the patients at home if they were too ill or frail to travel.

MEASURES

The main outcomes assessed were: recruitment rate and study completion rate (the proportion providing data at eight weeks), intervention concordance and symptom severity (primary symptom, secondary symptom, wellbeing) as demonstrated by the MYMOP2 at start of trial, at Week 4 and at Week 8.

DATA ANALYSIS

The results were analysed using the standard procedure for crossover trials (Welleck and Blettner, 2012). This aims to detect within-subject differences between study periods which is the crucial variable in this study design

RESULTS

PRIMARY END POINTS

MYMOP scores obtained across the treatment period are shown in Table 1. Using the traditional 5% cut-off for determining statistical significance, *t*-tests failed to show significant changes in primary target (Symptom 1) ratings in the 11 patients who completed the study. However, the change in ratings did show an improvement, and this approached significance very closely at 5.6% ($t = 2.16$, $p = 0.056$). There was no significant reduction in pain over the trial in the four patients with pain as primary symptom who completed the trial ($t = 1.67$, $p = 0.194$). Adding in the two patients who completed the trial and gave pain as Symptom 2 did not affect the significance of the result ($t = 1.11$, $p = 0.317$).

SECONDARY MEASURES

There was no difference in wellbeing ratings in the 11 patients who completed the study ($t = 0.711$, $p = 0.493$).

Table 1. Mean (and standard deviation) values for Symptom 1 and Wellbeing scores.

	Group A			Group B		
	Baseline	4 weeks	8 weeks	Baseline	4 weeks	8 weeks
N	17	13	9	6	4	2
Symptom 1	4.53 (1.38)	4.38 (1.50)	4.22 (1.99)	4.60 (0.58)	3.25 (2.22)	2.33 (1.16)
Wellbeing	4.24 (1.30)	4.15 (1.57)	4.33 (1.94)	3.60 (1.82)	3.50 (1.73)	2.67 (1.53)

SIDE EFFECTS

As with previous work (Curtis, 2001; Barnett, 2001) we observed no side effects specific to the hypnotherapy during the study, and patients were generally content to participate. One patient withdrew from the study because the very act of participation and addressing his symptoms was an unwelcome reminder of his illness.

WITHDRAWALS FROM THE STUDY

As might be predicted in a group with life limiting illness, there was a high dropout rate. Despite being seen and entered into the study as quickly as practicable, four patients (12.5% of those referred) died before entering the study, seven more (30% of those entered) died during the study, and five (22% of those entered) withdrew or became too ill to continue

during the study. Five patients (16% of those referred) declined to enter the study. Eleven patients completed the study which was only 34% of those referred or 48% of those entered.

RETENTION RATE

At four weeks 17 (73.9%) out of the original 23 patients remained in the study and at eight weeks only 12 (52.2%) remained.

ILLUSTRATIVE INDIVIDUAL COMMENTS

One patient who used the self hypnosis for anxiety found that it was extremely helpful in other parts of her treatment too. She was dreading a colonoscopy and observed that 'the self hypnosis saved my life'. One who withdrew found she 'felt very good in the hypnotic state'. Another who also withdrew said 'I wished I could be like that all the time ... liked seeing myself in control of my breathing'.

PARTICIPANT CHARACTERISTICS

Of those referred to the study 30 out of 32 (94%), and of those completing the study 10 out of 11 (91%), had a principal diagnosis of cancer.

There were 14 males and 18 females referred to the study: 5 males and 6 females completed the study. The average age of those referred was 63 years and of those who completed the study 57 years. These characteristics broadly reflect a typical palliative care population.

RECRUITMENT

Whilst complementary therapies in general are widely available, well organized and highly regarded in Hospiscare, hypnotherapy was new and untried. This meant considerable efforts to publicize the trial to healthcare staff and thus give the opportunity to offer this therapy to patients. We did not publicize the study directly to patients in case it applied pressure to them to participate and it was important that their regular nurse or doctor should offer referral to the study on an individual basis. The Ethics Committee who approved the study were also clear that this point was important.

The rate of referral over the two years of the study was as expected at one or two patients per month. Recruitment into the study once referred also reflected the high dropout rate of this patient group so that 23 (71.9%) out of the 32 patients referred were entered into the study, suggesting that with 95% confidence, we could predict that recruitment rates would generally be between 56.3% and 87.5% of referrals.

CONDUCT OF THE STUDY

A steering committee (TH, PJ, DS) met four times each year to monitor progress. It became clear that many of the referrals were for symptoms other than pain and the criteria were adjusted to reflect this. This vulnerable patient group often had competing demands on their time such as oncology appointments and treatment, intercurrent illnesses, time with family, travel and spells of being exhausted. This meant that rigidly sticking to the exact timings of treatment and MYMOP assessment of symptoms became impossible without being

burdensome for participants. Thus there were variations in treatment when patients might have a delay between treatments or miss one or more, so extending the trial period.

An integral part of treatment was having participants learn self hypnosis, to use between treatments. This meant that group A did not really have a crossover 'washout' spell as they generally continued with the self hypnosis when the formal part of treatment had finished.

DISCUSSION

The hypnotherapist considered that the study, and the hypnotherapy made possible by it, to be a good investment of time.

An important part of the referral process was to manage the patient's expectations. It was helpful for the patient to realize that they would need to make some effort themselves and to practice in between treatments. Clearly referral earlier in the patient's illness would have allowed them more time to benefit and to participate more easily.

That even a pilot study showed some improvement in symptoms, albeit not reaching statistical significance, especially in a group of patients who were by the nature of their illness deteriorating all the time, is encouraging.

As with medication for pain (Moore et al., 2013) there may be a similar bi-modal distribution of response to hypnotherapy, with some patients responding well and others very little. Thus average effect size may be helpful, but looking in detail at individual patients for particular symptoms may better reflect reality. This would need a larger study and consideration of responders and non-responders rather than just average effects.

There was a high dropout rate reflecting the characteristics of this patient group. The ethics of a purely control group and managing expectation effects in this vulnerable group is also important (de la Cruz et al., 2010). Thus we used a trial design to allow all patients referred to have the chance of treatment.

Using hypnotherapy in palliative care patients proved a practical proposition and a suitably resourced service would seem beneficial even though it would be demanding of therapist time. There was one patient who declined to enter the study on unspecified religious grounds, but no one else had this difficulty.

A service aimed at giving hypnotherapy without having to fit into the rigidity of a trial protocol would be easier to tailor to individual patient need. Personalized compact discs or downloads for MP3 players of the therapy session might be considered for a fully developed service.

LIMITATIONS OF STUDY

This was a small study – specifically a pilot study. The waiting list control group (group B) had small numbers and anyway was diluted by the effect of learning self-hypnosis referred to earlier. The trial protocol was adjusted to maximize benefit to individual patients – for instance with timings of sessions and measurements to accommodate illness, fatigue, personal events and other treatments. This produced some looseness of the data which diluted the exactitude of findings. We placed too much emphasis on pain as a symptom in drawing up the trial protocol and allowing a wider spectrum of symptoms to be included would have reflected the real problems of palliative care patients better (Kirkova et al. 2010).

The crossover design needed no washout period between treatment and control as there was nothing to actually 'wash out'. The treatment group carried on with their self hypnosis even during the control period so weakening the control condition.

This pragmatic study tells us nothing about any specific effect of hypnotherapy over placebo or over any other treatment.

SUGGESTIONS FOR FURTHER RESEARCH

This was a single-centre study. The hypnotherapist's time was covered by volunteer therapists covering her usual complementary therapy work. Larger studies looking at individual responses as well as overall effects and with less emphasis on pain would be useful. This would demand a multi-centre study to generate enough patients within a manageable timescale. Such a study would need funding of therapist time. The waiting list control was difficult in a group of patients with limited life expectancy and it might be better for future studies not to use a crossover design but instead use waiting list controls. A pragmatic study without a control group might still help with questions such as responder/non-responder effects and overall benefit.

This study has given some preliminary data allowing power calculations for future studies.

SAMPLE SIZE ESTIMATION

Not using a crossover design (for the reasons above) and allowing for the high rate of loss to follow up as demonstrated here we estimate a minimum of 168 patients to give 80% power to detect a meaningful symptom change (Guyatt et al., 1998).

CONCLUSION

Providing hypnotherapy in palliative care is a practical proposition, but takes therapist time and other infrastructure and travel costs. There is some evidence of hypnotherapy having beneficial effects on symptoms over and above usual care. A larger study would give a more definitive answer about any effect but might need to be multi-centre to attract sufficient numbers of participants.

ETHICS

Ethical approval was given 21 April 2011 by the South West Research Ethics Service reference 11/SW/0066

FUNDING

There was no specific funding of this study which was supported by the Department of Complementary Therapy, Hospiscare, Exeter.

CONFLICT OF INTEREST

One of the authors, PJ, was also the hypnotherapist in the study.

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This study would have been impossible without the good-humoured participation of the patients of Hospiscare, and their carers: we are in their debt. We are very grateful for the support and enthusiasm of the management, staff and volunteers of Hospiscare.

APPENDIX 1. INITIAL INFORMATION SHEET. HYPNOTHERAPY IN PALLIATIVE CARE, HOSPISCARE, 2011–2013

HYPNOTHERAPY IN PALLIATIVE CARE – INITIAL INFORMATION

At Hospiscare we offer a variety of ways to help with the symptoms of illness. This includes complementary treatments such as massage and aromatherapy.

We are starting to look at whether hypnotherapy (hypnosis used as a helpful treatment) may also be useful. It has been used successfully in some other areas, and some hospices in the country do offer it to their patients. There is not yet enough known about hypnotherapy to say for sure whether it is something we might want to offer routinely to people at Hospiscare.

We are starting a small-scale study to see how helpful, practical and acceptable hypnotherapy might be at Hospiscare. This would involve having hypnotherapy, to help with pain and perhaps other symptoms, over an eight-week period. If you are interested in knowing more and perhaps taking part we can arrange for you to meet the researcher, Paddy Jones, who is one of our regular complementary therapists, so that she can explain more.

For more details please contact Paddy Jones on 01392 688 000 or ask your Hospiscare Nurse.

APPENDIX 2. INFORMATION SHEET. HYPNOTHERAPY IN PALLIATIVE CARE STUDY, HOSPISCARE, 2011–2013

HYPNOTHERAPY IN PALLIATIVE CARE RESEARCH STUDY – INFORMATION SHEET

Background. At Hospiscare we offer a variety of different complementary therapies to help with the symptoms of illness. We are always trying to improve the service that we offer. In some areas of the country hospices use hypnotherapy to help with the symptoms that people are finding troublesome. At the moment there is not enough research that has been done into this area to say how useful it really is in palliative care. We also do not know how well hypnotherapy might work alongside our usual care: This all means we are not sure if it is something we might want to offer to people at Hospiscare in the future.

We are therefore planning to study whether people might find hypnotherapy here at Hospiscare helpful for pain and some other of the symptoms they find most troubling. You have been referred to find out more about this study and to see if you would like to take part.

What is hypnotherapy? Hypnotherapy is a technique to encourage parts of the brain activity to quieten down for a while which allows the unconscious parts to be helped. This can allow the

brain to deal with some symptoms more easily. No one can be hypnotized against their will and the hypnotherapist in this study always use the therapy only for helping you with troublesome symptoms. There is no need to go in to a deep hypnotic state to find real benefits and often learning self-hypnosis is one of the most important and helpful ways of using hypnotherapy.

How is the study organized? If you decide to participate the study will take place over eight weeks. You will be randomly allocated one of two groups; Group A or Group B.

The first group – Group A – will have four sessions of hypnotherapy at weekly intervals. Before starting, after four weeks (while having the weekly hypnotherapy) and at the end the researcher will ask you about your pain and most troublesome symptoms. As well as general discussion the researcher will use a questionnaire designed to measure these symptoms. At the end of that four weeks' treatment there will be a four-week period of no hypnotherapy with a measurement of your symptoms again.

The second – Group B – will have the same treatment and measurement at the beginning, four weeks and eight weeks but the hypnotherapy will happen in the *second* four weeks so the *first* four weeks will be without hypnotherapy.

People in both groups will carry on with all their usual treatment (medications, out-patients, complementary therapy etc) exactly as normal whichever group they are in. This will give us a chance to compare people who have hypnotherapy with those who do not and to see the effect in individual people. We do not expect any side effects from the hypnotherapy and where it has been used before people generally find it helpful and pleasant.

Your consent. You are completely free to decline to enter the study or to withdraw at any time, with or without giving a reason, if you wish. Your decision to take part or not, to continue or withdraw, will not affect any of the care you receive either from Hospiscare or from the NHS.

Concerns or complaints. If you have any worries or complaints about the study then please discuss them with the therapist, Paddy Jones. If you are still concerned then please contact Dr Tim Harlow (01392 688 000, or via reception at the hospice) who is a consultant at Hospiscare and has been closely involved in this study. He would be pleased to help with any concerns you might have about the study.

What will come out of the study? We plan to publish the results in a scientific journal to help those who work in this field to provide better care for people with life limiting illness. All names will have been removed. Reports on the study will available at Hospiscare.

This study has received ethical approval from the NHS Research Ethics Committee and the clinical governance committee at Hospiscare.

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