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Research Article

Which Pain Rehabilitation Programme Should Patients With Chronic Back Pain Attend? – A Practical Example of a Service Evaluation Based Upon Implementing Research Findings into Clinical Practice

Abstract

Background: To evaluate a service reconfiguration of pain rehabilitation programmes for chronic back pain using three programmes of differing intensity and duration and a clinical algorithm. This study describes the outcomes for each programme for three consecutive cohorts.

Method: Non randomised observational study of 120 consecutive patients with chronic pain treated by a Physiotherapy Department of a Specialist Orthopaedic and Rehabilitation hospital. Three different pain rehabilitation programmes each comprising of multidisciplinary rehabilitation with varying intensity and duration of content were compared for clinical and cost efficacy. The main outcomes used were Oswestry Disability Index (ODI), Pain visual analogue score (VAS), pain catastrophising scale (PCS), pain self efficacy questionnaire (PSEQ), Tampa scale for kinesiophobia (TSK) and physical tests of timed sit to stand and 5 minute walk test.

Results: Analysis of changes within groups was by Wilcoxon signed rank tests and found patients attending the 'gold standard' Functional Restoration Programme showed statistically and clinically significant improvements in mean change scores for VAS, PCS, TSK, PSEQ, sit to stand and 5 minute walk test - $p<0.001$; with effect sizes for the different outcomes ranging from 0.2-1.19. For the shorter Active Rehabilitation Programme there were significant improvements all outcomes except TSK and sit to stand (p0.004), with effect sizes varying from 0.48-0.81. For the Short Management Programme there were significant improvements all outcomes with effect sizes ranging from 0.18-1.14.

Conclusion: This research uses a novel approach where an existing service was redesigned adhering to key principles but varying intensity and duration and using a clinical algorithm to determine treatment allocation in order to translate research based findings into clinical practice.

Background

Seventy five percent of patients with back pain who consult a doctor will have symptoms one year later and about 30% of these will develop persistent disabling pain [1,2]. Physical rehabilitation incorporating a psychological approach has been shown to improve functional ability in patients with persistent back pain [3-7]. The NICE Clinical Guidance for the Management of Low Back Pain [8] recommends referral for a combined physical and psychological treatment programme for people with high disability and /or significant psychological distress, who have already received a less intensive treatment. However, there is a lack of sufficient resources to deliver long duration, multidisciplinary programmes [9,10].

Since the mid 1990's we have provided a functional restoration rehabilitation programme (FRP) that is physiotherapy led using cognitive behavioural principles, supported by a clinical psychologist. The results from this original programme were reported by Frost et al. [3], and Fairbank et al. [11] and long term results in Mannion et al. [12]. The success of the programme led to a tenfold increase in referrals to the programme, with no additional resources. We therefore looked at how we could adapt the 'gold standard'

programme we had originally used, to make it affordable and enable us to deliver it within the resources available, allowing for normal financial and commissioning constraints.

We reviewed the literature and published clinical guidelines about different types of physiotherapy led pain rehabilitation programmes. The evidence supports multi-disciplinary cognitive-behavioural and exercise rehabilitation programmes [13-17]. We compared the profile of patients reported in the literature to the patients referred to our own pain management services. Based on the published guidelines we identified that many of our patients could potentially be treated within programmes of shorter duration or lesser intensity. Therefore, we decided to reconfigure our clinical service to offer three types of pain rehabilitation programme. In addition to FRP, we therefore introduced two new programmes– Active Rehabilitation Programme (ARP) and Short Management Programme (SMP), with a selection algorithm to allocate patients to each programme. These new shorter programmes slightly differed in focus. SMP was aimed at patients who were working but who may have difficulties in work or leisure activities and the ARP was for more highly disabled patients that were likely to find the higher intensity FRP too physically demanding. We designed an algorithm to allocate patients to the different programmes (Table 1).

Our primary aim was to evaluate development to a clinical service; this paper reflects an evaluation of our standard clinical services, rather than a stand-alone research study. As such, it was not appropriate to randomise patients. We aimed to test the screening algorithm devised to characterise patients and to test the assumptions behind the re-designed programme using a non randomised observational study. Secondly, we sought to compare the cost of delivering the different rehabilitation programmes.

We hypothesised that whilst there were differences in the patient characteristics, intensity of programme and programme cost, there would still be clinically relevant improvements in patients' outcomes from each of the programmes.

Method

Patients

Patients were eligible to attend the rehabilitation programmes if they had disabling chronic non-specific low back pain of at least one year's duration and pain that was related to unhelpful cognitions.

Patients were excluded from participating in a rehabilitation group if they had co-existing health problems that precluded exercise, e.g. unstable cardiac conditions, active inflammatory disease, were under 18 years of age or were assessed by a clinical psychologist as unable to participate in a group setting, if they were awaiting/receiving further investigation and/or treatment for their pain problem or awaiting/receiving further investigation/treatment for co-existing health problems which would impact on group participation.

Patients not eligible to attend the rehabilitation programmes were offered treatment on an individual basis.

We included 40 consecutive patients attending each programme (n = 120).

As this was a service evaluation we did not seek ethical committee approval, however, all patients gave written consent for their data to be used for evaluation and audit purposes.

Screening algorithm and programme selection

A screening algorithm was developed which assessed patients based upon clinical characteristics and scores on questionnaires for function and mental status completed by the patient.

All patients attended a one hour assessment visit where they discussed the programme options with their physiotherapist. Patients were allocated to a particular programme based on: their level of functional disability as scored on the Oswestry Disability Index [19] and 5-minute walk-test (REF); work status; programme preference; severity or control of their pain; level of anxiety or depression as scored on the Hospital Anxiety and Depression scale [18]. Many of these same measures were also used at the end of the programmes to evaluate the effectiveness.

Further details are summarised in table 1.

Rehabilitation programmes

All of the programmes shared a similar philosophy – to encourage patients to adopt a positive approach to managing their pain, whilst decreasing functional disability and increasing the patients' confidence in their ability to manage their condition on a day to day basis. The programme was predominantly physiotherapy led, with input from a clinical psychologist and a physician. The programmes varied in duration and in intensity. The outcome measure data before and after the programmes was collected by a physiotherapy assistant.

Functional Restoration Programme (FRP): Each group had a maximum of 8 people. The programme ran for 6 hours a day for 4 days /week for 3 weeks (total of 72 hours). The patients spent approximately three hours per day engaged in activities including stretching, graded strengthening, aerobic conditioning, core stability based exercises, graded exposure to feared activities, circuit based (pacing) exercise, hydrotherapy and relaxation.

The remaining three hours were spent in educational or discussion sessions which included such topics as: how to increase activity, how to exercise safely, understanding pain which persists, sleep, healthy eating, medication, employment advice, exploring common worries and concerns, the role and limitations of investigations, plans for possible setbacks, how family can help, posture and lifting and leisure and recreation.

Goals were set according to S.M.A.R.T principles and divided to short term i.e. daily and weekly and long term goals monthly and yearly.

Active Rehabilitation Programme (ARP): Each group had a maximum of 8 people. The programme consisted of 8 sessions each lasting 5 hours and occurred once a week (total of 40 hours). Again the content was split between activities (exercises, hydrotherapy and relaxation) and education or discussion sessions. Generally the programme aimed to help patients explore new ways of managing persisting pain, improve confidence, help patients understand why

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pain persists, increase general fitness and reduce frustration and anxiety.

Short Management Programme (SMP): Each group had a maximum of 10 people. The programme consisted of 6 sessions, each lasting 2 hours, occurring on a weekly basis (total of 12 hours). Again the programme consisted of activities (exercises, hydrotherapy and relaxation) and education or discussion sessions.

All three programmes used paced exercise, individually tailored to the patients' ability and included a combination of stretching exercises, general muscle strengthening, spine stabilisation exercises, endurance and low impact aerobic exercise and relaxation. For the FRP and ARP programmes there were also sessions in the hydrotherapy pool. Full details of the programme are included in Appendix 1.

All patients kept exercise log diaries and utilised a shared goal setting approach. At the end of each programme patients agreed both short and long term goals. Patients were reviewed at two further appointments after the programme where their progress was reviewed against their set goals and also by change from their baseline outcome assessment measures.

Outcome measures

Before being allocated to a programme patients completed screening questionnaires of Pain visual analogue scale, Oswestry Diasability Index (ODI), Tampa scale for kinesiophobia (TSK) and a 5 minute walking test which was used in the algorithm to inform the programme selection. On starting each programme and 6 months after completion, patients completed these standard outcome assessments with the addition of the pain catastrophising scale (PCS), pain self-efficacy questionnaire (PSEQ) and physical tests of timed sit to stand. Pain was recorded using a 100mm VAS recording patient's average pain intensity level [20].

The Tampa Scale for Kinesiophobia (TSK) was used to assess the subjective rating of kinesiophobia or fear of movement. It is a 17 item self-completed questionnaire developed to "discriminate between non-excessive fear and phobia among patients with chronic musculoskeletal pain." The range of scores is from 17 to 68 where the higher scores indicate an increasing degree of kinesiophobia [21].

The Pain Catastrophising Scale was used to assess the three components of catastrophising: rumination, magnification and helplessness, defined as *"an exaggerated negative mental set brought to bear during actual or anticipated painful experience"*. It consists of 13 items, scored on a 0-5 scale with a range of scores from 0-52. A PCS of 30 or more is considered to represent a clinical level of catastrophising. These scales have good reported clinometric properties and are reported to be valid, reliable and responsive in a chronic low back pain population [22,23].

The Pain Self Efficacy Questionnaire was used to assess the confidence people in pain have in performing activities while in pain. It is a 10 item questionnaire scored on a 7 point scale with a range of scores from 0-60. Higher scores indicate greater self-efficacy. Low PSEQ scores of < 20 are associated with an unwillingness to participate in activities [24]. It is reported to have good content and construct validity, good internal consistency and to be reliable [25].

Functional physical tests - 5 minute walking distance and 1 minute standing up and sitting down from a chair were used to assess those aspects of physical performance most relevant to everyday activities.

Data analysis

Non-parametric statistics were used to compare outcome measures within the groups. Data were analysed using Wilcoxon's signed rank test and the statistical package SPSS 20 for Windows. Effect sizes (Hedges' g) were calculated for each outcome to show relative effectiveness of the programmes [26].

Statistical significance was set at the $p<0.05$ level.

Results

Distribution of patients

The proportion of patients allocated into each of the different groups from the entire population over a year using the clinical algorithm resulted in a distribution between the programmes of 45% to FRP, 30% ARP and 25% SMP. We have reported data from the first 40 consecutive patients in each programme.

The baseline characteristics of the participants are described in table 2.

Adherence to algorithm

After completion of the programme the characteristics of the participants were checked to see that they met the criteria agreed in the selection algorithm. The compliance with the algorithm was 100%.

Outcomes

Patients attending the 'gold standard' FRP programme showed statistically and clinically significant improvements in mean change scores for PCS (20.4 to 11.6), TSK (41.1 to 32.6) , PSEQ (28.9 to 38.2), and 5 minute walk test (228m to 306 m) – all $p<0.001$. They demonstrated a smaller decrease in VAS pain score from 6.12 to 4.82 (p 0.004), sit to stand 13.4 to 15.4 (p 0.009) and ODI from 41.7 to 38.3 (p 0.118).

For the ARP there were significant improvements in the mean change for VAS 8.7 to 7.45 (p0.000), PSEQ 24.2 to 32.07 (p 0.000) PCS 25.8 to 18.2; (p 0.000), ODI 52.4 to 45.9 (p0.000) and sit to stand (5.25 to 6.05; p0.001). Other outcomes were not statistically significant.

For the SMP there were significant improvements in the mean change for VAS 5.92 to 4.87 (p 0.000), PSEQ 29.9 to 36.1 (p 0.000), TSK 39.2 to 37.4 (p0.001), PCS (24.5 to 17.9; p0.000), sit to stand (15. to 17.5; p0.004) and walking (281 to 306m; p0.016) (Table 3).

We have not attempted to compare the relative efficacy of the three treatment approaches as the algorithm used to allocate patients to each programme ensured that the baseline characteristics of the patients in terms of pain and disability were very different; for example prior to treatment the mean pain VAS for the FRP was 6.12, but 8.7 in the ARP and the ODI was 41 for FRP but 52 for ARP. Effect

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Table 1: Programme Selection Algorithm.

	Shorter Self Management (SMP)	Functional Restoration (FRP)	Active Rehab (ARP)
Pain Severity / Control	Good pain control	Good pain control	Fair pain control
Disability Level [Oswestry Disability Index Score]	ODI 30 – 40%	ODI 40-60%	ODI >50 – 75%
Individual Factors	Happy to participate in a group setting	Happy to participate in a group setting	Happy to participate in a group setting
Anxiety & Depression score	HAD <15	HAD < 15 (or assessed by Clinical Psychologist)	HAD < 15 (or assessed by Clinical Psychologist)
Kinesiophobia score	Some fear avoidance (no higher than 50 on TSK) but not highly distressed.	Some fear avoidance.	Fear avoidance. Long periods of rest or sedentary lifestyle. May present as highly distressed.
Involvement of psychologist	If depressed / anxious, prepared to engage in psychological treatment / medication regime.	If depressed / anxious, prepared to engage in psychological treatment / medication regime.	If depressed / anxious, prepared to engage in psychological treatment / medication regime
Walking	Able to walk < 300 metres in a 5 minute walk test	Ability to walk < 250 metres in a 5 minute walk test without walking aids.	Ability to walk 70 metres uninterrupted with a walking aid.
Previous Interventions	No restriction	If completed ARP/ FRP in last 5 years consider 1:1 not full programme	If completed ARP/ FRP in last 5 years consider 1:1 not full programme
Work	Able to cope at home or work but having some functional difficulty.	Off work / struggling with work or low level of productivity at home	Off work. Low productivity at home
		If able to work has had significant periods off work in the last year (i.e. periods of one week or greater on multiple occasions).	If working only at low functional level or in a way that is adapted to disability.
Sport & Leisure	Has stopped some sport or leisure activities.	Has stopped some sport or leisure activities	Sedentary leisure pursuits only. Has stopped socialising / may be socially isolated

Table 2: Baseline Demographics.

Group	Age (mean, range, standard deviation)	ODI (mean, range, standard deviation)	HAD (mean, range, standard deviation)
FRP	43 [18-61] (10.35)	41.67 [18-76] (11.73)	7.71 [0-21] (4.19)
ARP	51 [33-71] (10.37)	52.42 [36-74] (9.96)	18.22 [5-31 (6.7)
SMP	45 [21-79] (14.72)	36.40 [10-66] (14.10)	8.3 [3-13] (8.3)

sizes for each outcome were calculated to show the efficacy of the programmes – see figure 1.

Cost breakdown of programmes

The programmes were costed based upon PLICS (Patient – level information costing system) comprising the staffing ratios, physical resources required and number of contact hours. The FRP equated to approximately 72 direct contact hours at a cost of £2,750. The ARP equated to 40 direct contact hours at a cost of £1,950 and the SMP equated to 12 contact hours at £699.

The review of the results from consecutive patients allocated to each of the three programmes demonstrated that significant improvements were made by patients in all groups. The programmes consumed differing levels of resource to deliver and consequently had varying costs to deliver.

Discussion

There is conflicting information about the efficacy of rehabilitation programmes related to duration or intensity. The UK NICE Clinical Guidelines for non-specific low back pain [8] recommended eight sessions over a 12 week period in a group setting. Guzman et al. [27] recommended that daily intensive programmes of over 100 hours were more effective than those of 30 hours or less. Conversely, van Geen et al. [9] compared programmes with over 30 hours of contact a week with those of fewer than 30 hours and found no difference in the effectiveness of the interventions. Flor et al. [28] similarly found no relationship between the number of contact hours and outcome. Waterschoot et al. [29] reviewed the effect of dose on effectiveness in pain rehabilitation programmes and concluded that it was not possible to disentangle the relationship between dose and content. Williams [30] argues that programme length in weeks is as important as contact hours as the rehabilitation model usually involves homework and working towards goals inside and outside the programme, making pure contact hours less relevant. Whilst many trials and systematic reviews have established that multidisciplinary pain rehabilitation programmes are effective for patients with chronic low back pain; it is also known that many hospitals struggle to provide such programmes due to the high cost of the resources that they require and due to difficulties in accessing clinical psychologists working in chronic pain [9,10,31]. The training of physiotherapists now encompasses behavioural and psychological treatment techniques and many programmes are run by physiotherapists based upon cognitive behavioural principles. A recent systematic review [10] found moderate to high quality evidence of small effects for physiotherapy led functional restoration programmes.

In this observational study we have only analysed a small data

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Table 3: Results of Programmes.

	Pre	Post	Diff	Sig	Effect Size
FRP					
ODI	41.67 (11.73)	38.30 (16.23)	3.37 (12.58)	NS	0.2
VAS	6.12 (1.88)	4.82 (2.27)	1.30 (2.39)	.004	0.57
PSE	28.87 (10.24)	38.17 (9.99)	9.3 (10.08)	.000	0.93
TSK	41.10 (8.95)	32.65 (7.07)	8.45 (8.04)	.000	1.19
PCS	20.37 (10.05)	11.62 (9.14)	8.75 (9.91)	.000	0.95
Walking	228 (127)	306 (160)	78 (68)	.000	0.53
Sit to Stand	13.4 (6.59)	15.4 (7.50)	2 (3.06)	.009	0.28
ARP					
ODI	52.42 (9.96)	45.9 (13.52)	6.45 (9.46)	.000	0.48
VAS	8.7 (1.28)	7.45 (1.44)	1.25 (1.56)	.000	0.86
PSE	24.17 (8.11)	32.07 (9.66)	-7.90 (7.61)	.000	0.81
TSK	40.00 (8.78)	37.35 (6.71)	2.65 (7.05)	0.46	0.39
PCS	25.85 (11.76)	18.17 (10.99)	7.67 (8.37)	.000	0.69
Walking	183 (88)	189 (104)	6.5 (48.15)	.455	0.06
Sit to Stand	5.25 (1.33)	6.05 (2.43)	1.8 (1.88)	.001	0.41
SMP					
OD1	36.40 (14.10)	33.05 (13.99)	3.35 (8.77)	.04	0.24
VAS	5.92 (1.45)	4.87 (1.95)	1.05 (.98)	.000	0.60
PSE	29.92 (10.54)	36.1 (9.28)	-6.07 (9.38)	.000	0.61
TSK	39.27 (6.76)	37.37(6.86)	1.9 (6.35)	.001	0.27
PCS	24.5 (11.46)	17.97 (8.96)	8.1 (1.41)	.000	0.64
Walking	281 (81)	306 (91)	24.9 (42.9)	.016	0.29
Sit to Stand	15 (7.2)	17.5 (8.2)	2.45 (3.52)	0.004	0.32

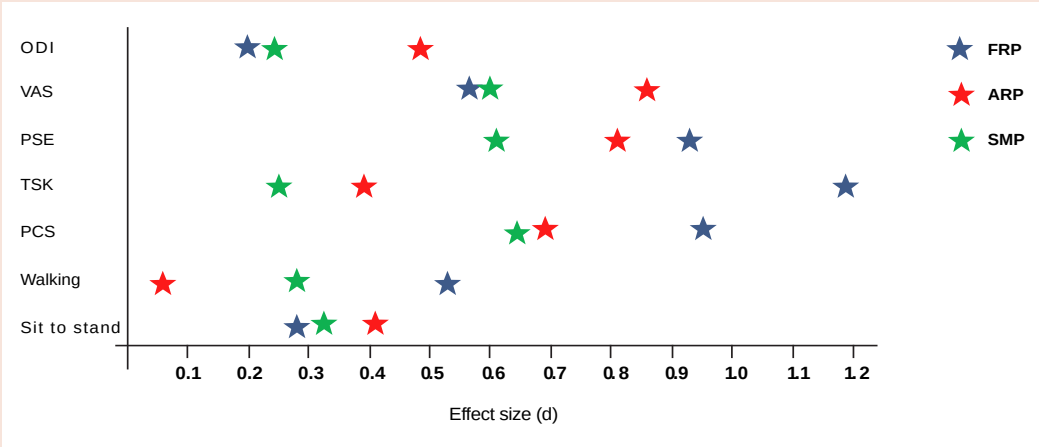

Figure 1:

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set for each programme. However, we found that we could achieve statistically significant changes in the range of outcomes used to assess the efficacy of the programmes in all three treatment programmes approaches. We further found that the shorter programmes were popular with patients, as they did not require patients with lesser levels of disability to take 3 weeks off work, or away from their homes. Indeed, the SMP programme is now offered in both the daytime and evening to facilitate patients remaining within the workplace. Similarly, the most disabled patients have benefitted from a more graduated introduction to rehabilitation with the ARP programme, as some of the more disabled patients had previously struggled with the change from little activity to a daily 6 hour programme.

It is a limitation of this paper that we have observed and described a service reconfiguration rather than a priori conducting a randomised controlled trial in order to investigate the relative efficacy of the three different programmes. We acknowledge that the allocation to group was made according to a level of function approach, rather than using random allocation. However, this decision was predicated on the expert opinion of the clinicians that there were problems in only offering one programme of 72 hours to all patients. Such a programme benefitted many, but was harder to access for the more severely disabled who struggled with the intensity of the programme; or for some older patients. For those who had chronic pain, but were just managing to continue to work, many could not afford to take the necessary time away from the workplace. The decision to design a selection screening algorithm would result in patients with different characteristics in each programme at baseline and precluded a randomised control design. Similarly we did not calculate a sample size for the number of participants included in the study, but rather chose a sample based upon consecutive cohorts for each programme.

In acknowledging the effectiveness of pain rehabilitation programmes described in many research trials, there are barriers to implementing the research findings into practice. It is recognised that health services are informed by the findings of research, but that there is often a gap in implementing the findings into routine practice [32-34].

In seeking to re-organise our model of service provision we aimed to both meet implementation of research evidence and to meet the operational efficiencies required to meet national access waiting times, stay within budget and provide clinical outcomes that demonstrate the effectiveness of our services. Our aim was to adapt the published research by modifying the intensity of the clinical programmes and also the intensity. We seek to demonstrate the day to day reality of managing evidence based programme in relation to resource constraints and the economic framework of a publically funded health system. By adopting a pragmatic research culture in our workplace we have overcome barriers that have been identified including the growing economic challenges for national health services and the strong focus on service delivery and meeting of access treatment time targets.

Improvements in outcome were observed in the cohorts of patients undergoing programmes of lesser duration and intensity than the original validated programme. As the study sample was small and the programme allocation was not randomised the ability to draw inferences about comparative outcomes is limited. However, this change to service delivery has enabled greater numbers of patients to access pain rehabilitation programmes whilst remaining within the financial, physical and staffing constraints available within this publically funded setting.

Conclusion

The results from patients allocated to each of the three programmes demonstrated that significant improvements were made by patients in all groups. These improvements in outcome were observed in the cohorts of patients undergoing programmes of lesser duration and intensity than the original validated programme. Resource constraints mean that it is not always possible to implement evidence-based clinical services that closely replicate the original trial protocol. In reporting our evaluation of implementing research based practice into existing services, we have sought to show how they can be redesigned adhering to key principles, but varying intensity and duration of the intervention, to make them affordable and practicable to implement within the constraints of a publically funded health service.

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Author's contributions

KB conceived, planned and secured funding for the study. LH collected all data and contributed to the design. EB and FT contributed to the study design. KB co-ordinated the study and drafted the manuscript. All authors contributed to and approved the final manuscript.

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