Treatment fidelity in Physiotherapy informed by Acceptance and Commitment Therapy (PACT) trial for chronic low back pain

Dr Emma Godfrey
Health Psychology Section, IoPPN and Department of Physiotherapy, FoLSM
**Background**

- Chronic low back pain (lasting ≥ 3 months) costs billions to treat & challenging for patients, NHS and society.

- Current guidelines recommend back classes, manual therapy and exercise, and combined physical and cognitive-behavioural programme when other treatment unsuccessful (NICE, 2016).

- All standard physiotherapy is moderately effective (Artus et al. 2010).

- Many patients over treated leading to huge demands on physiotherapy services & delays in active self-management.
Psychological approaches to CLBP

• CBT good for treating chronic pain but limited access to psychologists (Eccleston et al. 2009)

• CBT delivered by physiotherapists produced only modest improvements in CLBP (BeST Trial, Lamb et al. 2010)

• Acceptance and Commitment Therapy (ACT) has good evidence base & focuses on promoting openness, acceptance and living a valued life (McCracken & Morley, 2014, Veehof et al. 2016)

• Today: Fidelity study from the PACT trial
Physiotherapy informed by Acceptance and Commitment Therapy (PACT): protocol for a randomised controlled trial of PACT versus usual physiotherapy care for adults with chronic low back pain

Emma Godfrey, Melissa Galea Holmes, Vani Wileman, Lance McCracken, Sam Norton, Rona Mose-Morris, John Pallet, Duncan Sanders, Massimo Barcellona, Duncan Critchley

ABSTRACT
Introduction: Chronic low back pain (CLBP) is a common condition and source of significant suffering, disability and healthcare costs. Current physiotherapy treatment is moderately effective. Combining theory-based psychological methods with physiotherapy could improve outcomes for people with CLBP. The primary aim of this randomised controlled trial (RCT) is to evaluate the efficacy of PACT-care for adults with CLBP in comparison with usual physiotherapy for CLBP. This study will address the feasibility of delivering PACT-care in primary care settings.

Methods and analysis: This is a two-centred, parallel-group, multicentre RCT. The trial will compare PACT-care and usual physiotherapy for CLBP. The trial will be conducted at 3 National Health Service (NHS) hospitals trusts. Inclusion criteria are: age 18–65 years, CLBP ≥12-week duration, scoring ≥3 points on the Roland-Morris Disability Questionnaire (RMMDQ) and adequate understanding of spoken and written English to participate. The trial will allocate participants to PACT-care or usual physiotherapy (UC) by a computer-generated randomisation schedule. The sample size of 240 participants will be randomly allocated to receive PACT-care or UC (120 per arm stratified by centre) by an independent randomisation service and followed up at 3 and 12 months post randomisation. The sample size of 240 participants will be randomly allocated to receive PACT-care or UC (120 per arm stratified by centre) by an independent randomisation service and followed up at 3 and 12 months post randomisation. The sample size of 240 participants will be randomly allocated to receive PACT-care or UC (120 per arm stratified by centre) by an independent randomisation service and followed up at 3 and 12 months post randomisation. The sample size of 240 participants will be randomly allocated to receive PACT-care or UC (120 per arm stratified by centre) by an independent randomisation service and followed up at 3 and 12 months post randomisation. The sample size of 240 participants will be randomly allocated to receive PACT-care or UC (120 per arm stratified by centre) by an independent randomisation service and followed up at 3 and 12 months post randomisation.

Strengths and limitations of this study
- The physiotherapy informed by Acceptance and Commitment Therapy (PACT) trial will include the first randomised controlled trial to test the efficacy of a physiotherapy-led ACT-informed intervention for chronic low back pain (CLBP) against standard physiotherapy.
- The PACT trial will assess the feasibility of training physiotherapists to deliver a novel psychologically informed physiotherapy intervention.
- The ACT-based process of change is consistent with the psychological flexibility model and will be evaluated, providing evidence for the mechanisms underlying observed outcomes.
- Restriction to participants referred to physiotherapy services and speaking English may limit generalisability of findings.
- Patients with and those with prior treatment based on multidisciplinary or cognitive-behavioural therapy (CBT) pain management at any time and other physiotherapy treatment in the previous 6 months will be excluded due to possible contamination effects.
Physiotherapy informed by ACT (PACT)

• Brief physiotherapy intervention incorporating aspects of ACT, aiming to help people self-manage by improving function rather than reducing pain & uses goal setting and behavioural activation

• Two one hour sessions, one 20 min follow-up phone-call
  ➢ Assessment, feedback, rationale
  ➢ Shifting focus from struggle with pain
  ➢ Values-based goal setting plus anticipating and addressing barriers
  ➢ Psychological skills and physiotherapy exercises

• Delivered by 8 physiotherapists (band 6-8, mean age 40, 3 male)
CLBP physiotherapy referral (n=240)

Questionnaire Assessment (0 Months)

Randomised to Usual Care (n=120)
Randomised to PACT (n=120)

PACT Session 1
PACT Session 2
PACT Booster Call

Questionnaire Assessment (3 and 12 Months)
Questionnaire Assessment (3 and 12 Months)

Primary outcome: Function at 3 months using RMDQ
Training and supervision

- 2 days of face to face training including role play
- 2 or more individual sessions of supervision to assess competency
- On-going monthly group supervision and feedback
- Physiotherapist & patient manuals
- Checklist & audio recording of sessions
Fidelity study

• Measures: bespoke treatment fidelity measures, simple ACT scale assessing the core components of ACT, Therapeutic Alliance Scale

• Random sample of 72 (20%) audio-recorded PACT treatment sessions rated

• 2 trained independent assessors rated audiotaped PACT treatment sessions

• Sample stratified by physiotherapist & by time, to decrease bias resulting from physiotherapist differences, hospital areas & amount of experience over time
Treatment length

- Mean lengths of PACT treatment sessions: 59 minutes for Session 1 (range=38-80 minutes); 45 minutes for Session 2 (range=26-67 minutes) & 15 minutes for Session 3 (range=3-25 minutes)

- Total of 1 hour and 59 minutes of treatment.

- UC treatment was calculated from patients’ attendance records as 2 hours and 59 minutes on average, receiving 1 more hour of treatment than PACT patients
## Fidelity Results

<table>
<thead>
<tr>
<th>Session</th>
<th>Number of sessions randomly selected</th>
<th>Mean calibrated total score (SD)</th>
<th>Range of calibrated total scores</th>
<th>Percentage (%) of sessions delivered with ≥ 80% fidelity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1</td>
<td>32</td>
<td>31.06 (1.65)</td>
<td>24 - 32</td>
<td>97</td>
</tr>
<tr>
<td>Session 2</td>
<td>27</td>
<td>16.07 (1.82)</td>
<td>10 - 18</td>
<td>81</td>
</tr>
<tr>
<td>Session 3</td>
<td>13</td>
<td>15.69 (1.49)</td>
<td>13 - 18</td>
<td>77</td>
</tr>
</tbody>
</table>

Table 1: Descriptive statistics for treatment fidelity for Sessions 1, 2 and 3 from calibrated assessor ratings.  
*SD = Standard Deviation*
ACT therapeutic stance and therapeutic alliance

- Average total ACT fidelity across all 72 sessions = 16.40 out of 40 (range=10-23)

- This indicated that ‘a little’ ACT was delivered, according to the anchor point ‘2’ on the Likert scale

- Average total therapeutic alliance across all 72 sessions = 27.57 out of 42 (SD=5.24, range=14.50-36.50), around mid-point of scale, and between anchor points ‘3’ (somewhat) and ‘5’ (considerably) on Likert scale
Structural issues
Conclusions

• Practical monitoring and measuring strategies can deter low treatment fidelity

• PACT was delivered with high fidelity overall (80%)

• Physiotherapists found PACT acceptable and feasible but more training needed in some ACT specific areas

• Findings suggest PACT could successfully broaden scope of practice of physiotherapists treating CLBP & inform future research
Acknowledgements

V Wileman, M Galea Holmes, L McCracken, S McLachlan & D Critchley
MSc students at KCL
Patients and staff at GSTT, KCH, Ashford & St Peters

This abstract presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-1112-29055). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Presented by: Dr Emma Godfrey  Contact: emma.l.godfrey@kcl.ac.uk


• Scott W and McCracken L. Current Opinion in Psychology 2015, 2:91–96