BMJ Open

Testing a newly developed activity pacing framework for chronic pain/fatigue: a feasibility study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-045398
Article Type:	Original research
Date Submitted by the Author:	29-Sep-2020
Complete List of Authors:	Antcliff, Deborah; Bury and Rochdale Care Organisation, Northern Care Alliance NHS Group, Physiotherapy Department; University of Leeds Faculty of Medicine and Health, School of Healthcare Keenan, Anne-Maree; University of Leeds, School of Healthcare, University of Leeds Keeley, Philip; Keele University School of Nursing and Midwifery Woby, Steve ; Salford Royal NHS Foundation Trust, Research and Innovation Department; University of Salford School of Health and Society McGowan, Linda; University of Leeds, School of Healthcare
Keywords:	PAIN MANAGEMENT, REHABILITATION MEDICINE, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title: Testing a newly developed activity pacing framework for chronic pain/fatigue: a feasibility study

AUTHORS

Dr Deborah Antcliff (PhD)[a,b]

[a]Physiotherapy Department, Bury and Rochdale Care Organisation, Northern Care Alliance NHS Group, Bury, United Kingdom.

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom.

Professor Anne-Maree Keenan (PhD)[b]

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom

Professor Philip Keeley (PhD)[c]

[c]School of Nursing and Midwifery, Keele University, Keele, United Kingdom

Professor Steve Woby (PhD)[d,e,f]

[d]Research and Innovation Department, Northern Care Alliance NHS Group, Salford, United Kingdom.

[e]School of Health and Society, University of Salford, Salford, United Kingdom.

[f]Faculty of Science and Engineering, Manchester Metropolitan University, Manchester, United Kingdom.

Steve.Woby@srft.nhs.uk

Professor Linda McGowan (PhD)[b]

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom

CORRESPONDING AUTHOR

Dr Deborah Antcliff (PhD)

Physiotherapy Department

Fairfield General Hospital

Bury and Rochdale Care Organisation

Northern Care Alliance NHS Group

Rochdale Old Road

Bury, England

BL9 7TD

United Kingdom

Deborah.Antcliff@pat.nhs.uk

Tel: +44 (0)7769683646

Fax: Nil available

ORCID ID: 0000-0002-9771-8232

Institutional URL: http://www.leeds.ac.uk/

Word count: 4,122 words

KEY WORDS

Pain management; Rehabilitation medicine, Musculoskeletal disorders

ABSTRACT

Objectives: To test the feasibility of using a new activity pacing framework to standardise healthcare professionals' instructions of pacing, and explore whether measures of pacing/symptoms detected changes following treatment.

Design: Single-arm, repeated measures study.

Setting: A single NHS Pain Service in Northern England, U.K.

Participants: Adult patients with chronic pain/fatigue, including chronic low back pain, chronic widespread pain, fibromyalgia and chronic fatigue syndrome/myalgic encephalomyelitis.

Interventions: Six-week rehabilitation programme, standardised using the activity pacing framework.

Outcome measures: Feasibility was explored via patients' recruitment/attrition rates, adherence and satisfaction, and healthcare professionals' fidelity. Questionnaire data were collected from patients at the start and end of the six-week programme (T1/T2) and three months' follow-up (T3). Questionnaires included measures of activity pacing, current/usual pain, physical/mental fatigue, depression, anxiety, self-efficacy, avoidance, physical/mental function and quality of life. Mean changes and relationships between pacing and symptoms (T1-T2/T1-T3) were estimated.

Results: Of the 139 eligible patients, 107 patients consented (recruitment rate=77%); 65 patients completed T2 (T1-T2 attrition rate=39%), and 52 patients completed T3 (T1-T3 attrition rate=51%). At T2, patients' satisfaction ratings averaged 9/10, and 89% attended ≥5 sessions. Activity pacing and all symptoms improved between T1-T2, with smaller improvements maintained at T3. Between T1-

T2, changes in pacing significantly correlated with current pain (r_s=-0.29, p=0.019), self-efficacy (r_s=0.26-0.39, p<0.05) and mental function (r_s=0.27-0.28, p<0.05). Between T1-T3, there were additional significant correlations between changes in pacing and physical/mental fatigue, depression, anxiety and quality of life (p<0.05). There were no significant correlations with physical function/avoidance.

Conclusion: The activity pacing framework was feasible to implement and patients' ability to pace and manage their symptoms improved. Future work will employ a suitable comparison group and test the framework across wider settings to explore the effects of activity pacing in a randomised controlled trial.

Trial registration: ClinicalTrials.gov:NCT03497585

Funding: Health Education England/National Institute for Health Research

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This was the first study to test the feasibility of using a newly developed activity pacing framework in a rehabilitation programme to standardise the clinical instructions of activity pacing to patients with chronic pain/fatigue.
- This feasibility study recruited to target with satisfactory recruitment/attrition rates which form the basis of a future RCT.
- A comprehensive measure of pacing: the activity pacing questionnaire (APQ-28), and range of validated psychometric measures were suitable to detect changes before and after treatment.
- This study was not powered with a control arm to determine treatment effectiveness, and the exploratory statistical analyses do not indicate causation between increased activity pacing and improved symptoms.

- The generalisability of this study is limited to a sample of predominantly females, of white ethnic origin, and from a single Pain Service.

INTRODUCTION

Activity pacing is a principal coping strategy for patients with long-term conditions, including chronic low back pain, chronic widespread pain, fibromyalgia and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME),[1-5]. Chronic pain and chronic fatigue are known to co-exist,[6, 7] and overlap in symptoms, including depression, anxiety and disability,[8-11]. Conditions of chronic pain/fatigue may share similar disease processes: physical deconditioning following under-activity/avoidance, pathophysiological/psychological processes and central sensitisation,[11-16]. Treatments aim to reverse some of these processes: to improve physical/mental functioning, increase tolerance and improve quality of life,[12, 15, 17]. Recommended treatments include psychological therapies (for example, cognitive behavioural therapy) and graded exposure to activity/exercise,[15, 16]; of which activity pacing is a key component,[18-20].

Patients with chronic pain/fatigue may present with altered behaviours, including underactivity or avoidance of activities that are perceived as harmful or that may exacerbate symptoms; over-activity or excessive persistence to push through/distract from symptoms; or fluctuations between underactivity-overactivity,[21]. Activity pacing provides an alternative behaviour to enable patients to (re-)engage with activities in a manner that encourages their progression towards more regular or improved functioning,[4, 22, 23].

At present, there remains confusion regarding how activity pacing is defined or interpreted, and the effects on patients' symptoms,[5, 24, 25]. There is no widely-used guide to standardise how healthcare professionals instruct pacing to patients; and uncertainty whether different methods are required for symptoms of chronic pain versus chronic fatigue,[3, 26]. This poses challenges how to advise patients with both chronic pain and fatigue.

We have developed an activity pacing framework using an inclusive approach for patients who present at rehabilitation services with chronic pain and/or fatigue. Using the Medical Research Council guidelines for developing complex interventions, mixed methods were implemented to encompass theoretical and stakeholder standpoints,[27]. Stage I: Healthcare professionals' survey gathered opinions on activity pacing (n=92),[4]. These findings, together with existing research formed the first draft of the framework and accompanying appendices. Stage II: Nominal group technique refined the activity pacing framework using a consensus meeting between patients and healthcare professionals (n=10),[28].

The conceptual model of the activity pacing framework *(see Figure 1)* follows principles of quota-contingency/operant approach (for example, setting goals according to time/distance/activity), with a rehabilitative aim of improving participation in meaningful activities and self-efficacy while managing symptoms,[4, 28]. Quota-contingency is advised alongside concepts of flexibility and choice to enable relevance and sustainability in conditions where symptoms may vary. The framework refers to all types of activities including work, household activities,

cognitive activities, physical activities, exercise and relaxation to increase its wider relevance for patients with chronic pain and/or fatigue, for varying abilities and behaviours.

The aim of this study was to test the feasibility of using the activity pacing framework to underpin a rehabilitation programme for chronic pain/fatigue. To inform a future definitive trial, specific objectives included: (1)Exploring participant recruitment/attrition rates and adherence/acceptability (for both chronic pain and fatigue); (2)Exploring healthcare professionals' fidelity to the framework; (3)Exploring the suitability of the outcome measures, including the modified activity pacing questionnaire (APQ-28); and (4)Exploring associations between changes in activity pacing and self-reported symptoms.

METHODS

Study design

This single-arm, repeated measures study is reported as a non-randomised feasibility study using the extended CONSORT guidelines,[29, 30] *(See Supplementary Table 1)*. Quantitative questionnaire data were collected from patients at the start (T1) and end (T2) of the six-week rehabilitation programme, and at three month's follow-up (T3). The study was prospectively registered (protocol available at ClinicalTrials.gov: NCT03497585). Ethical approval was granted by the London-Surrey Research Ethics Committee (18/LO/0655). The acceptability interviews with patients and healthcare professionals will be reported elsewhere.

Participant recruitment

Participants were identified from consecutive referrals to a rehabilitation programme for chronic pain/fatigue in a Pain Service in Northern England, United Kingdom. All patients attended a minimum of one face-to-face appointment before referral to the programme. Participants received the study information via the post one week before attending the programme and/or during the first session of the programme. The consent form was completed either at home or during the first session.

Eligibility criteria

Eligible patients were aged ≥18 years, with symptoms for ≥3 months and with a general practitioner or hospital consultant diagnosis of chronic low back pain, chronic widespread pain, fibromyalgia or CFS/ME. Patients were required to read and write in English. Ineligible patients were those with evidence of a serious underlying pathology, such as a current diagnosis of cancer, or patients with severe mental health or cognitive functioning issues.

Sample size

A sample size of 50 patients has been recommended for feasibility studies to enable estimates of recruitment/attrition, means/standard deviations and changes in means to prepare for future clinical trials,[31]. To attain a sample of 50 participants at T3, it was estimated that 340 patients may need to be approached to allow for a 50%

recruitment rate at T1, a 40% attrition rate between T1-T2 and a 50% return rate at T3.

Existing rehabilitation programme

The existing rehabilitation programme comprised of six consecutive weekly sessions (each 3.5 hours) delivered by healthcare professionals (pain specialist physiotherapists and psychological wellbeing practitioners). The programme included understanding complex symptoms, sleep hygiene, graded exercise, goal setting, relaxation and mindfulness. Activity pacing was instructed in one session but was not informed by any particular framework.

Activity pacing framework standardised programme

The existing six-week programme was modified though re-structuring and standardisation using the activity pacing framework. Activity pacing was formally instructed on two sessions (weeks 2-3), but also referenced throughout the programme in relation to other coping strategies. Practical exercises included completing an activity diary to discuss patients' activity patterns and setting goals in which activity pacing could be practised. The healthcare professionals (as above) received training on the framework during a half-day session and could contact the lead researcher (DA) for any queries. All patients attended the standardised programme, but participants chose whether to complete the study questionnaires.

Data collection

Feasibility outcomes

Measures of feasibility included participant recruitment/attrition rates, adherence (number of sessions attended), acceptability (two satisfaction rating scales regarding the programme content and length where 0=dissatisfied and 10=fully satisfied), and missing data in the questionnaire. For every programme, healthcare professionals completed a 13-item fidelity checklist based on the conceptual model of the activity pacing framework to ensure their inclusion of key elements from the framework. Each clinician was observed once by the lead researcher.

Clinical measures

The self-reported questionnaire booklets (T1, T2 and T3) included standardised clinical measures. T1 could be completed during session one or at home, T2 could be completed during session six, and T3 was sent in the post to be completed at home. Telephone reminders were made if the T3 questionnaires were not returned within two weeks. The T1 booklet contained demographic questions, in addition to following measures included in T2 and T3:

(1) Activity pacing was measured using the Activity Pacing Questionnaire (APQ-28). The APQ 26-item version was initially validated among patients with chronic pain/fatigue and contained five subthemes: Activity adjustment, Activity planning, Activity consistency, Activity acceptance and Activity progression (Cronbach's

alpha=0.72-0.92),[32]. Each item is scored between 0='never did this' and 4='always did this'. Two items have been added that correspond to important aspects of pacing that emerged during the development of the activity pacing framework. The new items: APQ12:"I found a baseline amount of activities that I could do on 'good' and 'bad' days" and APQ15:"I had a flexible approach with my activities" were added to the subthemes of best conceptual fit (Activity adjustment and Activity acceptance respectively). Each subtheme was calculated as a mean score. The APQ-28 subthemes, similarly to the following scales, permitted one missing item per subscale.

(2) Current and usual pain were measured using two 11-point numerical rating scales (NRS), where 0='no pain' and 10='worst possible pain',[33].

(3) Physical fatigue (seven items) and mental fatigue (four items) were measured using the Chalder Fatigue Questionnaire (CFQ), where scores of 1='much worse than usual' and 4='better than usual',[34]. Two subscale scores were summated where higher scores indicated less fatigue.

(4) Depression was measured using the nine item Patient Health Questionnaire (PHQ-9). Items were rated between 0='not at all' and 3='nearly everyday'. Total scores of 1-4=minimal depression, 5-9=mild depression, 10-14=moderate depression and ≥15=severe depression,[35, 36].

(5) Anxiety was measured using the seven-item Generalised Anxiety Disorder Assessment (GAD-7). Total scores of 5-9=mild anxiety, 10-14=moderate anxiety and ≥15=severe anxiety,[37].

(6) Self-efficacy was measured using the 10-item Pain Self-Efficacy Questionnaire (PSEQ) where items were rated between 0='not at all confident' and 6='completely confident'. Total scores of PSEQ≥40 indicate those patients who are more likely to continue implementing coping strategies/behavioural changes, and PSEQ≤16 are considered low,[38].

(7) Avoidance was measured using the 'Escape and Avoidance' subscale of the Pain Anxiety Symptoms Scale-short version (PASS-20),[39]. The five items were rated between 0='never' and 5='always' where higher total scores indicated greater avoidance.

(8) Physical and mental function were measured using the 12-Item Short-Form Health Survey (SF-12). Two subscale scores (out of 100) were calculated using the SF-12 software (Version 2; one-week recall) where higher scores indicated better function,[40].

(9) Health-related quality of life was measured using the EQ-5D-5L (EuroQol). The EQ-5D-5L was calculated as an index score,[41, 42].

Data analysis

Feasibility outcomes and participants' demographics were analysed using descriptive statistics. Clinical outcomes were estimated as changes in activity pacing and symptoms between T1-T2, T2-T3 and T1-T3 (mean change, 95% confidence intervals), and exploratory analyses of correlations between changes in activity pacing and symptoms (T1-T2/T1-T3). The validity of the modified APQ-28 was estimated using Cronbach's alpha and item correlations; and sensitivity analyses explored the effects of including two new APQ items. Data were analysed using IBM SPSS Statistics 26 statistical software (IBM Corp, Armonk, New York).

Patient and Public Involvement

Patient and Public Involvement (PPI) commenced during the initial planning stages of the mixed methods programme to develop and test the activity pacing framework. A meeting with five PPI representatives discussed the study purpose and practical issues around the proposed methods (online survey, nominal group technique, and feasibility and acceptability studies). PPI guided on improving the accessibility of patients' participation and reducing burden. A PPI representative has acted as an advisor on the study, involving commenting on study documents/questionnaire booklets and coding qualitative interviews. Acceptability interviews with patients explored practical issues surrounding the feasibility study (to be reported elsewhere) which will further assist the planning of a future activity pacing RCT.

RESULTS

Recruitment and T1 data collection commenced in May 2018 and T3 data collection ended in December 2019 due to attaining the target sample.

Demographics

Among the 107 participants who completed the baseline (T1) measures, participants were predominantly female (n=92, 86.0%) with a mean age of 55.25 +/- 12.83 years. Low back pain was most frequently reported (n=79, 73.8%) and CFS/ME least frequently reported (n=12, 11.2%). Sixty-five participants (61.3%) reported two or more conditions of chronic pain and/or fatigue. Of the 12 participants with CFS/ME, 10 participants reported CFS/ME as their main condition, and 11 reported at least one co-morbidity of LBP (n=7), chronic widespread pain (n=6), fibromyalgia (n=7) or another condition (n=3). *(See Table 1 for participant demographics and Table 2 for baseline scores for activity pacing and symptoms.)*

Table 1. Participant demographics at baseline (T1)

	Participants who completed T1 but not T2	**Participants who completed T1 and T2**	**Total**
Gender	(n=42)	(n=65)	(n=107)
Male	6 (14.3%)	9 (13.8%)	15 (14.0%)
Female	36 (85.7%)	56 (86.2%)	92 (86.0%)
Age (years)	(n=41)	(n=65)	(n=106)
	Mean=56.07	Mean=54.74	Mean=55.25
	(SD=13.85)	(SD=12.22)	(SD=12.83)

Ethnicity	(n=41)	(n=65)	(n=106)
White (British, Irish, Other)	39 (92.9%)	60 (92.3%)	99 (93.4%)
Black (Caribbean, African)	0 (0.0%)	1 (1.5%)	1 (0.9%)
Mixed (white/black, white/Asian, other)	1 (2.4%)	2 (3.1%)	3 (2.8%)
Asian (Indian, Pakistani, Bangladeshi, other)	1 (2.4%)	2 (3.1%)	3 (2.8%)
Asian Eastern (Chinese, other)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Living situation*	(n=42)	(n=65)	(n=107)
Lives alone	7 (16.7%)	10 (15.4%)	17 (15.9%)
Lives with partner	25 (59.5%)	48 (73.8%)	73 (68.2%)
Lives with children	16 (38.1%)	24 (36.9%)	40 (37.4%)
Other	2 (4.8%)	1 (1.5%)	3 (2.8%)
Employment	(n=42)	(n=65)	(n=107)
Working (full-time, part-time, in the house, student)	13 (31.0%)	31 (47.7%)	44 (41.1%)
Not working (due to chronic pain/fatigue/other condition)	15 (35.7%)	19 (29.2%)	34 (31.8%)
Retired/semi-retired	14 (33.3%)	14 (21.5%)	28 (26.2%)
Other	0 (0.0%)	1 (1.5%)	1 (0.9%)

Conditions*:	(n=41)	(n=65)	(n=106)
Low back pain	30 (71.4%)	49 (75.4%)	79 (73.8%)
Widespread pain	19 (45.2%)	33 (50.8%)	52 (48.6%)
Fibromyalgia	9 (21.4%)	20 (30.8%)	29 (27.1%)
CFS/ME	6 (14.3%)	6 (9.2%)	12 (11.2%)
Other	9 (21.4%)	12 (18.5%)	21 (19.6%)
Number of the above conditions (multiple co-morbidities):	(n=41)	(n=65)	(n=106)
1	17 (40.5%)	24 (36.9%)	41 (38.7%)
2	19 (45.2%)	30 (46.2%)	49 (46.2%)
3	3 (7.1%)	9 (13.8%)	12 (11.2%)
4	1 (2.4%)	1 (1.5%)	2 (1.9%)
5	1 (2.4%)	1 (1.5%)	2 (1.9%)
Duration of participants' main condition (years)	(n=35) Mean=10.23 (SD=9.49)	(n=61) Mean=12.94 (SD=11.36)	(n=96) Mean=11.95 (SD=10.74)

**Patients could select more than one answer.*

Table 2. Baseline scores for activity pacing and symptoms for all patients completing the baseline questionnaires (T1)

Measures	Baseline scores for those completed T1 but not T2: Mean (SD)	Baseline scores for those completed T1 and T2: Mean (SD)	Total scores
APQ-28 Activity adjustment	(n=42) 1.96 (0.87)	(n=64) 1.74 (0.76)	(n=106) 1.83 (0.81)
APQ-28 Activity planning	(n=42) 1.57 (1.03)	(n=65) 1.44 (0.95)	(n=107) 1.49 (0.98)
APQ-28 Activity consistency	(n=42) 1.91 (0.91)	(n=65) 1.82 (0.96)	(n=107) 1.85 (0.94)
APQ-28 Activity acceptance	(n=42) 1.97 (1.02)	(n=65) 1.87 (0.84)	(n=107) 1.91 (0.92)
APQ-28 Activity progression	(n=42) 1.59 (1.05)	(n=65) 1.45 (0.88)	(n=107) 1.51 (0.95)
Current pain	(n=41) 6.83 (1.96)	(n=65) 6.63 (1.97)	(n=106) 6.71 (1.96)
Usual pain	(n=40) 7.72 (1.43)	(n=63) 7.30 (1.82)	(n=103) 7.47 (1.69)
Physical fatigue	(n=41) 14.18 (5.12)	(n=62) 15.22 (4.10)	(n=103) 14.81 (4.54)
Mental fatigue	(n=42) 8.79 (3.22)	(n=64) 8.86 (2.77)	(n=106) 8.83 (2.94)

Depression	(n=40) 12.63 (7.61)	(n=64) 13.66 (6.38)	(n=104) 13.26 (6.86)
Anxiety	(n=41) 9.86 (6.64)	(n=65) 9.91 (5.47)	(n=106) 9.89 (5.92)
Self-efficacy	(n=42) 26.26 (13.85)	(n=65) 25.29 (10.60)	(n=107) 25.67 (11.93)
Avoidance	(n=42) 12.95 (6.74)	(n=64) 13.27 (5.49)	(n=106) 13.14 (5.98)
Physical function	(n=42) 33.67 (9.75)	(n=63) 34.15 (8.23)	(n=105) 33.96 (8.82)
Mental function	(n=42) 42.22 (11.51)	(n=63) 38.52 (11.10)	(n=105) 40.00 (11.36)
Quality of life	(n=40) 0.41 (0.26)	(n=60) 0.43 (0.25)	(n=100) 0.42 (0.25)

Activity pacing (Activity Pacing Questionnaire-28, APQ-28), Pain (Numerical Rating Scale 0-10), Physical/mental fatigue (Chalder Fatigue Questionnaire), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain Self-Efficacy Questionnaire), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-Form 12), Quality of life (EQ-5D-5L index score)

Feasibility outcomes

Recruitment and attrition (Objective 1)

Of the 144 patients invited to participate, 139 were eligible (96.5%). The reasons for ineligibility included: three patients reported only neck pain, one patient reported neck/knee pain and one patient reported thoracic pain. Of the 139 eligible patients, 107 (77.0%) were recruited at T1, 69 (64.5%) completed the six-week programme and 65 (60.7%) completed the T2 measures (attrition rate=39.3%). Fifty-two participants completed T3 (80.0% of T2; attrition rate from T1=51.4%). There were no serious adverse events. *(See Figure 2. CONSORT flow diagram.)*

Of the 107 participants, the median number of rehabilitation programme sessions attended was five (58.9% participants attended ≥5 sessions); 83.2% participants attended at least one activity pacing session and 56.1% attended both pacing sessions. Of the 65 participants who completed T2, the median number of sessions attended was six (89.2% participants attended ≥5 sessions); 100% of participants attended at least one pacing specific session and 54 (83.1%) participants attended both pacing sessions. There were no statistically significant differences between participants who completed T2 or dropped out in terms of demographics or baseline symptoms. Of the 12 participants with CFS/ME, six completed T2 (50%) and six completed T3 (100% of T2, 50% of T1); whereas 59 of the 95 participants without CFS/ME completed T2 (62%) and 46 completed T3 (78% of T2 and 48% of T1).

Acceptability of the rehabilitation programme/questionnaires (Objective 1)

On T2, participants rated their satisfaction of the length and content of the rehabilitation programme as mean=8.8 (SD=1.7) and 9.1 (SD=1.5) respectively. The

satisfaction of only those participants with CFS/ME was mean=9.0 (SD=0.9) and 9.2 (SD=1.0).

There were minimal missing data in the questionnaire booklets (approximately 1%). Some participants wrote comments regarding their perceived benefits of implementing activity pacing and other coping strategies. Two participants wished for a longer programme or a follow-up session *(see Figure 3 for examples of participants' comments)*.

Fidelity to the activity pacing framework (Objective 2)

Each healthcare professional observation demonstrated good adherence to the framework against a number of key points. Healthcare professionals reported 100% adherence in their fidelity checklists for each rehabilitation programme. Healthcare professionals reported that some participants spent over 20 minutes completing the questionnaire booklet, and that not all patients completed the activity diaries.

Interventions between T2 and T3

Of the 52 respondents at T3, two patients received lumbar epidural steroid injections, one patient had acupuncture, one attended a chiropractor and one patient had knee surgery.

Clinical outcomes

Validity of the modified APQ-28 (Objective 3)

At T1, the two new APQ-28 items showed ease of completion through minimal missing answers (Item APQ12=0 missing answers, Item APQ15=1 missing answer). The scores of the new items utilised the full range, and the mean scores (Items APQ12=1.67 and APQ15=1.91) sat within the range of the other APQ-28 items (mean=1.17-2.78). The new items demonstrated optimal fit with their allocated subthemes via highest inter-item correlations and item-total correlations (Item total correlations: APQ12 and Activity adjustment, $r_s(106)=0.76$, $p<0.001$; Item APQ15 and Activity acceptance, $r(106)=0.68$, $p<0.001$). The internal consistency for Activity adjustment increased with the addition of Item APQ12 (Cronbach's alpha=0.86 to 0.88), and for Activity acceptance with the addition of Item APQ15 (Cronbach's alpha=0.68 to 0.72). The internal validity of the other APQ-28 subthemes were: Activity planning=0.86, Activity consistency=0.80 and Activity progression=0.69.

Mean changes in activity pacing and symptoms (Objective 3)

Between T1-T2, all five APQ-28 subtheme mean scores increased, indicating improved activity pacing. There were small reductions in APQ-28 scores between T2-T3. However, all five subthemes showed overall improvements between T1-T3, with Activity planning showing the greatest increases *(see Table 3).* Sensitivity analyses showed marginal increases in mean changes following the addition of the new APQ-28 items.

Between T1-T2, the mean scores of all symptoms improved. Current pain reduced more than usual pain. Physical and mental fatigue both improved, as did self-efficacy and quality of life. Mental function improved more than physical function. Depression, anxiety and avoidance all reduced. There was some deterioration in symptoms between T2-T3, but between T1-T3 all symptoms demonstrated clear improvements except avoidance (-1.46, 95% CI=-3.02 to 0.10) and physical function (1.62, 95% CI=-0.81 to 4.06) *(see Table 3.).* Observing only the subgroup of participants with CFS/ME, improvements were seen between T1-T2 and T1-T3 across all APQ-28 subthemes and symptoms.

Table 3. Mean change in the five subthemes of activity pacing (APQ-28) and all measures of symptoms between T1 (baseline), T2 (end of 6-weeks' treatment) and T3 (3-months' follow-up)

	T1 mean (SD) T2 mean (SD)	T2-T1 mean change (95% confidence interval)	T2 mean (SD) T3 mean (SD)	T3-T2 mean change (95% confidence interval)	T3 mean T1 mean	T3-T1 mean change (95% confidence interval)
APQ-28 Activity adjustment	(n=63) T1 mean=1.73(0.77) T2 mean=2.43(0.73)	0.70 (95% CI= 0.48 to 0.91)	(n=51) T2 mean=2.44(0.72) T3 mean=2.32(0.90)	-0.12 (95% CI= -0.36 to 0.11)	(n=50) T1 mean=1.75(0.78) T3 mean=2.33(0.90)	0.58 (95% CI= 0.33 to 0.83)
APQ-28 Activity planning	(n=65) T1 mean=1.44(0.95) T2 mean=2.42(0.87)	0.99 (95% CI= 0.72 to 1.26)	(n=52) T2 mean=2.45(0.87) T3 mean=2.06(1.02)	-0.39 (95% CI= -0.70 to -0.07)	(n=52) T1 mean=1.42(0.96) T3 mean=2.06(1.02)	0.64 (95% CI= 0.36 to 0.92)
APQ-28 Activity consistency	(n=65) T1 mean=1.82(0.96) T2 mean=2.65(0.74)	0.84 (95% CI= 0.60 to 1.07)	(n=52) T2 mean=2.66(0.71) T3 mean=2.37(0.72)	-0.29 (95% CI= -0.54 to -0.04)	(n=52) T1 mean=1.86(1.00) T3 mean=2.37(0.72)	0.51 (95% CI= 0.24 to 0.78)

APQ-28 Activity acceptance	(n=65) T1 mean=1.87(0.84) T2 mean=2.55(0.72)	0.67 (95% CI= 0.46 to 0.89)	(n=52) T2 mean=2.57(0.73) T3 mean=2.42(0.95)	-0.15 (95% CI= -0.38 to 0.08)	(n=52) T1 mean=1.84(0.91) T3 mean=2.42(0.95)	0.58 (95% CI= 0.33 to 0.84)
APQ-28 Activity progression	(n=65) T1 mean=1.45(0.88) T2 mean=2.39(0.89)	0.94 (95% CI= 0.65 to 1.22)	(n=52) T2 mean=2.40(0.91) T3 mean=2.00(0.91)	-0.40 (95% CI= -0.75 to -0.05)	(n=52) T1 mean=1.45(0.85) T3 mean=2.00(0.91)	0.56 (95% CI= 0.24 to 0.87)
Current pain	(n=65) T1 mean=6.63(1.97) T2 mean=5.31(2.38)	-1.32 (95% CI= -1.91 to -0.74)	(n=52) T2 mean=5.04(2.36) T3 mean=5.65(2.31)	0.62 (95% CI= -0.08 to 1.31)	(n=52) T1 mean=6.58(1.99) T3 mean=5.65(2.31)	-0.92 (95% CI= -1.58 to -0.27)
Usual pain	(n=65) T1 mean=7.30(1.82) T2 mean=6.62(2.08)	-0.68 (95% CI= -1.19 to -0.18)	(n=51) T2 mean=6.53(2.10) T3 mean=6.55(1.91)	0.02 (95% CI= -0.48 to 0.52)	(n=50) T1 mean=7.30(1.62) T3 mean=6.54(1.93)	-0.76 (95% CI= -1.27 to -0.25)
Physical fatigue	(n=62) T1 mean= 15.22(4.10) T2 mean= 20.31(3.92)	5.08 (95% CI= 3.95 to 6.21)	(n=51) T2 mean=20.47(4.13) T3 mean=18.12(4.18)	-2.35 (95% CI= -3.44 to -1.26)	(n=49) T1 mean=15.35(3.90) T3 mean=18.18(4.16)	2.84 (95% CI= 1.34 to 4.33)

Mental fatigue	(n=64) T1 mean=8.86(2.77) T2 mean=11.28(2.43)	2.42 (95% CI= 1.75 to 3.10)	(n=51) T2 mean=11.45(2.20) T3 mean=10.92(2.34)	-0.53 (95% CI= -1.17 to 0.11)	(n=51) T1 mean=8.94(2.51) T3 mean=10.92(2.34)	1.98 (95% CI= 1.33 to 2.64)
Depression	(n=63) T1 mean=13.65(6.44) T2 mean=7.14(6.09)	-6.51 (95% CI= -7.72 to -5.31)	(n=51) T2 mean=6.27(5.49) T3 mean=9.23(5.75)	2.96 (95% CI= 1.64 to 4.29)	(n=51) T1 mean=13.18(6.35) T3 mean=9.09(5.76)	-4.09 (95% CI= -5.61 to -2.57)
Anxiety	(n=65) T1 mean=9.91(5.47) T2 mean=5.40(5.13)	-4.51 (95% CI= -5.60 to -3.42)	(n=52) T2 mean=4.65(4.47) T3 mean=6.10(5.23)	1.44 (95% CI= 0.55 to 2.33)	(n=52) T1 mean=9.47(5.06) T3 mean=6.10(5.23)	-3.37 (95% CI= -4.63 to -2.12)
Self-efficacy	(n=65) T1 mean=25.29(10.60) T2 mean=36.29(14.12)	11.00 (95% CI= 8.44 to 13.56)	(n=52) T2 mean=37.96(14.12) T3 mean=34.68(14.26)	-3.28 (95% CI= -7.17 to 0.60)	(n=52) T1 mean=25.85(10.74) T3 mean=34.68(14.26)	8.83 (95% CI= 5.86 to 11.81)
Avoidance	(n=64) T1 mean=13.27(5.49) T2 mean=10.28(5.89)	-2.98 (95% CI= -4.43 to -1.54	(n=52) T2 mean=10.85(5.93) T3 mean=12.12(5.79)	1.27 (95% CI= -0.27 to 2.81)	(n=52) T1 mean=13.58(5.66) T3 mean=12.12(5.79)	-1.46 (95% CI= -3.02 to 0.10)

Physical function	(n=63) T1 mean=34.15(8.23) T2 mean=38.82(9.06)	4.67 (95% CI= 2.69 to 6.65)	(n=49) T2 mean=39.45(8.72) T3 mean=36.63(9.69)	-2.82 (95% CI= -5.29 to -0.35)	(n=47) T1 mean=34.92(7.98) T3 mean=36.55(9.81)	1.62 (95% CI= -0.81 to 4.06)
Mental function	(n=63) T1 mean=38.52(11.10) T2 mean=45.83(11.48)	7.30 (95% CI= 4.49 to 10.12)	(n=49) T2 mean=46.75(10.82) T3 mean=44.78(10.44)	-1.97 (95% CI= -5.22 to 1.29)	(n=47) T1 mean=38.61(10.65) T3 mean=44.56(10.60)	5.95 (95% CI= 2.83 to 9.08)
Quality of life	(n=59) T1 mean=0.43(0.25) T2 mean=0.56(0.28)	0.13 (95% CI=0.07 to 0.18)	(n=48) T2 mean=0.60(0.25) T3 mean=0.51(0.28)	-0.09 (95% CI= -0.14 to -0.03)	(n=45) T1 mean=0.45(0.24) T3 mean=0.52(0.29)	0.07 (95% CI= 0.001 to 0.14)

Activity pacing (Activity Pacing Questionnaire-28, APQ-28), Pain (Numerical Rating Scale 0-10), Physical/mental fatigue (Chalder Fatigue Questionnaire), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain Self-Efficacy Questionnaire), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-Form 12), Quality of life (EQ-5D-5L index score)

Associations between changes in activity pacing and symptoms: pre-post treatment (Objective 4)

Between T1-T2, there were significant correlations between increased APQ-28 Activity acceptance and decreased current pain ($r_s(65)=-0.29$, $p=0.019$). Increased self-efficacy significantly correlated with all APQ-28 subthemes ($p<0.05$) except APQ-28 Activity adjustment. Increased mental function was significantly correlated with increased APQ-28 Activity adjustment ($r_s(61)=0.28$, $p=0.030$) and Activity acceptance ($r_s(63)=0.27$, $p=0.031$). *(See Table 4.)*

There were no statistically significant correlations between the changes in any of the APQ-28 subthemes and changes in usual pain, physical/mental fatigue, depression, anxiety, avoidance, physical function or quality of life. Sensitivity analyses found the same pattern of significant/non-significant correlations when excluding the two new APQ-28 items.

Table 4. Associations between changes in activity pacing and changes in symptoms between T1 and T2

	APQ-28 Activity adjustment	APQ-28 Activity planning	APQ-28 Activity consistency	APQ-28 Activity acceptance	APQ-28 Activity progression
Current pain	$r_s(63)=-0.06$, p=0.655	r(65)=-0.15, p=0.223	$r_s(65)=-0.06$, p=0.616	**$r_s(65)=-0.29$, p=0.019**	r(65)=-0.17 p=0.189
Usual pain	$r_s(61)=0.04$, p=0.765	r(63)=-0.21, p=0.103	$r_s(63)=0.001$, p=0.996	$r_s(63)=-0.09$, p=0.508	r(63)=-0.15, p=0.910
Physical fatigue	$r_s(62)=0.14$, p=0.270	r(62)=0.09, p=0.473	$r_s(62)=0.20$, p=0.121	$r_s(62)=0.16$, p=0.205	r(62)=0.15, p=0.256
Mental fatigue	$r_s(63)=0.03$, p=0.836	$r_s(64)=-0.02$, p=0.849	$r_s(64)=0.07$, p=0.563	$r_s(64)=-0.07$, p=0.580	$r_s(63)=-0.02$, p=0.849
Depression	$r_s(61)=-0.17$, p=0.194	$r_s(63)=-0.13$, p=0.310	$r_s(63)=-0.04$, p=0.744	$r_s(63)=-0.18$, p=0.153	$r_s(63)=-0.19$, p=0.138
Anxiety	$r_s(63)=-0.11$, p=0.415	r(65)=-0.19, p=0.122	$r_s(65)=0.02$, p=0.899	$r_s(65)=-0.19$, p=0.132	r(65)=-0.21, p=0.101
Self-efficacy	$r_s(63)=0.23$, p=0.074	**r(65)=0.31, p=0.012**	**$r_s(65)=0.26$, p=0.034**	**$r_s(65)=0.39$, p=0.002**	**r(65)=0.34, p=0.006**
Avoidance	$r_s(63)=-0.03$, p=0.801	r(64)=-0.13, p=0.294	$r_s(64)=-0.01$, p=0.932	$r_s(64)=0.09$, p=0.495	r(64)=-0.10, p=0.430

Physical function	$r_s(61)=-0.05$, p=0.708	r(63)=0.11, p=0.395	$r_s(63)=0.04$, p=0.750	$r_s(63)=0.09$, p=0.474	r(63)=0.15, p=0.230
Mental function	**$r_s(61)=0.28$, p=0.030**	r(63)=0.22, p=0.079	$r_s(63)=0.19$, p=0.135	**$r_s(63)=0.27$, p=0.031**	r(63)=0.24, p=0.056
Quality of life	$r_s(58)=0.13$, p=0.325	r(59)=0.26, p=0.051	$r_s(59)=0.05$, p=0.695	$r_s(59)=0.23$, p=0.078	r(59)=0.14, p=0.302

Significant correlations are highlighted in bold

Activity pacing (Activity Pacing Questionnaire-28, APQ-28), Pain (Numerical rating scale 0-10), Physical/mental fatigue (Chalder fatigue scale), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain self-efficacy scale), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-form 12), Quality of life (EQ-5D-5L)

Associations between changes in activity pacing and symptoms: pre-treatment to 3-months follow-up (Objective 4)

In addition to the significant correlations found during the pre-post treatment period (T1-T2) between various APQ-28 subthemes and improved current pain, self-efficacy and mental function; during the T1-T3 period the APQ-28 subthemes additionally correlated with improved physical and mental fatigue, improved quality of life, and reduced depression and anxiety ($p<0.05$). *(See Table 5.)*

Similarly to the T1-T2 period, between T1-T3, there were no significant correlations between changes in any APQ-28 subthemes and usual pain, avoidance or physical function. Sensitivity analyses showed the same pattern of results when excluding the two new APQ-28 items with the exception of two non-significant associations between: Activity adjustment and mental function ($r_s(46)=2.78$, $p=0.062$) and Activity acceptance and depression ($r_s(51)=-0.25$, $p=0.073$).

Table 5. Associations between changes in activity pacing and changes in symptoms between T1 and T3

	APQ-28 Activity adjustment	APQ-28 Activity planning	APQ-28 Activity consistency	APQ-28 Activity acceptance	APQ-28 Activity progression
Current pain	$r_s(50)=-0.07$, p=0.627	r(52)=-0.15, p=0.305	**r(52)=-0.29, p=0.036**	$r_s(52)=-0.09$, p=0.522	r(52)=-0.22, p=0.120
Usual pain	$r_s(49)=-0.08$, p=0.588	r(50)=-0.02, p=0.895	r(50)=0.07, p=0.634	$r_s(50)=-0.15$, p=0.287	r(50)=0.13, p=0.355
Physical fatigue	**$r_s(48)=0.31$, p=0.031**	**$r_s(49)=0.36$, p=0.012**	**$r_s(49)=0.34$, p=0.018**	**$r_s(49)=0.35$, p=0.014**	**$r_s(49)=0.40$, p=0.005**
Mental fatigue	$r_s(49)=0.17$, p=0.236	**r(51)=0.40, p=0.004**	**r(51)=0.36, p=0.009**	$r_s(51)=0.24$, p=0.089	**$r_s(51)=0.39$, p=0.004**
Depression	**$r_s(49)=-0.34$, p=0.016**	$r_s(51)=-0.27$, p=0.052	**$r_s(51)=-0.42$, p=0.002**	**$r_s(51)=-0.34$, p=0.016**	**$r_s(51)=-0.35$, p=0.013**
Anxiety	$r_s(50)=-0.28$, p=0.051	**r(52)=-0.31, p=0.024**	**r(52)=-0.31, p=0.024**	**$r_s(52)=-0.46$, p=0.001**	**r(52)=-0.34, p=0.015**
Self-efficacy	$r_s(50)=0.003$, p=0.984	**r(52)=0.35, p=0.010**	**r(52)=0.42, p=0.002**	$r_s(52)=0.25$, p=0.070	**r(52)=0.38, p=0.005**

Avoidance	$r_s(50)=-0.08$, p=0.580	r(52)=-0.20, p=0.148	r(52)=-0.14, p=0.320	$r_s(52)=-0.24$, p=0.092	r(52)=-0.22, p=0.126
Physical function	$r_s(46)=-0.11$, p=0.461	r(47)=0.07, p=0.653	r(47)=0.17, p=0.267	$r_s(47)=0.09$, p=0.563	r(47)=0.19, p=0.214
Mental function	**$r_s(46)=0.29$, p=0.049**	**r(47)=0.44, p=0.002**	**r(47)=0.41, p=0.004**	$r_s(47)=0.18$, p=0.236	**r(47)=0.41, p=0.004**
Quality of life	$r_s(43)=0.25$, p=0.109	**r(45)=0.36, p=0.015**	r(45)=0.23, p=0.127	**$r_s(45)=0.46$, p=0.001**	**r(45)=0.40, p=0.006**

Significant correlations are highlighted in bold

Pain (Numerical rating scale 0-10), Physical/mental fatigue (Chalder fatigue scale), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain self-efficacy scale), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-form 12), Quality of life (EQ-5D-5L)

DISCUSSION

This study fulfilled the original aims of testing the feasibility and acceptability of using a new activity pacing framework to standardise instructions of activity pacing to assist planning a future effectiveness RCT. The study recruited to target and patients with chronic pain and chronic fatigue demonstrated improvements in pacing strategies and reductions in symptoms.

Feasibility

The activity pacing framework demonstrated feasibility through excellent fidelity to the framework by healthcare professionals via self-reported checklists and observations. Acceptability was demonstrated through patients' high satisfaction scores. Not all patients completed the activity diaries, however, this was optional for patients to facilitate their own self-reflection.

The recruitment rate (77%) was higher than estimated in the study protocol (50%). This was similar to a study exploring a five-week exercise programme for chronic hip pain (recruitment rate=76%),[43]; and this rate is considered 'Good' using cut-off levels of 80%=excellent and 70%=good from a feasibility study exploring a mind-body physical activity programme for chronic pain,[44]. The attrition rate between T1-T2 (39.3%) was as predicted in the protocol (40%), and lower than the 60% attrition rates reported across other studies investigating programmes for chronic pain,[20]. The attrition rate between T2-T3 (20.0%) was lower than predicted in the protocol

(50%), and the target sample size proved feasible to attain. These recruitment/attrition rates will inform a future definitive RCT.

Regarding treatment adherence, only 56.1% of participants recruited at T1 attended both pacing sessions. Many participants (n=18, 16.8%) dropped out after the first session and therefore did not attend any pacing sessions. Reasons for early drop-out often include unrealistic expectations of symptom improvement, low motivation, or confidence to commit to programmes or behavioural changes,[20]. In comparison, attendance rates of both pacing sessions among those who completed T2 were 83.1%, and 89.2% of participants attended five or more sessions. This is comparable to adherence rates of 81% seen elsewhere,[43]; and adherence rates have been considered as 'Excellent' when 70% or more participants complete 75% of sessions,[44].

Participants reported the condition of low back pain most frequently and CFS/ME the least frequently, as per current prevalence rates,[45, 46]. Our findings re-iterate the high occurrence of co-morbidities, and frequent co-existence of chronic pain among patients with CFS/ME,[9]. Participants with CFS/ME demonstrated improvements in symptoms following treatment, in comparison to other studies in which pacing has been ineffective,[47]. Disparate to the study by White et al.,[47], the activity pacing framework encourages a rehabilitative rather than an adaptive approach. The effects of rehabilitative approaches for patients with both chronic pain and fatigue requires causative investigation.

Clinical outcomes

Activity pacing improved across all APQ-28 subthemes, the largest improvement being for Activity planning. This theme refers to planning activities, setting time targets and assessing activity levels,[32]; practical facets of pacing which may be more accessible to change. Comparably, participants showed smaller improvements in Activity acceptance. This subtheme includes setting realistic goals and allowing flexibility; facets that involve changing previous behaviours or self-enforced rules. The APQ-28 detected multidimensional changes in activity pacing, and the two new items appeared to complement the scale. Further study will validate the APQ-28 in a larger sample and estimate minimally important changes.

The aims of the activity pacing framework are to improve patients' function and quality of life. Improvements in physical function were seen between T1-T2 (mean change=4.67) that were greater than the minimally clinically important change (3.29),[48]. However, much of this improvement was lost at T3. Together with avoidance, physical function showed improvements that were not sustained at three months' follow-up. Physical function may be a component of rehabilitation in which patients feel least confident, especially those with avoidant behaviours,[20]. This may have implications for future programmes to integrate follow-up sessions to encourage longer-term maintenance of physical activity. Contrastingly, improvements in mental fatigue between T1-T2 (mean change=7.3) were better maintained between T1-T3 (mean change=5.95); and both higher than the minimally clinically important change (3.77),[48]. Quality of life also improved between T1-T2 (mean change=0.13) and much this improvement was maintained between T1-T3

(mean change=0.07); both changes exceeded the minimally important difference (0.037 +/-0.008),[49].

The activity pacing framework additionally aims to increase patients' self-efficacy. Improvements in self-efficacy were found between T1 (mean=25.29) and T2 (mean=36.29), which were well maintained at T3 (mean=34.68). Scores were lower than the ≥40 cut off. However, an improvement of >5.5 was attained which is considered a minimally important change,[50]. Both physical and mental fatigue improved, and improvements in mental fatigue appeared to be better maintained at T3. Comparisons to minimally important changes are unavailable.

Psychological health improved following the rehabilitation programme, including reduced depression scores from moderate to mild (T1=13.7, T2=7.1, T3=9.1); with a clinically significant reduction (≥5) between T1-T2,[36]. Mean anxiety scores reduced (T1=9.9, T2=5.4 and T3=6.10), and remained within the classification of mild anxiety,[37]. Although reductions in pain were not a direct aim of treatment, lower pain severity was reported.

There were fewer significant correlations between changes in activity pacing and symptoms pre-post treatment (T1-T2) than longer-term (T1-T3). This may be due to participants undertaking a more experimental phase during T1-T2 (such as finding baselines, (re-)starting activities), whereas new routines were more established between T1-T3. Noticeably, changes in activity pacing were more frequently associated with improvements in psychological wellbeing rather than physical

wellbeing. Similarly, a meta-analysis found pacing was not associated with improved physical function among patients with chronic conditions,[5].

Strengths and limitations

Despite recruiting to target, this sample was not powered with a control arm to determine treatment effectiveness. The exploratory statistical analyses were correlative and do not indicate causation between increased activity pacing and improved symptoms. As per other studies exploring activity pacing, pacing was instructed as one component of the rehabilitation programme,[5]. Therefore, improvements in symptoms may have resulted from any combination of coping strategies. A future RCT will implement a suitable control to explore the effects of pacing, while implementing the activity pacing framework in a clinically relevant setting, including alongside other coping strategies.

The generalisability of this study is limited to a sample of predominantly females and white ethnic origin. Recruitment occurred only at one Pain Service and this service had an existing rehabilitation programme for both chronic pain and fatigue. Bias may have arisen through the lead researcher delivering the healthcare professionals' training and undertaking the observations. Further work will test the activity pacing framework and study protocol across other healthcare services and explore fidelity over wider geographical locations.

It is unknown what potential bias was caused by the attrition rate. However, there were no differences at baseline between those who completed the programme and

those who dropped out. The attrition rate may be reflective of some of the clinical challenges and missed appointments surrounding the complexity of chronic pain/fatigue. Further research could explore whether providing a follow-up improves commitment to activity pacing.

Modifications for future study

Since more patients completed the T1 questionnaires during the rehabilitation sessions than at home, this may be the preferable mode of distribution. To lessen the time taken to complete the questionnaires, the PASS-20 may be considered for exclusion in future study. The whole 20-item PASS scale was included for reliability and validity, but data from only the Escape and Avoidance subscale was explored. Modifications to the inclusion criteria may include patients with any chronic spinal pain, including cervical/thoracic pain due to the frequent and similar presentation at rehabilitation services.

Conclusion

To the authors' knowledge, this is the first study to explore the clinical utility of a comprehensive activity pacing framework developed for both chronic pain and chronic fatigue. The newly developed activity pacing framework proved feasible to use clinically by healthcare professionals. Patients with both chronic pain and fatigue implemented greater activity pacing strategies following treatment, alongside reporting improvements in quality of life, psychological wellbeing, self-efficacy, pain and fatigue. Physical function and avoidance improved to a lesser extent and for the

shorter-term. Improvements in activity pacing were significantly associated with improvements in cognitive/psychological wellbeing and quality of life, but not physical function or avoidance. Future study will use the activity pacing framework in an effectiveness RCT to explore the effects of activity pacing on symptoms.

ACKNOWLEDGEMENTS

We would like to acknowledge all of the patients and healthcare professionals who were involved in this study. We would also like to acknowledge our statistical support.

SOURCES OF FUNDING

Dr Deborah Antcliff is funded by a Health Education England/National Institute for Health Research (HEE/NIHR) Clinical Lectureship for this research project.

DISCLAIMER

This paper presents independent research funded by Health Education England/National Institute for Health Research (NIHR) [Clinical Lectureship (ICA-CL-2015-01-019)]. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

CONFLICT OF INTEREST

All authors declare no conflicts of interest

AUTHOR CONTRIBUTIONS

All authors contributed to the conception and design of the study. DA undertook the acquisition of the data. All authors contributed to the analysis and interpretation of data. All authors contributed to drafting the manuscript and revising it critically for important intellectual content and have approved the final version for publication. Authors are in agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

PATIENT CONSENT FOR PUBLICATION

Not required.

DATA SHARING AGREEMENT

Deidentified participant data are available from the corresponding author (Deborah.Antcliff@pat.nhs.uk) upon reasonable request. Reuse is permitted for health and care research as long as the original authors are acknowledged. The protocol can also be requested from the author or accessed at ClinicalTrials.gov (NCT03497585).

ETHICAL APPROVAL

Ethical approval was granted by the London-Surrey Research Ethics Committee (18/LO/0655).

REFERENCES

1. Torrance N, Smith BH, Elliott AM, et al. Potential pain management programmes in primary care. A UK-wide questionnaire and Delphi survey of experts. *Fam Pract* 2011;28:41-8.

2. Nijs J, Meeus M, De Meirleir K. Chronic musculoskeletal pain in chronic fatigue syndrome: recent developments and therapeutic implications. *Man Ther* 2006;11:187-91.

3. Nielson WR, Jensen MP, Karsdorp PA, et al. Activity pacing in chronic pain: concepts, evidence, and future directions. *Clin J Pain* 2013;29:461-8.

4. Antcliff D, Keenan AM, Keeley P, et al. Survey of activity pacing across healthcare professionals informs a new activity pacing framework for chronic pain/fatigue. *Musculoskeletal Care* 2019;17:335-45.

5. Abonie US, Sandercock GRH, Heesterbeek M, et al. Effects of activity pacing in patients with chronic conditions associated with fatigue complaints: a meta-analysis. *Disabil Rehabil* 2020;42:613-22.

6. Aggarwal VR, McBeth J, Zakrzewska JM, et al. The epidemiology of chronic syndromes that are frequently unexplained: do they have common associated factors? *Int J Epidemiol* 2006;35:468-76.

7. Meeus M, Nijs J. Central sensitization: a biopsychosocial explanation for chronic widespread pain in patients with fibromyalgia and chronic fatigue syndrome. *Clin Rheumatol* 2007;26:465-73.

8. Davis LL, Kroenke K, Monahan P, et al. The SPADE Symptom Cluster in Primary Care Patients With Chronic Pain. *Clin J Pain* 2016;32:388-93.

9. Meeus M, Nijs J, Meirleir KD. Chronic musculoskeletal pain in patients with the chronic fatigue syndrome: a systematic review. *Eur J Pain* 2007;11:377-86.

10. Tavel ME. Somatic symptom disorders without known physical causes: one disease with many names? *Am J Med* 2015;128:1054-8.

11. Yunus MB. Fibromyalgia and overlapping disorders: the unifying concept of central sensitivity syndromes. *Semin Arthritis Rheum* 2007;36:339-56.

12. Nijs J, Meeus M, Van Oosterwijck J, et al. In the mind or in the brain? Scientific evidence for central sensitisation in chronic fatigue syndrome. *Eur J Clin Invest* 2012;42:203-12.

13. Arendt-Nielsen L, Morlion B, Perrot S, et al. Assessment and manifestation of central sensitisation across different chronic pain conditions. *Eur J Pain* 2018;22:216-241.

14. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85:317-32.

15. Moseley GL. A pain neuromatrix approach to patients with chronic pain. *Man Ther* 2003;8:130-40.

16. Ericsson A, Mannerkorpi K. How to manage fatigue in fibromyalgia: nonpharmacological options. *Pain Manag* 2016;6:331-8.

17. British Pain Society. Guidelines for pain management programmes for adults. London: British Pain Society, 2013.

18. Beissner K, Henderson CR, Jr., Papaleontiou M, et al. Physical therapists' use of cognitive-behavioral therapy for older adults with chronic pain: a nationwide survey. *Phys Ther* 2009;89:456-69.

19. Booth J, Moseley GL, Schiltenwolf M, et al. Exercise for chronic musculoskeletal pain: A biopsychosocial approach. *Musculoskeletal Care* 2017;15:413-421.

20. Anderson RJ, Hurley RW, Staud R, et al. Cognitive-motivational influences on health behavior change in adults with chronic pain. *Pain Med* 2016;17:1079-1093.

21. Birkholtz M, Aylwin L, Harman RM. Activity pacing in chronic pain management: One aim, but which method? Part one: Introduction and literature review. *British Journal of Occupational Therapy* 2004;67:447-52.

22. Abonie US, Edwards AM, Hettinga FJ. Optimising activity pacing to promote a physically active lifestyle in medical settings: A narrative review informed by clinical and sports pacing research. *J Sports Sci* 2020;38:590-596.

23. Jamieson-Lega K, Berry R, Brown CA. Pacing: A concept analysis of a chronic pain intervention. *Pain Res Manag* 2013;18:207-13.

24. Andrews NE and Deen M. Defining activity pacing: Is it time to jump off the merry-go-round? *J Pain* 2016;17:1359-1362.

25. Andrews NE, Strong J, Meredith PJ. Activity pacing, avoidance, endurance, and associations with patient functioning in chronic pain: a systematic review and meta-analysis. *Arch Phys Med Rehabil* 2012;93:2109-2121 e7.

26. Murphy SL, Clauw DJ. Activity pacing: what are we measuring and how does that relate to intervention? *Pain* 2010;149:582-3.

27. Craig P, Dieppe P, Macintyre S, et al. Medical Research Council Guidance. Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ* 2008;337:a1655. doi: 10.1136/bmj.a1655.

28. Antcliff D, Keenan AM, Keeley P, et al. Engaging stakeholders to refine an activity pacing framework for chronic pain/fatigue: A nominal group technique. *Musculoskeletal Care* 2019;17:354-362.

29. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud* 2019;5:114.

30. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.

31. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301-8.

32. Antcliff D, Campbell M, Woby S, et al. Assessing the psychometric properties of an activity pacing questionnaire for chronic pain and fatigue. *Phys Ther* 2015;95:1274-86.

33. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels needed in pain intensity measurement? *Pain* 1994;58:387-92.

34. Chalder T, Berelowitz G, Pawlikowska T, et al. Development of a fatigue scale. *J Psychosom Res* 1993;37:147-53.

35. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606-13.

36. Kroenke K, Spitzer RL, Williams JB, et al. The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp Psychiatry* 2010;32:345-59.

37. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-7.

38. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur J Pain* 2007;11:153-63.

39. McCracken LM, Dhingra L. A short version of the Pain Anxiety Symptoms Scale (PASS-20): preliminary development and validity. *Pain Res Manag* 2002;7:45-50.

40. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical Care* 1996;34:220-33.

41. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36.

42. van Hout B, Janssen MF, Feng Y, et al. Interim Scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L Value Sets. *Value in Health* 2012;15:708 –715.

43. Bearne LM, Walsh NE, Jessep S, et al. Feasibility of an exercise-based rehabilitation programme for chronic hip pain. *Musculoskeletal Care* 2011;9:160-8.

44. Greenberg J, Lin A, Zale EL, et al. Development And Early Feasibility Testing Of A Mind-Body Physical Activity Program For Patients With Heterogeneous Chronic Pain; The GetActive Study. *J Pain Res* 2019;12:3279-3297.

45. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. *Lancet* 2018;391:2356-67.

46. NICE. Chronic fatigue syndrome/myalgic encephalomylitis (or encephalopathy). *NICE Clinical Guideline 53 London* 2007.

47. White PD, Goldsmith KA, Johnson AL, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet* 2011;377:823-36.

48. Diaz-Arribas MJ, Fernandez-Serrano M, Royuela A et al. Minimal Clinically Important Difference in Quality of Life for Patients With Low Back Pain. *Spine (Phila Pa 1976)* 2017;42:1908-1916.

49. McClure NS, Sayah FA, Xie F, et al. Instrument-Defined Estimates of the Minimally Important Difference for EQ-5D-5L Index Scores. *Value Health* 2017;20:644-650.

50. Chiarotto A, Vanti C, Cedraschi C, et al. Responsiveness and Minimal Important Change of the Pain Self-Efficacy Questionnaire and Short Forms in Patients With Chronic Low Back Pain. *J Pain* 2016;17:707-18.

FIGURE LEGENDS

Figure 1. Activity pacing conceptual model taken from the activity pacing framework

Figure 2: CONSORT diagram showing the flow of participants through the study

Figure 3. Participants' written comments following attending the rehabilitation programme

This framework uses the term 'Activity Pacing', which may be more similar to an operant approach, driven by quota-contingency rather than symptom-contingency. Our model of pacing moves beyond a purely behavioural approach since it also integrates thoughts and beliefs. Activity pacing within this framework encourages acceptance, active decision-making and flexibility, both in selecting which facets of pacing to implement and also when to pace.

This pacing model is based upon addressing behaviours such as fear-avoidance, excessive persistence and overactivity-underactivity cycling. This pacing model includes the potential for reversibility of some of the consequences of chronic pain/fatigue, for example, to reduce disability. As such, activity pacing is described as a rehabilitative strategy rather than an adaptive strategy in this framework.

In keeping with a rehabilitative approach, the aims of activity pacing within this framework include: improved physical and cognitive function, improved quality of life, increased sense of control and choice, and increased satisfaction with activities. Activity pacing may improve the management and ability to cope with symptoms where there is greater acceptance and flexibility. This framework does not advocate the use of activity pacing with the direct aim of reducing symptoms when this results in decreased function or dissatisfaction, or if this encourages avoidant behaviour/working below tolerance levels.

This activity pacing framework recognises pacing as a multidimensional concept that involves different facets, such as breaking down tasks, finding baselines of tolerable activities, implementing consistent levels of activities, planning activities, setting goals of meaningful activities, accepting activity levels and gradually increasing activities. Different facets of activity pacing are tailored to individuals' needs, aims and activity behaviours.

Figure 1. Activity pacing conceptual model taken from the activity pacing framework

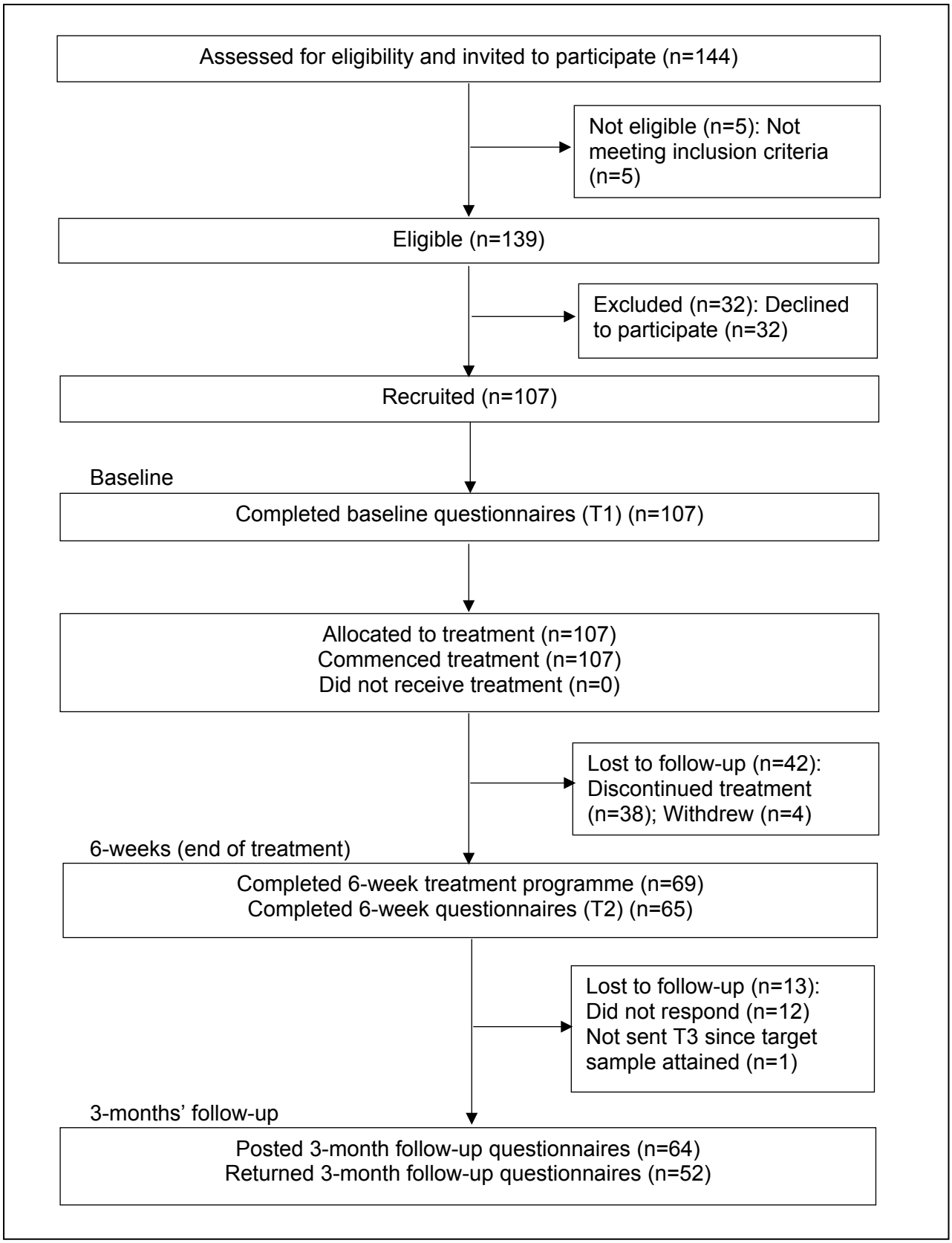

Figure 2: CONSORT diagram showing the flow of participants through the study

T2: “The pace and content has been good for me. It has helped me to focus on my belief that I have to own the situation, to be positive and to make use of the tools we have discussed. If I don't take this approach I believe my situation will not improve. There is no magic wand, but I can be the difference.” *(F070: Fibromyalgia)*

T3: “I have found pacing really helpful in my everyday life and feel I can achieve more day to day than 12 months ago.” *(F006: chronic widespread pain, fibromyalgia, chronic fatigue syndrome/myalgic encephalomyelitis)*

T3: “I found the pain service very helpful and informative. How I view my pain and react to and manage it has improved. Emotionally I feel more positive as a result of using strategies learned, and also more confident that I can manage my pain and how it makes me feel. Using pacing and realistic goals has enabled me to do some activities that I previously avoided i.e. hoovering, changing the bed. *(F068: fibromyalgia)*

T3: “Doing the 6 week course was extremely helpful and gave me some excellent information and resources to work with. The difficulty has been that there has been no follow up or support sessions since. It is great having the info, but then you are battling depression/anxiety it is difficult to apply knowledge without some support, even if that is over the phone every few weeks or maybe a support group facility.” *(F075: low back pain, chronic widespread pain)*

T3 “I have found ‘pacing’ a very good way to manage pain and get through the day completing activities” *(F105: low back pain, chronic widespread pain, fibromyalgia)*

Figure 3. Participants’ written comments following attending the rehabilitation programme

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Title page (Page 1)
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	The abstract is structured as per the *BMJ Open* format, but it contains the information as per the CONSORT checklist. (Page 3)
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pages 5-6
	2b	Specific objectives or research questions for pilot trial	Page 7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Page 7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Pages 8
	4b	Settings and locations where the data were collected	Page 10
	4c	How participants were identified and consented	Page 8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 9
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Pages 10-12

	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	Page 8-9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Page 12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Pages 18-19 Figure 2: CONSORT flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 14
	14b	Why the pilot trial ended or was stopped	Page 14. Figure 2: CONSORT flow diagram states T3 (follow up) was stopped due to attaining target sample

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables 1 and 2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Tables 3-5
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Tables 3-5
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Tables 4-5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 19
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	37-38
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	37-38
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Pages 33-37
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	38
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Abstract (Page 4); Page 7
Protocol	24	Where the pilot trial protocol can be accessed, if available	Page 7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 39
	26	Ethical approval or approval by research review committee, confirmed with reference number	Page 7

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Testing a newly developed activity pacing framework for chronic pain/fatigue: a feasibility study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-045398.R1
Article Type:	Original research
Date Submitted by the Author:	05-May-2021
Complete List of Authors:	Antcliff, Deborah; Northern Care Alliance NHS Group, Physiotherapy Department, Fairfield General Hospital; University of Leeds Faculty of Medicine and Health, School of Healthcare Keenan, Anne-Maree; University of Leeds Faculty of Medicine and Health, School of Healthcare; NIHR Leeds Musculoskeletal Biomedical Research Unit Keeley, Philip; Keele University School of Nursing and Midwifery Woby, Steve ; Northern Care Alliance NHS Group Research and Innovation Department; University of Salford School of Health and Society McGowan, Linda; University of Leeds Faculty of Medicine and Health, School of Healthcare
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	PAIN MANAGEMENT, REHABILITATION MEDICINE, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title: Testing a newly developed activity pacing framework for chronic pain/fatigue: a feasibility study

AUTHORS

Dr Deborah Antcliff (PhD)[a,b]

[a]Physiotherapy Department, Bury and Rochdale Care Organisation, Northern Care Alliance NHS Group, Bury, United Kingdom.

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom.

Professor Anne-Maree Keenan (PhD)[b,c]

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom

[c]NIHR Leeds Biomedical Research Centre, Leeds, England, UK

Professor Philip Keeley (PhD)[d]

[d]School of Nursing and Midwifery, Keele University, Keele, United Kingdom

Professor Steve Woby (PhD)[e,f,g]

[e]Research and Innovation Department, Northern Care Alliance NHS Group, Salford, United Kingdom.

[f]School of Health and Society, University of Salford, Salford, United Kingdom.

[g]Faculty of Science and Engineering, Manchester Metropolitan University, Manchester, United Kingdom.

Professor Linda McGowan (PhD)[b]

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom

CORRESPONDING AUTHOR

Dr Deborah Antcliff (PhD)

Physiotherapy Department

Fairfield General Hospital

Bury and Rochdale Care Organisation

Northern Care Alliance NHS Group

Rochdale Old Road

Bury, England

BL9 7TD

United Kingdom

Deborah.Antcliff@pat.nhs.uk

Tel: +44 (0)7769683646

Fax: Nil available

ORCID ID: 0000-0002-9771-8232

Institutional URL: http://www.leeds.ac.uk/

Word count: 4,759 words

KEY WORDS

Pain management; Rehabilitation medicine, Musculoskeletal disorders

ABSTRACT

Objectives: To test the feasibility of using a new activity pacing framework to standardise healthcare professionals' instructions of pacing, and explore whether measures of pacing/symptoms detected changes following treatment.

Design: Single-arm, repeated measures study.

Setting: A single NHS Pain Service in Northern England, U.K.

Participants: Adult patients with chronic pain/fatigue, including chronic low back pain, chronic widespread pain, fibromyalgia and chronic fatigue syndrome/myalgic encephalomyelitis.

Interventions: Six-week rehabilitation programme, standardised using the activity pacing framework.

Outcome measures: Feasibility was explored via patients' recruitment/attrition rates, adherence and satisfaction, and healthcare professionals' fidelity. Questionnaire data were collected from patients at the start and end of the six-week programme (T1/T2) and three months' follow-up (T3). Questionnaires included measures of activity pacing, current/usual pain, physical/mental fatigue, depression, anxiety, self-efficacy, avoidance, physical/mental function and quality of life. Mean changes and relationships between pacing and symptoms (T1-T2/T1-T3) were estimated.

Results: Of the 139 eligible patients, 107 patients consented (recruitment rate=77%); 65 patients completed T2 (T1-T2 attrition rate=39%), and 52 patients completed T3 (T1-T3 attrition rate=51%). At T2, patients' satisfaction ratings averaged 9/10, and 89% attended ≥5 sessions. Activity pacing and all symptoms improved between T1-T2, with smaller improvements maintained at T3. Between T1-

T2, changes in pacing significantly correlated with current pain (r_s=-0.29, p=0.019), self-efficacy (r_s=0.26-0.39, p<0.05) and mental function (r_s=0.27-0.28, p<0.05). Between T1-T3, there were additional significant correlations between changes in pacing and physical/mental fatigue, depression, anxiety and quality of life (p<0.05). There were no significant correlations with physical function/avoidance.

Conclusion: The activity pacing framework was feasible to implement and patients' ability to pace and manage their symptoms improved. Future work will employ a suitable comparison group and test the framework across wider settings to explore the effects of activity pacing in a randomised controlled trial.

Trial registration: ClinicalTrials.gov:NCT03497585

Funding: Health Education England/National Institute for Health Research

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This was the first study to test the feasibility of using a newly developed activity pacing framework in a rehabilitation programme to standardise the clinical instructions of activity pacing to patients with chronic pain/fatigue.
- This feasibility study recruited to target with satisfactory recruitment/attrition rates which form the basis of a future randomised controlled trial (RCT).
- A comprehensive measure of pacing: the activity pacing questionnaire (APQ-28), and range of validated psychometric measures were suitable to detect changes before and after treatment.
- This study was not powered with a control arm to determine treatment effectiveness, and the exploratory statistical analyses do not indicate causation between increased activity pacing and improved symptoms.

- The generalisability of this study is limited to a sample of predominantly females, of white ethnic origin, and from a single Pain Service.

INTRODUCTION

Activity pacing is a principal coping strategy for patients with long-term conditions, including chronic low back pain, chronic widespread pain, fibromyalgia and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME),[1-5]. Chronic pain and chronic fatigue are known to co-exist,[6, 7] and overlap in symptoms, including depression, anxiety and disability,[8-11]. Conditions of chronic pain/fatigue may share similar disease processes: physical deconditioning following under-activity/avoidance, pathophysiological/psychological processes and central sensitisation,[11-16]. Treatments aim to reverse some of these processes: to improve physical/mental functioning, increase tolerance and improve quality of life,[12, 15, 17]. Recommended treatments include psychological therapies (for example, cognitive behavioural therapy) and graded exposure to activity/exercise,[15, 16]; of which activity pacing is a key component,[18-20].

Patients with chronic pain/fatigue may present with altered behaviours, including underactivity or avoidance of activities that are perceived as harmful or that may exacerbate symptoms; over-activity or excessive persistence to push through/distract from symptoms; or fluctuations between underactivity-overactivity,[21]. Activity pacing provides an alternative behaviour to enable patients to (re-)engage with activities in a manner that encourages their progression towards more regular or improved functioning,[4, 22, 23].

At present, there remains confusion regarding how activity pacing is defined or interpreted, and the effects on patients' symptoms,[5, 24, 25]. There is no widely-used guide to standardise how healthcare professionals instruct pacing to patients; and uncertainty whether different methods are required for symptoms of chronic pain versus chronic fatigue,[3, 26]. This poses challenges how to advise patients with both chronic pain and fatigue.

We have developed an activity pacing framework using an inclusive approach for patients who present at rehabilitation services with chronic pain and/or fatigue. Using the Medical Research Council guidelines for developing complex interventions, mixed methods were implemented to encompass theoretical and stakeholder standpoints,[27]. Mixed methods comprise of quantitative and qualitative approaches to collecting and analysing data,[28]. Stage I: Healthcare professionals' survey gathered opinions on activity pacing (n=92),[4]. These findings, together with existing research formed the first draft of the framework and accompanying appendices. Stage II: Nominal group technique refined the activity pacing framework using a consensus meeting between patients and healthcare professionals (n=10),[29]. During the development of the activity pacing framework, stakeholders included healthcare professionals and patients with the aim of increasing the clinical utility and acceptability of the framework. *(See Supplementary Figure 1. Content of the Activity Pacing Framework: Theory and Overview, and Appendices and Teaching Guide booklets.)*

The conceptual model of the activity pacing framework *(see Figure 1)* follows principles of quota-contingency and the operant approach (for example, setting goals according to time/distance/activity). The activity pacing framework is underpinned by concepts of rehabilitation with aims of improving physical and cognitive function; and engagement in, and satisfaction with meaningful activities, while managing symptoms,[4, 29]. The activity pacing framework includes the potential for reversibility of some of the consequences of chronic pain/fatigue, such as the potential to reduce levels of disability. Together with containing themes of adjusting activities, planning and consistency, the activity pacing framework also includes themes of progression regarding the amount and/or variety of activities. Therefore, the activity pacing framework is considered to be a rehabilitative approach that moves forward from only adapting, or in some cases mal-adapting to the long-term condition. The activity pacing framework differs from energy conservation/adaptive pacing approaches which involve undertaking activities according to symptom severity (symptom-contingency) with an aim of reducing or avoiding symptoms,[30, 31]. Within the current activity pacing framework, quota-contingency is advised alongside concepts of flexibility and choice to enable relevance and sustainability in conditions where symptoms may vary. The framework refers to all types of activities including work, household activities, cognitive activities, physical activities, exercise and relaxation to increase its wider relevance for patients with chronic pain and/or fatigue, for varying abilities and behaviours.

The aim of this study was to test the feasibility of using the activity pacing framework to underpin a rehabilitation programme for chronic pain/fatigue. To inform a future definitive trial, specific objectives included: (1)Exploring participant

recruitment/attrition rates and adherence/acceptability (for both chronic pain and fatigue); (2)Exploring healthcare professionals' fidelity to the framework; (3)Exploring the suitability of the outcome measures, including the modified activity pacing questionnaire (APQ-28); and (4)Exploring associations between changes in activity pacing and self-reported symptoms.

METHODS

Study design

This single-arm, repeated measures study is reported as a non-randomised feasibility study using the extended CONSORT guidelines,[32, 33] *(See Supplementary Table 1)*. Quantitative questionnaire data were collected from patients at the start (T1) and end (T2) of the six-week rehabilitation programme, and at three month's follow-up (T3). The study was prospectively registered (protocol available at ClinicalTrials.gov: NCT03497585). Ethical approval was granted by the London-Surrey Research Ethics Committee (18/LO/0655). The acceptability of the framework, explored via interviews with patients and healthcare professionals is reported elsewhere *[Antcliff et al., 2021 accepted for publication].*

Participant recruitment

Participants were identified from consecutive referrals to a rehabilitation programme for chronic pain/fatigue in a Pain Service in Northern England, United Kingdom. All patients attended a minimum of one face-to-face appointment before referral to the

programme. Participants received the study information via the post one week before attending the programme and/or during the first session of the programme. The consent form was completed either at home or during the first session.

Eligibility criteria

Eligible patients were aged ≥18 years, with symptoms for ≥3 months and with a general practitioner or hospital consultant diagnosis of chronic low back pain, chronic widespread pain, fibromyalgia or CFS/ME. Patients were required to read and write in English. Ineligible patients were those with evidence of a serious underlying pathology, such as a current diagnosis of cancer, or patients with severe mental health or cognitive functioning issues.

Sample size

A sample size of 50 patients has been recommended for feasibility studies to enable estimates of recruitment/attrition, means/standard deviations and changes in means to prepare for future clinical trials,[34]. To attain a sample of 50 participants at T3, it was estimated that 340 patients may need to be approached to allow for a 50% recruitment rate at T1, a 40% attrition rate between T1-T2 and a 50% return rate at T3.

Existing rehabilitation programme

The existing rehabilitation programme comprised of six consecutive weekly sessions (each 3.5 hours) delivered by healthcare professionals (pain specialist physiotherapists and psychological wellbeing practitioners). The programme included understanding complex symptoms, sleep hygiene, graded exercise, goal setting, relaxation and mindfulness. Pacing was instructed in one session but was not informed by any particular framework.

Activity pacing framework standardised programme

The existing six-week programme was modified though re-structuring and standardisation using the activity pacing framework. Activity pacing was formally instructed on two sessions (weeks 2-3). However, activity pacing was referenced throughout the programme in relation to other coping strategies, for example, how activity pacing can assist graded exercise (weeks 1-5) or set-back management (week 6). Practical exercises included completing an activity diary to discuss patients' activity patterns and setting goals in which activity pacing could be practised. *(See Supplementary Figure 2. Content of the rehabilitation programme)*. Patients received a handout to summarise the key concepts of activity pacing. The healthcare professionals (as above) received training on the framework during a half-day session and could contact the lead researcher (DA) for any queries. All patients attended the standardised programme, but patients chose whether to participate in the study through their optional completion of the study questionnaires and consent form.

Data collection

Feasibility outcomes

Measures of feasibility included participant recruitment/attrition rates, adherence (number of sessions attended), acceptability (two satisfaction rating scales regarding the programme content and length where 0=dissatisfied and 10=fully satisfied), and missing data in the questionnaire. For every programme, healthcare professionals completed a 13-item fidelity checklist based on the conceptual model of the activity pacing framework to ensure their inclusion of key elements from the framework. Each clinician was observed once by the lead researcher.

Clinical measures

The self-reported questionnaire booklets (T1, T2 and T3) included standardised clinical measures. T1 could be completed during session one or at home, T2 could be completed during session six, and T3 was sent in the post to be completed at home. Telephone reminders were made if the T3 questionnaires were not returned within two weeks. The T1 booklet contained demographic questions, in addition to following measures included in T2 and T3:

(1) Activity pacing was measured using the Activity Pacing Questionnaire (APQ-28). The APQ 26-item version was initially validated among patients with chronic pain/fatigue and contained five subthemes: Activity adjustment, Activity planning, Activity consistency, Activity acceptance and Activity progression (Cronbach's

alpha=0.72-0.92),[35]. *(See Supplementary Table 2. Five themes of the activity pacing questionnaire (APQ) with examples.)* Each item is scored between 0='never did this' and 4='always did this'. Two items have been added that correspond to important aspects of pacing that emerged during the development of the activity pacing framework. The new items: APQ12:"I found a baseline amount of activities that I could do on 'good' and 'bad' days" and APQ15:"I had a flexible approach with my activities" were added to the subthemes of best conceptual fit (Activity adjustment and Activity acceptance respectively). Each subtheme was calculated as a mean score. The APQ-28 subthemes, similarly to the following scales, permitted one missing item per subscale.

(2) Current and usual pain were measured using two 11-point numerical rating scales (NRS), where 0='no pain' and 10='worst possible pain',[36].

(3) Physical fatigue (seven items) and mental fatigue (four items) were measured using the Chalder Fatigue Questionnaire (CFQ), where scores of 1='much worse than usual' and 4='better than usual',[37]. Two subscale scores were summated where higher scores indicated less fatigue.

(4) Depression was measured using the nine item Patient Health Questionnaire (PHQ-9), the items of which are based on the Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV),[38]. Items were rated between 0='not at all' and 3='nearly everyday'. Total scores of 1-4=minimal depression, 5-9=mild depression, 10-14=moderate depression and ≥15=severe depression,[38, 39].

(5) Anxiety was measured using the seven-item Generalised Anxiety Disorder Assessment (GAD-7). Items were rated between 0='not at all' and 3='nearly everyday'. Total scores of 5-9=mild anxiety, 10-14=moderate anxiety and ≥15=severe anxiety,[40].

(6) Self-efficacy was measured using the 10-item Pain Self-Efficacy Questionnaire (PSEQ) where items were rated between 0='not at all confident' and 6='completely confident'. Total scores of PSEQ≥40 indicate those patients who are more likely to continue implementing coping strategies/behavioural changes, and PSEQ≤16 are considered low,[41].

(7) Avoidance was measured using the 'Escape and Avoidance' subscale of the Pain Anxiety Symptoms Scale-short version (PASS-20),[42]. The five items were rated between 0='never' and 5='always' where higher total scores indicated greater avoidance.

(8) Physical and mental function were measured using the 12-Item Short-Form Health Survey (SF-12). Two subscale scores (out of 100) were calculated using the SF-12 software (Version 2; one-week recall) where higher scores indicated better function,[43].

(9) Health-related quality of life was measured using the EQ-5D-5L (EuroQol). The EQ-5D-5L was calculated as an index score,[44, 45].

Data analysis

Feasibility outcomes and participants' demographics were analysed using descriptive statistics. Clinical outcomes were estimated as changes in activity pacing and symptoms between T1-T2, T2-T3 and T1-T3 (mean change, 95% confidence intervals), and exploratory analyses of correlations between changes in activity pacing and symptoms (T1-T2/T1-T3). The validity of the modified APQ-28 was estimated using Cronbach's alpha and item correlations; and sensitivity analyses explored the effects of including two new APQ items. Data were analysed using IBM SPSS Statistics 26 statistical software (IBM Corp, Armonk, New York).

Patient and Public Involvement

Patient and Public Involvement (PPI) commenced during the initial planning stages of the mixed methods programme to develop and test the activity pacing framework. A meeting with five PPI representatives discussed the study purpose and practical issues around the proposed methods (online survey, nominal group technique, and feasibility and acceptability studies). PPI guided on improving the accessibility of patients' participation and reducing burden (for example, location and duration of meetings). A PPI representative has acted as an advisor on the study, involving commenting on study documents/questionnaire booklets and coding qualitative interviews. Acceptability interviews with patients explored practical issues surrounding the feasibility study *[Antcliff et al., 2021 accepted for publication]* which will further assist the planning of a future activity pacing randomised controlled trial (RCT).

RESULTS

Recruitment and T1 data collection commenced in May 2018 and T3 data collection ended in December 2019 due to attaining the target sample.

Demographics

Among the 107 participants who completed the baseline (T1) measures, participants were predominantly female (n=92, 86.0%) with a mean age of 55.25 +/- 12.83 years. Low back pain was most frequently reported (n=79, 73.8%) and CFS/ME least frequently reported (n=12, 11.2%). Sixty-five participants (61.3%) reported two or more conditions of chronic pain and/or fatigue. Of the 12 participants with CFS/ME, 10 participants reported CFS/ME as their main condition, and 11 reported at least one co-morbidity of LBP (n=7), chronic widespread pain (n=6), fibromyalgia (n=7) or another condition (n=3). *(See Table 1 for participant demographics and Table 2 for baseline scores for activity pacing and symptoms.)*

Table 1. Participant demographics at baseline (T1)

	Participants who completed T1 but not T2	**Participants who completed T1 and T2**	**Total**
Gender	(n=42)	(n=65)	(n=107)
Male	6 (14.3%)	9 (13.8%)	15 (14.0%)
Female	36 (85.7%)	56 (86.2%)	92 (86.0%)

Age (years)	(n=41) Mean=56.07 (SD=13.85)	(n=65) Mean=54.74 (SD=12.22)	(n=106) Mean=55.25 (SD=12.83)
Ethnicity	(n=41)	(n=65)	(n=106)
White (British, Irish, Other)	39 (95.1%)	60 (92.3%)	99 (93.4%)
Black (Caribbean, African)	0 (0.0%)	1 (1.5%)	1 (0.9%)
Mixed (white/black, white/Asian, other)	1 (2.4%)	2 (3.1%)	3 (2.8%)
Asian (Indian, Pakistani, Bangladeshi, other)	1 (2.4%)	2 (3.1%)	3 (2.8%)
Asian Eastern (Chinese, other)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Living situation*	(n=42)	(n=65)	(n=107)
Lives alone	7 (16.7%)	10 (15.4%)	17 (15.9%)
Lives with partner	25 (59.5%)	48 (73.8%)	73 (68.2%)
Lives with children	16 (38.1%)	24 (36.9%)	40 (37.4%)
Other	2 (4.8%)	1 (1.5%)	3 (2.8%)
Employment	(n=42)	(n=65)	(n=107)
Working (full-time, part-time, in the house, student)	13 (31.0%)	31 (47.7%)	44 (41.1%)
Not working (due to chronic pain/fatigue/other condition)	15 (35.7%)	19 (29.2%)	34 (31.8%)

Retired/semi-retired	14 (33.3%)	14 (21.5%)	28 (26.2%)
Other	0 (0.0%)	1 (1.5%)	1 (0.9%)
Conditions*:	(n=41)	(n=65)	(n=106)
Low back pain	30 (73.2%)	49 (75.4%)	79 (74.5%)
Widespread pain	19 (46.3%)	33 (50.8%)	52 (49.1%)
Fibromyalgia	9 (22.0%)	20 (30.8%)	29 (27.4%)
CFS/ME	6 (14.6%)	6 (9.2%)	12 (11.3%)
Other	9 (22.0%)	12 (18.5%)	21 (19.8%)
Number of the above conditions (multiple co-morbidities):	(n=41)	(n=65)	(n=106)
1	17 (41.5%)	24 (36.9%)	41 (38.7%)
2	19 (46.3%)	30 (46.2%)	49 (46.2%)
3	3 (7.3%)	9 (13.8%)	12 (11.3%)
4	1 (2.4%)	1 (1.5%)	2 (1.9%)
5	1 (2.4%)	1 (1.5%)	2 (1.9%)
Duration of participants' main condition (years)	(n=35) Mean=10.23 (SD=9.49)	(n=61) Mean=12.94 (SD=11.36)	(n=96) Mean=11.95 (SD=10.74)

**Patients could select more than one answer.*

Table 2. Baseline scores for activity pacing and symptoms for all patients completing the baseline questionnaires (T1)

Measures (range of scores)	Baseline scores for those completed T1 but not T2: Mean (SD)	Baseline scores for those completed T1 and T2: Mean (SD)	Total scores
APQ-28 Activity adjustment (0-4)	(n=42) 1.96 (0.87)	(n=64) 1.74 (0.76)	(n=106) 1.83 (0.81)
APQ-28 Activity planning (0-4)	(n=42) 1.57 (1.03)	(n=65) 1.44 (0.95)	(n=107) 1.49 (0.98)
APQ-28 Activity consistency (0-4)	(n=42) 1.91 (0.91)	(n=65) 1.82 (0.96)	(n=107) 1.85 (0.94)
APQ-28 Activity acceptance (0-4)	(n=42) 1.97 (1.02)	(n=65) 1.87 (0.84)	(n=107) 1.91 (0.92)
APQ-28 Activity progression (0-4)	(n=42) 1.59 (1.05)	(n=65) 1.45 (0.88)	(n=107) 1.51 (0.95)
Current pain (0-10)	(n=41) 6.83 (1.96)	(n=65) 6.63 (1.97)	(n=106) 6.71 (1.96)
Usual pain (0-10)	(n=40) 7.72 (1.43)	(n=63) 7.30 (1.82)	(n=103) 7.47 (1.69)
Physical fatigue (7-28)	(n=41) 14.18 (5.12)	(n=62) 15.22 (4.10)	(n=103) 14.81 (4.54)
Mental fatigue (4-16)	(n=42)	(n=64)	(n=106)

	8.79 (3.22)	8.86 (2.77)	8.83 (2.94)
Depression (0-27)	(n=40) 12.63 (7.61)	(n=64) 13.66 (6.38)	(n=104) 13.26 (6.86)
Anxiety (0-21)	(n=41) 9.86 (6.64)	(n=65) 9.91 (5.47)	(n=106) 9.89 (5.92)
Self-efficacy (0-60)	(n=42) 26.26 (13.85)	(n=65) 25.29 (10.60)	(n=107) 25.67 (11.93)
Avoidance (0-25)	(n=42) 12.95 (6.74)	(n=64) 13.27 (5.49)	(n=106) 13.14 (5.98)
Physical function (0-100)	(n=42) 33.67 (9.75)	(n=63) 34.15 (8.23)	(n=105) 33.96 (8.82)
Mental function (0-100)	(n=42) 42.22 (11.51)	(n=63) 38.52 (11.10)	(n=105) 40.00 (11.36)
Quality of life (0-1)	(n=40) 0.41 (0.26)	(n=60) 0.43 (0.25)	(n=100) 0.42 (0.25)

Activity pacing (Activity Pacing Questionnaire-28, APQ-28), Pain (Numerical Rating Scale 0-10), Physical/mental fatigue (Chalder Fatigue Questionnaire), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain Self-Efficacy Questionnaire), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-Form 12), Quality of life (EQ-5D-5L index score)

Feasibility outcomes

Recruitment and attrition (Objective 1)

Of the 144 patients invited to participate, 139 were eligible (96.5%). The reasons for ineligibility included: three patients reported only neck pain, one patient reported neck/knee pain and one patient reported thoracic pain. Of the 139 eligible patients, 107 (77.0%) were recruited at T1, 69 (64.5%) completed the six-week programme and 65 (60.7%) completed the T2 measures (attrition rate=39.3%). Fifty-two participants completed T3 (80.0% of T2; attrition rate from T1=51.4%). There were no serious adverse events. *(See Figure 2. CONSORT flow diagram.)*

Of the 107 participants, the median number of rehabilitation programme sessions attended was five (58.9% participants attended ≥5 sessions); 83.2% participants attended at least one activity pacing session and 56.1% attended both activity pacing sessions. Of the 65 participants who completed T2, the median number of sessions attended was six (89.2% participants attended ≥5 sessions); 100% of participants attended at least one activity pacing specific session and 54 (83.1%) participants attended both activity pacing sessions. There were no statistically significant differences between participants who completed T2 or dropped out in terms of demographics or baseline symptoms. Of the 12 participants with CFS/ME, six completed T2 (50%) and six completed T3 (100% of T2, 50% of T1); whereas 59 of the 95 participants without CFS/ME completed T2 (62%) and 46 completed T3 (78% of T2 and 48% of T1).

Acceptability of the rehabilitation programme/questionnaires (Objective 1)

On T2, participants rated their satisfaction of the length and content of the rehabilitation programme as mean=8.8 (SD=1.7) and 9.1 (SD=1.5) respectively. The satisfaction of only those participants with CFS/ME was mean=9.0 (SD=0.9) and 9.2 (SD=1.0).

There were minimal missing data in the questionnaire booklets (approximately 1%). Some participants wrote comments regarding their perceived benefits of implementing activity pacing and other coping strategies. Two participants wished for a longer programme or a follow-up session *(see Figure 3 for examples of participants' comments)*.

Fidelity to the activity pacing framework (Objective 2)

Each healthcare professional observation demonstrated good adherence to the framework against a number of key points. Healthcare professionals reported 100% adherence in their fidelity checklists for each rehabilitation programme. Healthcare professionals reported that some participants spent over 20 minutes completing the questionnaire booklet, and that not all patients completed the activity diaries.

Interventions between T2 and T3

Of the 52 respondents at T3, two patients received lumbar epidural steroid injections, one patient had acupuncture, one attended a chiropractor and one patient had knee surgery.

Clinical outcomes

Validity of the modified APQ-28 (Objective 3)

At T1, the two new APQ-28 items showed ease of completion through minimal missing answers (Item APQ12=0 missing answers, Item APQ15=1 missing answer). The scores of the new items utilised the full range, and the mean scores (Items APQ12=1.67 and APQ15=1.91) sat within the range of the other APQ-28 items (mean=1.17-2.78). The new items demonstrated optimal fit with their allocated subthemes via highest inter-item correlations and item-total correlations (item total correlations: APQ12 and Activity adjustment, $r_s(106)=0.76$, $p<0.001$; Item APQ15 and Activity acceptance, $r(106)=0.68$, $p<0.001$). The internal consistency for Activity adjustment increased with the addition of Item APQ12 (Cronbach's alpha=0.86 to 0.88), and for Activity acceptance with the addition of Item APQ15 (Cronbach's alpha=0.68 to 0.72). The internal validity of the other APQ-28 subthemes were: Activity planning=0.86, Activity consistency=0.80 and Activity progression=0.69.

Mean changes in activity pacing and symptoms (Objective 3)

Between T1-T2, all five APQ-28 subtheme mean scores increased, indicating improved activity pacing. There were small reductions in APQ-28 scores between T2-T3. However, all five subthemes showed overall improvements between T1-T3, with Activity planning showing the greatest increases *(see Table 3).* Sensitivity analyses showed marginal increases in mean changes following the addition of the two new APQ-28 items.

Between T1-T2, the mean scores of all symptoms improved. Current pain reduced more than usual pain. Physical and mental fatigue both improved, as did self-efficacy and quality of life. Mental function improved more than physical function. Depression, anxiety and avoidance all reduced. There was some deterioration in symptoms between T2-T3, but between T1-T3 all symptoms demonstrated clear improvements except avoidance (-1.46, 95% CI=-3.02 to 0.10) and physical function (1.62, 95% CI=-0.81 to 4.06) *(see Table 3.)*. Observing only the subgroup of participants with CFS/ME, improvements were seen between T1-T2 and T1-T3 across all APQ-28 subthemes and symptoms.

Table 3. Mean change in the five subthemes of activity pacing (APQ-28) and all measures of symptoms between T1 (baseline), T2 (end of 6-weeks' treatment) and T3 (3-months' follow-up)

Measures	T1 mean (SD) T2 mean (SD)	T2-T1 mean change (95% confidence interval); Effect size(d)	T2 mean (SD) T3 mean (SD)	T3-T2 mean change (95% confidence interval); Effect size(d)	T3 mean T1 mean	T3-T1 mean change (95% confidence interval); Effect size(d)
APQ-28 Activity adjustment	(n=63) T1 mean=1.73(0.77) T2 mean=2.43(0.73)	0.70 (95% CI= 0.48 to 0.91); Effect size (d)=0.91	(n=51) T2 mean=2.44(0.72) T3 mean=2.32(0.90)	-0.12 (95% CI= -0.36 to 0.11); Effect size (d)=-0.17	(n=50) T1 mean=1.75(0.78) T3 mean=2.33(0.90);	0.58 (95% CI= 0.33 to 0.83); Effect size (d)=0.74
APQ-28 Activity planning	(n=65) T1 mean=1.44(0.95) T2 mean=2.42(0.87)	0.99 (95% CI= 0.72 to 1.26); Effect size (d)=1.03	(n=52) T2 mean=2.45(0.87) T3 mean=2.06(1.02)	-0.39 (95% CI= -0.70 to -0.07); Effect size (d)=-0.45	(n=52) T1 mean=1.42(0.96) T3 mean=2.06(1.02)	0.64 (95% CI= 0.36 to 0.92) Effect size (d)=0.67

APQ-28 Activity consistency	(n=65) T1 mean=1.82(0.96) T2 mean=2.65(0.74)	0.84 (95% CI= 0.60 to 1.07) Effect size (d)=0.86	(n=52) T2 mean=2.66(0.71) T3 mean=2.37(0.72)	-0.29 (95% CI= -0.54 to -0.04) Effect size (d)=-0.41	(n=52) T1 mean=1.86(1.00) T3 mean=2.37(0.72)	0.51 (95% CI= 0.24 to 0.78) Effect size (d)=0.51
APQ-28 Activity acceptance	(n=65) T1 mean=1.87(0.84) T2 mean=2.55(0.72)	0.67 (95% CI= 0.46 to 0.89) Effect size (d)=0.81	(n=52) T2 mean=2.57(0.73) T3 mean=2.42(0.95)	-0.15 (95% CI= -0.38 to 0.08) Effect size (d)=-0.21	(n=52) T1 mean=1.84(0.91) T3 mean=2.42(0.95)	0.58 (95% CI= 0.33 to 0.84) Effect size (d)=0.64
APQ-28 Activity progression	(n=65) T1 mean=1.45(0.88) T2 mean=2.39(0.89)	0.94 (95% CI= 0.65 to 1.22) Effect size (d)=1.07	(n=52) T2 mean=2.40(0.91) T3 mean=2.00(0.91)	-0.40 (95% CI= -0.75 to -0.05) Effect size (d)=-0.44	(n=52) T1 mean=1.45(0.85) T3 mean=2.00(0.91)	0.56 (95% CI= 0.24 to 0.87) Effect size (d)=0.65
Current pain	(n=65) T1 mean=6.63(1.97) T2 mean=5.31(2.38)	-1.32 (95% CI= -1.91 to -0.74) Effect size (d)=-0.67	(n=52) T2 mean=5.04(2.36) T3 mean=5.65(2.31)	0.62 (95% CI= -0.08 to 1.31) Effect size (d)=0.26	(n=52) T1 mean=6.58(1.99) T3 mean=5.65(2.31)	-0.92 (95% CI= -1.58 to -0.27) Effect size (d)=-0.47

Usual pain	(n=65) T1 mean=7.30(1.82) T2 mean=6.62(2.08)	-0.68 (95% CI= -1.19 to -0.18) Effect size (d)=-0.37	(n=51) T2 mean=6.53(2.10) T3 mean=6.55(1.91)	0.02 (95% CI= -0.48 to 0.52) Effect size (d)=0.01	(n=50) T1 mean=7.30(1.62) T3 mean=6.54(1.93)	-0.76 (95% CI= -1.27 to -0.25) Effect size (d)=-0.47
Physical fatigue	(n=62) T1 mean= 15.22(4.10) T2 mean= 20.31(3.92)	5.08 (95% CI= 3.95 to 6.21) Effect size (d)=1.24	(n=51) T2 mean=20.47(4.13) T3 mean=18.12(4.18)	-2.35 (95% CI= -3.44 to -1.26) Effect size (d)=-0.57	(n=49) T1 mean=15.35(3.90) T3 mean=18.18(4.16)	2.84 (95% CI= 1.34 to 4.33) Effect size (d)=0.73
Mental fatigue	(n=64) T1 mean=8.86(2.77) T2 mean=11.28(2.43)	2.42 (95% CI= 1.75 to 3.10) Effect size (d)=0.87	(n=51) T2 mean=11.45(2.20) T3 mean=10.92(2.34)	-0.53 (95% CI= -1.17 to 0.11) Effect size (d)=-0.24	(n=51) T1 mean=8.94(2.51) T3 mean=10.92(2.34)	1.98 (95% CI= 1.33 to 2.64) Effect size (d)=0.79

Depression	(n=63) T1 mean=13.65(6.44) T2 mean=7.14(6.09)	-6.51 (95% CI= -7.72 to -5.31) Effect size (d)=-1.01	(n=51) T2 mean=6.27(5.49) T3 mean=9.23(5.75)	2.96 (95% CI= 1.64 to 4.29) Effect size (d)=0.54	(n=51) T1 mean=13.18(6.35) T3 mean=9.09(5.76)	-4.09 (95% CI= -5.61 to -2.57) Effect size (d)=-0.64
Anxiety	(n=65) T1 mean=9.91(5.47) T2 mean=5.40(5.13)	-4.51 (95% CI= -5.60 to -3.42) Effect size (d)=-0.82	(n=52) T2 mean=4.65(4.47) T3 mean=6.10(5.23)	1.44 (95% CI= 0.55 to 2.33) Effect size (d)=0.32	(n=52) T1 mean=9.47(5.06) T3 mean=6.10(5.23)	-3.37 (95% CI= -4.63 to -2.12) Effect size (d)=-0.67
Self- efficacy	(n=65) T1 mean=25.29(10.60) T2 mean=36.29(14.12)	11.00 (95% CI= 8.44 to 13.56) Effect size (d)=1.04	(n=52) T2 mean=37.96(14.12) T3 mean=34.68(14.26)	-3.28 (95% CI= -7.17 to 0.60) Effect size (d)=-0.23	(n=52) T1 mean=25.85(10.74) T3 mean=34.68(14.26)	8.83 (95% CI= 5.86 to 11.81) Effect size (d)=0.82
Avoidance	(n=64) T1 mean=13.27(5.49) T2 mean=10.28(5.89)	-2.98 (95% CI= -4.43 to -1.54 Effect size (d)=-0.54	(n=52) T2 mean=10.85(5.93) T3 mean=12.12(5.79)	1.27 (95% CI= -0.27 to 2.81) Effect size (d)=0.21	(n=52) T1 mean=13.58(5.66) T3 mean=12.12(5.79)	-1.46 (95% CI= -3.02 to 0.10) Effect size (d)=-0.26

Physical function	(n=63) T1 mean=34.15(8.23) T2 mean=38.82(9.06)	4.67 (95% CI= 2.69 to 6.65) Effect size (d)=0.57	(n=49) T2 mean=39.45(8.72) T3 mean=36.63(9.69)	-2.82 (95% CI= -5.29 to -0.35) Effect size (d)=-0.32	(n=47) T1 mean=34.92(7.98) T3 mean=36.55(9.81)	1.62 (95% CI= -0.81 to 4.06) Effect size (d)=0.20
Mental function	(n=63) T1 mean=38.52(11.10) T2 mean=45.83(11.48)	7.30 (95% CI= 4.49 to 10.12) Effect size (d)=0.66	(n=49) T2 mean=46.75(10.82) T3 mean=44.78(10.44)	-1.97 (95% CI= -5.22 to 1.29) Effect size (d)=-0.18	(n=47) T1 mean=38.61(10.65) T3 mean=44.56(10.60)	5.95 (95% CI= 2.83 to 9.08) Effect size (d)=0.56
Quality of life	(n=59) T1 mean=0.43(0.25) T2 mean=0.56(0.28)	0.13 (95% CI=0.07 to 0.18) Effect size (d)=0.52	(n=48) T2 mean=0.60(0.25) T3 mean=0.51(0.28)	-0.09 (95% CI= -0.14 to -0.03) Effect size (d)=-0.36	(n=45) T1 mean=0.45(0.24) T3 mean=0.52(0.29)	0.07 (95% CI= 0.001 to 0.14) Effect size (d)=0.29

Activity pacing (Activity Pacing Questionnaire-28, APQ-28), Pain (Numerical Rating Scale 0-10), Physical/mental fatigue (Chalder Fatigue Questionnaire), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain Self-Efficacy Questionnaire), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-Form 12), Quality of life (EQ-5D-5L index score).

Associations between changes in activity pacing and symptoms: pre-post treatment (Objective 4)

Between T1-T2, there were significant correlations between increased APQ-28 Activity acceptance and decreased current pain ($r_s(65)=-0.29$, $p=0.019$). Increased self-efficacy significantly correlated with all APQ-28 subthemes ($p<0.05$) except APQ-28 Activity adjustment. Increased mental function was significantly correlated with increased APQ-28 Activity adjustment ($r_s(61)=0.28$, $p=0.030$) and Activity acceptance ($r_s(63)=0.27$, $p=0.031$). *(See Table 4.)*

There were no statistically significant correlations between the changes in any of the APQ-28 subthemes and changes in usual pain, physical/mental fatigue, depression, anxiety, avoidance, physical function or quality of life. Sensitivity analyses found the same pattern of significant/non-significant correlations when excluding the two new APQ-28 items.

Table 4. Associations between changes in activity pacing and changes in symptoms between T1 and T2

	APQ-28 Activity adjustment	APQ-28 Activity planning	APQ-28 Activity consistency	APQ-28 Activity acceptance	APQ-28 Activity progression
Current pain	$r_s(63)=-0.06$, p=0.655	r(65)=-0.15, p=0.223	$r_s(65)=-0.06$, p=0.616	**$r_s(65)=-0.29$, p=0.019**	r(65)=-0.17 p=0.189
Usual pain	$r_s(61)=0.04$, p=0.765	r(63)=-0.21, p=0.103	$r_s(63)=0.001$, p=0.996	$r_s(63)=-0.09$, p=0.508	r(63)=-0.15, p=0.910
Physical fatigue	$r_s(62)=0.14$, p=0.270	r(62)=0.09, p=0.473	$r_s(62)=0.20$, p=0.121	$r_s(62)=0.16$, p=0.205	r(62)=0.15, p=0.256
Mental fatigue	$r_s(63)=0.03$, p=0.836	$r_s(64)=-0.02$, p=0.849	$r_s(64)=0.07$, p=0.563	$r_s(64)=-0.07$, p=0.580	$r_s(63)=-0.02$, p=0.849
Depression	$r_s(61)=-0.17$, p=0.194	$r_s(63)=-0.13$, p=0.310	$r_s(63)=-0.04$, p=0.744	$r_s(63)=-0.18$, p=0.153	$r_s(63)=-0.19$, p=0.138
Anxiety	$r_s(63)=-0.11$, p=0.415	r(65)=-0.19, p=0.122	$r_s(65)=0.02$, p=0.899	$r_s(65)=-0.19$, p=0.132	r(65)=-0.21, p=0.101
Self-efficacy	$r_s(63)=0.23$, p=0.074	**r(65)=0.31, p=0.012**	**$r_s(65)=0.26$, p=0.034**	**$r_s(65)=0.39$, p=0.002**	**r(65)=0.34, p=0.006**
Avoidance	$r_s(63)=-0.03$, p=0.801	r(64)=-0.13, p=0.294	$r_s(64)=-0.01$, p=0.932	$r_s(64)=0.09$, p=0.495	r(64)=-0.10, p=0.430

Physical function	$r_s(61)=-0.05$, p=0.708	r(63)=0.11, p=0.395	$r_s(63)=0.04$, p=0.750	$r_s(63)=0.09$, p=0.474	r(63)=0.15, p=0.230
Mental function	**$r_s(61)=0.28$, p=0.030**	r(63)=0.22, p=0.079	$r_s(63)=0.19$, p=0.135	**$r_s(63)=0.27$, p=0.031**	r(63)=0.24, p=0.056
Quality of life	$r_s(58)=0.13$, p=0.325	r(59)=0.26, p=0.051	$r_s(59)=0.05$, p=0.695	$r_s(59)=0.23$, p=0.078	r(59)=0.14, p=0.302

Significant correlations are highlighted in bold

Activity pacing (Activity Pacing Questionnaire-28, APQ-28), Pain (Numerical rating scale 0-10), Physical/mental fatigue (Chalder fatigue scale), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain self-efficacy scale), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-form 12), Quality of life (EQ-5D-5L)

Associations between changes in activity pacing and symptoms: pre-treatment to 3-months follow-up (Objective 4)

In addition to the significant correlations found during the pre-post treatment period (T1-T2) between various APQ-28 subthemes and improved current pain, self-efficacy and mental function; during the T1-T3 period the APQ-28 subthemes additionally correlated with improved physical and mental fatigue, improved quality of life, and reduced depression and anxiety ($p<0.05$). *(See Table 5.)*

Similarly to the T1-T2 period, between T1-T3, there were no significant correlations between changes in any APQ-28 subthemes and usual pain, avoidance or physical function. Sensitivity analyses showed the same pattern of results when excluding the two new APQ-28 items with the exception of two non-significant associations between: Activity adjustment and mental function ($r_s(46)=2.78$, $p=0.062$) and Activity acceptance and depression ($r_s(51)=-0.25$, $p=0.073$).

Table 5. Associations between changes in activity pacing and changes in symptoms between T1 and T3

	APQ-28 Activity adjustment	APQ-28 Activity planning	APQ-28 Activity consistency	APQ-28 Activity acceptance	APQ-28 Activity progression
Current pain	$r_s(50)=-0.07$, p=0.627	r(52)=-0.15, p=0.305	**r(52)=-0.29, p=0.036**	$r_s(52)=-0.09$, p=0.522	r(52)=-0.22, p=0.120
Usual pain	$r_s(49)=-0.08$, p=0.588	r(50)=-0.02, p=0.895	r(50)=0.07, p=0.634	$r_s(50)=-0.15$, p=0.287	r(50)=0.13, p=0.355
Physical fatigue	**$r_s(48)=0.31$, p=0.031**	**$r_s(49)=0.36$, p=0.012**	**$r_s(49)=0.34$, p=0.018**	**$r_s(49)=0.35$, p=0.014**	**$r_s(49)=0.40$, p=0.005**
Mental fatigue	$r_s(49)=0.17$, p=0.236	**r(51)=0.40, p=0.004**	**r(51)=0.36, p=0.009**	$r_s(51)=0.24$, p=0.089	**$r_s(51)=0.39$, p=0.004**
Depression	**$r_s(49)=-0.34$, p=0.016**	$r_s(51)=-0.27$, p=0.052	**$r_s(51)=-0.42$, p=0.002**	**$r_s(51)=-0.34$, p=0.016**	**$r_s(51)=-0.35$, p=0.013**
Anxiety	$r_s(50)=-0.28$, p=0.051	**r(52)=-0.31, p=0.024**	**r(52)=-0.31, p=0.024**	**$r_s(52)=-0.46$, p=0.001**	**r(52)=-0.34, p=0.015**
Self-efficacy	$r_s(50)=0.003$, p=0.984	**r(52)=0.35, p=0.010**	**r(52)=0.42, p=0.002**	$r_s(52)=0.25$, p=0.070	**r(52)=0.38, p=0.005**

Avoidance	$r_s(50)=-0.08$, p=0.580	r(52)=-0.20, p=0.148	r(52)=-0.14, p=0.320	$r_s(52)=-0.24$, p=0.092	r(52)=-0.22, p=0.126
Physical function	$r_s(46)=-0.11$, p=0.461	r(47)=0.07, p=0.653	r(47)=0.17, p=0.267	$r_s(47)=0.09$, p=0.563	r(47)=0.19, p=0.214
Mental function	**$r_s(46)=0.29$, p=0.049**	**r(47)=0.44, p=0.002**	**r(47)=0.41, p=0.004**	$r_s(47)=0.18$, p=0.236	**r(47)=0.41, p=0.004**
Quality of life	$r_s(43)=0.25$, p=0.109	**r(45)=0.36, p=0.015**	r(45)=0.23, p=0.127	**$r_s(45)=0.46$, p=0.001**	**r(45)=0.40, p=0.006**

Significant correlations are highlighted in bold

Pain (Numerical rating scale 0-10), Physical/mental fatigue (Chalder fatigue scale), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain self-efficacy scale), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20) Physical/mental function (Short-form 12), Quality of life (EQ-5D-5L)

DISCUSSION

This study fulfilled the original aims of testing the feasibility and acceptability of using a new activity pacing framework to standardise instructions of activity pacing to assist planning a future effectiveness RCT. The study recruited to target and patients with chronic pain and chronic fatigue demonstrated both improvements in pacing strategies and reductions in symptoms.

Feasibility

The activity pacing framework demonstrated feasibility through excellent fidelity to the framework by healthcare professionals via self-reported checklists and observations. Acceptability was demonstrated through patients' high satisfaction scores. Not all patients completed the activity diaries, however, this was optional for patients to facilitate their own self-reflection.

The recruitment rate (77%) was higher than estimated in the study protocol (50%). This was similar to a study exploring a five-week exercise programme for chronic hip pain (recruitment rate=76%),[46]; and this rate is considered 'Good' using cut-off levels of 80%=excellent and 70%=good from a feasibility study exploring a mind-body physical activity programme for chronic pain,[47]. The attrition rate between T1-T2 (39.3%) was as predicted in the protocol (40%), and lower than the 60% attrition rates reported across other studies investigating programmes for chronic pain,[20]. The attrition rate between T2-T3 (20.0%) was lower than predicted in the protocol

(50%), and the target sample size proved feasible to attain. These recruitment/attrition rates will inform a future definitive RCT.

Regarding treatment adherence, only 56.1% of participants recruited at T1 attended both activity pacing sessions. Many participants (n=18, 16.8%) dropped out after the first session and therefore did not attend any activity pacing sessions. Reasons for early drop-out often include unrealistic expectations of symptom improvement, low motivation, or confidence to commit to programmes or behavioural changes,[20]. In comparison, attendance rates of both activity pacing sessions among those who completed T2 were 83.1%, and 89.2% of participants attended five or more sessions. This is comparable to adherence rates of 81% seen elsewhere,[46]; and adherence rates have been considered as 'Excellent' when 70% or more participants complete 75% of sessions,[47]. However, within the present study, the interpretation of high attendance rates from those who completed T2 are considered more modestly following the drop outs after Week 1.

Participants reported the condition of low back pain most frequently and CFS/ME the least frequently, as per current prevalence rates,[48, 49]. Our findings re-iterate the high occurrence of co-morbidities, and frequent co-existence of chronic pain among patients with CFS/ME,[9]. Participants with CFS/ME demonstrated improvements in symptoms following treatment, in comparison to other studies in which pacing has been ineffective,[31]. Disparate to the study by White et al.,[31], the activity pacing framework encourages a rehabilitative approach that facilitates increased function rather than aiming to reduce symptoms. The effects of rehabilitative approaches to

activity pacing for patients with both chronic pain and fatigue requires further investigation using effectiveness trials.

Clinical outcomes

Activity pacing improved across all APQ-28 subthemes, the largest improvement being for Activity planning. This theme refers to planning activities, setting time targets and assessing activity levels,[35]; practical facets of pacing which may be more accessible to change. Comparably, participants showed smaller improvements in Activity acceptance. This subtheme includes setting realistic goals and allowing flexibility; facets that involve changing previous behaviours or self-enforced rules. The APQ-28 detected multidimensional changes in activity pacing, and the two new items appeared to complement the scale. Further study will validate the APQ-28 in a larger sample and estimate minimally important changes.

The aims of the activity pacing framework are to improve patients' function and quality of life. Improvements in physical function were seen between T1-T2 (mean change=4.67) that were greater than the minimally clinically important change (3.29),[50]. There were also reductions in avoidance between T1-T2. It is intended that the quota-contingent, operant approach of the activity pacing framework encourages a reduction in avoidance through setting meaningful and realistic goals towards activity, rather than stopping activities with the aim of reducing/avoiding symptoms as per energy conservation approaches. Similarly, in a RCT comparing an operant approach with energy conservation, Racine et al.,[30] found the operant approach, but not energy conservation was associated with reduced avoidance

among patients with fibromyalgia. This, together with greater improvements in depressive symptoms following the operant approach over energy conservation, led to recommendations towards the operant approach for patients with fibromyalgia,[30]. The current study found that pre-post treatment (T1-T2) improvements in both avoidance and physical function showed some decline at three months' follow-up. The authors suggest that physical function may be a component of rehabilitation in which patients feel least confident, especially those with avoidant behaviours,[20]. This may have implications for future programmes to integrate follow-up sessions to encourage longer-term maintenance of physical activity. In comparison, Racine et al.,[30] found improvements in physical activity following both operant pacing and energy conservation approaches. Similarly to the present study, Racine et al.,[30] implemented handouts, homework and goal setting to encourage patients' uptake of activity pacing. However, both of the interventions explored by Racine et al.,[30] were of greater duration than the current study, comprising of 10 two-hour stand-alone pacing sessions with a 3-month booster session. Within the current study, improvements in mental function between T1-T2 (mean change=7.3) were better maintained between T1-T3 (mean change=5.95); and both higher than the minimally clinically important change (3.77),[50]. Quality of life also improved between T1-T2 (mean change=0.13) and much of this improvement was maintained between T1-T3 (mean change=0.07); both changes exceeded the minimally important difference (0.037 +/-0.008),[51].

The activity pacing framework additionally aims to increase patients' self-efficacy. Improvements in self-efficacy were found between T1 (mean=25.29) and T2 (mean=36.29), which were well maintained at T3 (mean=34.68). Scores were lower

than the ≥40 cut off. However, an improvement of >5.5 was attained which is considered a minimally important change,[52]. Both physical and mental fatigue improved, and improvements in mental fatigue appeared to be better maintained at T3. Comparisons to minimally important changes are unavailable.

Psychological health improved following the rehabilitation programme, including reduced depression scores from moderate to mild (T1=13.7, T2=7.1, T3=9.1); with a clinically significant reduction (≥5) between T1-T2,[39]. Mean anxiety scores reduced (T1=9.9, T2=5.4 and T3=6.10), and remained within the classification of mild anxiety,[40]. Although reductions in pain were not a direct aim of the current treatment, lower pain severity was reported. Despite the increased intensity of pacing sessions contained within the RCT comparing the operant approach to energy conservation, Racine et al.,[30] found that neither pacing approach effectively reduced symptoms of pain or fatigue.

There were fewer significant correlations between changes in activity pacing and symptoms pre-post treatment (T1-T2) than longer-term (T1-T3). This may be due to participants undertaking a more experimental phase during T1-T2 (such as finding baselines, (re-)starting activities), whereas new routines were more established between T1-T3. However, such differences may have occurred due to differences among those patients who completed the T3 data collection (n=52) and those who completed T2 but did not complete T3 (n=13). It is suggested that patients who completed T3 possibly felt greater benefits from the treatment and were more motivated to respond to the follow-up questionnaire. Such potential bias could be explored in future study involving a larger sample. Noticeably, changes in activity

pacing were more frequently associated with improvements in psychological wellbeing rather than physical wellbeing. Similarly, a meta-analysis found pacing was not associated with improved physical function among patients with chronic conditions,[5].

Strengths and limitations

Despite recruiting to target, this sample was not powered with a control arm to determine treatment effectiveness. The exploratory statistical analyses were correlative and do not indicate causation between increased activity pacing and improved symptoms. As per other studies exploring activity pacing, pacing was instructed as one component of the rehabilitation programme,[5]. Therefore, improvements in symptoms may have resulted from any combination of coping strategies. A future RCT will implement a suitable control to explore the effects of pacing, while implementing the activity pacing framework in a clinically relevant setting, including alongside other coping strategies.

The generalisability of this study is limited to a sample of predominantly females and white ethnic origin. Recruitment occurred only at one Pain Service and this service had an existing rehabilitation programme for both chronic pain and fatigue. Bias may have arisen through the lead researcher delivering the healthcare professionals' training and undertaking the observations. Further work will test the activity pacing framework and study protocol across other healthcare services and explore feasibility and fidelity over wider geographical locations.

It is unknown what potential bias was caused by the attrition rate. However, there were no differences at baseline between those who completed the programme and those who dropped out. The attrition rate may be reflective of some of the clinical challenges and missed appointments surrounding the complexity of chronic pain/fatigue. Further research could explore whether providing a follow-up improves commitment to activity pacing.

Modifications for future study

Since more patients completed the T1 questionnaires during the rehabilitation sessions than at home, this may be the preferable mode of distribution. To lessen the time taken to complete the questionnaires, the PASS-20 may be considered for exclusion in future study. The whole 20-item PASS scale was included for reliability and validity, but data from only the Escape and Avoidance subscale was explored. Modifications to the inclusion criteria may include patients with any chronic spinal pain, including cervical/thoracic pain due to the frequent and similar presentation at rehabilitation services.

Conclusion

To the authors' knowledge, this is the first study to explore the clinical utility of a comprehensive activity pacing framework developed for both chronic pain and chronic fatigue. The newly developed activity pacing framework proved feasible to use clinically by healthcare professionals. Patients with both chronic pain and fatigue implemented greater activity pacing strategies following treatment, alongside

reporting improvements in quality of life, psychological wellbeing, self-efficacy, pain and fatigue. Physical function and avoidance improved to a lesser extent and for the shorter-term. Improvements in activity pacing were significantly associated with improvements in cognitive/psychological wellbeing and quality of life, but not physical function or avoidance. Future study will use the activity pacing framework in an effectiveness RCT to explore the effects of activity pacing on symptoms.

ACKNOWLEDGEMENTS

We would like to acknowledge all of the patients and healthcare professionals who were involved in this study. We would also like to acknowledge our statistical support.

CONFLICT OF INTEREST

All authors declare no conflicts of interest

AUTHOR CONTRIBUTIONS

DA, AMK, PK, SW and LMc all contributed to the conception and design of the study. DA undertook the acquisition of the data. DA, AMK, PK, SW and LMc all contributed to the analysis and interpretation of data. DA, AMK, PK, SW and LMc contributed to drafting the manuscript and revising it critically for important intellectual content and have approved the final version for publication. DA, AMK, PK, SW and LMc are in

agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

PATIENT CONSENT FOR PUBLICATION

Not required.

DATA SHARING AGREEMENT

De-identified participant data are available from the corresponding author (Deborah.Antcliff@pat.nhs.uk) upon reasonable request. Reuse is permitted for health and care research as long as the original authors are acknowledged. The protocol can also be requested from the author or accessed at ClinicalTrials.gov (NCT03497585).

ETHICAL APPROVAL

Ethical approval was granted by the London-Surrey Research Ethics Committee (18/LO/0655).

DISCLAIMER

This paper presents independent research funded by Health Education England/National Institute for Health Research (NIHR) [Clinical Lectureship (ICA-CL-2015-01-019)]. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

SOURCES OF FUNDING

This work was supported by a Health Education England/National Institute for Health Research (HEE/NIHR) Clinical Lectureship (grant number: ICA-CL-2015-01-019).

REFERENCES

1. Torrance N, Smith BH, Elliott AM, et al. Potential Pain Management Programmes in primary care. A UK-wide questionnaire and Delphi survey of experts. *Fam Pract* 2011;28:41-8.

2. Nijs J, Meeus M, De Meirleir K. Chronic musculoskeletal pain in chronic fatigue syndrome: recent developments and therapeutic implications. *Man Ther* 2006;11:187-91.

3. Nielson WR, Jensen MP, Karsdorp PA, et al. Activity pacing in chronic pain: concepts, evidence, and future directions. *Clin J Pain* 2013;29:461-8.

4. Antcliff D, Keenan AM, Keeley P, et al. Survey of activity pacing across healthcare professionals informs a new activity pacing framework for chronic pain/fatigue. *Musculoskeletal Care* 2019;17:335-45.

5. Abonie US, Sandercock GRH, Heesterbeek M, et al. Effects of activity pacing in patients with chronic conditions associated with fatigue complaints: a meta-analysis. *Disabil Rehabil* 2020;42:613-22.

6. Aggarwal VR, McBeth J, Zakrzewska JM, et al. The epidemiology of chronic syndromes that are frequently unexplained: do they have common associated factors? *Int J Epidemiol* 2006;35:468-76.

7. Meeus M. Nijs J. Central sensitization: a biopsychosocial explanation for chronic widespread pain in patients with fibromyalgia and chronic fatigue syndrome. *Clin Rheumatol* 2007;26:465-73.

8. Davis LL, Kroenke K, Monahan P, et al. The SPADE Symptom Cluster in Primary Care Patients With Chronic Pain. *Clin J Pain* 2016;32:388-93.

9. Meeus M, Nijs J, Meirleir KD. Chronic musculoskeletal pain in patients with the chronic fatigue syndrome: a systematic review. *Eur J Pain* 2007;11:377-86.

10. Tavel ME. Somatic symptom disorders without known physical causes: one disease with many names? *Am J Med* 2015;128:1054-8.

11. Yunus MB. Fibromyalgia and overlapping disorders: the unifying concept of central sensitivity syndromes. *Semin Arthritis Rheum* 2007;36:339-56.

12. Nijs J, Meeus M, Van Oosterwijck J, et al. In the mind or in the brain? Scientific evidence for central sensitisation in chronic fatigue syndrome. *Eur J Clin Invest* 2012;42:203-12.

13. Arendt-Nielsen L, Morlion B, Perrot S, et al. Assessment and manifestation of central sensitisation across different chronic pain conditions. *Eur J Pain* 2018;22:216-241.

14. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85:317-32.

15. Moseley GL. A pain neuromatrix approach to patients with chronic pain. *Man Ther* 2003;8:130-40.

16. Ericsson A, Mannerkorpi K. How to manage fatigue in fibromyalgia: nonpharmacological options. *Pain Manag* 2016;6:331-8.

17. British Pain Society. Guidelines for pain management programmes for adults. London: British Pain Society, 2013.

18. Beissner K, Henderson CR, Jr., Papaleontiou M, et al. Physical therapists' use of cognitive-behavioral therapy for older adults with chronic pain: a nationwide survey. *Phys Ther* 2009;89:456-69.

19. Booth J, Moseley GL, Schiltenwolf M, et al. Exercise for chronic musculoskeletal pain: A biopsychosocial approach. *Musculoskeletal Care* 2017;15:413-421.

20. Anderson RJ, Hurley RW, Staud R, et al. Cognitive-motivational influences on health behavior change in adults with chronic pain. *Pain Med* 2016;17:1079-1093.

21. Birkholtz M, Aylwin L, Harman RM. Activity pacing in chronic pain management: One aim, but which method? Part one: Introduction and literature review. *British Journal of Occupational Therapy* 2004;67:447-52.

22. Abonie US, Edwards AM, Hettinga FJ. Optimising activity pacing to promote a physically active lifestyle in medical settings: A narrative review informed by clinical and sports pacing research. *J Sports Sci* 2020;38:590-596.

23. Jamieson-Lega K, Berry R, Brown CA. Pacing: A concept analysis of a chronic pain intervention. *Pain Res Manag* 2013;18:207-13.

24. Andrews NE, Deen M. Defining Activity Pacing: Is It Time to Jump Off the Merry-Go-Round? *J Pain* 2016;17:1359-1362.

25. Andrews NE, Strong J, Meredith PJ. Activity pacing, avoidance, endurance, and associations with patient functioning in chronic pain: a systematic review and meta-analysis. *Arch Phys Med Rehabil* 2012;93:2109-2121 e7.

26. Murphy SL. Clauw DJ. Activity pacing: what are we measuring and how does that relate to intervention? *Pain* 2010;149:582-583.

27. Craig P, Dieppe P, Macintyre S, et al. Medical Research Council Guidance. Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ* 2008;337:a1655. doi: 10.1136/bmj.a1655

28. Creswell JW, Plano-Clark VL. *Designing and conducting mixed methods research*. California, USA: Sage Publications Ltd, 2011.

29. Antcliff D, Keenan AM, Keeley P, et al. Engaging stakeholders to refine an activity pacing framework for chronic pain/fatigue: A nominal group technique. *Musculoskeletal Care* 2019;17:354-362.

30. Racine M, Jensen MP, Harth M, et al. Operant Learning Versus Energy Conservation Activity Pacing Treatments in a Sample of Patients With Fibromyalgia Syndrome: A Pilot Randomized Controlled Trial. *J Pain* 2019;20:420-439.

31. White PD, Goldsmith KA, Johnson AL, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet* 2011;377:823-36.

32. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud* 2019;5:114.

33. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.

34. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301-8.

35. Antcliff D, Campbell M, Woby S, et al. Assessing the Psychometric Properties of an Activity Pacing Questionnaire for Chronic Pain and Fatigue. *Phys Ther* 2015;95:1274-86.

36. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels needed in pain intensity measurement? *Pain* 1994;58:387-92.

37. Chalder T, Berelowitz G, Pawlikowska T, et al. Development of a fatigue scale. *Journal of Psychosomatic Research* 1993;37:147-53.

38. Kroenke K, Spitzer RL , Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606-13.

39. Kroenke K, Spitzer RL, Williams JB, et al.. The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp Psychiatry* 2010;32:345-59.

40. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-7.

41. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur J Pain* 2007;11:153-63.

42. McCracken LM, Dhingra L. A short version of the Pain Anxiety Symptoms Scale (PASS-20): preliminary development and validity. *Pain Res Manag* 2002;7:45-50.

43. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical Care* 1996;34:220-33.

44. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36.

45. van Hout B, Janssen MF, Feng Y, et al. Interim Scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L Value Sets. *Value in Health* 2012;15:708 –715.

46. Bearne LM, Walsh NE, Jessep S, et al. Feasibility of an exercise-based rehabilitation programme for chronic hip pain. *Musculoskeletal Care* 2011;9:160-8.

47. Greenberg J, Lin A, Zale EL, et al. Development And Early Feasibility Testing Of A Mind-Body Physical Activity Program For Patients With Heterogeneous Chronic Pain; The GetActive Study. *J Pain Res* 2019;12:3279-3297.

48. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. *Lancet* 2018;391:2356-67.

49. NICE. Chronic fatigue syndrome/myalgic encephalomylitis (or encephalopathy). *NICE Clinical Guideline 53 London* 2007.

50. Diaz-Arribas MJ, Fernandez-Serrano M, Royuela A, et al. Minimal Clinically Important Difference in Quality of Life for Patients With Low Back Pain. *Spine (Phila Pa 1976)* 2017;42:1908-1916.

51. McClure NS, Sayah FA, Xie F, et al. Instrument-Defined Estimates of the Minimally Important Difference for EQ-5D-5L Index Scores. *Value Health* 2017;20:644-650.

52. Chiarotto A, Vanti C, Cedraschi C, et al. Responsiveness and Minimal Important Change of the Pain Self-Efficacy Questionnaire and Short Forms in Patients With Chronic Low Back Pain. *J Pain* 2016;17:707-18.

FIGURE LEGENDS

Figure 1. Activity pacing conceptual model taken from the activity pacing framework

Figure 2: CONSORT diagram showing the flow of participants through the study

Figure 3. Participants' written comments following attending the rehabilitation programme

This framework uses the term 'Activity Pacing', which may be more similar to an operant approach, driven by quota-contingency rather than symptom-contingency. Our model of pacing moves beyond a purely behavioural approach since it also integrates thoughts and beliefs. Activity pacing within this framework encourages acceptance, active decision-making and flexibility, both in selecting which facets of pacing to implement and also when to pace.

This pacing model is based upon addressing behaviours such as fear-avoidance, excessive persistence and overactivity-underactivity cycling. This pacing model includes the potential for reversibility of some of the consequences of chronic pain/fatigue, for example, to reduce disability. As such, activity pacing is described as a rehabilitative strategy rather than an adaptive strategy in this framework.

In keeping with a rehabilitative approach, the aims of activity pacing within this framework include: improved physical and cognitive function, improved quality of life, increased sense of control and choice, and increased satisfaction with activities. Activity pacing may improve the management and ability to cope with symptoms where there is greater acceptance and flexibility. This framework does not advocate the use of activity pacing with the direct aim of reducing symptoms when this results in decreased function or dissatisfaction, or if this encourages avoidant behaviour/working below tolerance levels.

This activity pacing framework recognises pacing as a multidimensional concept that involves different facets, such as breaking down tasks, finding baselines of tolerable activities, implementing consistent levels of activities, planning activities, setting goals of meaningful activities, accepting activity levels and gradually increasing activities. Different facets of activity pacing are tailored to individuals' needs, aims and activity behaviours.

Figure 1. Activity pacing conceptual model taken from the activity pacing framework

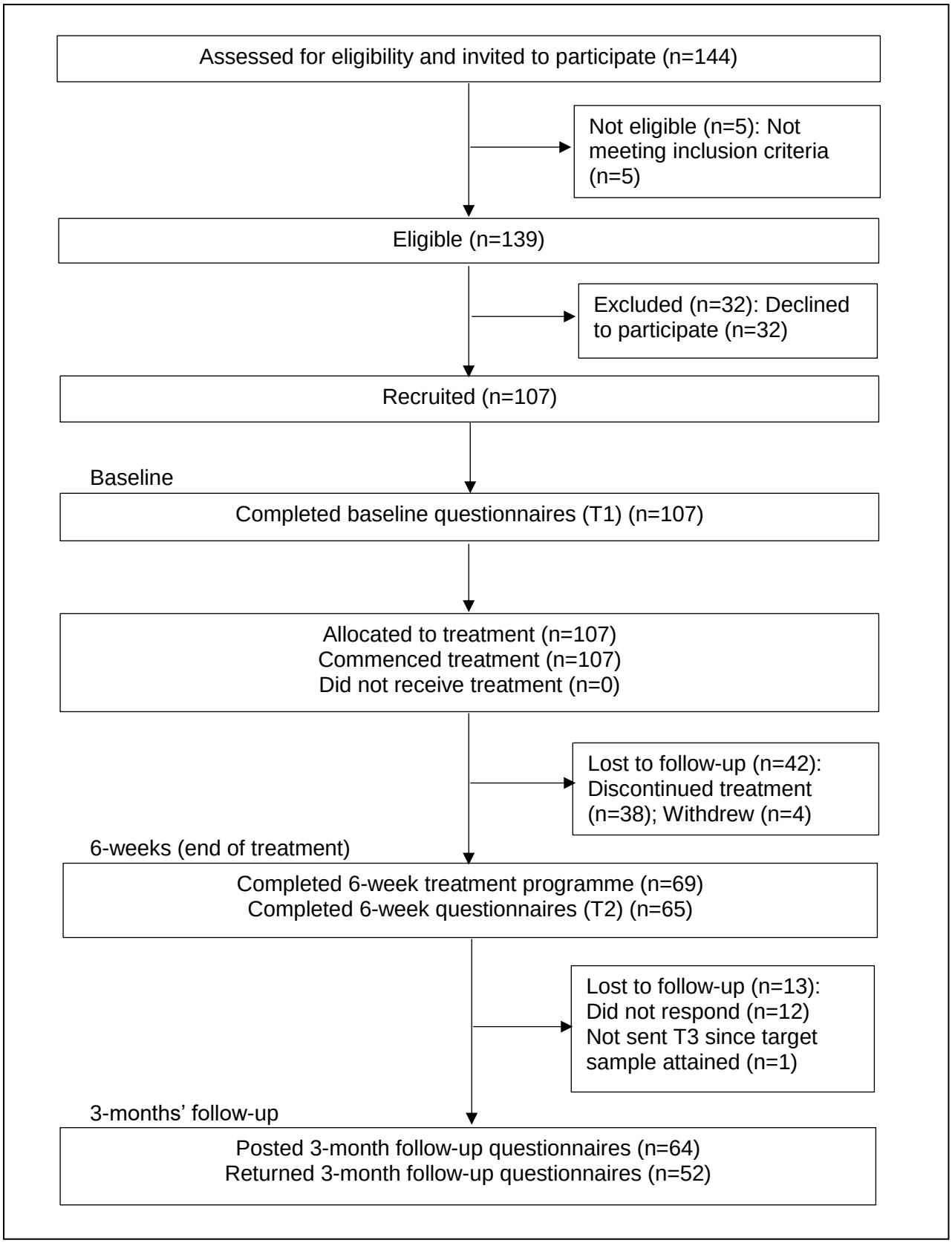

Figure 2: CONSORT diagram showing the flow of participants through the study

T2: “The pace and content has been good for me. It has helped me to focus on my belief that I have to own the situation, to be positive and to make use of the tools we have discussed. If I don't take this approach I believe my situation will not improve. There is no magic wand, but I can be the difference.” *(F070: Fibromyalgia)*

T3: “I have found pacing really helpful in my everyday life and feel I can achieve more day to day than 12 months ago.” *(F006: chronic widespread pain, fibromyalgia, chronic fatigue syndrome/myalgic encephalomyelitis)*

T3: “I found the pain service very helpful and informative. How I view my pain and react to and manage it has improved. Emotionally, I feel more positive as a result of using strategies learned, and also more confident that I can manage my pain and how it makes me feel. Using pacing and realistic goals has enabled me to do some activities that I previously avoided i.e. hoovering, changing the bed. *(F068: fibromyalgia)*

T3: “Doing the 6 week course was extremely helpful and gave me some excellent information and resources to work with. The difficulty has been that there has been no follow up or support sessions since. It is great having the info, but then you are battling depression/anxiety it is difficult to apply knowledge without some support, even if that is over the phone every few weeks or maybe a support group facility.” *(F075: low back pain, chronic widespread pain)*

T3 “I have found ‘pacing’ a very good way to manage pain and get through the day completing activities” *(F105: low back pain, chronic widespread pain, fibromyalgia)*

Figure 3. Participants’ written comments following attending the rehabilitation programme

SUPPLEMENTARY MATERIAL

Supplementary Figure 1. Content of the Activity Pacing Framework: Overview and Theory, and Appendices and Teaching Guide booklets

A. Overview and Theory

1. Glossary
2. Introduction:
    - Why is an activity pacing framework needed?
    - How has the activity pacing framework been developed?
3. Definition of activity pacing
4. Aims of pacing
    - Examples of aims of pacing and their clinical application
5. Who can benefit from pacing?
6. Activity behaviours:
    - Avoidance behaviour/fear-avoidance
    - Over-exertion/excessive persistence
    - Boom-bust/overactivity-underactivity cycling
7. Quota-contingent and symptom-contingent pacing
8. Models of pacing:
    - Operant approach
    - Energy conservation
    - Activity pacing framework model of pacing
9. Facets of pacing:
    - Facets of pacing, broader pacing themes and individuals who may benefit
    - Facets of pacing that are not endorsed for routine use, but may be considered during a flare-up of symptoms
10. Getting started with pacing: stages of pacing
11. Potential barriers to pacing:
    - Addressing barriers
12. How pacing relates to other coping strategies
    - Pacing and graded exercise/graded activity
    - Pacing and cognitive behavioural therapy
    - Pacing and acceptance and commitment therapy
    - Pacing and mindfulness
    - Pacing and relaxation

SUPPLEMENTARY MATERIAL

B. Appendices and teaching guide

SUPPLEMENTARY MATERIAL

Blank activity diary and example of a completed diary

Appendix 11. Goal setting

Appendix 12. Checklist for health care professionals

Appendix 13. References

SUPPLEMENTARY MATERIAL

Supplementary Table 1. CONSORT checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Title page (Page 1)
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	The abstract is structured as per the *BMJ Open* format, but it contains the information as per the CONSORT checklist. (Page 3)
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pages 5-7
	2b	Specific objectives or research questions for pilot trial	Page 7

SUPPLEMENTARY MATERIAL

Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Page 8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Page 9
	4b	Settings and locations where the data were collected	Page 12
	4c	How participants were identified and consented	Pages 8-9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 10 and supplemen-tary figure 2
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Pages 11-13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	Page 8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

SUPPLEMENTARY MATERIAL

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Page 14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Page 20 Figure 2: CONSORT flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 15
	14b	Why the pilot trial ended or was stopped	Page 15. Figure 2: CONSORT flow diagram states T3 (follow up) was stopped due to attaining

SUPPLEMENTARY MATERIAL

			target sample
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables 1 and 2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Tables 3-5
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Tables 3-5
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Tables 4-5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 20
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Pages 40-41
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Page 40
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Pages 35-41
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	41
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Abstract; Page 8
Protocol	24	Where the pilot trial protocol can be accessed, if available	Page 8

SUPPLEMENTARY MATERIAL

Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 44
	26	Ethical approval or approval by research review committee, confirmed with reference number	Pages 8, 43

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

SUPPLEMENTARY MATERIAL

Supplementary Figure 2: Content of the rehabilitation programme

Week 1

Introduction to the programme

Aims and concerns of the programme

Understanding chronic pain

Chronic pain/fatigue cycle

Benefits of exercise

Graded exercise (circuit exercises)

Relaxation session

Goal setting (SMART goals)

Week 2

Goal review

Understanding pain and the emotional effects: negative thinking and unhelpful thoughts

Pacing Session 1:

- Activity patterns (boom-bust, avoidance and excessive persistence)
- Aims of pacing
- Barriers to pacing
- Using activity diaries for the week ahead

Graded exercise (circuit exercises)

Mindfulness session

Goal setting

Week 3

Goal review

Pacing Session 2:

- Discuss the completed activity diaries
- Facets of pacing
- Stages of pacing

Dealing with difficult thoughts

Graded exercise (circuit exercises)

Mindfulness session

SUPPLEMENTARY MATERIAL

Goal setting: specific pacing goal

Week 4

Pacing goal review

Choice V's demand activities

Increasing positive thoughts

Work and employment

Graded exercise (circuit exercises)

Mindfulness session

Goal setting

Week 5

Goal review

Sleep hygiene

Medication

Graded exercise (circuit exercises)

Mindfulness session

Goal setting

Week 6

Goal review

Managing setbacks

Mindfulness session

Maintaining progress

Signposting to community resources

SUPPLEMENTARY MATERIAL

Supplementary Table 2. Five themes of the activity pacing questionnaire (APQ) with examples

APQ Theme	Example of items
Activity adjustment	"I broke tasks up into periods of activity and rest" "I alternated the type of activity that I was doing"
Activity consistency	"I did a similar amount of activity on 'good' and 'bad' days" "I made sure I did some activity every day, even if I had a "bad" day"
Activity progression	"I gradually increased how long I could spend on my activities" "I gradually increased activities that I had been avoiding because of my symptoms"
Activity planning	"I set activity goals that were meaningful for me" "I planned in advance how long I would spend on each activity"
Activity acceptance	"I changed my activity targets if they were unrealistic" "I set activity goals that were realistic for me"

BMJ Open

Testing a newly developed activity pacing framework for chronic pain/fatigue: a feasibility study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-045398.R2
Article Type:	Original research
Date Submitted by the Author:	17-Oct-2021
Complete List of Authors:	Antcliff, Deborah; Northern Care Alliance NHS Group, Physiotherapy Department, Fairfield General Hospital; University of Leeds Faculty of Medicine and Health, School of Healthcare Keenan, Anne-Maree; University of Leeds Faculty of Medicine and Health, School of Healthcare; NIHR Leeds Musculoskeletal Biomedical Research Unit Keeley, Philip; Keele University School of Nursing and Midwifery Woby, Steve ; Northern Care Alliance NHS Group Research & Innovation, Research and Innovation Department; University of Salford School of Health and Society McGowan, Linda; University of Leeds Faculty of Medicine and Health, School of Healthcare
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	PAIN MANAGEMENT, REHABILITATION MEDICINE, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title: Testing a newly developed activity pacing framework for chronic pain/fatigue: a feasibility study

AUTHORS

Dr Deborah Antcliff (PhD)[a,b]

[a]Physiotherapy Department, Bury Care Organisation, Northern Care Alliance NHS Group, Bury, United Kingdom.

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom.

Professor Anne-Maree Keenan (PhD)[b,c]

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom

[c]NIHR Leeds Biomedical Research Centre, Leeds, England, UK

Professor Philip Keeley (PhD)[d]

[d]School of Nursing and Midwifery, Keele University, Keele, United Kingdom

Professor Steve Woby (PhD)[e,f,g]

[e]Research and Innovation Department, Northern Care Alliance NHS Group, Salford, United Kingdom.

[f]School of Health and Society, University of Salford, Salford, United Kingdom.

[g]Faculty of Science and Engineering, Manchester Metropolitan University, Manchester, United Kingdom.

Professor Linda McGowan (PhD)[b]

[b]School of Healthcare, University of Leeds, Leeds, United Kingdom

CORRESPONDING AUTHOR

Dr Deborah Antcliff (PhD)

Physiotherapy Department

Fairfield General Hospital

Bury Care Organisation

Northern Care Alliance NHS Group

Rochdale Old Road

Bury, England

BL9 7TD

United Kingdom

Deborah.Antcliff@nca.nhs.uk

Tel: +44 (0)161 7242168

Fax: Nil available

ORCID ID: 0000-0002-9771-8232

Institutional URL: http://www.leeds.ac.uk/

Word count: 4,542 words

KEY WORDS

Pain management; Rehabilitation medicine, Musculoskeletal disorders

ABSTRACT

Objectives: To test the feasibility of using a new activity pacing framework to standardise healthcare professionals' instructions of pacing, and explore whether measures of activity pacing/symptoms detected changes following treatment.

Design: Single-arm, repeated measures study.

Setting: One NHS Pain Service in Northern England, U.K.

Participants: Adult patients with chronic pain/fatigue, including chronic low back pain, chronic widespread pain, fibromyalgia and chronic fatigue syndrome/myalgic encephalomyelitis.

Interventions: Six-week rehabilitation programme, standardised using the activity pacing framework.

Outcome measures: Feasibility was explored via patients' recruitment/attrition rates, adherence and satisfaction, and healthcare professionals' fidelity. Questionnaire data were collected from patients at the start and end of the programme (T1 and T2 respectively) and three months' follow-up (T3). Questionnaires included measures of activity pacing, current/usual pain, physical/mental fatigue, depression, anxiety, self-efficacy, avoidance, physical/mental function and quality of life. Mean changes in activity pacing and symptoms between T1-T2, T2-T3 and T1-T3 were estimated.

Results: Of the 139 eligible patients, 107 patients consented (recruitment rate=77%); 65 patients completed T2 (T1-T2 attrition rate=39%), and 52 patients completed T3 (T1-T3 attrition rate=51%). At T2, patients' satisfaction ratings averaged 9/10, and 89% attended ≥5 rehabilitation programme sessions. Activity

pacing and all symptoms improved between T1-T2, with smaller improvements maintained at T3.

Conclusion: The activity pacing framework was feasible to implement and patients' ability to pace and manage their symptoms improved. Future work will employ a suitable comparison group and test the framework across wider settings to explore the effects of activity pacing in a randomised controlled trial.

Trial registration: ClinicalTrials.gov:NCT03497585

Funding: Health Education England/National Institute for Health Research

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This was the first study to test the feasibility of using a newly developed activity pacing framework in a rehabilitation programme to standardise the clinical instructions of activity pacing to patients with chronic pain/fatigue.
- This feasibility study recruited to target with satisfactory recruitment/attrition rates.
- A comprehensive measure of activity pacing: the 28-item Activity Pacing Questionnaire (APQ-28), and range of validated psychometric measures were suitable to detect changes before and after treatment.
- This study was not powered with a control arm to determine treatment effectiveness.
- The generalisability of this study is limited to a sample of predominantly females, of white ethnic origin, and from a single Pain Service.

INTRODUCTION

Activity pacing is a principal coping strategy for patients with long-term conditions, including chronic low back pain, chronic widespread pain, fibromyalgia and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME),[1-5]. Chronic pain and chronic fatigue are known to co-exist,[6, 7] and overlap in symptoms, including depression, anxiety and disability,[8-11]. Conditions of chronic pain/fatigue may share similar disease processes: physical deconditioning following under-activity/avoidance, pathophysiological/psychological processes and central sensitisation,[11-16]. Treatments aim to reverse some of these processes: to improve physical/mental functioning, increase tolerance and improve quality of life,[12, 15, 17]. Recommended treatments include psychological therapies (for example, cognitive behavioural therapy) and graded exposure to activity/exercise,[15, 16]; of which activity pacing is a key component,[18-20].

Patients with chronic pain/fatigue may present with altered behaviours, including underactivity or avoidance of activities that are perceived as harmful or that may exacerbate symptoms; over-activity or excessive persistence to push through/distract from symptoms; or fluctuations between overactivity-underactivity,[21]. Activity pacing provides an alternative behaviour to enable patients to (re-)engage with activities in a manner that encourages their progression towards more regular or improved functioning,[4, 22, 23].

At present, there remains confusion regarding how activity pacing is defined or interpreted, and the effects on patients' symptoms,[5, 24, 25]. There is no widely-

used guide to standardise how healthcare professionals instruct activity pacing to patients; and uncertainty whether different methods are required for symptoms of chronic pain versus chronic fatigue,[3, 26]. This poses challenges how to advise patients with both chronic pain and fatigue.

We have developed an activity pacing framework using an inclusive approach for patients who present at rehabilitation services with chronic pain and/or fatigue. Using the Medical Research Council guidelines for developing complex interventions, mixed methods were implemented to encompass theoretical and stakeholder standpoints,[27]. Mixed methods comprise of quantitative and qualitative approaches to collecting and analysing data,[28]. Stage I: Healthcare professionals' survey gathered opinions on activity pacing (n=92),[4]. These findings, together with existing research formed the first draft of the framework and accompanying appendices. Stage II: Nominal group technique refined the activity pacing framework using a consensus meeting between patients and healthcare professionals (n=10),[29]. During the development of the activity pacing framework, stakeholders included healthcare professionals and patients with the aim of increasing the clinical utility and acceptability of the framework. *(See Supplementary Figure 1. Content of the Activity Pacing Framework: Theory and Overview, and Appendices and Teaching Guide booklets.)*

The conceptual model of the activity pacing framework *(see Figure 1)* follows principles of quota-contingency and the operant approach (for example, setting goals according to time/distance/activity). The activity pacing framework is underpinned by concepts of rehabilitation with aims of improving physical and cognitive function; and

engagement in, and satisfaction with meaningful activities, while managing symptoms,[4, 29]. The activity pacing framework includes the potential for reversibility of some of the consequences of chronic pain/fatigue, such as the potential to reduce levels of disability. Together with containing themes of adjusting activities, planning and consistency, the activity pacing framework also includes themes of progression regarding the amount and/or variety of activities. Therefore, the activity pacing framework is considered to be a rehabilitative approach that moves forward from only adapting, or in some cases mal-adapting to the long-term condition. The activity pacing framework differs from energy conservation/adaptive pacing approaches which involve undertaking activities according to symptom severity (symptom-contingency) with an aim of reducing or avoiding symptoms,[30, 31]. Within the current activity pacing framework, quota-contingency is advised alongside concepts of flexibility and choice to enable relevance and sustainability in conditions where symptoms may vary. The framework refers to all types of activities including work, household activities, cognitive activities, physical activities, exercise and relaxation to increase its wider relevance for patients with chronic pain and/or fatigue, for varying abilities and behaviours.

The aim of this study was to test the feasibility of using the activity pacing framework to underpin a rehabilitation programme for chronic pain/fatigue. In preparation for a future clinical trial, specific objectives included: (1)Exploring participant recruitment/attrition rates and adherence/acceptability (for both chronic pain and fatigue); (2)Exploring healthcare professionals' fidelity to the framework; and (3)Exploring the suitability of the outcome measures, including the modified 28-item Activity Pacing Questionnaire (APQ-28).

METHODS

Study design

This single-arm, repeated measures study is reported as a non-randomised feasibility study using the extended CONSORT guidelines,[32, 33] *(See Supplementary Table 1)*. Quantitative questionnaire data were collected from patients at the start (T1) and end (T2) of the six-week rehabilitation programme, and at three month's follow-up (T3). The study was prospectively registered (protocol available at ClinicalTrials.gov: NCT03497585). Ethical approval was granted by the London-Surrey Research Ethics Committee (18/LO/0655). The acceptability of the framework, explored via interviews with patients and healthcare professionals is reported elsewhere,[34].

Participant recruitment

Participants were identified from consecutive referrals to a rehabilitation programme for chronic pain/fatigue in a Pain Service in Northern England, United Kingdom. All patients attended a minimum of one face-to-face appointment before referral to the programme. Participants received the study information via the post one week before attending the programme and/or during the first session of the programme. The consent form was completed either at home or during the first session.

Eligibility criteria

Eligible patients were aged ≥18 years, with symptoms for ≥3 months and with a general practitioner or hospital consultant diagnosis of chronic low back pain, chronic widespread pain, fibromyalgia or CFS/ME. Patients were required to read and write in English. Ineligible patients were those with evidence of a serious underlying pathology, such as a current diagnosis of cancer, or patients with severe mental health or cognitive functioning issues.

Sample size

A sample size of 50 patients has been recommended for feasibility studies to enable estimates of recruitment/attrition, means/standard deviations and changes in means to prepare for future clinical trials,[35]. To attain a sample of 50 participants at T3, it was estimated that 340 patients may need to be approached to allow for a 50% recruitment rate at T1, a 40% attrition rate between T1-T2 and a 50% return rate at T3.

Existing rehabilitation programme

The existing rehabilitation programme comprised of six consecutive weekly sessions (each 3.5 hours) delivered by healthcare professionals (pain specialist physiotherapists and psychological wellbeing practitioners). The programme included understanding complex symptoms, sleep hygiene, graded exercise, goal

setting, relaxation and mindfulness. Pacing was instructed in one session but was not informed or standardised by any particular guide or framework.

Activity pacing framework standardised programme

The existing six-week programme was modified though re-structuring and standardisation using the activity pacing framework. Activity pacing was formally instructed on two sessions (weeks 2-3). However, activity pacing was referenced throughout the programme in relation to other coping strategies, for example, how activity pacing can assist graded exercise (weeks 1-5) or set-back management (week 6). In comparison to the existing rehabilitation programme, the activity pacing framework standardised programme included more in-depth discussions of activity behaviours (avoidance, overactivity-underactivity cycling and excessive persistence) to assist patients to identify their current approach to activities. This aimed to facilitate patients' recognition of which facets of activity pacing were most relevant to them. The two activity pacing sessions focused on the aims of activity pacing, barriers to activity pacing, facets of activity pacing (for example, breaking down tasks, switching between activities, having more consistent activity levels, allowing flexibility, gradually increasing the amount or variety of activities), and stages of activity pacing (introducing activity pacing, finding baselines, adjusting activities, planning, consistency, learning and progressing). Practical exercises included completing an activity diary to discuss patients' activity patterns and setting goals in which activity pacing could be practised. *(See Supplementary Figure 2. Content of the rehabilitation programme)*. Patients received a handout to summarise the key concepts of activity pacing. The healthcare professionals (as above) received

training on the framework during a half-day session and could contact the lead researcher (DA) for any queries. All patients attended the standardised programme, but patients chose whether to participate in the study through their optional completion of the study questionnaires and consent form.

Data collection

Feasibility outcomes

Measures of feasibility included participant recruitment/attrition rates, adherence (number of sessions attended), acceptability (two satisfaction rating scales regarding the programme content and length where 0=dissatisfied and 10=fully satisfied), and missing data in the questionnaire. For every programme, healthcare professionals completed a 13-item fidelity checklist based on the conceptual model of the activity pacing framework to ensure their inclusion of key elements from the framework. Each clinician was observed once by the lead researcher.

Clinical measures

The self-reported paper questionnaire booklets (T1, T2 and T3) included standardised clinical measures. T1 could be completed during session one or at home, T2 could be completed during session six, and T3 was sent in the post to be completed at home. Telephone reminders were made if the T3 questionnaires were not returned within two weeks. The T1 booklet contained demographic questions, in addition to following measures included in T2 and T3:

(1) Activity pacing was measured using the 28-item Activity Pacing Questionnaire (APQ-28). The 26-item Activity Pacing Questionnaire (APQ-26) was initially validated among patients with chronic pain/fatigue and contained five subthemes: Activity adjustment, Activity planning, Activity consistency, Activity acceptance and Activity progression (Cronbach's alpha=0.72-0.92),[36]. *(See Supplementary Table 2. Five themes of the 28-item Activity Pacing Questionnaire (APQ-28) with examples.)* Each item is scored between 0='never did this' and 4='always did this'. Two items have been added that correspond to important aspects of activity pacing that emerged during the development of the activity pacing framework. The new items: APQ12:"I found a baseline amount of activities that I could do on 'good' and 'bad' days" and APQ15:"I had a flexible approach with my activities" were added to the subthemes of best conceptual fit (Activity adjustment and Activity acceptance respectively). Each subtheme was calculated as a mean score. The APQ-28 subthemes, similarly to the following scales, permitted one missing item per subscale.

(2) Current and usual pain were measured using two 11-point numerical rating scales (NRS), where 0='no pain' and 10='worst possible pain',[37].

(3) Physical fatigue (seven items) and mental fatigue (four items) were measured using the Chalder Fatigue Questionnaire (CFQ), where scores of 1='much worse than usual' and 4='better than usual',[38]. Two subscale scores were summated where higher scores indicated less fatigue.

(4) Depression was measured using the nine item Patient Health Questionnaire (PHQ-9), the items of which are based on the Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV),[39]. Items were rated between 0='not at all' and 3='nearly everyday'. Total scores of 1-4=minimal depression, 5-9=mild depression, 10-14=moderate depression and ≥15=severe depression,[39, 40].

(5) Anxiety was measured using the seven-item Generalised Anxiety Disorder Assessment (GAD-7). Items were rated between 0='not at all' and 3='nearly everyday'. Total scores of 5-9=mild anxiety, 10-14=moderate anxiety and ≥15=severe anxiety,[41].

(6) Self-efficacy was measured using the 10-item Pain Self-Efficacy Questionnaire (PSEQ) where items were rated between 0='not at all confident' and 6='completely confident'. Total scores of PSEQ≥40 indicate those patients who are more likely to continue implementing coping strategies/behavioural changes, and PSEQ≤16 are considered low,[42].

(7) Avoidance was measured using the 'Escape and Avoidance' subscale of the Pain Anxiety Symptoms Scale-short version (PASS-20),[43]. The five items were rated between 0='never' and 5='always' where higher total scores indicated greater avoidance.

(8) Physical and mental function were measured using the 12-Item Short-Form Health Survey (SF-12). Two subscale scores (out of 100) were calculated using the

SF-12 software (Version 2; one-week recall) where higher scores indicated better function,[44].

(9) Health-related quality of life was measured using the EQ-5D-5L (EuroQol). The EQ-5D-5L was calculated as an index score,[45, 46].

Data analysis

Feasibility outcomes and participants' demographics were analysed using descriptive statistics. Clinical outcomes were estimated as changes in activity pacing and symptoms between T1-T2, T2-T3 and T1-T3 (mean change, 95% confidence intervals). The validity of the modified APQ-28 was estimated using Cronbach's alpha and item correlations; and sensitivity analyses explored the effects of including two new APQ-28 items. Data were analysed using IBM SPSS Statistics 26 statistical software (IBM Corp, Armonk, New York).

Patient and Public Involvement

Patient and Public Involvement (PPI) commenced during the initial planning stages of the mixed methods programme to develop and test the activity pacing framework. A meeting with five PPI representatives discussed the study purpose and practical issues around the proposed methods (online survey, nominal group technique, and feasibility and acceptability studies). PPI guided on improving the accessibility of patients' participation and reducing burden (for example, location and duration of meetings). A PPI representative has acted as an advisor on the study, involving

commenting on study documents/questionnaire booklets and coding qualitative interviews. Acceptability interviews with patients explored practical issues surrounding the feasibility study,[34] which will further assist the planning of a future randomised controlled trial (RCT) of activity pacing.

RESULTS

Recruitment and T1 data collection commenced in May 2018 and T3 data collection ended in December 2019 due to attaining the target sample.

Demographics

Among the 107 participants who completed the baseline (T1) measures, participants were predominantly female (n=92, 86.0%) with a mean age of 55.25 +/- 12.83 years. Low back pain was most frequently reported (n=79, 73.8%) and CFS/ME least frequently reported (n=12, 11.2%). Sixty-five participants (61.3%) reported two or more conditions of chronic pain and/or fatigue. Of the 12 participants with CFS/ME, 10 participants reported CFS/ME as their main condition, and 11 reported at least one co-morbidity of LBP (n=7), chronic widespread pain (n=6), fibromyalgia (n=7) or another condition (n=3). *(See Table 1 for participant demographics and Table 2 for baseline scores for activity pacing and symptoms.)*

Table 1. Participant demographics at baseline (T1)

	Participants who completed T1 but not T2	Participants who completed T1 and T2	Total
Gender	(n=42)	(n=65)	(n=107)
Male	6 (14.3%)	9 (13.8%)	15 (14.0%)
Female	36 (85.7%)	56 (86.2%)	92 (86.0%)
Age (years)	(n=41) Mean=56.07 (SD=13.85)	(n=65) Mean=54.74 (SD=12.22)	(n=106) Mean=55.25 (SD=12.83)
Ethnicity	(n=41)	(n=65)	(n=106)
White (British, Irish, Other)	39 (95.1%)	60 (92.3%)	99 (93.4%)
Black (Caribbean, African)	0 (0.0%)	1 (1.5%)	1 (0.9%)
Mixed (white/black, white/Asian, other)	1 (2.4%)	2 (3.1%)	3 (2.8%)
Asian (Indian, Pakistani, Bangladeshi, other)	1 (2.4%)	2 (3.1%)	3 (2.8%)
Asian Eastern (Chinese, other)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Living situation*	(n=42)	(n=65)	(n=107)
Lives alone	7 (16.7%)	10 (15.4%)	17 (15.9%)
Lives with partner	25 (59.5%)	48 (73.8%)	73 (68.2%)
Lives with children	16 (38.1%)	24 (36.9%)	40 (37.4%)
Other	2 (4.8%)	1 (1.5%)	3 (2.8%)
Employment	(n=42)	(n=65)	(n=107)
Working (full-time, part-time, in the house, student)	13 (31.0%)	31 (47.7%)	44 (41.1%)
Not working (due to chronic pain/fatigue/other condition)	15 (35.7%)	19 (29.2%)	34 (31.8%)
Retired/semi-retired	14 (33.3%)	14 (21.5%)	28 (26.2%)
Other	0 (0.0%)	1 (1.5%)	1 (0.9%)

Conditions*:	(n=41)	(n=65)	(n=106)
Low back pain	30 (73.2%)	49 (75.4%)	79 (74.5%)
Widespread pain	19 (46.3%)	33 (50.8%)	52 (49.1%)
Fibromyalgia	9 (22.0%)	20 (30.8%)	29 (27.4%)
CFS/ME	6 (14.6%)	6 (9.2%)	12 (11.3%)
Other	9 (22.0%)	12 (18.5%)	21 (19.8%)
Number of the above conditions:	(n=41)	(n=65)	(n=106)
1	17 (41.5%)	24 (36.9%)	41 (38.7%)
2	19 (46.3%)	30 (46.2%)	49 (46.2%)
3	3 (7.3%)	9 (13.8%)	12 (11.3%)
4	1 (2.4%)	1 (1.5%)	2 (1.9%)
5	1 (2.4%)	1 (1.5%)	2 (1.9%)
Duration of participants' main condition (years)	(n=35) Mean=10.23 (SD=9.49)	(n=61) Mean=12.94 (SD=11.36)	(n=96) Mean=11.95 (SD=10.74)

**Patients could select more than one answer.*

Table 2. Baseline scores for activity pacing and symptoms for all patients completing the baseline questionnaires (T1)

Measures (range of scores)	Baseline scores for those completed T1 but not T2: Mean (SD)	Baseline scores for those completed T1 and T2: Mean (SD)	Total scores
APQ-28 Activity adjustment (0-4)	(n=42) 1.96 (0.87)	(n=64) 1.74 (0.76)	(n=106) 1.83 (0.81)
APQ-28 Activity planning (0-4)	(n=42) 1.57 (1.03)	(n=65) 1.44 (0.95)	(n=107) 1.49 (0.98)
APQ-28 Activity consistency (0-4)	(n=42) 1.91 (0.91)	(n=65) 1.82 (0.96)	(n=107) 1.85 (0.94)
APQ-28 Activity acceptance (0-4)	(n=42) 1.97 (1.02)	(n=65) 1.87 (0.84)	(n=107) 1.91 (0.92)
APQ-28 Activity progression (0-4)	(n=42) 1.59 (1.05)	(n=65) 1.45 (0.88)	(n=107) 1.51 (0.95)
Current pain (0-10)	(n=41) 6.83 (1.96)	(n=65) 6.63 (1.97)	(n=106) 6.71 (1.96)
Usual pain (0-10)	(n=40) 7.72 (1.43)	(n=63) 7.30 (1.82)	(n=103) 7.47 (1.69)
Physical fatigue (7-28)	(n=41) 14.18 (5.12)	(n=62) 15.22 (4.10)	(n=103) 14.81 (4.54)
Mental fatigue (4-16)	(n=42) 8.79 (3.22)	(n=64) 8.86 (2.77)	(n=106) 8.83 (2.94)
Depression (0-27)	(n=40) 12.63 (7.61)	(n=64) 13.66 (6.38)	(n=104) 13.26 (6.86)
Anxiety (0-21)	(n=41) 9.86 (6.64)	(n=65) 9.91 (5.47)	(n=106) 9.89 (5.92)
Self-efficacy (0-60)	(n=42) 26.26 (13.85)	(n=65) 25.29 (10.60)	(n=107) 25.67 (11.93)
Avoidance (0-25)	(n=42)	(n=64)	(n=106)

	12.95 (6.74)	13.27 (5.49)	13.14 (5.98)
Physical function (0-100)	(n=42) 33.67 (9.75)	(n=63) 34.15 (8.23)	(n=105) 33.96 (8.82)
Mental function (0-100)	(n=42) 42.22 (11.51)	(n=63) 38.52 (11.10)	(n=105) 40.00 (11.36)
Quality of life (0-1)	(n=40) 0.41 (0.26)	(n=60) 0.43 (0.25)	(n=100) 0.42 (0.25)

Activity pacing (28-item Activity Pacing Questionnaire, APQ-28), Pain (Numerical Rating Scale 0-10), Physical/mental fatigue (Chalder Fatigue Questionnaire), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain Self-Efficacy Questionnaire), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20), Physical/mental function (Short-Form 12), Quality of life (EQ-5D-5L index score)

Feasibility outcomes

Recruitment and attrition (Objective 1)

Of the 144 patients invited to participate, 139 were eligible (96.5%). The reasons for ineligibility included: three patients reported only neck pain, one patient reported neck/knee pain and one patient reported thoracic pain. Of the 139 eligible patients, 107 (77.0%) were recruited at T1, 69 (64.5%) completed the six-week programme and 65 (60.7%) completed the T2 measures (attrition rate=39.3%). Fifty-two participants completed T3 (80.0% of T2; attrition rate from T1=51.4%). There were no serious adverse events. *(See Figure 2. CONSORT flow diagram.)*

Of the 107 participants, the median number of rehabilitation programme sessions attended was five (58.9% participants attended ≥5 sessions); 83.2% participants attended at least one activity pacing session and 56.1% attended both activity pacing sessions. Of the 65 participants who completed T2, the median number of sessions

attended was six (89.2% participants attended ≥5 sessions); 100% of participants attended at least one activity pacing specific session and 54 (83.1%) participants attended both activity pacing sessions. There were no statistically significant differences between participants who completed T2 or dropped out in terms of demographics or baseline symptoms. Of the 12 participants with CFS/ME, six completed T2 (50%) and six completed T3 (100% of T2, 50% of T1); whereas 59 of the 95 participants without CFS/ME completed T2 (62%) and 46 completed T3 (78% of T2 and 48% of T1).

Acceptability of the rehabilitation programme/questionnaires (Objective 1)

On T2, participants rated their satisfaction of the length and content of the rehabilitation programme as mean=8.8 (SD=1.7) and 9.1 (SD=1.5) respectively. The satisfaction of only those participants with CFS/ME was mean=9.0 (SD=0.9) and 9.2 (SD=1.0).

There were minimal missing data in the questionnaire booklets (approximately 1%). Some participants wrote comments regarding their perceived benefits of implementing activity pacing and other coping strategies. Two participants wished for a longer programme or a follow-up session *(see Figure 3 for examples of participants' comments)*.

Fidelity to the activity pacing framework (Objective 2)

Each healthcare professional observation demonstrated good adherence to the framework against a number of key points. Healthcare professionals reported 100% adherence in their fidelity checklists for each rehabilitation programme. Healthcare professionals reported that some participants spent over 20 minutes completing the questionnaire booklet, and that not all patients completed the activity diaries.

Interventions between T2 and T3

Of the 52 respondents at T3, two patients received lumbar epidural steroid injections, one patient had acupuncture, one attended a chiropractor and one patient had knee surgery.

Clinical outcomes

Validity of the APQ-28 (Objective 3)

At T1, the two new APQ-28 items showed ease of completion through minimal missing answers (Item APQ12=0 missing answers, Item APQ15=1 missing answer). The scores of the new items utilised the full range, and the mean scores (Items APQ12=1.67 and APQ15=1.91) sat within the range of the other APQ-28 items (mean=1.17-2.78). The new items demonstrated optimal fit with their allocated subthemes via highest inter-item correlations and item-total correlations (item total correlations: APQ12 and Activity adjustment, $r_s(106)=0.76$, $p<0.001$; Item APQ15 and Activity acceptance, $r(106)=0.68$, $p<0.001$). The internal consistency for Activity adjustment increased with the addition of Item APQ12 (Cronbach's alpha=0.86 to

0.88), and for Activity acceptance with the addition of Item APQ15 (Cronbach's alpha=0.68 to 0.72). The internal validity of the other APQ-28 subthemes were: Activity planning=0.86, Activity consistency=0.80 and Activity progression=0.69.

Mean changes in activity pacing and symptoms (Objective 3)

Between T1-T2, all five APQ-28 subtheme mean scores increased, indicating improved activity pacing. There were small reductions in APQ-28 scores between T2-T3. However, all five subthemes showed overall improvements between T1-T3, with Activity planning showing the greatest increases *(see Table 3).* Sensitivity analyses showed marginal increases in mean changes following the addition of the two new APQ-28 items.

Table 3. Mean changes in the five subthemes of activity pacing (APQ-28) between T1 (baseline), T2 (end of 6-weeks' treatment) and T3 (3-months' follow-up)

Measures	T1 mean (SD) T2 mean (SD)	T2-T1 mean change (95% CI); Effect size(d)	T2 mean (SD) T3 mean (SD)	T3-T2 mean change (95% CI); Effect size(d)	T3 mean T1 mean	T3-T1 mean change (95% CI); Effect size(d)
APQ-28 Activity adjustment	(n=63) T1 mean=1.73(0.77) T2 mean=2.43(0.73)	0.70 (95% CI= 0.48 to 0.91); d=0.91	(n=51) T2 mean=2.44(0.72) T3 mean=2.32(0.90)	-0.12 (95% CI= -0.36 to 0.11); d=-0.17	(n=50) T1 mean=1.75(0.78) T3 mean=2.33(0.90)	0.58 (95% CI= 0.33 to 0.83); d=0.74
APQ-28 Activity planning	(n=65) T1 mean=1.44(0.95) T2 mean=2.42(0.87)	0.99 (95% CI= 0.72 to 1.26); d=1.03	(n=52) T2 mean=2.45(0.87) T3 mean=2.06(1.02)	-0.39 (95% CI= -0.70 to -0.07); d=-0.45	(n=52) T1 mean=1.42(0.96) T3 mean=2.06(1.02)	0.64 (95% CI= 0.36 to 0.92); d=0.67
APQ-28 Activity consistency	(n=65) T1 mean=1.82(0.96) T2 mean=2.65(0.74)	0.84 (95% CI= 0.60 to 1.07); d=0.86	(n=52) T2 mean=2.66(0.71) T3 mean=2.37(0.72)	-0.29 (95% CI= -0.54 to -0.04); d=-0.41	(n=52) T1 mean=1.86(1.00) T3 mean=2.37(0.72)	0.51 (95% CI= 0.24 to 0.78); d=0.51
APQ-28 Activity acceptance	(n=65) T1 mean=1.87(0.84) T2 mean=2.55(0.72)	0.67 (95% CI= 0.46 to 0.89); d=0.81	(n=52) T2 mean=2.57(0.73) T3 mean=2.42(0.95)	-0.15 (95% CI= -0.38 to 0.08); d=-0.21	(n=52) T1 mean=1.84(0.91) T3 mean=2.42(0.95)	0.58 (95% CI= 0.33 to 0.84); d=0.64
APQ-28 Activity progression	(n=65) T1 mean=1.45(0.88) T2 mean=2.39(0.89)	0.94 (95% CI= 0.65 to 1.22); d=1.07	(n=52) T2 mean=2.40(0.91) T3 mean=2.00(0.91)	-0.40 (95% CI= -0.75 to -0.05); d=-0.44	(n=52) T1 mean=1.45(0.85) T3 mean=2.00(0.91)	0.56 (95% CI= 0.24 to 0.87); d=0.65

Activity pacing (28-item Activity Pacing Questionnaire, APQ-28); 95% confidence interval (95% CI)

Between T1-T2, the mean scores of all symptoms improved. Current pain reduced more than usual pain. Physical and mental fatigue both improved, as did self-efficacy and quality of life. Mental function improved more than physical function. Depression, anxiety and avoidance all reduced. There was some deterioration in symptoms between T2-T3, but between T1-T3 all symptoms demonstrated clear improvements except avoidance (-1.46, 95% CI=-3.02 to 0.10) and physical function (1.62, 95% CI=-0.81 to 4.06) *(see Table 4.).* Observing only the subgroup of participants with CFS/ME, improvements were seen between T1-T2 and T1-T3 across all APQ-28 subthemes and symptoms.

Table 4. Mean changes in measures of symptoms between T1 (baseline), T2 (end of 6-weeks' treatment) and T3 (3-months' follow-up)

Measures	T1 mean (SD) T2 mean (SD)	T2-T1 mean change (95% CI); Effect size(d)	T2 mean (SD) T3 mean (SD)	T3-T2 mean change (95% CI); Effect size(d)	T3 mean T1 mean	T3-T1 mean change (95% CI); Effect size(d)
Current pain	(n=65) T1 mean=6.63(1.97) T2 mean=5.31(2.38)	-1.32 (95% CI= -1.91 to -0.74); d=-0.67	(n=52) T2 mean=5.04(2.36) T3 mean=5.65(2.31)	0.62 (95% CI= -0.08 to 1.31); d=0.26	(n=52) T1 mean=6.58(1.99) T3 mean=5.65(2.31)	-0.92 (95% CI= -1.58 to -0.27); d=-0.47
Usual pain	(n=65) T1 mean=7.30(1.82) T2 mean=6.62(2.08)	-0.68 (95% CI= -1.19 to -0.18); d=-0.37	(n=51) T2 mean=6.53(2.10) T3 mean=6.55(1.91)	0.02 (95% CI= -0.48 to 0.52); d=0.01	(n=50) T1 mean=7.30(1.62) T3 mean=6.54(1.93)	-0.76 (95% CI= -1.27 to -0.25); d=-0.47
Physical fatigue	(n=62) T1 mean=15.22(4.10) T2 mean=20.31(3.92)	5.08 (95% CI= 3.95 to 6.21); d=1.24	(n=51) T2 mean=20.47(4.13) T3 mean=18.12(4.18)	-2.35 (95% CI= -3.44 to -1.26); d=-0.57	(n=49) T1 mean=15.35(3.90) T3 mean=18.18(4.16)	2.84 (95% CI= 1.34 to 4.33); d=0.73
Mental fatigue	(n=64) T1 mean=8.86(2.77) T2 mean=11.28(2.43)	2.42 (95% CI= 1.75 to 3.10); d=0.87	(n=51) T2 mean=11.45(2.20) T3 mean=10.92(2.34)	-0.53 (95% CI= -1.17 to 0.11); d=-0.24	(n=51) T1 mean=8.94(2.51) T3 mean=10.92(2.34)	1.98 (95% CI= 1.33 to 2.64); d=0.79
Depression	(n=63) T1 mean=13.65(6.44) T2 mean=7.14(6.09)	-6.51 (95% CI= -7.72 to -5.31); d=-1.01	(n=51) T2 mean=6.27(5.49) T3 mean=9.23(5.75)	2.96 (95% CI= 1.64 to 4.29); d=0.54	(n=51) T1 mean=13.18(6.35) T3 mean=9.09(5.76)	-4.09 (95% CI= -5.61 to -2.57); d=-0.64

Anxiety	(n=65) T1 mean=9.91(5.47) T2 mean=5.40(5.13)	-4.51 (95% CI= -5.60 to -3.42); d=-0.82	(n=52) T2 mean=4.65(4.47) T3 mean=6.10(5.23)	1.44 (95% CI= 0.55 to 2.33); d=0.32	(n=52) T1 mean=9.47(5.06) T3 mean=6.10(5.23)	-3.37 (95% CI= -4.63 to -2.12); d=-0.67
Self-efficacy	(n=65) T1 mean=25.29(10.60) T2 mean=36.29(14.12)	11.00 (95% CI= 8.44 to 13.56); d=1.04	(n=52) T2 mean=37.96(14.12) T3 mean=34.68(14.26)	-3.28 (95% CI= -7.17 to 0.60); d=-0.23	(n=52) T1 mean=25.85(10.74) T3 mean=34.68(14.26)	8.83 (95% CI= 5.86 to 11.81); d=0.82
Avoidance	(n=64) T1 mean=13.27(5.49) T2 mean=10.28(5.89)	-2.98 (95% CI= -4.43 to -1.54); d=-0.54	(n=52) T2 mean=10.85(5.93) T3 mean=12.12(5.79)	1.27 (95% CI= -0.27 to 2.81); d=0.21	(n=52) T1 mean=13.58(5.66) T3 mean=12.12(5.79)	-1.46 (95% CI= -3.02 to 0.10); d=-0.26
Physical function	(n=63) T1 mean=34.15(8.23) T2 mean=38.82(9.06)	4.67 (95% CI= 2.69 to 6.65); d=0.57	(n=49) T2 mean=39.45(8.72) T3 mean=36.63(9.69)	-2.82 (95% CI= -5.29 to -0.35); d=-0.32	(n=47) T1 mean=34.92(7.98) T3 mean=36.55(9.81)	1.62 (95% CI= -0.81 to 4.06); d=0.20
Mental function	(n=63) T1 mean=38.52(11.10) T2 mean=45.83(11.48)	7.30 (95% CI= 4.49 to 10.12); d=0.66	(n=49) T2 mean=46.75(10.82) T3 mean=44.78(10.44)	-1.97 (95% CI= -5.22 to 1.29); d=-0.18	(n=47) T1 mean=38.61(10.65) T3 mean=44.56(10.60)	5.95 (95% CI= 2.83 to 9.08); d=0.56
Quality of life	(n=59) T1 mean=0.43(0.25) T2 mean=0.56(0.28)	0.13 (95% CI=0.07 to 0.18); d=0.52	(n=48) T2 mean=0.60(0.25) T3 mean=0.51(0.28)	-0.09 (95% CI= -0.14 to -0.03); d=-0.36	(n=45) T1 mean=0.45(0.24) T3 mean=0.52(0.29)	0.07 (95% CI= 0.001 to 0.14); d=0.29

Pain (Numerical Rating Scale 0-10), Physical/mental fatigue (Chalder Fatigue Questionnaire), Depression (Patient Health Questionnaire-9), Anxiety (Generalised Anxiety Disorder-7), Self-efficacy (Pain Self-Efficacy Questionnaire), Avoidance (Escape and avoidance subscale of the Pain Anxiety Symptoms Scale-20), Physical/mental function (Short-Form 12), Quality of life (EQ-5D-5L index score); 95% confidence interval (95% CI)

DISCUSSION

This study fulfilled the original aims of testing the feasibility and acceptability of using a new activity pacing framework to standardise instructions of activity pacing to assist planning a future effectiveness RCT. The study recruited to target and patients with chronic pain and chronic fatigue demonstrated both improvements in activity pacing strategies and reductions in symptoms.

Feasibility

The activity pacing framework demonstrated feasibility through excellent fidelity to the framework by healthcare professionals via self-reported checklists and observations. Acceptability was demonstrated through patients' high satisfaction scores. Not all patients completed the activity diaries, however, this was optional for patients to facilitate their own self-reflection.

The recruitment rate (77%) was higher than estimated in the study protocol (50%). This was similar to a study exploring a five-week exercise programme for chronic hip pain (recruitment rate=76%),[47]; and this rate is considered 'Good' using cut-off levels of 80%=excellent and 70%=good from a feasibility study exploring a mind-body physical activity programme for chronic pain,[48]. The attrition rate between T1-T2 (39.3%) was as predicted in the protocol (40%), and lower than the 60% attrition rates reported across other studies investigating programmes for chronic pain,[20]. The attrition rate between T2-T3 (20.0%) was lower than predicted in the protocol (50%), and the target sample size proved feasible to attain. These

recruitment/attrition rates will help to plan the progression criteria used in a future pilot RCT of activity pacing.

Regarding treatment adherence, only 56.1% of participants recruited at T1 attended both activity pacing sessions. Many participants (n=18, 16.8%) dropped out after the first session and therefore did not attend any activity pacing sessions. Reasons for early drop-out often include unrealistic expectations of symptom improvement, low motivation, or confidence to commit to programmes or behavioural changes,[20]. In comparison, attendance rates of both activity pacing sessions among those who completed T2 were 83.1%, and 89.2% of participants attended five or more sessions. This is comparable to adherence rates of 81% seen elsewhere,[47]; and adherence rates have been considered as 'Excellent' when 70% or more participants complete 75% of sessions,[48]. However, within the present study, the interpretation of high attendance rates from those who completed T2 are considered more modestly following the drop outs after Week 1.

Participants reported the condition of low back pain most frequently and CFS/ME the least frequently, as per current prevalence rates,[49, 50]. Our findings re-iterate the high occurrence of co-morbidities, and frequent co-existence of chronic pain among patients with CFS/ME,[9]. Participants with CFS/ME demonstrated improvements in symptoms following treatment, in comparison to other studies in which pacing has been ineffective,[31]. Disparate to the study by White et al.,[31], the activity pacing framework encourages a rehabilitative approach that facilitates increased function rather than aiming to reduce symptoms. The effects of rehabilitative approaches to

activity pacing for patients with both chronic pain and fatigue requires further investigation using effectiveness trials.

Clinical outcomes

Activity pacing improved across all APQ-28 subthemes, the largest improvement being for Activity planning. This theme refers to planning activities, setting time targets and assessing activity levels,[36]; practical facets of activity pacing which may be more accessible to change. Comparably, participants showed smaller improvements in Activity acceptance. This subtheme includes setting realistic goals and allowing flexibility; facets that involve changing previous behaviours or self-enforced rules. The APQ-28 detected multidimensional changes in activity pacing, and the two new items appeared to complement the scale. Further study will fully validate the APQ-28 in a larger sample and estimate minimally important changes.

The aims of the activity pacing framework are to improve patients' function and quality of life. Improvements in physical function were seen between T1-T2 (mean change=4.67) that were greater than the minimally clinically important change (3.29),[51]. There were also reductions in avoidance between T1-T2. It is intended that the quota-contingent, operant approach of the activity pacing framework encourages a reduction in avoidance through setting meaningful and realistic goals towards activity, rather than stopping activities with the aim of reducing/avoiding symptoms as per energy conservation approaches. Similarly, in a RCT comparing an operant approach with energy conservation, Racine et al.,[30] found the operant approach, but not energy conservation was associated with reduced avoidance

among patients with fibromyalgia. This, together with greater improvements in depressive symptoms following the operant approach over energy conservation, led to recommendations towards the operant approach for patients with fibromyalgia,[30]. The current study found that pre-post treatment (T1-T2) improvements in both avoidance and physical function showed some decline at three months' follow-up. The authors suggest that physical function may be a component of rehabilitation in which patients feel least confident, especially those with avoidant behaviours,[20]. This may have implications for future programmes to integrate follow-up sessions to encourage longer-term maintenance of physical activity. In comparison, Racine et al.,[30] found improvements in physical activity following both operant pacing and energy conservation approaches. Similarly to the present study, Racine et al.,[30] implemented handouts, homework and goal setting to encourage patients' uptake of activity pacing. However, both of the interventions explored by Racine et al.,[30] were of greater duration than the current study, comprising of 10 two-hour stand-alone pacing sessions with a 3-month booster session. Within the current study, improvements in mental function between T1-T2 (mean change=7.3) were better maintained between T1-T3 (mean change=5.95); and both higher than the minimally clinically important change (3.77),[51]. Quality of life also improved between T1-T2 (mean change=0.13) and much of this improvement was maintained between T1-T3 (mean change=0.07); both changes exceeded the minimally important difference (0.037 +/-0.008),[52].

The activity pacing framework additionally aims to increase patients' self-efficacy. Improvements in self-efficacy were found between T1 (mean=25.29) and T2 (mean=36.29), which were well maintained at T3 (mean=34.68). Scores were lower

than the ≥40 cut off. However, an improvement of >5.5 was attained which is considered a minimally important change,[53]. Both physical and mental fatigue improved, and improvements in mental fatigue appeared to be better maintained at T3. Comparisons to minimally important changes are unavailable.

Psychological health improved following the rehabilitation programme, including reduced depression scores from moderate to mild (T1=13.7, T2=7.1, T3=9.1); with a clinically significant reduction (≥5) between T1-T2,[40]. Mean anxiety scores reduced (T1=9.9, T2=5.4 and T3=6.10), and remained within the classification of mild anxiety,[41]. Although reductions in pain were not a direct aim of the current treatment, lower pain severity was reported. Despite the increased intensity of pacing sessions contained within the RCT comparing the operant approach to energy conservation, Racine et al.,[30] found that neither pacing approach effectively reduced symptoms of pain or fatigue.

Strengths and limitations

This study was an early feasibility study that primarily aimed to explore whether a new activity pacing framework could be implemented in the clinical setting. Whilst this study fulfilled its original aims, it is limited by the absence of *a priori* progression criteria. However, the findings from this study will help to inform the progression criteria that are used to determine whether to progress to a full clinical trial from a future pilot RCT. Despite recruiting to target, this sample was not powered with a control arm to determine treatment effectiveness. As per other studies exploring activity pacing, activity pacing was instructed as one component of the rehabilitation

programme,[5]. Therefore, improvements in symptoms may have resulted from any combination of coping strategies. A future RCT will implement a suitable control to explore the effects of activity pacing, while implementing the activity pacing framework in a clinically relevant setting, including alongside other coping strategies.

The generalisability of this study is limited to a sample of predominantly females and white ethnic origin. Recruitment occurred only at one Pain Service and this service had an existing rehabilitation programme for both chronic pain and fatigue. Bias may have arisen through the lead researcher delivering the healthcare professionals' training and undertaking the observations. Further work will test the activity pacing framework and study protocol across other healthcare services and explore feasibility and fidelity over wider geographical locations.

It is unknown what potential bias was caused by the attrition rate. However, there were no differences at baseline between those who completed the programme and those who dropped out. It is possible that patients who completed T2 and T3 possibly felt greater benefits from the treatment and were more motivated to respond to the follow-up questionnaires. The attrition rate may be reflective of some of the clinical challenges and missed appointments surrounding the complexity of chronic pain/fatigue. Further research could explore whether providing a follow-up treatment session improves commitment to activity pacing.

Modifications for future study

Since more patients completed the T1 questionnaires during the rehabilitation sessions than at home, this may be the preferable mode of distribution of paper questionnaires. To lessen the time taken to complete the questionnaires, the PASS-20 may be considered for exclusion in future study. The whole 20-item PASS scale was included for reliability and validity, but data specifically from the Escape and Avoidance subscale was explored. Modifications to the inclusion criteria may include patients with any chronic spinal pain, including cervical/thoracic pain due to the frequent and similar presentation at rehabilitation services.

Conclusion

To the authors' knowledge, this is the first study to explore the clinical utility of a comprehensive activity pacing framework developed for both chronic pain and chronic fatigue. The newly developed activity pacing framework proved feasible to use clinically by healthcare professionals. Patients with both chronic pain and fatigue implemented greater activity pacing strategies following treatment, alongside reporting improvements in quality of life, psychological wellbeing, self-efficacy, pain and fatigue. Physical function and avoidance improved to a lesser extent and for the shorter-term. Future study will use the activity pacing framework in an effectiveness RCT to explore the effects of activity pacing on symptoms.

ACKNOWLEDGEMENTS

We would like to acknowledge all of the patients and healthcare professionals who were involved in this study. We would also like to acknowledge our statistical support.

CONFLICT OF INTEREST

All authors declare no conflicts of interest

AUTHOR CONTRIBUTIONS

DA, AMK, PK, SW and LMc all contributed to the conception and design of the study. DA undertook the acquisition of the data. DA, AMK, PK, SW and LMc all contributed to the analysis and interpretation of data. DA, AMK, PK, SW and LMc contributed to drafting the manuscript and revising it critically for important intellectual content and have approved the final version for publication. DA, AMK, PK, SW and LMc are in agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

PATIENT CONSENT FOR PUBLICATION

Not required.

DATA SHARING AGREEMENT

De-identified participant data are available from the corresponding author (Deborah.Antcliff@nca.nhs.uk) upon reasonable request. Re-use is permitted for health and care research as long as the original authors are acknowledged. The protocol can also be requested from the author or accessed at ClinicalTrials.gov (NCT03497585).

ETHICAL APPROVAL

Ethical approval was granted by the London-Surrey Research Ethics Committee (18/LO/0655).

DISCLAIMER

This paper presents independent research funded by Health Education England/National Institute for Health Research (NIHR) [Clinical Lectureship (ICA-CL-2015-01-019)]. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

SOURCES OF FUNDING

This work was supported by a Health Education England/National Institute for Health Research (HEE/NIHR) Clinical Lectureship (grant number: ICA-CL-2015-01-019).

REFERENCES

1. Torrance N, Smith BH, Elliott AM, et al. Potential Pain Management Programmes in primary care. A UK-wide questionnaire and Delphi survey of experts. *Fam Pract* 2011;28:41-8.

2. Nijs J, Meeus M, De Meirleir K. Chronic musculoskeletal pain in chronic fatigue syndrome: recent developments and therapeutic implications. *Man Ther* 2006;11:187-91.

3. Nielson WR, Jensen MP, Karsdorp PA, et al. Activity pacing in chronic pain: concepts, evidence, and future directions. *Clin J Pain* 2013;29:461-8.

4. Antcliff D, Keenan AM, Keeley P, et al. Survey of activity pacing across healthcare professionals informs a new activity pacing framework for chronic pain/fatigue. *Musculoskeletal Care* 2019;17:335-45.

5. Abonie US, Sandercock GRH, Heesterbeek M, et al. Effects of activity pacing in patients with chronic conditions associated with fatigue complaints: a meta-analysis. *Disabil Rehabil* 2020;42:613-22.

6. Aggarwal VR, McBeth J, Zakrzewska JM, et al. The epidemiology of chronic syndromes that are frequently unexplained: do they have common associated factors? *Int J Epidemiol* 2006;35:468-76.

7. Meeus M, Nijs J. Central sensitization: a biopsychosocial explanation for chronic widespread pain in patients with fibromyalgia and chronic fatigue syndrome. *Clin Rheumatol* 2007;26:465-73.

8. Davis LL, Kroenke K, Monahan P, et al. The SPADE Symptom Cluster in Primary Care Patients With Chronic Pain. *Clin J Pain* 2016;32:388-93.

9. Meeus M, Nijs J, Meirleir KD. Chronic musculoskeletal pain in patients with the chronic fatigue syndrome: a systematic review. *Eur J Pain* 2007;11:377-86.

10. Tavel ME. Somatic symptom disorders without known physical causes: one disease with many names? *Am J Med* 2015;128:1054-8.

11. Yunus MB. Fibromyalgia and overlapping disorders: the unifying concept of central sensitivity syndromes. *Semin Arthritis Rheum* 2007;36:339-56.

12. Nijs J, Meeus M, Van Oosterwijck J, et al. In the mind or in the brain? Scientific evidence for central sensitisation in chronic fatigue syndrome. *Eur J Clin Invest* 2012;42:203-12.

13. Arendt-Nielsen L, Morlion B, Perrot S, et al. Assessment and manifestation of central sensitisation across different chronic pain conditions. *Eur J Pain* 2018;22:216-241.

14. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85:317-32.

15. Moseley GL. A pain neuromatrix approach to patients with chronic pain. *Man Ther* 2003;8:130-40.

16. Ericsson A, Mannerkorpi K. How to manage fatigue in fibromyalgia: nonpharmacological options. *Pain Manag* 2016;6:331-8.

17. British Pain Society. Guidelines for pain management programmes for adults. London: British Pain Society, 2013.

18. Beissner K, Henderson CR, Jr., Papaleontiou M, et al. Physical therapists' use of cognitive-behavioral therapy for older adults with chronic pain: a nationwide survey. *Phys Ther* 2009;89:456-69.

19. Booth J, Moseley GL, Schiltenwolf M, et al. Exercise for chronic musculoskeletal pain: A biopsychosocial approach. *Musculoskeletal Care* 2017;15:413-421.

20. Anderson RJ, Hurley RW, Staud R, et al. Cognitive-motivational influences on health behavior change in adults with chronic pain. *Pain Med* 2016;17:1079-1093.

21. Birkholtz M, Aylwin L, Harman RM. Activity pacing in chronic pain management: One aim, but which method? Part one: Introduction and literature review. *British Journal of Occupational Therapy* 2004;67:447-52.

22. Abonie US, Edwards AM, Hettinga FJ. Optimising activity pacing to promote a physically active lifestyle in medical settings: A narrative review informed by clinical and sports pacing research. *J Sports Sci* 2020;38:590-596.

23. Jamieson-Lega K, Berry R, Brown CA. Pacing: A concept analysis of a chronic pain intervention. *Pain Res Manag* 2013;18:207-13.

24. Andrews NE, Deen M. Defining Activity Pacing: Is It Time to Jump Off the Merry-Go-Round? *J Pain* 2016;17:1359-1362.

25. Andrews NE, Strong J, Meredith PJ. Activity pacing, avoidance, endurance, and associations with patient functioning in chronic pain: a systematic review and meta-analysis. *Arch Phys Med Rehabil* 2012;93:2109-2121 e7.

26. Murphy SL, Clauw DJ. Activity pacing: what are we measuring and how does that relate to intervention? *Pain* 2010;149:582-583.

27. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ* 2008;337:a1655. doi: 10.1136/bmj.a1655

28. Creswell JW, Piano-Clark VL. *Designing and conducting mixed methods research*. California, USA: Sage Publications Ltd, 2011.

29. Antcliff D, Keenan AM, Keeley P, et al. Engaging stakeholders to refine an activity pacing framework for chronic pain/fatigue: A nominal group technique. *Musculoskeletal Care* 2019;17:354-362.

30. Racine M, Jensen MP, Harth M, et al. Operant Learning Versus Energy Conservation Activity Pacing Treatments in a Sample of Patients With Fibromyalgia Syndrome: A Pilot Randomized Controlled Trial. *J Pain* 2019;20:420-439.

31. White PD, Goldsmith KA, Johnson AL, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet* 2011;377:823-36.

32. Lancaster GA and Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud* 2019;5:114.

33. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.

34. Antcliff D, Keenan AM, Keeley P, et al. "Pacing does help you get your life back": The acceptability of a newly developed activity pacing framework for chronic pain/fatigue. *Musculoskeletal Care* 2021 [ePub ahead of print] doi.org/10.1002/msc.1557

35. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301-8.

36. Antcliff D, Campbell M, Woby S, et al. Assessing the Psychometric Properties of an Activity Pacing Questionnaire for Chronic Pain and Fatigue. *Phys Ther* 2015;95:1274-86.

37. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels needed in pain intensity measurement? *Pain* 1994;58:387-92.

38. Chalder T, Berelowitz G, Pawlikowska T, et al. Development of a fatigue scale. *J Psychosom Res* 1993;37:147-53.

39. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606-13.

40. Kroenke K, Spitzer RL, Williams JB, et al. The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp Psychiatry* 2010;32:345-59.

41. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-7.

42. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur J Pain* 2007;11:153-63.

43. McCracken LM, Dhingra L. A short version of the Pain Anxiety Symptoms Scale (PASS-20): preliminary development and validity. *Pain Res Manag* 2002;7:45-50.

44. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical Care* 1996;34:220-33.

45. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36.

46. van Hout B, Janssen MF, Feng Y, et al. Interim Scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L Value Sets. *Value in Health* 2012;15:708 –715.

47. Bearne LM, Walsh NE, Jessep S, et al. Feasibility of an exercise-based rehabilitation programme for chronic hip pain. *Musculoskeletal Care* 2011;9:160-8.

48. Greenberg J, Lin A, Zale EL, et al. Development And Early Feasibility Testing Of A Mind-Body Physical Activity Program For Patients With Heterogeneous Chronic Pain; The GetActive Study. *J Pain Res* 2019;12:3279-3297.

49. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. *Lancet* 2018;391:2356-67.

50. NICE. Chronic fatigue syndrome/myalgic encephalomylitis (or encephalopathy). *NICE Clinical Guideline 53 London* 2007.

51. Diaz-Arribas MJ, Fernandez-Serrano M, Royuela A, et al. Minimal Clinically Important Difference in Quality of Life for Patients With Low Back Pain. *Spine (Phila Pa 1976)* 2017;42:1908-1916.

52. McClure NS, Sayah FA, Xie F, et al. Instrument-Defined Estimates of the Minimally Important Difference for EQ-5D-5L Index Scores. *Value Health* 2017;20:644-650.

53. Chiarotto A, Vanti C, Cedraschi C, et al. Responsiveness and Minimal Important Change of the Pain Self-Efficacy Questionnaire and Short Forms in Patients With Chronic Low Back Pain. *J Pain* 2016;17:707-18.

FIGURE LEGENDS

Figure 1. Activity pacing conceptual model taken from the activity pacing framework

Figure 2: CONSORT diagram showing the flow of participants through the study

Figure 3. Participants' written comments following attending the rehabilitation programme

This framework uses the term 'Activity Pacing', which may be more similar to an operant approach, driven by quota-contingency rather than symptom-contingency. Our model of pacing moves beyond a purely behavioural approach since it also integrates thoughts and beliefs. Activity pacing within this framework encourages acceptance, active decision-making and flexibility, both in selecting which facets of pacing to implement and also when to pace.

This pacing model is based upon addressing behaviours such as fear-avoidance, excessive persistence and overactivity-underactivity cycling. This pacing model includes the potential for reversibility of some of the consequences of chronic pain/fatigue, for example, to reduce disability. As such, activity pacing is described as a rehabilitative strategy rather than an adaptive strategy in this framework.

In keeping with a rehabilitative approach, the aims of activity pacing within this framework include: improved physical and cognitive function, improved quality of life, increased sense of control and choice, and increased satisfaction with activities. Activity pacing may improve the management and ability to cope with symptoms where there is greater acceptance and flexibility. This framework does not advocate the use of activity pacing with the direct aim of reducing symptoms when this results in decreased function or dissatisfaction, or if this encourages avoidant behaviour/working below tolerance levels.

This activity pacing framework recognises pacing as a multidimensional concept that involves different facets, such as breaking down tasks, finding baselines of tolerable activities, implementing consistent levels of activities, planning activities, setting goals of meaningful activities, accepting activity levels and gradually increasing activities. Different facets of activity pacing are tailored to individuals' needs, aims and activity behaviours.

Figure 1. Activity pacing conceptual model taken from the activity pacing framework

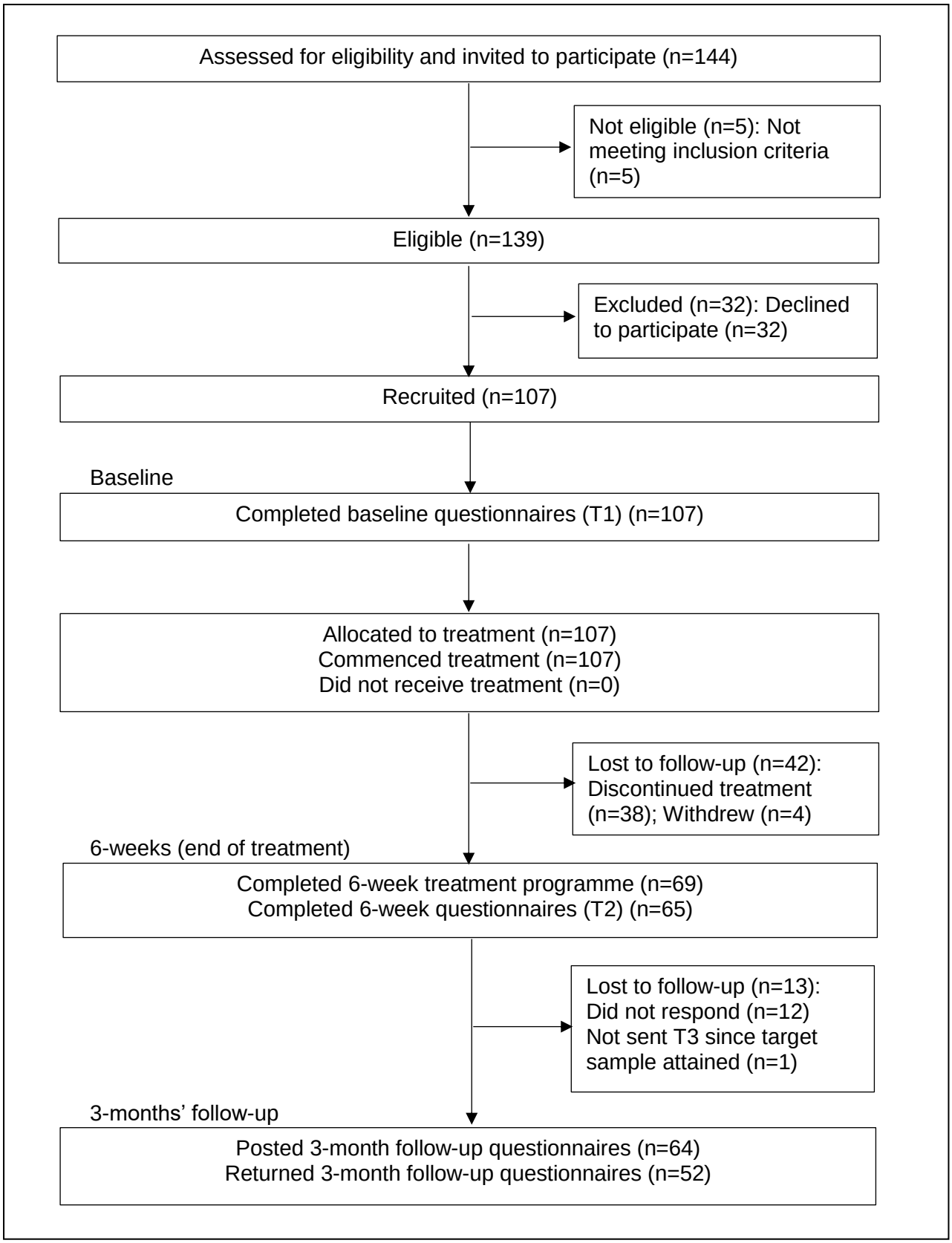

Figure 2: CONSORT diagram showing the flow of participants through the study

T2: “The pace and content has been good for me. It has helped me to focus on my belief that I have to own the situation, to be positive and to make use of the tools we have discussed. If I don't take this approach I believe my situation will not improve. There is no magic wand, but I can be the difference.” *(F070: Fibromyalgia)*

T3: “I have found pacing really helpful in my everyday life and feel I can achieve more day to day than 12 months ago.” *(F006: chronic widespread pain, fibromyalgia, chronic fatigue syndrome/myalgic encephalomyelitis)*

T3: “I found the pain service very helpful and informative. How I view my pain and react to and manage it has improved. Emotionally, I feel more positive as a result of using strategies learned, and also more confident that I can manage my pain and how it makes me feel. Using pacing and realistic goals has enabled me to do some activities that I previously avoided i.e. hoovering, changing the bed. *(F068: fibromyalgia)*

T3: “Doing the 6 week course was extremely helpful and gave me some excellent information and resources to work with. The difficulty has been that there has been no follow up or support sessions since. It is great having the info, but then you are battling depression/anxiety it is difficult to apply knowledge without some support, even if that is over the phone every few weeks or maybe a support group facility.” *(F075: low back pain, chronic widespread pain)*

T3 “I have found ‘pacing’ a very good way to manage pain and get through the day completing activities” *(F105: low back pain, chronic widespread pain, fibromyalgia)*

Figure 3. Participants’ written comments following attending the rehabilitation programme

SUPPLEMENTARY MATERIAL

Supplementary Figure 1. Content of the Activity Pacing Framework: Overview and Theory, and Appendices and Teaching Guide booklets

A. Overview and Theory

1. Glossary
2. Introduction:
    - Why is an activity pacing framework needed?
    - How has the activity pacing framework been developed?
3. Definition of activity pacing
4. Aims of pacing
    - Examples of aims of pacing and their clinical application
5. Who can benefit from pacing?
6. Activity behaviours:
    - Avoidance behaviour/fear-avoidance
    - Over-exertion/excessive persistence
    - Boom-bust/overactivity-underactivity cycling
7. Quota-contingent and symptom-contingent pacing
8. Models of pacing:
    - Operant approach
    - Energy conservation
    - Activity pacing framework model of pacing
9. Facets of pacing:
    - Facets of pacing, broader pacing themes and individuals who may benefit
    - Facets of pacing that are not endorsed for routine use, but may be considered during a flare-up of symptoms
10. Getting started with pacing: stages of pacing
11. Potential barriers to pacing:
    - Addressing barriers
12. How pacing relates to other coping strategies
    - Pacing and graded exercise/graded activity
    - Pacing and cognitive behavioural therapy
    - Pacing and acceptance and commitment therapy
    - Pacing and mindfulness
    - Pacing and relaxation

SUPPLEMENTARY MATERIAL

B. Appendices and teaching guide

SUPPLEMENTARY MATERIAL

Blank activity diary and example of a completed diary

Appendix 11. Goal setting

Appendix 12. Checklist for health care professionals

Appendix 13. References

SUPPLEMENTARY MATERIAL

Supplementary Table 1. CONSORT checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Title page (Page 1)
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	The abstract is structured as per the *BMJ Open* format, but it contains the information as per the CONSORT checklist. (Page 3)
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pages 5-7
	2b	Specific objectives or research questions for pilot trial	Page 7

SUPPLEMENTARY MATERIAL

Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Page 8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	This was not a pilot trial that ran into a RCT. Any suggested modifications following this feasibility study are included on Pages 32-33
Participants	4a	Eligibility criteria for participants	Page 9
	4b	Settings and locations where the data were collected	Page 11
	4c	How participants were identified and consented	Page 8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 9-11 and Supplemen-tary Figures 1-2
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Pages 11-14
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	This was not a pilot trial that ran into a RCT. Any suggested

SUPPLEMENTARY MATERIAL

			modifications following this feasibility study are included on Pages 32-33
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A. This was not a pilot trial that ran into a RCT. There were no prespecified criteria in this single-arm feasibility study
Sample size	7a	Rationale for numbers in the pilot trial	Page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	This was not a pilot trial that ran into a RCT. No interim analyses or stopping guidelines were included in this feasibility study.

SUPPLEMENTARY MATERIAL

Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	There was no randomisation in this single-arm feasibility study
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	There was no randomisation in this single-arm feasibility study
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	There was no randomisation in this single-arm feasibility study
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	There was no randomisation in this single-arm feasibility study
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	There was no blinding in this single-arm feasibility study

SUPPLEMENTARY MATERIAL

	11b	If relevant, description of the similarity of interventions	This was a single arm study
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Page 14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Page 19 Figure 2: CONSORT flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	This was a single arm study without randomisation. The recruitment and attrition rates are included on Page 19 and Figure 2. CONSORT flow diagram
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 15
	14b	Why the pilot trial ended or was stopped	Page 15. Figure 2: CONSORT flow diagram

SUPPLEMENTARY MATERIAL

			states T3 (follow up) was stopped due to attaining target sample
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables 1 and 2
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Tables 3 and 4
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Tables 3 and 4
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Pages 21-22
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 19
	19a	If relevant, other important unintended consequences	N/A. (Page 19 states no adverse events)
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Pages 31-32
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Page 32
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Pages 27-31
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	32-33

SUPPLEMENTARY MATERIAL

Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Abstract; Page 8
Protocol	24	Where the pilot trial protocol can be accessed, if available	Page 8
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 35
	26	Ethical approval or approval by research review committee, confirmed with reference number	Pages 8, 35

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

SUPPLEMENTARY MATERIAL

Supplementary Figure 2: Content of the rehabilitation programme

Week 1

Introduction to the programme

Aims and concerns of the programme

Understanding chronic pain

Chronic pain/fatigue cycle

Benefits of exercise

Graded exercise (circuit exercises)

Relaxation session: Breathing exercises and Progressive Muscle Relaxation (led by a psychological wellbeing practitioner)

Goal setting (SMART goals)

Week 2

Goal review

Understanding pain and the emotional effects: negative thinking and unhelpful thoughts

Pacing Session 1:

- Activity patterns (boom-bust, avoidance and excessive persistence)
- Aims of pacing
- Barriers to pacing
- Using activity diaries for the week ahead

Graded exercise (circuit exercises)

Mindfulness session: Introduction to mindfulness & Body Scan (led by a psychological wellbeing practitioner)

Goal setting

Week 3

Goal review

Pacing Session 2:

- Discuss the completed activity diaries
- Facets of pacing
- Stages of pacing

Dealing with difficult thoughts

SUPPLEMENTARY MATERIAL

Graded exercise (circuit exercises)

Mindfulness session: Leaves on the stream (led by a psychological wellbeing practitioner)

Goal setting: specific pacing goal

Week 4

Pacing goal review

Choice V's demand activities

Increasing positive thoughts

Work and employment

Graded exercise (circuit exercises)

Mindfulness session: Compassionate acceptance (led by a psychological wellbeing practitioner)

Goal setting

Week 5

Goal review

Sleep hygiene

Medication

Graded exercise (circuit exercises)

Mindfulness session: Treasure of pleasure (led by a psychological wellbeing practitioner)

Goal setting

Week 6

Goal review

Managing setbacks

Mindfulness session: Open Heart (led by a psychological wellbeing practitioner)

Maintaining progress

Signposting to community resources

SUPPLEMENTARY MATERIAL

Supplementary Table 2. Five themes of the 28-item Activity Pacing Questionnaire (APQ-28) with examples

APQ Theme	Example of items
Activity adjustment	"I broke tasks up into periods of activity and rest" "I alternated the type of activity that I was doing"
Activity consistency	"I did a similar amount of activity on 'good' and 'bad' days" "I made sure I did some activity every day, even if I had a "bad" day"
Activity progression	"I gradually increased how long I could spend on my activities" "I gradually increased activities that I had been avoiding because of my symptoms"
Activity planning	"I set activity goals that were meaningful for me" "I planned in advance how long I would spend on each activity"
Activity acceptance	"I changed my activity targets if they were unrealistic" "I set activity goals that were realistic for me"