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Physical Therapy Informed by Acceptance and Commitment Therapy (PACT) Versus Usual Care Physical Therapy for Adults With Chronic Low Back Pain: A Randomized Controlled Trial

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Abstract: Chronic low back pain (CLBP) is a major cause of global disability and improving management is essential. Acceptance and commitment therapy (ACT) is a promising treatment for chronic pain but has not been modified for physical therapy. This randomized controlled trial (RCT) compared physical therapy informed by ACT (PACT) against standard care physical therapy for patients with CLBP. Patients with CLBP (duration ≥12 weeks, mean 3 years) were recruited from physical therapy clinics in 4 UK public hospitals. The Roland-Morris Disability Questionnaire (RMDQ) at 3 months' post-randomization was the primary outcome. Two hundred forty-eight participants (59% female, mean age = 48) were recruited and 219 (88.3%) completed measures at 3 and/or 12 months' follow-up. At 3 months, PACT participants reported better outcomes for disability (RMDQ mean difference = 1.07, p = .037, 95% CI = −2.08 to −.07, d = .2), Patient Specific Functioning (p = .008), SF12 physical health (p = .032), and treatment credibility (p < .001). At 12 months' follow-up, there were no significant differences between groups. PACT was acceptable to patients and clinicians and feasible to deliver. Physical therapists incorporated psychological principles successfully and treatment was delivered with high (≥80%) fidelity. Our results may inform the management of CLBP, with potential benefits for patients, health care providers, and society.

Perspective: *Psychologically informed physical therapy has great potential but there are challenges in implementation. The training and support included in the PACT trial enabled the intervention to be delivered as planned. This successfully reduced disability in the short but not long term. Findings could inform physical therapists' treatment of CLBP.*

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Low back pain is the leading cause of global disability[1-3] and urgently requires better management.[2] Eighty percent of the adult population experiences a significant episode of disabling low back pain over their life. Most people recover, however, 10 to 15% go on to develop chronic low back pain (CLBP), defined as pain lasting over 12 weeks.[4] Ninety percent of people with CLBP have a non-specific problem with no clearly identifiable cause for their pain.[5] CLBP is increasing in prevalence and is globally the second most frequent reason for time off work.[1,3] Total costs associated with back pain in the United States are estimated at between $100 and $200 billion per year, one-third due to healthcare costs, with the remainder due to lost wages and lower productivity.[6] It is a complex condition associated with psychological comorbidities, such as sleep disorders, anxiety, and depression.[7] CLBP is often ineffectively managed[5] and thus debilitating for patients, challenging for healthcare providers, and costly for society.[1,2]

Many people with CLBP are referred for physical therapy but within the range of treatments used by physical therapists, there is little consensus about which are the most effective and cost effective.[8] Trials have shown only modest improvements in pain and disability following usual physical therapy treatment.[9] Self-management programs can be effective for people with CLBP[10] and individualized treatment may facilitate better self-care.[8] Recent guidelines promote a combined psychological/physical approach if previous treatments have proved ineffective or where there is a medium to high risk of chronicity.[8,11] Psychologically informed practice is proposed as a middle way, integrating traditional biomechanical and impairment-focused practice with cognitive behavioral approaches.[12] Interest in this approach is growing, however, many questions remain, such as how much treatment is required and whether it can be delivered with adequate fidelity.[13] Physical therapists frequently report a lack of confidence in using psychological techniques successfully[14] and may have difficulty identifying psychological factors associated with CLBP.[15] Recent reviews have concluded that this could be rectified with additional training and support.[16] Other findings have suggested patients with CLBP want to discuss personal issues with their physical therapist,[17] although many physical therapists perceive they lack the skills or confidence to address these concerns.[14] This highlights the need to develop psychologically informed interventions that are suitable for physical therapists and the training to help them provide it.

Cognitive behavioral therapy (CBT) is an effective intervention for CLBP[18] although it remains challenging to implement approaches to physical therapy that are based on CBT.[19] Acceptance and commitment therapy (ACT), a newer third wave CBT, has a good evidence base in the treatment of chronic pain[3,20] but its underlying principles of psychological flexibility have not been applied to physical therapy. ACT focuses on improving functioning, rather than reducing pain, using acceptance, mindfulness strategies, and values-based action.[21,22] This approach is particularly suitable for CLBP, as a focus on symptom reduction is frequently counter-productive.[23] A trial of ACT for CLBP delivered by psychologists found patients referred for physical therapy were somewhat resistant to seeing a psychologist and consequently recommended combining ACT with physical therapy.[24] A mixed method study reported challenges and opportunities to embedding ACT within pain rehabilitations settings that include physical therapists.[25] We have developed a brief physical therapist-delivered intervention, theoretically underpinned by ACT, called PACT (physical therapy informed by ACT).[26] The main objective of this trial was to evaluate the efficacy of PACT on functioning at the primary end point of 3 months' follow-up, compared with standard, usual care (UC) physical therapy.

Methods

Study Design and Participants

A phase II, assessor blind, 2-armed, parallel group, multicenter randomized controlled trial compared the efficacy of PACT with UC physical therapy treatment for patients with CLBP. Participants were recruited from secondary care physical therapy clinics in 3 UK NHS (Public) Hospital trusts in London UK (Guy's, St Thomas', and Kings College Hospitals) and 1 in suburban/rural south east England (Ashford and St Peter's Hospital). The trial received full Research Ethics Committee (REC) approval (National Research Ethics Committee South Central - Berkshire; 14/SC/0277) and conformed to current guidelines for ethical research. The trial was registered prospectively: ISRCTN95392287.

Participants

Eligible patients were adults (aged ≥18 years), with nonspecific CLBP with or without associated leg pain, of greater than 12 weeks' duration, and reporting a score of ≥3 points on the Roland Morris Disability Questionnaire (RMDQ).[27] Potential participants required a good understanding of spoken and written English to complete trial data collection and participate in the PACT program. People who had prior treatment from multidisciplinary CBT pain management at any time and/or other physical therapy treatment in the previous 6 months, or injection therapy within the last 3 months, were excluded. People with specific spinal pathology were excluded, as were people with severe psychiatric illness and/or current drug or alcohol misuse, as these issues require different treatment priorities. Potential participants referred to outpatient physical therapy were identified over an 18-month period by physical therapists from each hospital center at their triage sessions. They were provided with written and verbal information about the PACT trial and invited to participate. Interested participants were then contacted by the research associate to screen for eligibility. All participants gave written informed consent before taking part.

Randomization and Masking

Participants were randomized to receive either PACT or UC physical therapy. Random allocation to the 2 groups employed random block sizes stratified by recruiting

center (Guy's & St Thomas', King's College, and Ashford & St Peter's Hospitals); implemented via the King's College London Clinical Trials Unit online system, with emails generated automatically and sent to relevant physical therapy staff at study sites. Face-to-face treatment meant it was not possible to blind participants or the physical therapists delivering the interventions. However, the research associate conducting outcome assessment and the trial statistician analyzing the data were blinded to group allocation. No hypothesis was proposed to participants about the superiority of either treatment and separate groups of clinicians delivered PACT and UC physical therapy to avoid contamination.

Procedures

PACT was a brief physical therapy intervention, guided by principles of ACT, designed to promote self-management. PACT consisted of 3 individual treatment sessions as follows: two 60-minute face-to-face sessions 2 weeks apart conducted in a private room, plus one 20-minute telephone call 1 month later. Treatment included an initial physical assessment with feedback, identification of value-based goals, individualized physical exercise prescription, addressing barriers and facilitators to self-management, and skills training to promote psychological flexibility. It excluded manual therapy. Total contact time was designed to be similar to the average amount of time patients with CLBP receive as part of UC physical therapy treatment, as reported in UK RCTs for CLBP where UC physical therapy was used as the control arm.[28] The aim was to maximize the potential for a treatment effect within a timeframe that was similar to the contact received, on average, in standard physical therapy, as this was considered a feasible way to ensure eventual implementation and cost effectiveness. However, PACT altered the context, content and duration of physical therapy treatment, so that it was delivered in fewer but longer sessions compared to usual care in the UK. Further details of PACT treatment are reported in the protocol paper.[26]

Eight experienced (Band 6 and 7) physical therapists received a bespoke training package, including a manual and 2-day face-to-face training program, followed by ongoing monthly group supervision from a clinical/health psychologist and a physical therapist. Differences in boundaries between psychologists and physical therapists were carefully communicated during training, as this was not designed to alter these boundaries. A patient manual individualized to patient needs was provided during the first session. UC physical therapy was provided by physical therapists (Bands 5–8) employed in the Public Hospitals and comprised any treatment considered suitable by the treating physical therapist, including individual physical therapy and/or back rehabilitation classes, dynamic control classes, manual therapy, and hydrotherapy. All PACT sessions were audio recorded to check treatment fidelity. Attendance at UC sessions was documented to record volume (duration and frequency) and components (1:1, class) of UC physical therapy by clinicians. All treatment in the trial took place in the physical therapy clinics based at the participating hospitals. Training the physical therapists effectively in PACT treatment was an integral part of the study. To assess fidelity, a randomly selected sample of 20% of the audio-recorded PACT sessions was rated by 2 trained, independent assessors. The randomization was stratified by session (initial face-to-face, 2-week face-to-face, 1-month telephone call) and physical therapist to ensure at least 1 session per physical therapist was assessed.

Outcomes

Self-reported questionnaires were completed by patients at baseline, 3 (primary end point) and 12 months, either online or via postal questionnaires, to avoid any influence of the study team on the responses. The primary outcome was patient-reported functioning at 3 months, assessed with the RMDQ.[29] The RMDQ is a widely used well-validated measure with good reliability, where a 2- to 3-point change from baseline is considered clinically meaningful.[27] Demographic data collected at baseline included: age, gender, ethnicity, marital and work status, and educational attainment. Secondary outcomes included all core domains recommended in chronic pain research (IMMPACT recommendations).[30] Secondary outcome measures were: the Patient Health Questionnaire-9 (PHQ-9),[31] to assess depression; the Generalized Anxiety Disorder-7 (GAD-7),[32] to assess anxiety; the Patient-Specific Functional Scale (PSFS)[33] and Work and Social Adjustment Scale (WSAS)[34] to assess functioning; a life satisfaction scale; and a pain numeric analogue scale to assess pain severity. Global Improvement,[35] Outcome Satisfaction,[36] and Treatment Credibility[37] questionnaires were completed at both follow-ups. Process measures were chosen with the intention to stay theoretically clear without redundancy, as well as the need to maintain reasonable participant burden from the assessment. Process variables included the Chronic Pain Acceptance Questionnaire-8 (CPAQ-8)[38]; and Committed Action Questionnaire-8 (CAQ-8)[39]; as well as the Pain self-efficacy Questionnaire (PSEQ).[40] Nested qualitative studies were completed with 20 PACT patients and all PACT physical therapists (reported elsewhere). In addition, proposed therapeutic mechanisms of action (process variables)[38,39] were assessed. Three bespoke treatment fidelity measures, 1 for each PACT session, were developed to appraise physical therapists' adherence to the PACT intervention. A cost-consequences estimation of the economic impact of the interventions on CLBP was completed using patient data from 2 health-related quality of life measures, the EQ-5D-5L,[41] and MOS Short Form-12v2 (SF-12)[42] Questionnaires. Serious adverse events were reviewed by the chief investigator and reported to an independent trial steering committee for consideration.

Patient Involvement

The PACT study was developed with contributions from 4 dedicated patient representatives, who were recruited from local physical therapy services and

included 2 participants from the proof of concept feasibility study. Their contributions included the development of PACT treatment components and materials to determine appropriateness of content, language and format; feedback on key documents, such as patient information sheets and consent forms; piloting of assessments, including questionnaire content and delivery via an online questionnaire database, to determine acceptability, length of surveys and estimated completion time, and resonance of items within surveys to check relevance and acceptability. One patient was a coapplicant on the grant funding the trial and 2 patients were patient and public involvement representatives on the Trial Steering Committee to ensure it addressed issues relevant to service users.

Sample Size

The trial was designed to detect a standardized mean difference of .4 in the primary outcome (RMDQ; 5% significance, 80% power) assuming attrition of 20%. This difference equates to a 3-point difference between groups (assuming the standard deviation of the RMDQ is 7.4, as suggested by our small feasibility study and previous research in a similar population[43] where a 2- to 3-point difference in the RMDQ score is considered clinically important.[27] We calculated that in total 240 participants needed to be randomized.

Statistical Analysis

Data were analyzed using Stata version 14.1 statistical software. Estimates of treatment effect at the 3-month and 12 months' follow-up followed the intention-to-treat principle. Between-group differences (treatment effect) were estimated for the primary outcome (RMDQ) at the postintervention assessments. Estimates of treatment effect at the 3- and 12 months' postrandomization follow-up assessments were based on adjusted mean differences using linear-mixed models following the intention-to-treat principle.[44] A 3-level model was estimated including random effects for the patient to account for repeated assessment over time and a random effect for physical therapist to account for partial-clustering of patients by physical therapist in the PACT arm. Covariates in the model included an indicator variable for group assignment, an indicator for follow-up time, an interaction term for group by time, the baseline level of the outcome variable and indicator variables for center, as this was a stratification factor in the randomization. Residual diagnostics indicated heteroscedasticity for RMDQ. Standard errors that are robust to violations of the normality and homoscedasticity assumption were estimated by bootstrapping with 1,000 replications. Treatment effects were converted into standardized mean differences as Cohen's *d* to allow comparison of effect sizes across outcomes. Costs associated with delivering PACT and UC were estimated using a combination of actual resource used, derived from logs kept by the physical therapists and NHS Executive reference costs for 2015/16.

Results

Participant Characteristics

Between November 2014 and March 2016, 660 patients were informed about the study by their physical therapist and 478 (72%) agreed to be screened for eligibility. Two hundred forty-eight (51•8%) met eligibility criteria and consented to participate and so were randomized to receive either PACT (n = 124) or UC physical therapy (n = 124). Of 124 people randomized to PACT, 17 (14%) received no treatment and 4 (3%) had UC physical therapy. Of 124 randomized to UC physical therapy, 30 (24%) received no treatment and 2 (1•6%) patients had PACT. Administrative delay and some confusion about attending appointments that had already been allocated led to a few people inadvertently receiving the wrong treatment. Overall, 204 patients (83%) completed follow-up assessments at 3 months and 181 (73%) at 12 months. In total, 219 patients (88.3%) provided data on at least 1 follow-up occasion and were retained for the intention-to-treat analysis, irrespective of whether they received treatment. Of those receiving PACT, 23 had 1 face-to-face session, 14 had 2 face-to-face sessions, and 66 received both face-to-face sessions plus the telephone session. Overall, 103 patients (83%) completed at least 1 session of PACT. Of those allocated to UC physical therapy, 92 (74%) received UC treatment and they all had at least 1 face-to-face session with a physical therapist, with the majority referred to some form of group-based intervention after this (eg, back rehabilitation or hydrotherapy classes). On average, participants in UC attended 3 hours of physical therapy (eg, three 30 minutes 1:1 sessions and one and a half 60-minute classes), compared to 2 hours treatment in PACT. There were no patients who were withdrawn or opted to withdraw from the trial. Patient flow through the study is presented in Fig. 1.

Baseline demographic and clinical characteristics by treatment group are presented in Tables 1 and 2. Fifty-nine percent of participants were female, 59% described their ethnicity as white, and participants' average age was 48 years. Our participants had RMDQ mean scores that are typical of people with CLBP seeking physical therapy.[43] Patients in our sample were in the mid-range of pain intensity scores and many were experiencing mild depression and anxiety symptoms, but these were below the level where treatment should be considered. There was good variability across the range of scores at baseline, with sound balance across the groups achieved by randomization. At the baseline assessment, 8 individuals in the PACT arm and 6 patients in the UC arm had a RMDQ score <3 (although they had scored ≥3 during screening and so were eligible). Of these, 6 patients in the PACT arm and 3 patients in the UC arm were retained in the intention-to-treat analysis as they provided data.

Primary Outcome

Twenty-nine patients provided no postbaseline data and so were not included in the analysis sample. We
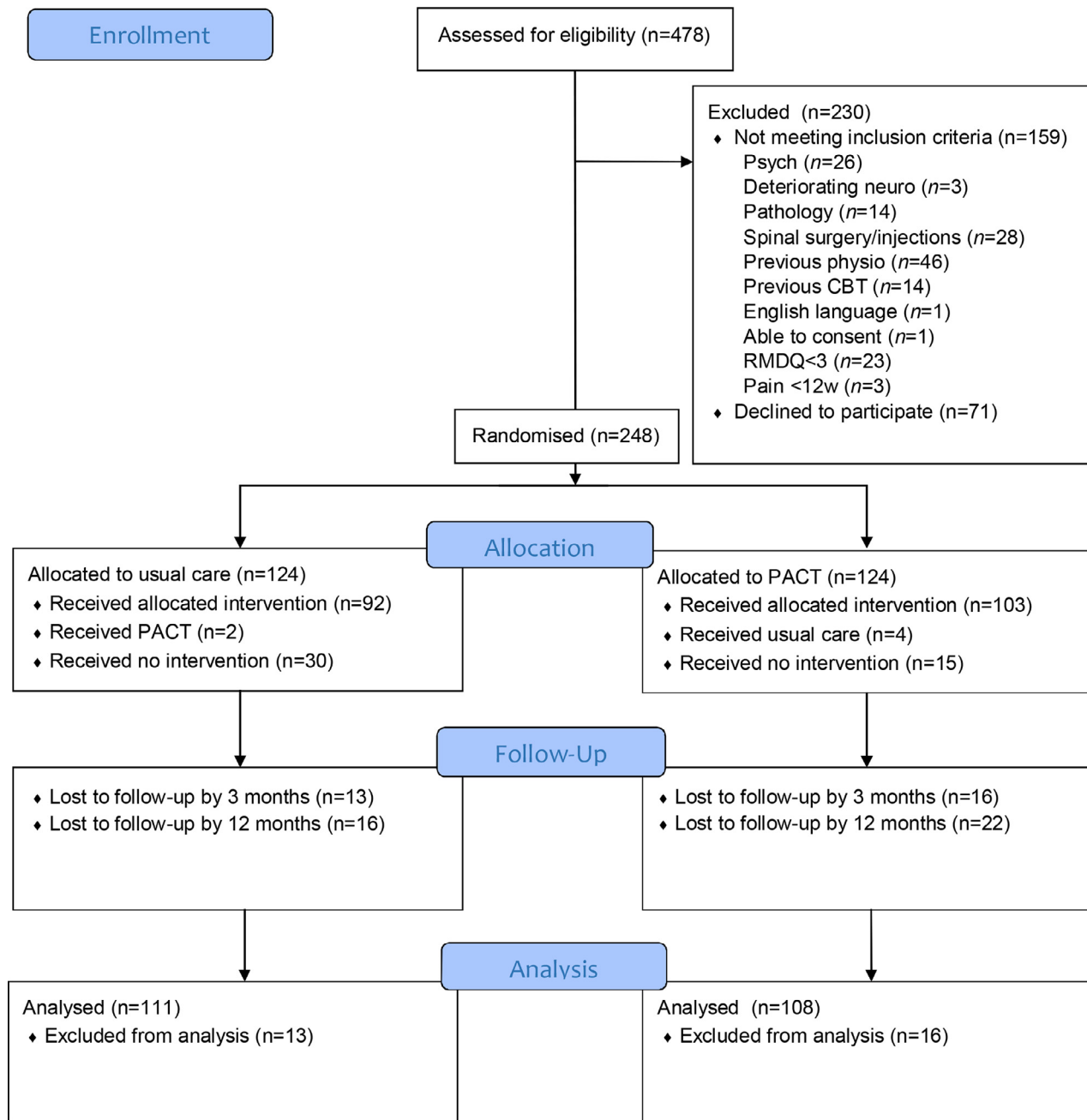
Figure 1. Consort Flow diagram.

included careful sensitivity analysis to determine whether excluding these patients impacted on the results. There was a trend for those who were not retained for the intention-to-treat analysis or not completing 12 months' follow-up to be younger, male, unmarried, have less education, and to report worse health at baseline. However, only the difference in age for those completing the 12 months' follow-up was statistically significant, with younger patients more likely to be lost to follow-up.

Fig. 2 shows the treatment effects based on the intention to treat sample. The mean reduction in RMDQ score from baseline to 3 months in the PACT group was 3.4, compared to 2.1 in the UC group (Table 3, Supplementary Materials), where a change of 2 to 3 units in the

RMDQ is considered clinically meaningful.[27] The intention-to-treat adjusted mean difference between groups indicated people who received PACT reported significantly better functioning (RMDQ) at the primary end point of 3 months than those receiving UC (mean difference = −1.07, $P = .037$, 95% CI = −2.08 to −0•07, $d = .2$). Clinically important reductions in RMDQ levels were maintained at 12 months in the PACT group, although the intention-to-treat adjusted mean difference compared to UC was reduced and nonsignificant (mean difference −.38, $P = .52$, 95% CI = −1.54 to .78, $d = .1$). Sensitivity analysis with the per-protocol sample (only included those meeting the inclusion criteria at baseline, ie, RMDQ ≥3 and receiving at least 1 session of PACT or UC) and using baseline observation carried

Table 1. Baseline Continuous Demographic and Clinical Characteristics by Treatment Group, Randomized Sample

	Usual Care (N = 124)			PACT (N = 124)			Total (N = 248)		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Age	124	47.5	14.0	124	48.4	14.6	248	47.9	14.3
BMI	112	29.1	5.2	113	28.6	5.9	225	28.9	5.6
RMDQ*,[27]	124	10.8	5.8	124	10.7	5.7	248	10.7	5.7
Pain	123	6.1	1.9	123	6.1	2.1	246	6.1	2.0
PSFS[33]	122	4.7	2.3	120	4.6	2.3	242	4.7	2.3
WSAS[34]	124	16.7	9.3	124	17.2	9.5	248	16.9	9.4
Life satisfaction	122	5.9	2.6	120	5.8	2.6	242	5.9	2.6
PHQ9[31]	124	7.4	5.7	124	7.6	6.2	248	7.5	5.9
GAD7[32]	124	6.6	5.6	124	6.3	5.5	248	6.4	5.5
CPAQ[38]	123	24.3	8.6	124	25.3	8.3	247	24.8	8.5
CAQ[34]	123	32.3	8.8	124	30.6	8.7	247	31.5	8.8
PSEQ[40]	123	36.5	13.5	124	37.6	14.7	247	37.1	14.1
SF12 physical[42]	123	37.3	7.9	122	38.3	8.7	245	37.8	8.3
SF12 mental[42]	123	46.8	10.6	122	46.1	10.5	245	46.5	10.6

BMI, body mass index.
*Measures reference numbers in superscript.

Table 2. Baseline Categorical Demographic and Clinical Characteristics by Treatment Group, Randomized Sample

		Usual Care (N = 124)		PACT (N = 124)		Total N = 248	
		N	%	N	%	N	%
Gender	Male	53	42.7	48	38.7	101	40.7
	Female	71	57.3	76	61.3	147	59.3
	Total	124	100.0	124	100.0	248	100.0
Ethnicity	White	74	59.7	72	58.1	146	58.9
	Mixed	7	5.6	7	5.6	14	5.6
	Asian	9	7.3	10	8.1	19	7.7
	Black	32	25.8	31	25.0	63	25.4
	Other/unknown	2	1.6	4	3.2	6	2.4
	Total	124	100.0	124	100.0	248	100.0
Marital status	Unmarried	35	28.5	32	26.0	67	27.2
	Married/partner	64	52.0	63	51.2	127	51.6
	Separated/divorced/widowed	24	19.5	28	22.8	52	21.1
	Total	123	100.0	123	100.0	246	100.0
Education	No qualifications	17	13.8	24	19.7	41	16.7
	High school diploma equivalent	34	27.6	36	29.5	70	28.6
	AP equivalent	27	22.0	24	19.7	51	20.8
	Degree/equivalent	45	36.6	38	31.1	83	33.9
	Total	123	100.0	122	100.0	245	100.0
Work status	Employed F/T	59	48.4	50	41.3	109	44.9
	Employed P/T	28	23.0	31	25.6	59	24.3
	Unemployed	17	13.9	17	14.0	34	14.0
	Retired	18	14.8	23	19.0	41	16.9
	Total	122	100.0	121	100.0	243	100.0

forward to impute missing data were carried out. These confirmed the robustness of the intention-to-treat estimate with estimates of the treatment effect of -1.43 ($P = .008$) and $-.85$ ($P = .041$), respectively (Table 4, Supplementary Materials).

Secondary Outcomes and Process Variables

Participants who received PACT rated their treatment as more credible compared then those receiving UC physical
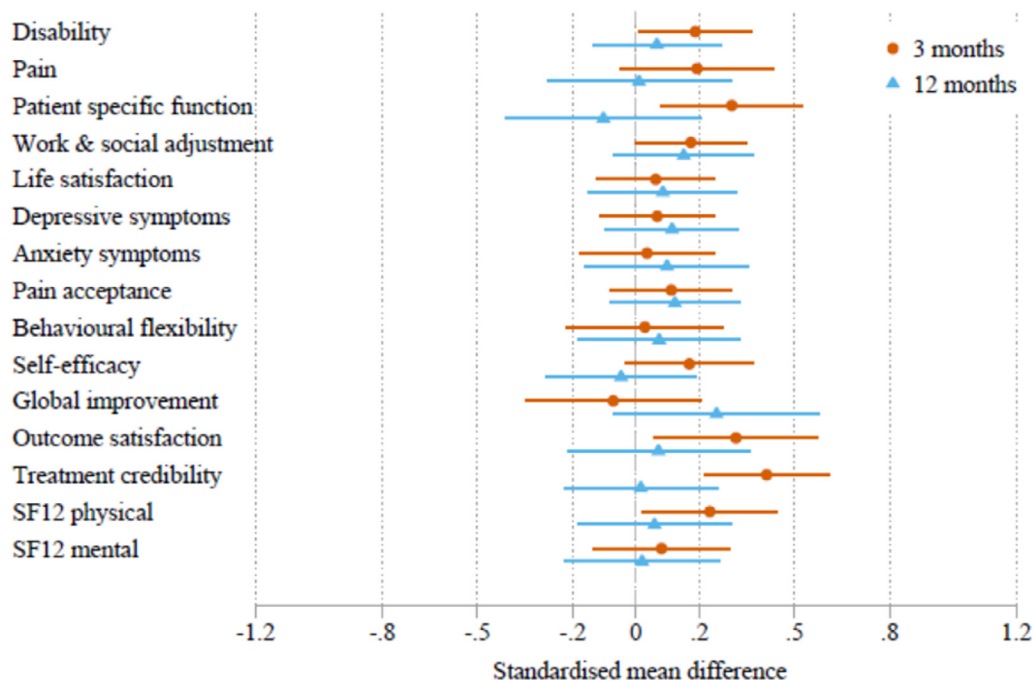
Figure 2. Standardized treatment effect sizes with 95% confidence intervals.

therapy at 3 months. PACT patients also reported better outcome on the Patient-Specific Functional Scale, SF-12 physical health scale and Work and Social Adjustment Scale at 3, but not 12 months (supplementary Materials). No group differences were observed for measures of pain, mood, self-efficacy, or the ACT process variables (acceptance [CPAQ-8] and committed action [CAQ-8]) at 3 or 12 months. Twenty-one trial participants reported adverse events, 9 from PACT and 12 from UC. The Trial Steering Committee concluded that no adverse events reported by patients were related to treatment.

Fidelity

Eight physical therapists delivered PACT (mean age 33, range = 24−44 years; 5 female). Bespoke fidelity measures were developed for this trial, including all the elements of treatment that were expected to be delivered in each session. Seventy-two (20%) audio tapes were rated by independent assessors. Prior to the calibration of scores, overall agreement between raters was 85% (474/560 decisions; 95% CI = 81−88%), when rating whether treatment elements were fully completed, partially completed, or not completed. Treatment fidelity was calculated according to whether a minimum of 80% of treatment elements were rated as being completed/partially completed by the physical therapist, from calibrated total scores for each individual session. The results confirmed physical therapist adherence to the PACT intervention was high,[45] with overall 88% (95% CI = 78−94%) treatment fidelity achieved across sessions (session 1: 97%, 95% CI = 84−100%; session 2: 81%, 95% CI = 62−94%; session 3: 77%, 95% CI = 46 −95%). Fidelity assessment also revealed that only a few core ACT methods were delivered overall, with average ACT fidelity across all 72 sessions scored as 16.4 out of

40. This was as expected after only 2 days' training in this ACT informed physical therapy treatment.

Cost Consequences

The cost-consequences analysis revealed the total CLBP-associated costs in the PACT arm were £19,776, or £193.88 per patient, compared to £20,286 or £220.50 per patient, in the UC physical therapy arm. However, PACT had additional one-off training costs of £11,958. UK NHS (public health service) resource use across the 3-time points was very comparable between the 2 groups. Over the 12-month follow-up period, resource utilization was similar between groups, with direct NHS healthcare costs accounting for 25% (£151,345.77/ £595,821.07) of total costs, while 13% (£77,673.00) was attributable to private costs paid for by the patient and 62% (£366,802.30) to societal costs, such as time off work. Direct NHS healthcare costs reduced in both groups over time and were £98.79 per person cheaper at 12 months' follow-up in UC and £104.63 cheaper per person in PACT. Costs associated with absenteeism fell from £597.25 to £223.63 per person in UC and from £447.72 to £244.43 per person in PACT.

Discussion

This is the first trial to test the efficacy of an ACT-informed physical therapist-delivered intervention for people with CLBP. PACT significantly improved participants' back pain disability at the primary end point of 3 months' follow-up compared to UC physical therapy, although effect sizes were small and not sustained at 12 months. PACT participants achieved a clinically meaningful reduction of over 3 points on the RMDQ at both 3 and 12 months compared to baseline levels; UC also

achieved a clinically meaningful reduction of 2 points at 3 months and 12 months, where 2 to 3 points are generally judged to be clinically important.[27] PACT participants showed significantly greater improvements in secondary measures of pain-related interference at 3 but not 12 months. People who received PACT rated their treatment as having greater credibility. The cost-consequences analysis revealed no major cost differences between PACT and UC (with PACT training costs excluded, as this type of brief training could be incorporated into continuing professional development) and that resource use reduced over time in both groups, which could reflect improvements due to treatment or simply the natural history of the condition. PACT had lower attrition and total treatment was completed within a mean of 2 hours, in contrast to 3 hours for UC. No between-group differences were observed on the remaining secondary outcomes including pain, mood, self-efficacy, or the ACT process variables (acceptance and committed action). PACT was designed to shift the focus from pain to daily functioning and as reducing pain was not the primary aim of treatment, it was not surprising that there was no difference between groups. Depression and anxiety scores in the PACT trial were below clinical cut-offs at baseline and were minimally targeted as part of treatment, which could explain the lack of change in these measures.

Previous research established ACT was effective for treating chronic pain,[20,46] with small to medium effects on functioning and disability and suggested combining it with physical therapy might make it more acceptable to patients with CLBP referred to that service.[24] Our results support these findings and are in line with a recent meta-analysis of CBT for non-specific low back pain, which found the effect of CBT versus other recommended active treatments ranged from small to moderate; and that most studies maintained a clinically meaningful 30% decrease in the RMDQ over the long term.[18]

Recruitment and retention data suggest the trial was well designed and implemented and that PACT was an acceptable treatment approach for patients with CLBP referred to physical therapy. Of the 660 patients informed about the study by their physical therapist, 72% (478) were screened and 248 (51.8%) met selection criteria and agreed to participate. Retention in the trial was excellent, with 219 (88.3%) providing follow-up data. These findings are supported by our nested qualitative study of 20 PACT participants, which also indicated treatment was acceptable to participants. This is essential as treatment expectancy and credibility have been shown to be associated with better outcome in physical and CBT treatments of patients with CLBP.[47]

The PACT treatment approach also has potential to address physical therapists' barriers to using psychological techniques effectively.[25] Recent research has highlighted some of the complexity in psychologically informed treatment,[13] such as treatment specification, cost, and intervention fidelity, which we have explored in this trial. In addition, systematic reviews have concluded that physical therapists' lack of confidence in successfully delivering psychological interventions might be rectified with additional training and support.[16,19] We have demonstrated that

ACT-related skills could be successfully integrated into usual physical therapy with additional staff training and support. Our 2-day training and on-going monthly supervision seem to have provided suitable support, enabling physical therapists to deliver PACT with high fidelity. Feedback within training sessions indicated that none of the methods trained deviated substantially from what the physical therapists would consider within their scope of practice. This is imperative because higher levels of treatment fidelity are associated with better retention rates and treatment outcomes.[45] Our nested qualitative study of PACT physical therapist found treatment was acceptable and feasible. These findings suggest PACT could successfully broaden physical therapists' scope of practice when treating patients with CLBP. However, our results suggest structural barriers, like the availability of private rooms and supervision/support, need to be addressed for physical therapists to incorporate psychological techniques successfully.

Both groups in the trial were comparable at baseline demonstrating randomization worked well and both received physical therapy, with separate groups of clinicians delivering the treatments, which limits bias and strengthens the validity of results. However, there were some sources of bias that need to be considered. Some aspects of the trial were more pragmatic than explanatory (see PRECIS figure in Supplementary Materials) and as a result, a higher percentage of UC participants received no treatment. However, the rate of non-attendance was similar to previous reports from UK physical therapy trials in this population.[43] A weakness of the study was our inability to collect accurate information on the number and type of care providers in the UC arm or comparable data on the UC sessions patients attended. In addition, as most participants who were lost to follow-up did not return questionnaires, we were not able to collect the reasons why they were lost to follow-up. The PACT trial restricted eligibility to participants speaking good English, referred to physical therapy in public hospitals in London and South East England and excluded those with severe psychiatric comorbidities common in chronic pain, which somewhat limits generalizability.

PACT was not designed to turn physical therapists into ACT practitioners and, as expected, the fidelity assessment showed that few ACT-consistent methods were delivered. Moreover, the theory-derived measures, used to assess acceptance and committed action, indicated no differences between groups. This means the mechanisms of action behind the improvement in disability with PACT are unclear and suggests the treatment needs some redesign and/or the training could be enhanced, to ensure PACT is delivered with higher competency and with greater impact on these key processes.[48] More research is required to refine the PACT intervention, enhance efficacy, and maintain effects over the longer term. It would be valuable to explore how to optimize impact on the specific intended processes of change, namely acceptance and committed action, as an important question persist about how to facilitate this with clear implications for wider delivery and training. Furthermore, in terms of mechanisms of action, it is

impossible to disentangle the benefits of employing a more psychological model of treatment delivery (longer sessions, private rooms, and on-going therapist supervision) from the specific content of sessions. In future research, we intended to further investigate training, fidelity, and competency questions. There may also have been some contamination in UC, as CBT-based methods are sometimes employed within routine physical therapy.[15,19] It is possible that PACT treatment was too brief, as it involved 1 hour less treatment than UC, and increasing the dose with additional sessions might help maintain benefits. Additional training and support materials might address these issues and could increase access to PACT. In addition, it might be fruitful to investigate if the advantages of PACT over UC are clearer in patients with greater disability or more psychosocial risk factors at baseline.

The findings from the PACT trial are encouraging and have the potential to improve the management of people with CLBP. The PACT treatment approach can address physical therapists' barriers to using psychological techniques,[25] as well as patients' concerns about finding a credible treatment offering aspects of care they value.[17] As physical therapy is a common treatment for CLBP and millions of patients are referred to physical therapists every year, even small additional benefits could have a considerable impact for patients, healthcare providers, and society. Next steps might include refining the training and support for physical therapists, as well as investigating whether to select patients and/ or provide additional treatment sessions. Further booster sessions should be considered and could be delivered remotely, as in other musculoskeletal conditions, to help maintain the effects of treatment over time. More research is warranted to develop successful care in the long term and to determine whether PACT is effective and cost effective in a larger trial.

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Ethics Committee Approval

Acknowledgments

Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jpain.2019.05.012.

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