

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

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

Journal:	<i>BMJ Open</i>
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

SCHOLARONE™
Manuscripts



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.

1
2
3 **Title: Testing a newly developed activity pacing framework for chronic**
4 **pain/fatigue: a feasibility study**
5
6
7
8
9

10 **AUTHORS**
11

12 Dr Deborah Antcliff (PhD)^{a,b}
13

14 ^aPhysiotherapy Department, Bury and Rochdale Care Organisation, Northern Care
15 Alliance NHS Group, Bury, United Kingdom.
16

17 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom.
18

19
20
21
22
23 Professor Anne-Maree Keenan (PhD)^b
24

25 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom
26
27
28
29

30 Professor Philip Keeley (PhD)^c
31

32 ^cSchool of Nursing and Midwifery, Keele University, Keele, United Kingdom
33
34
35
36

37 Professor Steve Woby (PhD)^{d,e,f}
38

39 ^dResearch and Innovation Department, Northern Care Alliance NHS Group, Salford,
40 United Kingdom.
41
42

43 ^eSchool of Health and Society, University of Salford, Salford, United Kingdom.
44

45 ^fFaculty of Science and Engineering, Manchester Metropolitan University,
46 Manchester, United Kingdom.
47
48

49 Steve.Woby@srft.nhs.uk
50
51
52
53

54 Professor Linda McGowan (PhD)^b
55

56 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom
57
58
59
60

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-

1
2
3 T2, changes in pacing significantly correlated with current pain ($r_s=-0.29$, $p=0.019$),
4 self-efficacy ($r_s=0.26-0.39$, $p<0.05$) and mental function ($r_s=0.27-0.28$, $p<0.05$).
5
6

7
8 Between T1-T3, there were additional significant correlations between changes in
9
10 pacing and physical/mental fatigue, depression, anxiety and quality of life ($p<0.05$).
11

12 There were no significant correlations with physical function/avoidance.
13

14 **Conclusion:** The activity pacing framework was feasible to implement and patients'
15 ability to pace and manage their symptoms improved. Future work will employ a
16 suitable comparison group and test the framework across wider settings to explore
17 the effects of activity pacing in a randomised controlled trial.
18
19
20
21
22

23 **Trial registration:** ClinicalTrials.gov:NCT03497585
24

25 **Funding:** Health Education England/National Institute for Health Research
26
27
28
29

30 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

31
32
33
34

- 35 • This was the first study to test the feasibility of using a newly developed
36 activity pacing framework in a rehabilitation programme to standardise the
37 clinical instructions of activity pacing to patients with chronic pain/fatigue.
38
39
- 40 • This feasibility study recruited to target with satisfactory recruitment/attrition
41 rates which form the basis of a future RCT.
42
43
- 44 • A comprehensive measure of pacing: the activity pacing questionnaire (APQ-
45 28), and range of validated psychometric measures were suitable to detect
46 changes before and after treatment.
47
48
- 49 • This study was not powered with a control arm to determine treatment
50 effectiveness, and the exploratory statistical analyses do not indicate
51 causation between increased activity pacing and improved symptoms.
52
53
54
55
56
57
58
59
60

- 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].

1
2
3
4
5 At present, there remains confusion regarding how activity pacing is defined or
6 interpreted, and the effects on patients' symptoms,[5, 24, 25]. There is no widely-
7
8 used guide to standardise how healthcare professionals instruct pacing to patients;
9
10 and uncertainty whether different methods are required for symptoms of chronic pain
11
12 versus chronic fatigue,[3, 26]. This poses challenges how to advise patients with
13
14 both chronic pain and fatigue.
15
16
17
18
19
20
21

22 We have developed an activity pacing framework using an inclusive approach for
23 patients who present at rehabilitation services with chronic pain and/or fatigue. Using
24 the Medical Research Council guidelines for developing complex interventions,
25 mixed methods were implemented to encompass theoretical and stakeholder
26 standpoints,[27]. Stage I: Healthcare professionals' survey gathered opinions on
27 activity pacing (n=92),[4]. These findings, together with existing research formed the
28 first draft of the framework and accompanying appendices. Stage II: Nominal group
29 technique refined the activity pacing framework using a consensus meeting between
30 patients and healthcare professionals (n=10),[28].
31
32
33
34
35
36
37
38
39
40
41
42
43
44

45 The conceptual model of the activity pacing framework (see *Figure 1*) follows
46 principles of quota-contingency/operant approach (for example, setting goals
47 according to time/distance/activity), with a rehabilitative aim of improving
48 participation in meaningful activities and self-efficacy while managing symptoms,[4,
49 28]. Quota-contingency is advised alongside concepts of flexibility and choice to
50 enable relevance and sustainability in conditions where symptoms may vary. The
51 framework refers to all types of activities including work, household activities,
52
53
54
55
56
57
58
59
60

1
2
3 cognitive activities, physical activities, exercise and relaxation to increase its wider
4
5 relevance for patients with chronic pain and/or fatigue, for varying abilities and
6
7 behaviours.
8
9

10
11
12 The aim of this study was to test the feasibility of using the activity pacing framework
13
14 to underpin a rehabilitation programme for chronic pain/fatigue. To inform a future
15
16 definitive trial, specific objectives included: (1) Exploring participant
17
18 recruitment/attrition rates and adherence/acceptability (for both chronic pain and
19
20 fatigue); (2) Exploring healthcare professionals' fidelity to the framework; (3) Exploring
21
22 the suitability of the outcome measures, including the modified activity pacing
23
24 questionnaire (APQ-28); and (4) Exploring associations between changes in activity
25
26 pacing and self-reported symptoms.
27
28
29
30
31
32

33 **METHODS**

34 **Study design**

35
36
37
38
39
40
41
42 This single-arm, repeated measures study is reported as a non-randomised
43
44 feasibility study using the extended CONSORT guidelines,[29, 30] (See
45
46 *Supplementary Table 1*). Quantitative questionnaire data were collected from
47
48 patients at the start (T1) and end (T2) of the six-week rehabilitation programme, and
49
50 at three month's follow-up (T3). The study was prospectively registered (protocol
51
52 available at ClinicalTrials.gov: NCT03497585). Ethical approval was granted by the
53
54 London-Surrey Research Ethics Committee (18/LO/0655). The acceptability
55
56 interviews with patients and healthcare professionals will be reported elsewhere.
57
58
59
60

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%

1
2
3 recruitment rate at T1, a 40% attrition rate between T1-T2 and a 50% return rate at
4
5 T3.
6
7
8
9

10 **Existing rehabilitation programme**

11
12
13

14 The existing rehabilitation programme comprised of six consecutive weekly sessions
15 (each 3.5 hours) delivered by healthcare professionals (pain specialist
16 physiotherapists and psychological wellbeing practitioners). The programme
17 included understanding complex symptoms, sleep hygiene, graded exercise, goal
18 setting, relaxation and mindfulness. Activity pacing was instructed in one session but
19 was not informed by any particular framework.
20
21
22
23
24
25
26
27
28
29

30 **Activity pacing framework standardised programme**

31
32
33

34 The existing six-week programme was modified through re-structuring and
35 standardisation using the activity pacing framework. Activity pacing was formally
36 instructed on two sessions (weeks 2-3), but also referenced throughout the
37 programme in relation to other coping strategies. Practical exercises included
38 completing an activity diary to discuss patients' activity patterns and setting goals in
39 which activity pacing could be practised. The healthcare professionals (as above)
40 received training on the framework during a half-day session and could contact the
41 lead researcher (DA) for any queries. All patients attended the standardised
42 programme, but participants chose whether to complete the study questionnaires.
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 alpha=0.72-0.92),[32]. Each item is scored between 0='never did this' and 4='always
4 did this'. Two items have been added that correspond to important aspects of pacing
5 that emerged during the development of the activity pacing framework. The new
6 items: APQ12:"I found a baseline amount of activities that I could do on 'good' and
7 'bad' days" and APQ15:"I had a flexible approach with my activities" were added to
8 the subthemes of best conceptual fit (Activity adjustment and Activity acceptance
9 respectively). Each subtheme was calculated as a mean score. The APQ-28
10 subthemes, similarly to the following scales, permitted one missing item per
11 subscale.
12
13
14
15
16
17
18
19
20
21
22
23
24
25

26 (2) Current and usual pain were measured using two 11-point numerical rating
27 scales (NRS), where 0='no pain' and 10='worst possible pain',[33].
28
29
30
31
32

33 (3) Physical fatigue (seven items) and mental fatigue (four items) were measured
34 using the Chalder Fatigue Questionnaire (CFQ), where scores of 1='much worse
35 than usual' and 4='better than usual',[34]. Two subscale scores were summated
36 where higher scores indicated less fatigue.
37
38
39
40
41
42
43

44 (4) Depression was measured using the nine item Patient Health Questionnaire
45 (PHQ-9). Items were rated between 0='not at all' and 3='nearly everyday'. Total
46 scores of 1-4=minimal depression, 5-9=mild depression, 10-14=moderate
47 depression and ≥ 15 =severe depression,[35, 36].
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 (5) Anxiety was measured using the seven-item Generalised Anxiety Disorder
4
5 Assessment (GAD-7). Total scores of 5-9=mild anxiety, 10-14=moderate anxiety and
6
7 ≥ 15 =severe anxiety,[37].
8
9

10
11
12 (6) Self-efficacy was measured using the 10-item Pain Self-Efficacy Questionnaire
13
14 (PSEQ) where items were rated between 0='not at all confident' and 6='completely
15
16 confident'. Total scores of $PSEQ \geq 40$ indicate those patients who are more likely to
17
18 continue implementing coping strategies/behavioural changes, and $PSEQ \leq 16$ are
19
20 considered low,[38].
21
22
23

24
25
26 (7) Avoidance was measured using the 'Escape and Avoidance' subscale of the Pain
27
28 Anxiety Symptoms Scale-short version (PASS-20),[39]. The five items were rated
29
30 between 0='never' and 5='always' where higher total scores indicated greater
31
32 avoidance.
33
34
35

36
37
38 (8) Physical and mental function were measured using the 12-Item Short-Form
39
40 Health Survey (SF-12). Two subscale scores (out of 100) were calculated using the
41
42 SF-12 software (Version 2; one-week recall) where higher scores indicated better
43
44 function,[40].
45
46
47

48
49 (9) Health-related quality of life was measured using the EQ-5D-5L (EuroQol). The
50
51 EQ-5D-5L was calculated as an index score,[41, 42].
52
53
54

55 56 **Data analysis** 57 58 59 60

1
2
3 Feasibility outcomes and participants' demographics were analysed using
4
5 descriptive statistics. Clinical outcomes were estimated as changes in activity pacing
6
7 and symptoms between T1-T2, T2-T3 and T1-T3 (mean change, 95% confidence
8
9 intervals), and exploratory analyses of correlations between changes in activity
10
11 pacing and symptoms (T1-T2/T1-T3). The validity of the modified APQ-28 was
12
13 estimated using Cronbach's alpha and item correlations; and sensitivity analyses
14
15 explored the effects of including two new APQ items. Data were analysed using IBM
16
17 SPSS Statistics 26 statistical software (IBM Corp, Armonk, New York).
18
19
20
21
22

23 24 **Patient and Public Involvement**

25
26
27
28 Patient and Public Involvement (PPI) commenced during the initial planning stages
29
30 of the mixed methods programme to develop and test the activity pacing framework.
31
32 A meeting with five PPI representatives discussed the study purpose and practical
33
34 issues around the proposed methods (online survey, nominal group technique, and
35
36 feasibility and acceptability studies). PPI guided on improving the accessibility of
37
38 patients' participation and reducing burden. A PPI representative has acted as an
39
40 advisor on the study, involving commenting on study documents/questionnaire
41
42 booklets and coding qualitative interviews. Acceptability interviews with patients
43
44 explored practical issues surrounding the feasibility study (to be reported elsewhere)
45
46
47 which will further assist the planning of a future activity pacing RCT.
48
49
50
51
52

53 54 **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 comorbidities):	(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)	(n=61)	(n=96)
	Mean=10.23 (SD=9.49)	Mean=12.94 (SD=11.36)	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)

1
2
3 Of the 144 patients invited to participate, 139 were eligible (96.5%). The reasons for
4 ineligibility included: three patients reported only neck pain, one patient reported
5 neck/knee pain and one patient reported thoracic pain. Of the 139 eligible patients,
6 107 (77.0%) were recruited at T1, 69 (64.5%) completed the six-week programme
7 and 65 (60.7%) completed the T2 measures (attrition rate=39.3%). Fifty-two
8 participants completed T3 (80.0% of T2; attrition rate from T1=51.4%). There were
9 no serious adverse events. (See *Figure 2. CONSORT flow diagram.*)
10
11
12
13
14
15
16
17
18
19
20

21 Of the 107 participants, the median number of rehabilitation programme sessions
22 attended was five (58.9% participants attended ≥ 5 sessions); 83.2% participants
23 attended at least one activity pacing session and 56.1% attended both pacing
24 sessions. Of the 65 participants who completed T2, the median number of sessions
25 attended was six (89.2% participants attended ≥ 5 sessions); 100% of participants
26 attended at least one pacing specific session and 54 (83.1%) participants attended
27 both pacing sessions. There were no statistically significant differences between
28 participants who completed T2 or dropped out in terms of demographics or baseline
29 symptoms. Of the 12 participants with CFS/ME, six completed T2 (50%) and six
30 completed T3 (100% of T2, 50% of T1); whereas 59 of the 95 participants without
31 CFS/ME completed T2 (62%) and 46 completed T3 (78% of T2 and 48% of T1).
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48

49 **Acceptability of the rehabilitation programme/questionnaires (Objective 1)**

50
51
52
53 On T2, participants rated their satisfaction of the length and content of the
54 rehabilitation programme as mean=8.8 (SD=1.7) and 9.1 (SD=1.5) respectively. The
55
56
57
58
59
60

1
2
3 satisfaction of only those participants with CFS/ME was mean=9.0 (SD=0.9) and 9.2
4
5 (SD=1.0).
6
7
8
9

10 There were minimal missing data in the questionnaire booklets (approximately 1%).

11
12 Some participants wrote comments regarding their perceived benefits of
13
14 implementing activity pacing and other coping strategies. Two participants wished for
15
16 a longer programme or a follow-up session (*see Figure 3 for examples of*
17
18 *participants' comments*).
19
20
21
22
23

24 **Fidelity to the activity pacing framework (Objective 2)**

25
26
27
28 Each healthcare professional observation demonstrated good adherence to the
29
30 framework against a number of key points. Healthcare professionals reported 100%
31
32 adherence in their fidelity checklists for each rehabilitation programme. Healthcare
33
34 professionals reported that some participants spent over 20 minutes completing the
35
36 questionnaire booklet, and that not all patients completed the activity diaries.
37
38
39
40
41

42 **Interventions between T2 and T3**

43
44
45
46 Of the 52 respondents at T3, two patients received lumbar epidural steroid injections,
47
48 one patient had acupuncture, one attended a chiropractor and one patient had knee
49
50 surgery.
51
52
53
54
55

56 **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.

1
2
3 Between T1-T2, the mean scores of all symptoms improved. Current pain reduced
4 more than usual pain. Physical and mental fatigue both improved, as did self-efficacy
5 and quality of life. Mental function improved more than physical function. Depression,
6 anxiety and avoidance all reduced. There was some deterioration in symptoms
7
8 between T2-T3, but between T1-T3 all symptoms demonstrated clear improvements
9
10 except avoidance (-1.46, 95% CI=-3.02 to 0.10) and physical function (1.62, 95%
11
12 CI=-0.81 to 4.06) (see *Table 3.*). Observing only the subgroup of participants with
13
14 CFS/ME, improvements were seen between T1-T2 and T1-T3 across all APQ-28
15
16 subthemes and symptoms.
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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)

1
2
3 **Associations between changes in activity pacing and symptoms: pre-post**
4 **treatment (Objective 4)**
5
6
7
8
9

10 Between T1-T2, there were significant correlations between increased APQ-28
11 Activity acceptance and decreased current pain ($r_s(65)=-0.29$, $p=0.019$). Increased
12 self-efficacy significantly correlated with all APQ-28 subthemes ($p<0.05$) except
13 APQ-28 Activity adjustment. Increased mental function was significantly correlated
14 with increased APQ-28 Activity adjustment ($r_s(61)=0.28$, $p=0.030$) and Activity
15 acceptance ($r_s(63)=0.27$, $p=0.031$). (See Table 4.)
16
17
18
19
20
21
22
23
24
25

26 There were no statistically significant correlations between the changes in any of the
27 APQ-28 subthemes and changes in usual pain, physical/mental fatigue, depression,
28 anxiety, avoidance, physical function or quality of life. Sensitivity analyses found the
29 same pattern of significant/non-significant correlations when excluding the two new
30 APQ-28 items.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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)

1
2
3 **Associations between changes in activity pacing and symptoms: pre-**
4 **treatment to 3-months follow-up (Objective 4)**
5
6
7
8
9

10 In addition to the significant correlations found during the pre-post treatment period
11 (T1-T2) between various APQ-28 subthemes and improved current pain, self-
12 efficacy and mental function; during the T1-T3 period the APQ-28 subthemes
13 additionally correlated with improved physical and mental fatigue, improved quality of
14 life, and reduced depression and anxiety ($p < 0.05$). (See Table 5.)
15
16
17
18
19
20
21
22
23

24 Similarly to the T1-T2 period, between T1-T3, there were no significant correlations
25 between changes in any APQ-28 subthemes and usual pain, avoidance or physical
26 function. Sensitivity analyses showed the same pattern of results when excluding the
27 two new APQ-28 items with the exception of two non-significant associations
28 between: Activity adjustment and mental function ($r_s(46) = 2.78$, $p = 0.062$) and Activity
29 acceptance and depression ($r_s(51) = -0.25$, $p = 0.073$).
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 (50%), and the target sample size proved feasible to attain. These
4
5 recruitment/attrition rates will inform a future definitive RCT.
6
7
8
9

10 Regarding treatment adherence, only 56.1% of participants recruited at T1 attended
11 both pacing sessions. Many participants (n=18, 16.8%) dropped out after the first
12 session and therefore did not attend any pacing sessions. Reasons for early drop-
13 out often include unrealistic expectations of symptom improvement, low motivation,
14 or confidence to commit to programmes or behavioural changes,[20]. In comparison,
15 attendance rates of both pacing sessions among those who completed T2 were
16 83.1%, and 89.2% of participants attended five or more sessions. This is comparable
17 to adherence rates of 81% seen elsewhere,[43]; and adherence rates have been
18 considered as 'Excellent' when 70% or more participants complete 75% of
19 sessions,[44].
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34

35 Participants reported the condition of low back pain most frequently and CFS/ME the
36 least frequently, as per current prevalence rates,[45, 46]. Our findings re-iterate the
37 high occurrence of co-morbidities, and frequent co-existence of chronic pain among
38 patients with CFS/ME,[9]. Participants with CFS/ME demonstrated improvements in
39 symptoms following treatment, in comparison to other studies in which pacing has
40 been ineffective,[47]. Disparate to the study by White et al.,[47], the activity pacing
41 framework encourages a rehabilitative rather than an adaptive approach. The effects
42 of rehabilitative approaches for patients with both chronic pain and fatigue requires
43 causative investigation.
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 (mean change=0.07); both changes exceeded the minimally important difference
4
5 (0.037 +/-0.008),[49].
6
7
8
9

10 The activity pacing framework additionally aims to increase patients' self-efficacy.
11
12 Improvements in self-efficacy were found between T1 (mean=25.29) and T2
13
14 (mean=36.29), which were well maintained at T3 (mean=34.68). Scores were lower
15
16 than the ≥ 40 cut off. However, an improvement of >5.5 was attained which is
17
18 considered a minimally important change,[50]. Both physical and mental fatigue
19
20 improved, and improvements in mental fatigue appeared to be better maintained at
21
22 T3. Comparisons to minimally important changes are unavailable.
23
24
25
26
27

28 Psychological health improved following the rehabilitation programme, including
29
30 reduced depression scores from moderate to mild (T1=13.7, T2=7.1, T3=9.1); with a
31
32 clinically significant reduction (≥ 5) between T1-T2,[36]. Mean anxiety scores reduced
33
34 (T1=9.9, T2=5.4 and T3=6.10), and remained within the classification of mild
35
36 anxiety,[37]. Although reductions in pain were not a direct aim of treatment, lower
37
38 pain severity was reported.
39
40
41
42
43

44 There were fewer significant correlations between changes in activity pacing and
45
46 symptoms pre-post treatment (T1-T2) than longer-term (T1-T3). This may be due to
47
48 participants undertaking a more experimental phase during T1-T2 (such as finding
49
50 baselines, (re-)starting activities), whereas new routines were more established
51
52 between T1-T3. Noticeably, changes in activity pacing were more frequently
53
54 associated with improvements in psychological wellbeing rather than physical
55
56
57
58
59
60

1
2
3 wellbeing. Similarly, a meta-analysis found pacing was not associated with improved
4
5 physical function among patients with chronic conditions,[5].
6
7
8
9

10 **Strengths and limitations**

11
12
13

14 Despite recruiting to target, this sample was not powered with a control arm to
15
16 determine treatment effectiveness. The exploratory statistical analyses were
17
18 correlative and do not indicate causation between increased activity pacing and
19
20 improved symptoms. As per other studies exploring activity pacing, pacing was
21
22 instructed as one component of the rehabilitation programme,[5]. Therefore,
23
24 improvements in symptoms may have resulted from any combination of coping
25
26 strategies. A future RCT will implement a suitable control to explore the effects of
27
28 pacing, while implementing the activity pacing framework in a clinically relevant
29
30 setting, including alongside other coping strategies.
31
32
33
34
35
36

37 The generalisability of this study is limited to a sample of predominantly females and
38
39 white ethnic origin. Recruitment occurred only at one Pain Service and this service
40
41 had an existing rehabilitation programme for both chronic pain and fatigue. Bias may
42
43 have arisen through the lead researcher delivering the healthcare professionals'
44
45 training and undertaking the observations. Further work will test the activity pacing
46
47 framework and study protocol across other healthcare services and explore fidelity
48
49 over wider geographical locations.
50
51
52
53
54

55 It is unknown what potential bias was caused by the attrition rate. However, there
56
57 were no differences at baseline between those who completed the programme and
58
59
60

1
2
3 those who dropped out. The attrition rate may be reflective of some of the clinical
4 challenges and missed appointments surrounding the complexity of chronic
5 pain/fatigue. Further research could explore whether providing a follow-up improves
6 commitment to activity pacing.
7
8
9
10
11
12
13

14 **Modifications for future study**

15
16
17
18
19 Since more patients completed the T1 questionnaires during the rehabilitation
20 sessions than at home, this may be the preferable mode of distribution. To lessen
21 the time taken to complete the questionnaires, the PASS-20 may be considered for
22 exclusion in future study. The whole 20-item PASS scale was included for reliability
23 and validity, but data from only the Escape and Avoidance subscale was explored.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
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.

40 **Conclusion**

41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
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

1
2
3 shorter-term. Improvements in activity pacing were significantly associated with
4
5 improvements in cognitive/psychological wellbeing and quality of life, but not physical
6
7 function or avoidance. Future study will use the activity pacing framework in an
8
9 effectiveness RCT to explore the effects of activity pacing on symptoms.
10
11
12
13

14 **ACKNOWLEDGEMENTS**

15
16
17
18
19 We would like to acknowledge all of the patients and healthcare professionals who
20
21 were involved in this study. We would also like to acknowledge our statistical
22
23 support.
24
25
26
27

28 **SOURCES OF FUNDING**

29
30
31
32
33 Dr Deborah Antcliff is funded by a Health Education England/National Institute for
34
35 Health Research (HEE/NIHR) Clinical Lectureship for this research project.
36
37
38
39

40 **DISCLAIMER**

41
42
43
44 This paper presents independent research funded by Health Education
45
46 England/National Institute for Health Research (NIHR) [Clinical Lectureship (ICA-CL-
47
48 2015-01-019)]. The views expressed are those of the author(s) and not necessarily
49
50 those of the NHS, the NIHR or the Department of Health and Social Care.
51
52
53
54

55 **CONFLICT OF INTEREST**

1
2
3 All authors declare no conflicts of interest
4
5
6

7
8 **AUTHOR CONTRIBUTIONS**
9

10 All authors contributed to the conception and design of the study. DA undertook the
11 acquisition of the data. All authors contributed to the analysis and interpretation of
12 data. All authors contributed to drafting the manuscript and revising it critically for
13 important intellectual content and have approved the final version for publication.
14
15
16
17
18

19 Authors are in agreement to be accountable for all aspects of the work in ensuring
20 that questions related to the accuracy or integrity of any part of the work are
21 appropriately investigated and resolved.
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

35 **PATIENT CONSENT FOR PUBLICATION**
36

37 Not required.
38
39
40
41

42 **DATA SHARING AGREEMENT**
43

44 Deidentified participant data are available from the corresponding author
45 (Deborah.Antcliff@pat.nhs.uk) upon reasonable request. Reuse is permitted for
46 health and care research as long as the original authors are acknowledged. The
47 protocol can also be requested from the author or accessed at ClinicalTrials.gov
48 (NCT03497585).
49
50
51
52
53
54
55
56
57
58
59
60

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.

- 1
2
3 8. Davis LL, Kroenke K, Monahan P, et al. The SPADE Symptom Cluster in Primary
4
5 Care Patients With Chronic Pain. *Clin J Pain* 2016;32:388-93.
6
- 7
8 9. Meeus M, Nijs J, Meirleir KD. Chronic musculoskeletal pain in patients with the
9
10 chronic fatigue syndrome: a systematic review. *Eur J Pain* 2007;11:377-86.
11
- 12
13 10. Tavel ME. Somatic symptom disorders without known physical causes: one
14
15 disease with many names? *Am J Med* 2015;128:1054-8.
16
- 17
18 11. Yunus MB. Fibromyalgia and overlapping disorders: the unifying concept of
19
20 central sensitivity syndromes. *Semin Arthritis Rheum* 2007;36:339-56.
21
- 22
23 12. Nijs J, Meeus M, Van Oosterwijck J, et al. In the mind or in the brain? Scientific
24
25 evidence for central sensitisation in chronic fatigue syndrome. *Eur J Clin Invest*
26
27 2012;42:203-12.
28
- 29
30 13. Arendt-Nielsen L, Morlion B, Perrot S, et al. Assessment and manifestation of
31
32 central sensitisation across different chronic pain conditions. *Eur J Pain*
33
34 2018;22:216-241.
35
- 36
37 14. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic
38
39 musculoskeletal pain: a state of the art. *Pain* 2000;85:317-32.
40
- 41
42 15. Moseley GL. A pain neuromatrix approach to patients with chronic pain. *Man*
43
44 *Ther* 2003;8:130-40.
45
- 46
47 16. Ericsson A, Mannerkorpi K. How to manage fatigue in fibromyalgia:
48
49 nonpharmacological options. *Pain Manag* 2016;6:331-8.
50
- 51
52 17. British Pain Society. Guidelines for pain management programmes for adults.
53
54 London: British Pain Society, 2013.
55
- 56
57 18. Beissner K, Henderson CR, Jr., Papaleontiou M, et al. Physical therapists' use of
58
59 cognitive-behavioral therapy for older adults with chronic pain: a nationwide survey.
60
Phys Ther 2009;89:456-69.

- 1
2
3 19. Booth J, Moseley GL, Schiltenswolf M, et al. Exercise for chronic musculoskeletal
4 pain: A biopsychosocial approach. *Musculoskeletal Care* 2017;15:413-421.
5
6
7 20. Anderson RJ, Hurley RW, Staud R, et al. Cognitive-motivational influences on
8 health behavior change in adults with chronic pain. *Pain Med* 2016;17:1079-1093.
9
10
11 21. Birkholtz M, Aylwin L, Harman RM. Activity pacing in chronic pain management:
12 One aim, but which method? Part one: Introduction and literature review. *British*
13 *Journal of Occupational Therapy* 2004;67:447-52.
14
15
16 22. Abonie US, Edwards AM, Hettinga FJ. Optimising activity pacing to promote a
17 physically active lifestyle in medical settings: A narrative review informed by clinical
18 and sports pacing research. *J Sports Sci* 2020;38:590-596.
19
20
21 23. Jamieson-Lega K, Berry R, Brown CA. Pacing: A concept analysis of a chronic
22 pain intervention. *Pain Res Manag* 2013;18:207-13.
23
24
25 24. Andrews NE and Deen M. Defining activity pacing: Is it time to jump off the
26 merry-go-round? *J Pain* 2016;17:1359-1362.
27
28
29 25. Andrews NE, Strong J, Meredith PJ. Activity pacing, avoidance, endurance, and
30 associations with patient functioning in chronic pain: a systematic review and meta-
31 analysis. *Arch Phys Med Rehabil* 2012;93:2109-2121 e7.
32
33
34 26. Murphy SL, Clauw DJ. Activity pacing: what are we measuring and how does
35 that relate to intervention? *Pain* 2010;149:582-3.
36
37
38 27. Craig P, Dieppe P, Macintyre S, et al. Medical Research Council Guidance.
39 Developing and evaluating complex interventions: The new Medical Research
40 Council guidance. *BMJ* 2008;337:a1655. doi: 10.1136/bmj.a1655.
41
42
43 28. Antcliff D, Keenan AM, Keeley P, et al. Engaging stakeholders to refine an
44 activity pacing framework for chronic pain/fatigue: A nominal group technique.
45
46
47 *Musculoskeletal Care* 2019;17:354-362.
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 29. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and
4 feasibility studies. *Pilot Feasibility Stud* 2019;5:114.
5
6
7
8 30. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement:
9 extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
10
11
12 31. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in
13 relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301-
14 8.
15
16
17
18 32. Antcliff D, Campbell M, Woby S, et al. Assessing the psychometric properties of
19 an activity pacing questionnaire for chronic pain and fatigue. *Phys Ther*
20 2015;95:1274-86.
21
22
23
24 33. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels
25 needed in pain intensity measurement? *Pain* 1994;58:387-92.
26
27
28
29 34. Chalder T, Berelowitz G, Pawlikowska T, et al. Development of a fatigue scale. *J*
30 *Psychosom Res* 1993;37:147-53.
31
32
33
34 35. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression
35 severity measure. *J Gen Intern Med* 2001;16:606-13.
36
37
38
39 36. Kroenke K, Spitzer RL, Williams JB, et al. The Patient Health Questionnaire
40 Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp*
41 *Psychiatry* 2010;32:345-59.
42
43
44
45 37. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing
46 generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-7.
47
48
49
50 38. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur*
51 *J Pain* 2007;11:153-63.
52
53
54
55 39. McCracken LM, Dhingra L. A short version of the Pain Anxiety Symptoms Scale
56 (PASS-20): preliminary development and validity. *Pain Res Manag* 2002;7:45-50.
57
58
59
60

- 1
2
3 40. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey:
4 construction of scales and preliminary tests of reliability and validity. *Medical Care*
5 1996;34:220-33.
6
7
8
9
10 41. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the
11 new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36.
12
13 42. van Hout B, Janssen MF, Feng Y, et al. Interim Scoring for the EQ-5D-5L:
14 Mapping the EQ-5D-5L to EQ-5D-3L Value Sets. *Value in Health* 2012;15:708 –715.
15
16
17 43. Bearne LM, Walsh NE, Jessep S, et al. Feasibility of an exercise-based
18 rehabilitation programme for chronic hip pain. *Musculoskeletal Care* 2011;9:160-8.
19
20 44. Greenberg J, Lin A, Zale EL, et al. Development And Early Feasibility Testing Of
21 A Mind-Body Physical Activity Program For Patients With Heterogeneous Chronic
22 Pain; The GetActive Study. *J Pain Res* 2019;12:3279-3297.
23
24 45. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we
25 need to pay attention. *Lancet* 2018;391:2356-67.
26
27 46. NICE. Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy).
28 *NICE Clinical Guideline 53 London* 2007.
29
30 47. White PD, Goldsmith KA, Johnson AL, et al. Comparison of adaptive pacing
31 therapy, cognitive behaviour therapy, graded exercise therapy, and specialist
32 medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet*
33 2011;377:823-36.
34
35 48. Diaz-Arribas MJ, Fernandez-Serrano M, Royuela A et al. Minimal Clinically
36 Important Difference in Quality of Life for Patients With Low Back Pain. *Spine (Phila*
37 *Pa 1976)* 2017;42:1908-1916.
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 49. McClure NS, Sayah FA, Xie F, et al. Instrument-Defined Estimates of the
4
5 Minimally Important Difference for EQ-5D-5L Index Scores. *Value Health*
6
7 2017;20:644-650.
8
9

10 50. Chiarotto A, Vanti C, Cedraschi C, et al. Responsiveness and Minimal Important
11
12 Change of the Pain Self-Efficacy Questionnaire and Short Forms in Patients With
13
14 Chronic Low Back Pain. *J Pain* 2016;17:707-18.
15
16

17 18 19 **FIGURE LEGENDS**

20
21 Figure 1. Activity pacing conceptual model taken from the activity pacing framework

22
23 Figure 2: CONSORT diagram showing the flow of participants through the study

24
25 Figure 3. Participants' written comments following attending the rehabilitation
26
27 programme
28
29

1
2
3
4
5 This framework uses the term 'Activity Pacing', which may be more similar to an
6 operant approach, driven by quota-contingency rather than symptom-contingency.
7
8 Our model of pacing moves beyond a purely behavioural approach since it also
9
10 integrates thoughts and beliefs. Activity pacing within this framework encourages
11
12 acceptance, active decision-making and flexibility, both in selecting which facets of
13
14 pacing to implement and also when to pace.

15
16
17 This pacing model is based upon addressing behaviours such as fear-avoidance,
18
19 excessive persistence and overactivity-underactivity cycling. This pacing model
20
21 includes the potential for reversibility of some of the consequences of chronic
22
23 pain/fatigue, for example, to reduce disability. As such, activity pacing is described
24
25 as a rehabilitative strategy rather than an adaptive strategy in this framework.

26
27 In keeping with a rehabilitative approach, the aims of activity pacing within this
28
29 framework include: improved physical and cognitive function, improved quality of
30
31 life, increased sense of control and choice, and increased satisfaction with
32
33 activities. Activity pacing may improve the management and ability to cope with
34
35 symptoms where there is greater acceptance and flexibility. This framework does
36
37 not advocate the use of activity pacing with the direct aim of reducing symptoms
38
39 when this results in decreased function or dissatisfaction, or if this encourages
40
41 avoidant behaviour/working below tolerance levels.

42
43 This activity pacing framework recognises pacing as a multidimensional concept
44
45 that involves different facets, such as breaking down tasks, finding baselines of
46
47 tolerable activities, implementing consistent levels of activities, planning activities,
48
49 setting goals of meaningful activities, accepting activity levels and gradually
50
51 increasing activities. Different facets of activity pacing are tailored to individuals'
52
53 needs, aims and activity behaviours.

54
55
56 *Figure 1. Activity pacing conceptual model taken from the activity pacing framework*
57
58
59
60

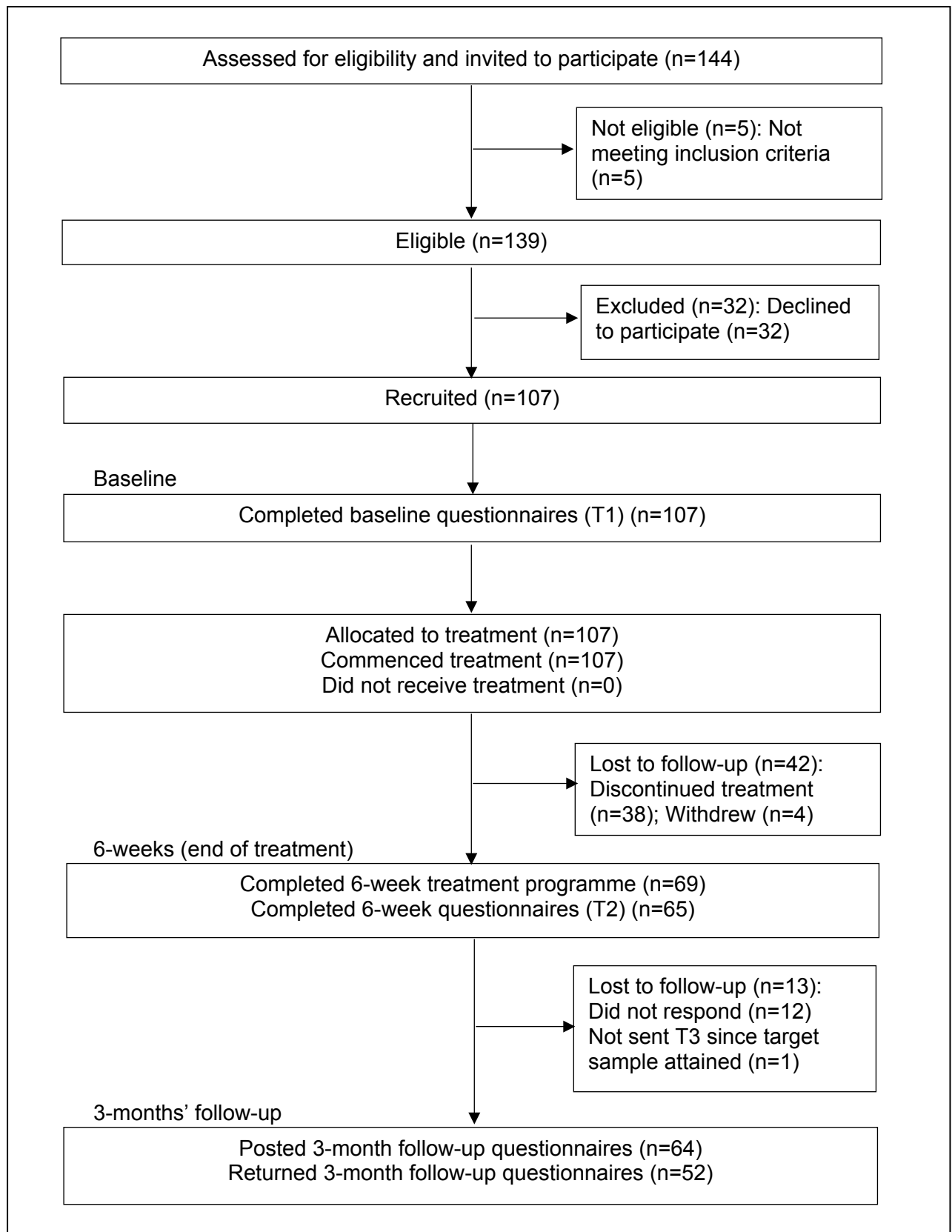


Figure 2: CONSORT diagram showing the flow of participants through the study

1
2
3
4 T2: "The pace and content has been good for me. It has helped me to focus on
5 my belief that I have to own the situation, to be positive and to make use of the
6 tools we have discussed. If I don't take this approach I believe my situation will
7 not improve. There is no magic wand, but I can be the difference." (F070:
8

9 *Fibromyalgia*
10
11
12

13
14 T3: "I have found pacing really helpful in my everyday life and feel I can achieve
15 more day to day than 12 months ago." (F006: *chronic widespread pain,*
16 *fibromyalgia, chronic fatigue syndrome/myalgic encephalomyelitis*)
17
18
19

20
21 T3: "I found the pain service very helpful and informative. How I view my pain and
22 react to and manage it has improved. Emotionally I feel more positive as a result
23 of using strategies learned, and also more confident that I can manage my pain
24 and how it makes me feel. Using pacing and realistic goals has enabled me to do
25 some activities that I previously avoided i.e. hoovering, changing the bed. (F068:
26 *fibromyalgia*)
27
28
29
30
31

32
33 T3: "Doing the 6 week course was extremely helpful and gave me some excellent
34 information and resources to work with. The difficulty has been that there has
35 been no follow up or support sessions since. It is great having the info, but then
36 you are battling depression/anxiety it is difficult to apply knowledge without some
37 support, even if that is over the phone every few weeks or maybe a support group
38 facility." (F075: *low back pain, chronic widespread pain*)
39
40
41
42
43
44

45 T3 "I have found 'pacing' a very good way to manage pain and get through the
46 day completing activities" (F105: *low back pain, chronic widespread pain,*
47 *fibromyalgia*)
48
49
50

51
52
53 *Figure 3. Participants' written comments following attending the rehabilitation*
54 *programme*
55
56
57
58
59
60



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 <i>BMJ Open</i> 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:	<i>BMJ Open</i>
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

SCHOLARONE™
Manuscripts



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.

1
2
3 **Title: Testing a newly developed activity pacing framework for chronic**
4 **pain/fatigue: a feasibility study**
5
6
7
8
9

10 **AUTHORS**
11

12 Dr Deborah Antcliff (PhD)^{a,b}
13

14 ^aPhysiotherapy Department, Bury and Rochdale Care Organisation, Northern Care
15 Alliance NHS Group, Bury, United Kingdom.
16
17

18 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom.
19
20
21
22

23
24 Professor Anne-Maree Keenan (PhD)^{b,c}
25

26 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom
27
28

29 ^cNIHR Leeds Biomedical Research Centre, Leeds, England, UK
30
31
32

33 Professor Philip Keeley (PhD)^d
34

35 ^dSchool of Nursing and Midwifery, Keele University, Keele, United Kingdom
36
37
38
39

40 Professor Steve Woby (PhD)^{e,f,g}
41

42 ^eResearch and Innovation Department, Northern Care Alliance NHS Group, Salford,
43 United Kingdom.
44
45

46 ^fSchool of Health and Society, University of Salford, Salford, United Kingdom.
47
48

49 ^gFaculty of Science and Engineering, Manchester Metropolitan University,
50 Manchester, United Kingdom.
51
52
53

54
55 Professor Linda McGowan (PhD)^b
56

57 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom
58
59
60

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-

1
2
3 T2, changes in pacing significantly correlated with current pain ($r_s=-0.29$, $p=0.019$),
4 self-efficacy ($r_s=0.26-0.39$, $p<0.05$) and mental function ($r_s=0.27-0.28$, $p<0.05$).
5
6

7
8 Between T1-T3, there were additional significant correlations between changes in
9
10 pacing and physical/mental fatigue, depression, anxiety and quality of life ($p<0.05$).
11

12 There were no significant correlations with physical function/avoidance.
13

14 **Conclusion:** The activity pacing framework was feasible to implement and patients'
15 ability to pace and manage their symptoms improved. Future work will employ a
16 suitable comparison group and test the framework across wider settings to explore
17 the effects of activity pacing in a randomised controlled trial.
18
19
20
21
22

23 **Trial registration:** ClinicalTrials.gov:NCT03497585
24

25 **Funding:** Health Education England/National Institute for Health Research
26
27
28
29

30 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

31
32
33
34

- 35 • This was the first study to test the feasibility of using a newly developed
36 activity pacing framework in a rehabilitation programme to standardise the
37 clinical instructions of activity pacing to patients with chronic pain/fatigue.
38
- 39 • This feasibility study recruited to target with satisfactory recruitment/attrition
40 rates which form the basis of a future randomised controlled trial (RCT).
41
- 42 • A comprehensive measure of pacing: the activity pacing questionnaire (APQ-
43 28), and range of validated psychometric measures were suitable to detect
44 changes before and after treatment.
45
- 46 • This study was not powered with a control arm to determine treatment
47 effectiveness, and the exploratory statistical analyses do not indicate
48 causation between increased activity pacing and improved symptoms.
49
50
51
52
53
54
55
56
57
58
59
60

- 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].

1
2
3
4
5 At present, there remains confusion regarding how activity pacing is defined or
6 interpreted, and the effects on patients' symptoms,[5, 24, 25]. There is no widely-
7
8 used guide to standardise how healthcare professionals instruct pacing to patients;
9
10 and uncertainty whether different methods are required for symptoms of chronic pain
11
12 versus chronic fatigue,[3, 26]. This poses challenges how to advise patients with
13
14 both chronic pain and fatigue.
15
16
17
18
19
20

21 We have developed an activity pacing framework using an inclusive approach for
22 patients who present at rehabilitation services with chronic pain and/or fatigue. Using
23 the Medical Research Council guidelines for developing complex interventions,
24 mixed methods were implemented to encompass theoretical and stakeholder
25 standpoints,[27]. Mixed methods comprise of quantitative and qualitative approaches
26 to collecting and analysing data,[28]. Stage I: Healthcare professionals' survey
27 gathered opinions on activity pacing (n=92),[4]. These findings, together with existing
28 research formed the first draft of the framework and accompanying appendices.
29
30 Stage II: Nominal group technique refined the activity pacing framework using a
31 consensus meeting between patients and healthcare professionals (n=10),[29].
32
33 During the development of the activity pacing framework, stakeholders included
34 healthcare professionals and patients with the aim of increasing the clinical utility and
35 acceptability of the framework. (See *Supplementary Figure 1. Content of the Activity*
36
37 *Pacing Framework: Theory and Overview, and Appendices and Teaching Guide*
38
39 *booklets.*)
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 The conceptual model of the activity pacing framework (see *Figure 1*) follows
4 principles of quota-contingency and the operant approach (for example, setting goals
5 according to time/distance/activity). The activity pacing framework is underpinned by
6 concepts of rehabilitation with aims of improving physical and cognitive function; and
7 engagement in, and satisfaction with meaningful activities, while managing
8 symptoms,[4, 29]. The activity pacing framework includes the potential for
9 reversibility of some of the consequences of chronic pain/fatigue, such as the
10 potential to reduce levels of disability. Together with containing themes of adjusting
11 activities, planning and consistency, the activity pacing framework also includes
12 themes of progression regarding the amount and/or variety of activities. Therefore,
13 the activity pacing framework is considered to be a rehabilitative approach that
14 moves forward from only adapting, or in some cases mal-adapting to the long-term
15 condition. The activity pacing framework differs from energy conservation/adaptive
16 pacing approaches which involve undertaking activities according to symptom
17 severity (symptom-contingency) with an aim of reducing or avoiding symptoms,[30,
18 31]. Within the current activity pacing framework, quota-contingency is advised
19 alongside concepts of flexibility and choice to enable relevance and sustainability in
20 conditions where symptoms may vary. The framework refers to all types of activities
21 including work, household activities, cognitive activities, physical activities, exercise
22 and relaxation to increase its wider relevance for patients with chronic pain and/or
23 fatigue, for varying abilities and behaviours.

24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54 The aim of this study was to test the feasibility of using the activity pacing framework
55 to underpin a rehabilitation programme for chronic pain/fatigue. To inform a future
56 definitive trial, specific objectives included: (1) Exploring participant
57
58
59
60

1
2
3 recruitment/attrition rates and adherence/acceptability (for both chronic pain and
4 fatigue); (2) Exploring healthcare professionals' fidelity to the framework; (3) Exploring
5 the suitability of the outcome measures, including the modified activity pacing
6 questionnaire (APQ-28); and (4) Exploring associations between changes in activity
7 pacing and self-reported symptoms.
8
9
10
11
12
13
14
15
16

17 **METHODS**

18 **Study design**

19
20
21
22
23
24
25
26
27 This single-arm, repeated measures study is reported as a non-randomised
28 feasibility study using the extended CONSORT guidelines,[32, 33] (See
29 *Supplementary Table 1*). Quantitative questionnaire data were collected from
30 patients at the start (T1) and end (T2) of the six-week rehabilitation programme, and
31 at three month's follow-up (T3). The study was prospectively registered (protocol
32 available at ClinicalTrials.gov: NCT03497585). Ethical approval was granted by the
33 London-Surrey Research Ethics Committee (18/LO/0655). The acceptability of the
34 framework, explored via interviews with patients and healthcare professionals is
35 reported elsewhere [*Antcliff et al., 2021 accepted for publication*].
36
37
38
39
40
41
42
43
44
45
46
47
48
49

50 **Participant recruitment**

51
52
53
54 Participants were identified from consecutive referrals to a rehabilitation programme
55 for chronic pain/fatigue in a Pain Service in Northern England, United Kingdom. All
56 patients attended a minimum of one face-to-face appointment before referral to the
57
58
59
60

1
2
3 programme. Participants received the study information via the post one week before
4 attending the programme and/or during the first session of the programme. The
5 consent form was completed either at home or during the first session.
6
7
8
9
10

11 **Eligibility criteria**

12
13
14
15
16
17 Eligible patients were aged ≥ 18 years, with symptoms for ≥ 3 months and with a
18 general practitioner or hospital consultant diagnosis of chronic low back pain, chronic
19 widespread pain, fibromyalgia or CFS/ME. Patients were required to read and write
20 in English. Ineligible patients were those with evidence of a serious underlying
21 pathology, such as a current diagnosis of cancer, or patients with severe mental
22 health or cognitive functioning issues.
23
24
25
26
27
28
29
30
31
32

33 **Sample size**

34
35
36
37 A sample size of 50 patients has been recommended for feasibility studies to enable
38 estimates of recruitment/attrition, means/standard deviations and changes in means
39 to prepare for future clinical trials,[34]. To attain a sample of 50 participants at T3, it
40 was estimated that 340 patients may need to be approached to allow for a 50%
41 recruitment rate at T1, a 40% attrition rate between T1-T2 and a 50% return rate at
42 T3.
43
44
45
46
47
48
49
50
51
52

53 **Existing rehabilitation programme**

1
2
3 The existing rehabilitation programme comprised of six consecutive weekly sessions
4 (each 3.5 hours) delivered by healthcare professionals (pain specialist
5
6 physiotherapists and psychological wellbeing practitioners). The programme
7
8 included understanding complex symptoms, sleep hygiene, graded exercise, goal
9
10 setting, relaxation and mindfulness. Pacing was instructed in one session but was
11
12 not informed by any particular framework.
13
14
15
16
17
18

19 **Activity pacing framework standardised programme**

20
21
22

23
24 The existing six-week programme was modified through re-structuring and
25
26 standardisation using the activity pacing framework. Activity pacing was formally
27
28 instructed on two sessions (weeks 2-3). However, activity pacing was referenced
29
30 throughout the programme in relation to other coping strategies, for example, how
31
32 activity pacing can assist graded exercise (weeks 1-5) or set-back management
33
34 (week 6). Practical exercises included completing an activity diary to discuss
35
36 patients' activity patterns and setting goals in which activity pacing could be
37
38 practised. (*See Supplementary Figure 2. Content of the rehabilitation programme*).
39
40
41
42 Patients received a handout to summarise the key concepts of activity pacing. The
43
44 healthcare professionals (as above) received training on the framework during a half-
45
46 day session and could contact the lead researcher (DA) for any queries. All patients
47
48 attended the standardised programme, but patients chose whether to participate in
49
50 the study through their optional completion of the study questionnaires and consent
51
52 form.
53
54
55
56
57
58
59
60

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

1
2
3 alpha=0.72-0.92),[35]. (See Supplementary Table 2. Five themes of the activity
4 *pacing questionnaire (APQ) with examples.*) Each item is scored between 0='never
5 did this' and 4='always did this'. Two items have been added that correspond to
6 important aspects of pacing that emerged during the development of the activity
7 pacing framework. The new items: APQ12:"I found a baseline amount of activities
8 that I could do on 'good' and 'bad' days" and APQ15:"I had a flexible approach with
9 my activities" were added to the subthemes of best conceptual fit (Activity
10 adjustment and Activity acceptance respectively). Each subtheme was calculated as
11 a mean score. The APQ-28 subthemes, similarly to the following scales, permitted
12 one missing item per subscale.
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

(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].

1
2
3 (5) Anxiety was measured using the seven-item Generalised Anxiety Disorder
4
5 Assessment (GAD-7). Items were rated between 0='not at all' and 3='nearly
6
7 everyday'. Total scores of 5-9=mild anxiety, 10-14=moderate anxiety and
8
9 ≥ 15 =severe anxiety,[40].
10
11
12
13

14 (6) Self-efficacy was measured using the 10-item Pain Self-Efficacy Questionnaire
15
16 (PSEQ) where items were rated between 0='not at all confident' and 6='completely
17
18 confident'. Total scores of $PSEQ \geq 40$ indicate those patients who are more likely to
19
20 continue implementing coping strategies/behavioural changes, and $PSEQ \leq 16$ are
21
22 considered low,[41].
23
24
25
26
27

28 (7) Avoidance was measured using the 'Escape and Avoidance' subscale of the Pain
29
30 Anxiety Symptoms Scale-short version (PASS-20),[42]. The five items were rated
31
32 between 0='never' and 5='always' where higher total scores indicated greater
33
34 avoidance.
35
36
37
38
39

40 (8) Physical and mental function were measured using the 12-Item Short-Form
41
42 Health Survey (SF-12). Two subscale scores (out of 100) were calculated using the
43
44 SF-12 software (Version 2; one-week recall) where higher scores indicated better
45
46 function,[43].
47
48
49
50

51 (9) Health-related quality of life was measured using the EQ-5D-5L (EuroQol). The
52
53 EQ-5D-5L was calculated as an index score,[44, 45].
54
55
56
57
58
59
60

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 comorbidities):	(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)	(n=61)	(n=96)
	Mean=10.23 (SD=9.49)	Mean=12.94 (SD=11.36)	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) 14.18 (5.12)	(n=64) 15.22 (4.10)	(n=106) 14.81 (4.54)

	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)

1
2
3 On T2, participants rated their satisfaction of the length and content of the
4
5 rehabilitation programme as mean=8.8 (SD=1.7) and 9.1 (SD=1.5) respectively. The
6
7 satisfaction of only those participants with CFS/ME was mean=9.0 (SD=0.9) and 9.2
8
9 (SD=1.0).
10
11
12
13

14 There were minimal missing data in the questionnaire booklets (approximately 1%).

15
16 Some participants wrote comments regarding their perceived benefits of
17
18 implementing activity pacing and other coping strategies. Two participants wished for
19
20 a longer programme or a follow-up session (see *Figure 3 for examples of*
21
22 *participants' comments*).
23
24
25
26
27

28 **Fidelity to the activity pacing framework (Objective 2)**

29
30
31
32
33 Each healthcare professional observation demonstrated good adherence to the
34
35 framework against a number of key points. Healthcare professionals reported 100%
36
37 adherence in their fidelity checklists for each rehabilitation programme. Healthcare
38
39 professionals reported that some participants spent over 20 minutes completing the
40
41 questionnaire booklet, and that not all patients completed the activity diaries.
42
43
44
45
46

47 **Interventions between T2 and T3**

48
49
50
51 Of the 52 respondents at T3, two patients received lumbar epidural steroid injections,
52
53 one patient had acupuncture, one attended a chiropractor and one patient had knee
54
55 surgery.
56
57
58
59
60

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.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1 2 3 4 5 6 7 8 9 10 11 12	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
13 14 15 16 17 18 19 20 21	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
22 23 24 25 26 27 28 29 30	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
31 32 33 34 35 36 37 38 39 40	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).

1
2
3 **Associations between changes in activity pacing and symptoms: pre-post**
4 **treatment (Objective 4)**
5
6
7
8
9

10 Between T1-T2, there were significant correlations between increased APQ-28
11 Activity acceptance and decreased current pain ($r_s(65)=-0.29$, $p=0.019$). Increased
12 self-efficacy significantly correlated with all APQ-28 subthemes ($p<0.05$) except
13 APQ-28 Activity adjustment. Increased mental function was significantly correlated
14 with increased APQ-28 Activity adjustment ($r_s(61)=0.28$, $p=0.030$) and Activity
15 acceptance ($r_s(63)=0.27$, $p=0.031$). (See Table 4.)
16
17
18
19
20
21
22
23
24
25

26 There were no statistically significant correlations between the changes in any of the
27 APQ-28 subthemes and changes in usual pain, physical/mental fatigue, depression,
28 anxiety, avoidance, physical function or quality of life. Sensitivity analyses found the
29 same pattern of significant/non-significant correlations when excluding the two new
30 APQ-28 items.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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)

1
2
3 **Associations between changes in activity pacing and symptoms: pre-**
4 **treatment to 3-months follow-up (Objective 4)**
5
6
7
8
9

10 In addition to the significant correlations found during the pre-post treatment period
11 (T1-T2) between various APQ-28 subthemes and improved current pain, self-
12 efficacy and mental function; during the T1-T3 period the APQ-28 subthemes
13 additionally correlated with improved physical and mental fatigue, improved quality of
14 life, and reduced depression and anxiety ($p < 0.05$). (See Table 5.)
15
16
17
18
19
20
21
22
23

24 Similarly to the T1-T2 period, between T1-T3, there were no significant correlations
25 between changes in any APQ-28 subthemes and usual pain, avoidance or physical
26 function. Sensitivity analyses showed the same pattern of results when excluding the
27 two new APQ-28 items with the exception of two non-significant associations
28 between: Activity adjustment and mental function ($r_s(46) = 2.78$, $p = 0.062$) and Activity
29 acceptance and depression ($r_s(51) = -0.25$, $p = 0.073$).
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 (50%), and the target sample size proved feasible to attain. These
4
5 recruitment/attrition rates will inform a future definitive RCT.
6
7
8
9

10 Regarding treatment adherence, only 56.1% of participants recruited at T1 attended
11 both activity pacing sessions. Many participants (n=18, 16.8%) dropped out after the
12 first session and therefore did not attend any activity pacing sessions. Reasons for
13 early drop-out often include unrealistic expectations of symptom improvement, low
14 motivation, or confidence to commit to programmes or behavioural changes,[20]. In
15 comparison, attendance rates of both activity pacing sessions among those who
16 completed T2 were 83.1%, and 89.2% of participants attended five or more
17 sessions. This is comparable to adherence rates of 81% seen elsewhere,[46]; and
18 adherence rates have been considered as 'Excellent' when 70% or more participants
19 complete 75% of sessions,[47]. However, within the present study, the interpretation
20 of high attendance rates from those who completed T2 are considered more
21 modestly following the drop outs after Week 1.
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39

40 Participants reported the condition of low back pain most frequently and CFS/ME the
41 least frequently, as per current prevalence rates,[48, 49]. Our findings re-iterate the
42 high occurrence of co-morbidities, and frequent co-existence of chronic pain among
43 patients with CFS/ME,[9]. Participants with CFS/ME demonstrated improvements in
44 symptoms following treatment, in comparison to other studies in which pacing has
45 been ineffective,[31]. Disparate to the study by White et al.,[31], the activity pacing
46 framework encourages a rehabilitative approach that facilitates increased function
47 rather than aiming to reduce symptoms. The effects of rehabilitative approaches to
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 activity pacing for patients with both chronic pain and fatigue requires further
4
5 investigation using effectiveness trials.
6
7
8
9

10 **Clinical outcomes**

11
12
13

14 Activity pacing improved across all APQ-28 subthemes, the largest improvement
15 being for Activity planning. This theme refers to planning activities, setting time
16 targets and assessing activity levels,[35]; practical facets of pacing which may be
17 more accessible to change. Comparably, participants showed smaller improvements
18 in Activity acceptance. This subtheme includes setting realistic goals and allowing
19 flexibility; facets that involve changing previous behaviours or self-enforced rules.
20 The APQ-28 detected multidimensional changes in activity pacing, and the two new
21 items appeared to complement the scale. Further study will validate the APQ-28 in a
22 larger sample and estimate minimally important changes.
23
24
25
26
27
28
29
30
31
32
33
34
35
36

37 The aims of the activity pacing framework are to improve patients' function and
38 quality of life. Improvements in physical function were seen between T1-T2 (mean
39 change=4.67) that were greater than the minimally clinically important change
40 (3.29),[50]. There were also reductions in avoidance between T1-T2. It is intended
41 that the quota-contingent, operant approach of the activity pacing framework
42 encourages a reduction in avoidance through setting meaningful and realistic goals
43 towards activity, rather than stopping activities with the aim of reducing/avoiding
44 symptoms as per energy conservation approaches. Similarly, in a RCT comparing an
45 operant approach with energy conservation, Racine et al.,[30] found the operant
46 approach, but not energy conservation was associated with reduced avoidance
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 among patients with fibromyalgia. This, together with greater improvements in
4 depressive symptoms following the operant approach over energy conservation, led
5 to recommendations towards the operant approach for patients with
6 fibromyalgia,[30]. The current study found that pre-post treatment (T1-T2)
7 improvements in both avoidance and physical function showed some decline at three
8 months' follow-up. The authors suggest that physical function may be a component
9 of rehabilitation in which patients feel least confident, especially those with avoidant
10 behaviours,[20]. This may have implications for future programmes to integrate
11 follow-up sessions to encourage longer-term maintenance of physical activity. In
12 comparison, Racine et al.,[30] found improvements in physical activity following both
13 operant pacing and energy conservation approaches. Similarly to the present study,
14 Racine et al.,[30] implemented handouts, homework and goal setting to encourage
15 patients' uptake of activity pacing. However, both of the interventions explored by
16 Racine et al.,[30] were of greater duration than the current study, comprising of 10
17 two-hour stand-alone pacing sessions with a 3-month booster session. Within the
18 current study, improvements in mental function between T1-T2 (mean change=7.3)
19 were better maintained between T1-T3 (mean change=5.95); and both higher than
20 the minimally clinically important change (3.77),[50]. Quality of life also improved
21 between T1-T2 (mean change=0.13) and much of this improvement was maintained
22 between T1-T3 (mean change=0.07); both changes exceeded the minimally
23 important difference (0.037 +/-0.008),[51].

24
25
26 The activity pacing framework additionally aims to increase patients' self-efficacy.
27 Improvements in self-efficacy were found between T1 (mean=25.29) and T2
28 (mean=36.29), which were well maintained at T3 (mean=34.68). Scores were lower
29
30

1
2
3 than the ≥ 40 cut off. However, an improvement of >5.5 was attained which is
4
5 considered a minimally important change,[52]. Both physical and mental fatigue
6
7 improved, and improvements in mental fatigue appeared to be better maintained at
8
9 T3. Comparisons to minimally important changes are unavailable.
10
11
12
13

14 Psychological health improved following the rehabilitation programme, including
15
16 reduced depression scores from moderate to mild (T1=13.7, T2=7.1, T3=9.1); with a
17
18 clinically significant reduction (≥ 5) between T1-T2,[39]. Mean anxiety scores reduced
19
20 (T1=9.9, T2=5.4 and T3=6.10), and remained within the classification of mild
21
22 anxiety,[40]. Although reductions in pain were not a direct aim of the current
23
24 treatment, lower pain severity was reported. Despite the increased intensity of
25
26 pacing sessions contained within the RCT comparing the operant approach to
27
28 energy conservation, Racine et al.,[30] found that neither pacing approach effectively
29
30 reduced symptoms of pain or fatigue.
31
32
33
34
35
36
37

38 There were fewer significant correlations between changes in activity pacing and
39
40 symptoms pre-post treatment (T1-T2) than longer-term (T1-T3). This may be due to
41
42 participants undertaking a more experimental phase during T1-T2 (such as finding
43
44 baselines, (re-)starting activities), whereas new routines were more established
45
46 between T1-T3. However, such differences may have occurred due to differences
47
48 among those patients who completed the T3 data collection (n=52) and those who
49
50 completed T2 but did not complete T3 (n=13). It is suggested that patients who
51
52 completed T3 possibly felt greater benefits from the treatment and were more
53
54 motivated to respond to the follow-up questionnaire. Such potential bias could be
55
56 explored in future study involving a larger sample. Noticeably, changes in activity
57
58
59
60

1
2
3 pacing were more frequently associated with improvements in psychological
4
5 wellbeing rather than physical wellbeing. Similarly, a meta-analysis found pacing was
6
7 not associated with improved physical function among patients with chronic
8
9 conditions,[5].
10
11
12
13

14 **Strengths and limitations**

15
16
17
18
19 Despite recruiting to target, this sample was not powered with a control arm to
20
21 determine treatment effectiveness. The exploratory statistical analyses were
22
23 correlative and do not indicate causation between increased activity pacing and
24
25 improved symptoms. As per other studies exploring activity pacing, pacing was
26
27 instructed as one component of the rehabilitation programme,[5]. Therefore,
28
29 improvements in symptoms may have resulted from any combination of coping
30
31 strategies. A future RCT will implement a suitable control to explore the effects of
32
33 pacing, while implementing the activity pacing framework in a clinically relevant
34
35 setting, including alongside other coping strategies.
36
37
38
39
40
41

42 The generalisability of this study is limited to a sample of predominantly females and
43
44 white ethnic origin. Recruitment occurred only at one Pain Service and this service
45
46 had an existing rehabilitation programme for both chronic pain and fatigue. Bias may
47
48 have arisen through the lead researcher delivering the healthcare professionals'
49
50 training and undertaking the observations. Further work will test the activity pacing
51
52 framework and study protocol across other healthcare services and explore
53
54 feasibility and fidelity over wider geographical locations.
55
56
57
58
59
60

1
2
3 It is unknown what potential bias was caused by the attrition rate. However, there
4
5 were no differences at baseline between those who completed the programme and
6
7 those who dropped out. The attrition rate may be reflective of some of the clinical
8
9 challenges and missed appointments surrounding the complexity of chronic
10
11 pain/fatigue. Further research could explore whether providing a follow-up improves
12
13 commitment to activity pacing.
14
15
16
17
18

19 **Modifications for future study**

20
21
22
23
24 Since more patients completed the T1 questionnaires during the rehabilitation
25
26 sessions than at home, this may be the preferable mode of distribution. To lessen
27
28 the time taken to complete the questionnaires, the PASS-20 may be considered for
29
30 exclusion in future study. The whole 20-item PASS scale was included for reliability
31
32 and validity, but data from only the Escape and Avoidance subscale was explored.
33
34
35 Modifications to the inclusion criteria may include patients with any chronic spinal
36
37 pain, including cervical/thoracic pain due to the frequent and similar presentation at
38
39 rehabilitation services.
40
41
42
43
44

45 **Conclusion**

46
47
48
49 To the authors' knowledge, this is the first study to explore the clinical utility of a
50
51 comprehensive activity pacing framework developed for both chronic pain and
52
53 chronic fatigue. The newly developed activity pacing framework proved feasible to
54
55 use clinically by healthcare professionals. Patients with both chronic pain and fatigue
56
57 implemented greater activity pacing strategies following treatment, alongside
58
59
60

1
2
3 reporting improvements in quality of life, psychological wellbeing, self-efficacy, pain
4 and fatigue. Physical function and avoidance improved to a lesser extent and for the
5 shorter-term. Improvements in activity pacing were significantly associated with
6 improvements in cognitive/psychological wellbeing and quality of life, but not physical
7 function or avoidance. Future study will use the activity pacing framework in an
8 effectiveness RCT to explore the effects of activity pacing on symptoms.
9
10
11
12
13
14
15
16
17
18

19 **ACKNOWLEDGEMENTS**

20
21
22
23 We would like to acknowledge all of the patients and healthcare professionals who
24 were involved in this study. We would also like to acknowledge our statistical
25 support.
26
27
28
29
30
31
32

33 **CONFLICT OF INTEREST**

34
35
36
37 All authors declare no conflicts of interest
38
39
40
41

42 **AUTHOR CONTRIBUTIONS**

43
44
45
46 DA, AMK, PK, SW and LMc all contributed to the conception and design of the study.
47 DA undertook the acquisition of the data. DA, AMK, PK, SW and LMc all contributed
48 to the analysis and interpretation of data. DA, AMK, PK, SW and LMc contributed to
49 drafting the manuscript and revising it critically for important intellectual content and
50
51
52
53
54
55
56
57 have approved the final version for publication. DA, AMK, PK, SW and LMc are in
58
59
60

1
2
3 agreement to be accountable for all aspects of the work in ensuring that questions
4
5
6
7 related to the accuracy or integrity of any part of the work are appropriately
8
9
10 investigated and resolved.
11
12
13
14
15
16

17 **PATIENT CONSENT FOR PUBLICATION**

18
19
20
21 Not required.
22
23
24
25

26 **DATA SHARING AGREEMENT**

27
28
29
30 De-identified participant data are available from the corresponding author
31
32 (Deborah.Antcliff@pat.nhs.uk) upon reasonable request. Reuse is permitted for
33
34 health and care research as long as the original authors are acknowledged. The
35
36 protocol can also be requested from the author or accessed at ClinicalTrials.gov
37
38 (NCT03497585).
39
40
41
42
43
44

45 **ETHICAL APPROVAL**

46
47
48
49 Ethical approval was granted by the London-Surrey Research Ethics Committee
50
51 (18/LO/0655).
52
53
54
55

56 **DISCLAIMER**

1
2
3 This paper presents independent research funded by Health Education
4
5 England/National Institute for Health Research (NIHR) [Clinical Lectureship (ICA-CL-
6
7 2015-01-019)]. The views expressed are those of the author(s) and not necessarily
8
9 those of the NHS, the NIHR or the Department of Health and Social Care.
10
11
12
13

14 **SOURCES OF FUNDING**

15
16
17
18
19 This work was supported by a Health Education England/National Institute for Health
20
21 Research (HEE/NIHR) Clinical Lectureship (grant number: ICA-CL-2015-01-019).
22
23
24
25

26 **REFERENCES**

- 27
28
29
30
31 1. Torrance N, Smith BH, Elliott AM, et al. Potential Pain Management Programmes
32
33 in primary care. A UK-wide questionnaire and Delphi survey of experts. *Fam Pract*
34
35 2011;28:41-8.
36
37
38 2. Nijs J, Meeus M, De Meirleir K. Chronic musculoskeletal pain in chronic fatigue
39
40 syndrome: recent developments and therapeutic implications. *Man Ther*
41
42 2006;11:187-91.
43
44
45 3. Nielson WR, Jensen MP, Karsdorp PA, et al. Activity pacing in chronic pain:
46
47 concepts, evidence, and future directions. *Clin J Pain* 2013;29:461-8.
48
49
50 4. Antcliff D, Keenan AM, Keeley P, et al. Survey of activity pacing across healthcare
51
52 professionals informs a new activity pacing framework for chronic pain/fatigue.
53
54 *Musculoskeletal Care* 2019;17:335-45.
55
56
57
58
59
60

- 1
2
3 5. Abonie US, Sandercock GRH, Heesterbeek M, et al. Effects of activity pacing in
4 patients with chronic conditions associated with fatigue complaints: a meta-analysis.
5
6 *Disabil Rehabil* 2020;42:613-22.
7
- 8
9
10 6. Aggarwal VR, McBeth J, Zakrzewska JM, et al. The epidemiology of chronic
11 syndromes that are frequently unexplained: do they have common associated
12 factors? *Int J Epidemiol* 2006;35:468-76.
13
14
- 15
16
17 7. Meeus M, Nijs J. Central sensitization: a biopsychosocial explanation for chronic
18 widespread pain in patients with fibromyalgia and chronic fatigue syndrome. *Clin*
19 *Rheumatol* 2007;26:465-73.
20
21
- 22
23
24 8. Davis LL, Kroenke K, Monahan P, et al. The SPADE Symptom Cluster in Primary
25 Care Patients With Chronic Pain. *Clin J Pain* 2016;32:388-93.
26
27
- 28
29
30 9. Meeus M, Nijs J, Meirleir KD. Chronic musculoskeletal pain in patients with the
31 chronic fatigue syndrome: a systematic review. *Eur J Pain* 2007;11:377-86.
32
33
- 34
35
36 10. Tavel ME. Somatic symptom disorders without known physical causes: one
37 disease with many names? *Am J Med* 2015;128:1054-8.
38
39
- 40
41
42 11. Yunus MB. Fibromyalgia and overlapping disorders: the unifying concept of
43 central sensitivity syndromes. *Semin Arthritis Rheum* 2007;36:339-56.
44
45
- 46
47
48 12. Nijs J, Meeus M, Van Oosterwijck J, et al. In the mind or in the brain? Scientific
49 evidence for central sensitisation in chronic fatigue syndrome. *Eur J Clin Invest*
50 2012;42:203-12.
51
52
- 53
54
55 13. Arendt-Nielsen L, Morlion B, Perrot S, et al. Assessment and manifestation of
56 central sensitisation across different chronic pain conditions. *Eur J Pain*
57 2018;22:216-241.
58
59
- 60 14. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic
musculoskeletal pain: a state of the art. *Pain* 2000;85:317-32.

- 1
2
3 15. Moseley GL. A pain neuromatrix approach to patients with chronic pain. *Man*
4
5 *Ther* 2003;8:130-40.
6
7
8 16. Ericsson A, Mannerkorpi K. How to manage fatigue in fibromyalgia:
9
10 nonpharmacological options. *Pain Manag* 2016;6:331-8.
11
12 17. British Pain Society. Guidelines for pain management programmes for adults.
13
14 London: British Pain Society, 2013.
15
16 18. Beissner K, Henderson CR, Jr., Papaleontiou M, et al. Physical therapists' use of
17
18 cognitive-behavioral therapy for older adults with chronic pain: a nationwide survey.
19
20 *Phys Ther* 2009;89:456-69.
21
22
23 19. Booth J, Moseley GL, Schiltenswolf M, et al. Exercise for chronic musculoskeletal
24
25 pain: A biopsychosocial approach. *Musculoskeletal Care* 2017;15:413-421.
26
27 20. Anderson RJ, Hurley RW, Staud R, et al. Cognitive-motivational influences on
28
29 health behavior change in adults with chronic pain. *Pain Med* 2016;17:1079-1093.
30
31 21. Birkholtz M, Aylwin L, Harman RM. Activity pacing in chronic pain management:
32
33 One aim, but which method? Part one: Introduction and literature review. *British*
34
35 *Journal of Occupational Therapy* 2004;67:447-52.
36
37
38 22. Abonie US, Edwards AM, Hettinga FJ. Optimising activity pacing to promote a
39
40 physically active lifestyle in medical settings: A narrative review informed by clinical
41
42 and sports pacing research. *J Sports Sci* 2020;38:590-596.
43
44
45 23. Jamieson-Lega K, Berry R, Brown CA. Pacing: A concept analysis of a chronic
46
47 pain intervention. *Pain Res Manag* 2013;18:207-13.
48
49
50 24. Andrews NE, Deen M. Defining Activity Pacing: Is It Time to Jump Off the Merry-
51
52 Go-Round? *J Pain* 2016;17:1359-1362.
53
54
55
56
57
58
59
60

- 1
2
3 25. Andrews NE, Strong J, Meredith PJ. Activity pacing, avoidance, endurance, and
4 associations with patient functioning in chronic pain: a systematic review and meta-
5 analysis. *Arch Phys Med Rehabil* 2012;93:2109-2121 e7.
6
7
8
9
10 26. Murphy SL, Clauw DJ. Activity pacing: what are we measuring and how does
11 that relate to intervention? *Pain* 2010;149:582-583.
12
13
14 27. Craig P, Dieppe P, Macintyre S, et al. Medical Research Council Guidance.
15 Developing and evaluating complex interventions: The new Medical Research
16 Council guidance. *BMJ* 2008;337:a1655. doi: 10.1136/bmj.a1655
17
18
19 28. Creswell JW, Plano-Clark VL. *Designing and conducting mixed methods*
20 *research*. California, USA: Sage Publications Ltd, 2011.
21
22
23 29. Antcliff D, Keenan AM, Keeley P, et al. Engaging stakeholders to refine an
24 activity pacing framework for chronic pain/fatigue: A nominal group technique.
25 *Musculoskeletal Care* 2019;17:354-362.
26
27
28 30. Racine M, Jensen MP, Harth M, et al. Operant Learning Versus Energy
29 Conservation Activity Pacing Treatments in a Sample of Patients With Fibromyalgia
30 Syndrome: A Pilot Randomized Controlled Trial. *J Pain* 2019;20:420-439.
31
32
33 31. White PD, Goldsmith KA, Johnson AL, et al. Comparison of adaptive pacing
34 therapy, cognitive behaviour therapy, graded exercise therapy, and specialist
35 medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet*
36 2011;377:823-36.
37
38
39 32. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and
40 feasibility studies. *Pilot Feasibility Stud* 2019;5:114.
41
42
43 33. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement:
44 extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 34. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in
4 relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301-
5
6 8.
7
8
9
10 35. Antcliff D, Campbell M, Woby S, et al. Assessing the Psychometric Properties of
11 an Activity Pacing Questionnaire for Chronic Pain and Fatigue. *Phys Ther*
12 2015;95:1274-86.
13
14
15
16 36. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels
17 needed in pain intensity measurement? *Pain* 1994;58:387-92.
18
19
20 37. Chalder T, Berelowitz G, Pawlikowska T, et al. Development of a fatigue scale.
21 *Journal of Psychosomatic Research* 1993;37:147-53.
22
23
24 38. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression
25 severity measure. *J Gen Intern Med* 2001;16:606-13.
26
27
28 39. Kroenke K, Spitzer RL, Williams JB, et al.. The Patient Health Questionnaire
29 Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp*
30 *Psychiatry* 2010;32:345-59.
31
32
33 40. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing
34 generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-7.
35
36
37 41. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur*
38 *J Pain* 2007;11:153-63.
39
40
41 42. McCracken LM, Dhingra L. A short version of the Pain Anxiety Symptoms Scale
42 (PASS-20): preliminary development and validity. *Pain Res Manag* 2002;7:45-50.
43
44
45 43. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey:
46 construction of scales and preliminary tests of reliability and validity. *Medical Care*
47 1996;34:220-33.
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 44. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the
4 new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36.
5
6
7 45. van Hout B, Janssen MF, Feng Y, et al. Interim Scoring for the EQ-5D-5L:
8 Mapping the EQ-5D-5L to EQ-5D-3L Value Sets. *Value in Health* 2012;15:708 –715.
9
10
11 46. Bearne LM, Walsh NE, Jessep S, et al. Feasibility of an exercise-based
12 rehabilitation programme for chronic hip pain. *Musculoskeletal Care* 2011;9:160-8.
13
14
15 47. Greenberg J, Lin A, Zale EL, et al. Development And Early Feasibility Testing Of
16 A Mind-Body Physical Activity Program For Patients With Heterogeneous Chronic
17 Pain; The GetActive Study. *J Pain Res* 2019;12:3279-3297.
18
19
20 48. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we
21 need to pay attention. *Lancet* 2018;391:2356-67.
22
23
24 49. NICE. Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy).
25 *NICE Clinical Guideline 53 London* 2007.
26
27
28 50. Diaz-Arribas MJ, Fernandez-Serrano M, Royuela A, et al. Minimal Clinically
29 Important Difference in Quality of Life for Patients With Low Back Pain. *Spine (Phila*
30 *Pa 1976)* 2017;42:1908-1916.
31
32
33 51. McClure NS, Sayah FA, Xie F, et al. Instrument-Defined Estimates of the
34 Minimally Important Difference for EQ-5D-5L Index Scores. *Value Health*
35 2017;20:644-650.
36
37
38 52. Chiarotto A, Vanti C, Cedraschi C, et al. Responsiveness and Minimal Important
39 Change of the Pain Self-Efficacy Questionnaire and Short Forms in Patients With
40 Chronic Low Back Pain. *J Pain* 2016;17:707-18.
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55

56 **FIGURE LEGENDS**

57
58 Figure 1. Activity pacing conceptual model taken from the activity pacing framework
59
60

1
2
3 Figure 2: CONSORT diagram showing the flow of participants through the study
4

5 Figure 3. Participants' written comments following attending the rehabilitation
6

7
8 programme
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

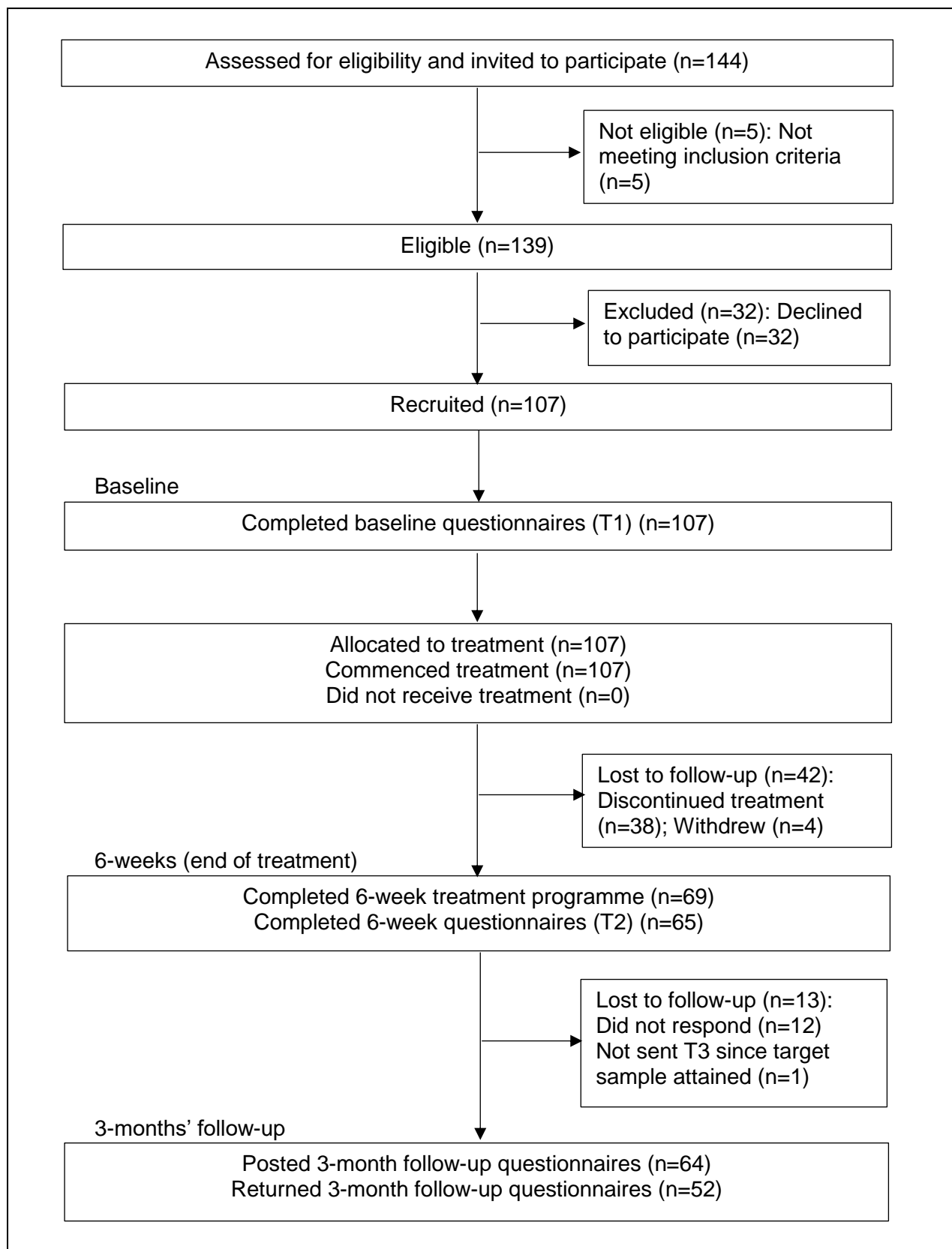


Figure 2: CONSORT diagram showing the flow of participants through the study

1
2
3
4 T2: "The pace and content has been good for me. It has helped me to focus on
5 my belief that I have to own the situation, to be positive and to make use of the
6 tools we have discussed. If I don't take this approach I believe my situation will
7 not improve. There is no magic wand, but I can be the difference." (F070:
8
9

10 *Fibromyalgia*)
11
12

13
14 T3: "I have found pacing really helpful in my everyday life and feel I can achieve
15 more day to day than 12 months ago." (F006: *chronic widespread pain,*
16 *fibromyalgia, chronic fatigue syndrome/myalgic encephalomyelitis*)
17
18

19
20
21 T3: "I found the pain service very helpful and informative. How I view my pain and
22 react to and manage it has improved. Emotionally, I feel more positive as a result
23 of using strategies learned, and also more confident that I can manage my pain
24 and how it makes me feel. Using pacing and realistic goals has enabled me to do
25 some activities that I previously avoided i.e. hoovering, changing the bed. (F068:
26 *fibromyalgia*)
27
28
29
30

31
32
33 T3: "Doing the 6 week course was extremely helpful and gave me some excellent
34 information and resources to work with. The difficulty has been that there has
35 been no follow up or support sessions since. It is great having the info, but then
36 you are battling depression/anxiety it is difficult to apply knowledge without some
37 support, even if that is over the phone every few weeks or maybe a support group
38 facility." (F075: *low back pain, chronic widespread pain*)
39
40
41
42

43
44
45 T3 "I have found 'pacing' a very good way to manage pain and get through the
46 day completing activities" (F105: *low back pain, chronic widespread pain,*
47 *fibromyalgia*)
48
49
50

51
52
53 *Figure 3. Participants' written comments following attending the rehabilitation*
54 *programme*
55
56
57
58
59
60

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

Pacing and sleep hygiene

Pacing and other strategies

13. Pacing aids

Activity diaries

Goal setting

B. Appendices and teaching guide

Part 1. Conceptual model of pacing

Appendix 1. Activity pacing and the fear-avoidance model

Appendix 2. Pacing as a health behaviour:

The Health Action Process Approach (HAPA)

The Transtheoretical model

Part 2. Pacing guide for healthcare professionals

Appendix 3. Chronic pain/fatigue cycle

Appendix 4. Overactivity-underactivity (boom-bust) cycle:

Boom-bust, avoidance and excessive persistence behaviours

Appendix 5. Activity pacing framework model of pacing

Appendix 6. Facets of pacing:

Facets of pacing, explanation/examples and who may benefit

Appendix 7. Stages of pacing

Appendix 8. Patient exemplars:

Avoidance

Excessive persistence

Boom-bust

Patients who are predominantly bedbound

Appendix 9. Questions for healthcare professionals to ask patients:

Exploring current patterns of activity

Exploring current baselines of activity

Exploring possible barriers to pacing

Exploring individuals' aims

Part 3. Pacing tools

Appendix 10. Activity diary:

SUPPLEMENTARY MATERIAL

- 1
- 2
- 3
- 4 Blank activity diary and example of a completed diary
- 5 Appendix 11. Goal setting
- 6 Appendix 12. Checklist for health care professionals
- 7
- 8 Appendix 13. References
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

For peer review only

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 <i>BMJ Open</i> 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 supplementary 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

1
2
3 Goal setting: specific pacing goal
4
5

6
7 **Week 4**

8 Pacing goal review
9

10 Choice V's demand activities
11

12 Increasing positive thoughts
13

14 Work and employment
15

16 Graded exercise (circuit exercises)
17

18 Mindfulness session
19

20 Goal setting
21

22 **Week 5**

23 Goal review
24

25 Sleep hygiene
26

27 Medication
28

29 Graded exercise (circuit exercises)
30

31 Mindfulness session
32

33 Goal setting
34

35 **Week 6**

36 Goal review
37

38 Managing setbacks
39

40 Mindfulness session
41

42 Maintaining progress
43

44 Signposting to community resources
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

SUPPLEMENTARY MATERIAL

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

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

BMJ Open

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

Journal:	<i>BMJ Open</i>
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

SCHOLARONE™
Manuscripts



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.

1
2
3 **Title: Testing a newly developed activity pacing framework for chronic**
4 **pain/fatigue: a feasibility study**
5
6
7
8
9

10 **AUTHORS**
11

12 Dr Deborah Antcliff (PhD)^{a,b}
13

14 ^aPhysiotherapy Department, Bury Care Organisation, Northern Care Alliance NHS
15 Group, Bury, United Kingdom.
16
17

18 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom.
19
20
21
22

23
24 Professor Anne-Maree Keenan (PhD)^{b,c}
25

26 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom
27

28 ^cNIHR Leeds Biomedical Research Centre, Leeds, England, UK
29
30
31
32

33 Professor Philip Keeley (PhD)^d
34

35 ^dSchool of Nursing and Midwifery, Keele University, Keele, United Kingdom
36
37
38
39

40 Professor Steve Woby (PhD)^{e,f,g}
41

42 ^eResearch and Innovation Department, Northern Care Alliance NHS Group, Salford,
43 United Kingdom.
44
45

46 ^fSchool of Health and Society, University of Salford, Salford, United Kingdom.
47
48

49 ^gFaculty of Science and Engineering, Manchester Metropolitan University,
50 Manchester, United Kingdom.
51
52
53
54

55
56 Professor Linda McGowan (PhD)^b
57

58 ^bSchool of Healthcare, University of Leeds, Leeds, United Kingdom
59
60

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

1
2
3 pacing and all symptoms improved between T1-T2, with smaller improvements
4
5 maintained at T3.
6

7
8 **Conclusion:** The activity pacing framework was feasible to implement and patients'
9
10 ability to pace and manage their symptoms improved. Future work will employ a
11
12 suitable comparison group and test the framework across wider settings to explore
13
14 the effects of activity pacing in a randomised controlled trial.
15

16
17 **Trial registration:** ClinicalTrials.gov:NCT03497585
18

19
20 **Funding:** Health Education England/National Institute for Health Research
21
22

23 24 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 25
26
27
28 • This was the first study to test the feasibility of using a newly developed
29
30 activity pacing framework in a rehabilitation programme to standardise the
31
32 clinical instructions of activity pacing to patients with chronic pain/fatigue.
33
34
- 35
36 • This feasibility study recruited to target with satisfactory recruitment/attrition
37
38 rates.
39
- 40
41 • A comprehensive measure of activity pacing: the 28-item Activity Pacing
42
43 Questionnaire (APQ-28), and range of validated psychometric measures were
44
45 suitable to detect changes before and after treatment.
46
- 47
48 • This study was not powered with a control arm to determine treatment
49
50 effectiveness.
51
- 52
53 • The generalisability of this study is limited to a sample of predominantly
54
55 females, of white ethnic origin, and from a single Pain Service.
56
57
58
59
60

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-

1
2
3 used guide to standardise how healthcare professionals instruct activity pacing to
4 patients; and uncertainty whether different methods are required for symptoms of
5 chronic pain versus chronic fatigue,[3, 26]. This poses challenges how to advise
6 patients with both chronic pain and fatigue.
7
8
9
10
11
12

13
14 We have developed an activity pacing framework using an inclusive approach for
15 patients who present at rehabilitation services with chronic pain and/or fatigue. Using
16 the Medical Research Council guidelines for developing complex interventions,
17 mixed methods were implemented to encompass theoretical and stakeholder
18 standpoints,[27]. Mixed methods comprise of quantitative and qualitative approaches
19 to collecting and analysing data,[28]. Stage I: Healthcare professionals' survey
20 gathered opinions on activity pacing (n=92),[4]. These findings, together with existing
21 research formed the first draft of the framework and accompanying appendices.
22
23 Stage II: Nominal group technique refined the activity pacing framework using a
24 consensus meeting between patients and healthcare professionals (n=10),[29].
25
26 During the development of the activity pacing framework, stakeholders included
27 healthcare professionals and patients with the aim of increasing the clinical utility and
28 acceptability of the framework. (*See Supplementary Figure 1. Content of the Activity
29 Pacing Framework: Theory and Overview, and Appendices and Teaching Guide
30 booklets.*)
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50

51 The conceptual model of the activity pacing framework (*see Figure 1*) follows
52 principles of quota-contingency and the operant approach (for example, setting goals
53 according to time/distance/activity). The activity pacing framework is underpinned by
54 concepts of rehabilitation with aims of improving physical and cognitive function; and
55
56
57
58
59
60

1
2
3 engagement in, and satisfaction with meaningful activities, while managing
4 symptoms,[4, 29]. The activity pacing framework includes the potential for
5
6 reversibility of some of the consequences of chronic pain/fatigue, such as the
7
8 potential to reduce levels of disability. Together with containing themes of adjusting
9
10 activities, planning and consistency, the activity pacing framework also includes
11
12 themes of progression regarding the amount and/or variety of activities. Therefore,
13
14 the activity pacing framework is considered to be a rehabilitative approach that
15
16 moves forward from only adapting, or in some cases mal-adapting to the long-term
17
18 condition. The activity pacing framework differs from energy conservation/adaptive
19
20 pacing approaches which involve undertaking activities according to symptom
21
22 severity (symptom-contingency) with an aim of reducing or avoiding symptoms,[30,
23
24 31]. Within the current activity pacing framework, quota-contingency is advised
25
26 alongside concepts of flexibility and choice to enable relevance and sustainability in
27
28 conditions where symptoms may vary. The framework refers to all types of activities
29
30 including work, household activities, cognitive activities, physical activities, exercise
31
32 and relaxation to increase its wider relevance for patients with chronic pain and/or
33
34 fatigue, for varying abilities and behaviours.
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 setting, relaxation and mindfulness. Pacing was instructed in one session but was
4
5 not informed or standardised by any particular guide or framework.
6
7
8
9

10 **Activity pacing framework standardised programme**

11
12
13

14 The existing six-week programme was modified through re-structuring and
15
16 standardisation using the activity pacing framework. Activity pacing was formally
17
18 instructed on two sessions (weeks 2-3). However, activity pacing was referenced
19
20 throughout the programme in relation to other coping strategies, for example, how
21
22 activity pacing can assist graded exercise (weeks 1-5) or set-back management
23
24 (week 6). In comparison to the existing rehabilitation programme, the activity pacing
25
26 framework standardised programme included more in-depth discussions of activity
27
28 behaviours (avoidance, overactivity-underactivity cycling and excessive persistence)
29
30 to assist patients to identify their current approach to activities. This aimed to
31
32 facilitate patients' recognition of which facets of activity pacing were most relevant to
33
34 them. The two activity pacing sessions focused on the aims of activity pacing,
35
36 barriers to activity pacing, facets of activity pacing (for example, breaking down
37
38 tasks, switching between activities, having more consistent activity levels, allowing
39
40 flexibility, gradually increasing the amount or variety of activities), and stages of
41
42 activity pacing (introducing activity pacing, finding baselines, adjusting activities,
43
44 planning, consistency, learning and progressing). Practical exercises included
45
46 completing an activity diary to discuss patients' activity patterns and setting goals in
47
48 which activity pacing could be practised. (See *Supplementary Figure 2. Content of*
49
50 *the rehabilitation programme*). Patients received a handout to summarise the key
51
52 concepts of activity pacing. The healthcare professionals (as above) received
53
54
55
56
57
58
59
60

1
2
3 training on the framework during a half-day session and could contact the lead
4 researcher (DA) for any queries. All patients attended the standardised programme,
5
6 but patients chose whether to participate in the study through their optional
7
8 completion of the study questionnaires and consent form.
9
10
11
12
13

14 **Data collection**

15 **Feasibility outcomes**

16
17
18
19
20
21
22
23
24 Measures of feasibility included participant recruitment/attrition rates, adherence
25
26 (number of sessions attended), acceptability (two satisfaction rating scales regarding
27
28 the programme content and length where 0=dissatisfied and 10=fully satisfied), and
29
30 missing data in the questionnaire. For every programme, healthcare professionals
31
32 completed a 13-item fidelity checklist based on the conceptual model of the activity
33
34 pacing framework to ensure their inclusion of key elements from the framework.
35
36
37 Each clinician was observed once by the lead researcher.
38
39
40
41

42 **Clinical measures**

43
44
45
46
47 The self-reported paper questionnaire booklets (T1, T2 and T3) included
48
49 standardised clinical measures. T1 could be completed during session one or at
50
51 home, T2 could be completed during session six, and T3 was sent in the post to be
52
53 completed at home. Telephone reminders were made if the T3 questionnaires were
54
55 not returned within two weeks. The T1 booklet contained demographic questions, in
56
57 addition to following measures included in T2 and T3:
58
59
60

1
2
3
4
5 (1) Activity pacing was measured using the 28-item Activity Pacing Questionnaire
6 (APQ-28). The 26-item Activity Pacing Questionnaire (APQ-26) was initially validated
7
8 among patients with chronic pain/fatigue and contained five subthemes: Activity
9
10 adjustment, Activity planning, Activity consistency, Activity acceptance and Activity
11
12 progression (Cronbach's alpha=0.72-0.92),[36]. (See *Supplementary Table 2. Five*
13
14 *themes of the 28-item Activity Pacing Questionnaire (APQ-28) with examples.*) Each
15
16 item is scored between 0='never did this' and 4='always did this'. Two items have
17
18 been added that correspond to important aspects of activity pacing that emerged
19
20 during the development of the activity pacing framework. The new items: APQ12:"I
21
22 found a baseline amount of activities that I could do on 'good' and 'bad' days" and
23
24 APQ15:"I had a flexible approach with my activities" were added to the subthemes of
25
26 best conceptual fit (Activity adjustment and Activity acceptance respectively). Each
27
28 subtheme was calculated as a mean score. The APQ-28 subthemes, similarly to the
29
30 following scales, permitted one missing item per subscale.
31
32
33
34
35
36
37
38
39

40 (2) Current and usual pain were measured using two 11-point numerical rating
41
42 scales (NRS), where 0='no pain' and 10='worst possible pain',[37].
43
44
45

46 (3) Physical fatigue (seven items) and mental fatigue (four items) were measured
47
48 using the Chalder Fatigue Questionnaire (CFQ), where scores of 1='much worse
49
50 than usual' and 4='better than usual',[38]. Two subscale scores were summated
51
52 where higher scores indicated less fatigue.
53
54
55
56
57
58
59
60

1
2
3 (4) Depression was measured using the nine item Patient Health Questionnaire
4
5 (PHQ-9), the items of which are based on the Diagnostic and Statistical Manual of
6
7 Mental Disorders 4th Edition (DSM-IV),[39]. Items were rated between 0='not at all'
8
9 and 3='nearly everyday'. Total scores of 1-4=minimal depression, 5-9=mild
10
11 depression, 10-14=moderate depression and ≥ 15 =severe depression,[39, 40].
12
13
14

15
16
17 (5) Anxiety was measured using the seven-item Generalised Anxiety Disorder
18
19 Assessment (GAD-7). Items were rated between 0='not at all' and 3='nearly
20
21 everyday'. Total scores of 5-9=mild anxiety, 10-14=moderate anxiety and
22
23 ≥ 15 =severe anxiety,[41].
24
25
26

27
28 (6) Self-efficacy was measured using the 10-item Pain Self-Efficacy Questionnaire
29
30 (PSEQ) where items were rated between 0='not at all confident' and 6='completely
31
32 confident'. Total scores of $PSEQ \geq 40$ indicate those patients who are more likely to
33
34 continue implementing coping strategies/behavioural changes, and $PSEQ \leq 16$ are
35
36 considered low,[42].
37
38
39

40
41 (7) Avoidance was measured using the 'Escape and Avoidance' subscale of the Pain
42
43 Anxiety Symptoms Scale-short version (PASS-20),[43]. The five items were rated
44
45 between 0='never' and 5='always' where higher total scores indicated greater
46
47 avoidance.
48
49
50

51
52 (8) Physical and mental function were measured using the 12-Item Short-Form
53
54 Health Survey (SF-12). Two subscale scores (out of 100) were calculated using the
55
56
57
58
59
60

1
2
3 SF-12 software (Version 2; one-week recall) where higher scores indicated better
4
5 function,[44].
6
7
8
9

10 (9) Health-related quality of life was measured using the EQ-5D-5L (EuroQol). The
11
12 EQ-5D-5L was calculated as an index score,[45, 46].
13
14
15
16

17 **Data analysis**

18
19
20
21 Feasibility outcomes and participants' demographics were analysed using
22
23 descriptive statistics. Clinical outcomes were estimated as changes in activity pacing
24
25 and symptoms between T1-T2, T2-T3 and T1-T3 (mean change, 95% confidence
26
27 intervals). The validity of the modified APQ-28 was estimated using Cronbach's
28
29 alpha and item correlations; and sensitivity analyses explored the effects of including
30
31 two new APQ-28 items. Data were analysed using IBM SPSS Statistics 26 statistical
32
33 software (IBM Corp, Armonk, New York).
34
35
36
37
38
39

40 **Patient and Public Involvement**

41
42
43
44 Patient and Public Involvement (PPI) commenced during the initial planning stages
45
46 of the mixed methods programme to develop and test the activity pacing framework.
47
48 A meeting with five PPI representatives discussed the study purpose and practical
49
50 issues around the proposed methods (online survey, nominal group technique, and
51
52 feasibility and acceptability studies). PPI guided on improving the accessibility of
53
54 patients' participation and reducing burden (for example, location and duration of
55
56 meetings). A PPI representative has acted as an advisor on the study, involving
57
58
59
60

1
2
3 commenting on study documents/questionnaire booklets and coding qualitative
4
5 interviews. Acceptability interviews with patients explored practical issues
6
7 surrounding the feasibility study,[34] which will further assist the planning of a future
8
9 randomised controlled trial (RCT) of activity pacing.
10
11
12
13

14 **RESULTS**

15
16
17
18
19 Recruitment and T1 data collection commenced in May 2018 and T3 data collection
20
21 ended in December 2019 due to attaining the target sample.
22
23
24
25

26 **Demographics**

27
28
29
30
31 Among the 107 participants who completed the baseline (T1) measures, participants
32
33 were predominantly female (n=92, 86.0%) with a mean age of 55.25 +/- 12.83 years.
34
35 Low back pain was most frequently reported (n=79, 73.8%) and CFS/ME least
36
37 frequently reported (n=12, 11.2%). Sixty-five participants (61.3%) reported two or
38
39 more conditions of chronic pain and/or fatigue. Of the 12 participants with CFS/ME,
40
41 10 participants reported CFS/ME as their main condition, and 11 reported at least
42
43 one co-morbidity of LBP (n=7), chronic widespread pain (n=6), fibromyalgia (n=7) or
44
45 another condition (n=3). (See Table 1 for participant demographics and Table 2 for
46
47 *baseline scores for activity pacing and symptoms.*)
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 attended was six (89.2% participants attended ≥ 5 sessions); 100% of participants
4
5 attended at least one activity pacing specific session and 54 (83.1%) participants
6
7 attended both activity pacing sessions. There were no statistically significant
8
9 differences between participants who completed T2 or dropped out in terms of
10
11 demographics or baseline symptoms. Of the 12 participants with CFS/ME, six
12
13 completed T2 (50%) and six completed T3 (100% of T2, 50% of T1); whereas 59 of
14
15 the 95 participants without CFS/ME completed T2 (62%) and 46 completed T3 (78%
16
17 of T2 and 48% of T1).
18
19
20
21
22
23

24 **Acceptability of the rehabilitation programme/questionnaires (Objective 1)**

25
26
27
28 On T2, participants rated their satisfaction of the length and content of the
29
30 rehabilitation programme as mean=8.8 (SD=1.7) and 9.1 (SD=1.5) respectively. The
31
32 satisfaction of only those participants with CFS/ME was mean=9.0 (SD=0.9) and 9.2
33
34 (SD=1.0).
35
36
37
38
39

40 There were minimal missing data in the questionnaire booklets (approximately 1%).

41
42 Some participants wrote comments regarding their perceived benefits of
43
44 implementing activity pacing and other coping strategies. Two participants wished for
45
46 a longer programme or a follow-up session (*see Figure 3 for examples of*
47
48 *participants' comments*).
49
50
51
52
53

54 **Fidelity to the activity pacing framework (Objective 2)**

1
2
3 Each healthcare professional observation demonstrated good adherence to the
4 framework against a number of key points. Healthcare professionals reported 100%
5 adherence in their fidelity checklists for each rehabilitation programme. Healthcare
6 professionals reported that some participants spent over 20 minutes completing the
7 questionnaire booklet, and that not all patients completed the activity diaries.
8
9
10
11
12
13
14
15
16

17 **Interventions between T2 and T3**

18
19
20
21 Of the 52 respondents at T3, two patients received lumbar epidural steroid injections,
22 one patient had acupuncture, one attended a chiropractor and one patient had knee
23 surgery.
24
25
26
27
28
29

30 **Clinical outcomes**

31 **Validity of the APQ-28 (Objective 3)**

32
33
34
35
36
37
38
39
40 At T1, the two new APQ-28 items showed ease of completion through minimal
41 missing answers (Item APQ12=0 missing answers, Item APQ15=1 missing answer).
42
43 The scores of the new items utilised the full range, and the mean scores (Items
44 APQ12=1.67 and APQ15=1.91) sat within the range of the other APQ-28 items
45 (mean=1.17-2.78). The new items demonstrated optimal fit with their allocated
46 subthemes via highest inter-item correlations and item-total correlations (item total
47 correlations: APQ12 and Activity adjustment, $r_s(106)=0.76$, $p<0.001$; Item APQ15
48 and Activity acceptance, $r(106)=0.68$, $p<0.001$). The internal consistency for Activity
49 adjustment increased with the addition of Item APQ12 (Cronbach's alpha=0.86 to
50
51
52
53
54
55
56
57
58
59
60

1
2
3 0.88), and for Activity acceptance with the addition of Item APQ15 (Cronbach's
4 alpha=0.68 to 0.72). The internal validity of the other APQ-28 subthemes were:
5
6 Activity planning=0.86, Activity consistency=0.80 and Activity progression=0.69.
7
8
9
10
11

12 **Mean changes in activity pacing and symptoms (Objective 3)**

13
14
15
16

17 Between T1-T2, all five APQ-28 subtheme mean scores increased, indicating
18 improved activity pacing. There were small reductions in APQ-28 scores between
19 T2-T3. However, all five subthemes showed overall improvements between T1-T3,
20 with Activity planning showing the greatest increases (*see Table 3*). Sensitivity
21 analyses showed marginal increases in mean changes following the addition of the
22 two new APQ-28 items.
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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)

1
2
3 Between T1-T2, the mean scores of all symptoms improved. Current pain reduced
4 more than usual pain. Physical and mental fatigue both improved, as did self-efficacy
5 and quality of life. Mental function improved more than physical function. Depression,
6 anxiety and avoidance all reduced. There was some deterioration in symptoms
7
8 between T2-T3, but between T1-T3 all symptoms demonstrated clear improvements
9
10 except avoidance (-1.46, 95% CI=-3.02 to 0.10) and physical function (1.62, 95%
11
12 CI=-0.81 to 4.06) (see *Table 4.*). Observing only the subgroup of participants with
13
14 CFS/ME, improvements were seen between T1-T2 and T1-T3 across all APQ-28
15
16 subthemes and symptoms.
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 recruitment/attrition rates will help to plan the progression criteria used in a future
4
5 pilot RCT of activity pacing.
6
7
8
9

10 Regarding treatment adherence, only 56.1% of participants recruited at T1 attended
11
12 both activity pacing sessions. Many participants (n=18, 16.8%) dropped out after the
13
14 first session and therefore did not attend any activity pacing sessions. Reasons for
15
16 early drop-out often include unrealistic expectations of symptom improvement, low
17
18 motivation, or confidence to commit to programmes or behavioural changes,[20]. In
19
20 comparison, attendance rates of both activity pacing sessions among those who
21
22 completed T2 were 83.1%, and 89.2% of participants attended five or more
23
24 sessions. This is comparable to adherence rates of 81% seen elsewhere,[47]; and
25
26 adherence rates have been considered as 'Excellent' when 70% or more participants
27
28 complete 75% of sessions,[48]. However, within the present study, the interpretation
29
30 of high attendance rates from those who completed T2 are considered more
31
32 modestly following the drop outs after Week 1.
33
34
35
36
37
38
39

40 Participants reported the condition of low back pain most frequently and CFS/ME the
41
42 least frequently, as per current prevalence rates,[49, 50]. Our findings re-iterate the
43
44 high occurrence of co-morbidities, and frequent co-existence of chronic pain among
45
46 patients with CFS/ME,[9]. Participants with CFS/ME demonstrated improvements in
47
48 symptoms following treatment, in comparison to other studies in which pacing has
49
50 been ineffective,[31]. Disparate to the study by White et al.,[31], the activity pacing
51
52 framework encourages a rehabilitative approach that facilitates increased function
53
54 rather than aiming to reduce symptoms. The effects of rehabilitative approaches to
55
56
57
58
59
60

1
2
3 activity pacing for patients with both chronic pain and fatigue requires further
4
5 investigation using effectiveness trials.
6
7
8
9

10 **Clinical outcomes**

11
12
13

14 Activity pacing improved across all APQ-28 subthemes, the largest improvement
15 being for Activity planning. This theme refers to planning activities, setting time
16 targets and assessing activity levels,[36]; practical facets of activity pacing which
17 may be more accessible to change. Comparably, participants showed smaller
18 improvements in Activity acceptance. This subtheme includes setting realistic goals
19 and allowing flexibility; facets that involve changing previous behaviours or self-
20 enforced rules. The APQ-28 detected multidimensional changes in activity pacing,
21 and the two new items appeared to complement the scale. Further study will fully
22 validate the APQ-28 in a larger sample and estimate minimally important changes.
23
24
25
26
27
28
29
30
31
32
33
34
35
36

37 The aims of the activity pacing framework are to improve patients' function and
38 quality of life. Improvements in physical function were seen between T1-T2 (mean
39 change=4.67) that were greater than the minimally clinically important change
40 (3.29),[51]. There were also reductions in avoidance between T1-T2. It is intended
41 that the quota-contingent, operant approach of the activity pacing framework
42 encourages a reduction in avoidance through setting meaningful and realistic goals
43 towards activity, rather than stopping activities with the aim of reducing/avoiding
44 symptoms as per energy conservation approaches. Similarly, in a RCT comparing an
45 operant approach with energy conservation, Racine et al.,[30] found the operant
46 approach, but not energy conservation was associated with reduced avoidance
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 among patients with fibromyalgia. This, together with greater improvements in
4 depressive symptoms following the operant approach over energy conservation, led
5 to recommendations towards the operant approach for patients with
6 fibromyalgia,[30]. The current study found that pre-post treatment (T1-T2)
7 improvements in both avoidance and physical function showed some decline at three
8 months' follow-up. The authors suggest that physical function may be a component
9 of rehabilitation in which patients feel least confident, especially those with avoidant
10 behaviours,[20]. This may have implications for future programmes to integrate
11 follow-up sessions to encourage longer-term maintenance of physical activity. In
12 comparison, Racine et al.,[30] found improvements in physical activity following both
13 operant pacing and energy conservation approaches. Similarly to the present study,
14 Racine et al.,[30] implemented handouts, homework and goal setting to encourage
15 patients' uptake of activity pacing. However, both of the interventions explored by
16 Racine et al.,[30] were of greater duration than the current study, comprising of 10
17 two-hour stand-alone pacing sessions with a 3-month booster session. Within the
18 current study, improvements in mental function between T1-T2 (mean change=7.3)
19 were better maintained between T1-T3 (mean change=5.95); and both higher than
20 the minimally clinically important change (3.77),[51]. Quality of life also improved
21 between T1-T2 (mean change=0.13) and much of this improvement was maintained
22 between T1-T3 (mean change=0.07); both changes exceeded the minimally
23 important difference (0.037 +/-0.008),[52].

24
25
26 The activity pacing framework additionally aims to increase patients' self-efficacy.
27 Improvements in self-efficacy were found between T1 (mean=25.29) and T2
28 (mean=36.29), which were well maintained at T3 (mean=34.68). Scores were lower
29
30

1
2
3 than the ≥ 40 cut off. However, an improvement of > 5.5 was attained which is
4
5 considered a minimally important change,[53]. Both physical and mental fatigue
6
7 improved, and improvements in mental fatigue appeared to be better maintained at
8
9 T3. Comparisons to minimally important changes are unavailable.
10
11
12
13

14 Psychological health improved following the rehabilitation programme, including
15
16 reduced depression scores from moderate to mild (T1=13.7, T2=7.1, T3=9.1); with a
17
18 clinically significant reduction (≥ 5) between T1-T2,[40]. Mean anxiety scores reduced
19
20 (T1=9.9, T2=5.4 and T3=6.10), and remained within the classification of mild
21
22 anxiety,[41]. Although reductions in pain were not a direct aim of the current
23
24 treatment, lower pain severity was reported. Despite the increased intensity of
25
26 pacing sessions contained within the RCT comparing the operant approach to
27
28 energy conservation, Racine et al.,[30] found that neither pacing approach effectively
29
30 reduced symptoms of pain or fatigue.
31
32
33
34
35
36
37

38 **Strengths and limitations**

39
40
41
42 This study was an early feasibility study that primarily aimed to explore whether a
43
44 new activity pacing framework could be implemented in the clinical setting. Whilst
45
46 this study fulfilled its original aims, it is limited by the absence of *a priori* progression
47
48 criteria. However, the findings from this study will help to inform the progression
49
50 criteria that are used to determine whether to progress to a full clinical trial from a
51
52 future pilot RCT. Despite recruiting to target, this sample was not powered with a
53
54 control arm to determine treatment effectiveness. As per other studies exploring
55
56 activity pacing, activity pacing was instructed as one component of the rehabilitation
57
58
59
60

1
2
3 programme,[5]. Therefore, improvements in symptoms may have resulted from any
4 combination of coping strategies. A future RCT will implement a suitable control to
5 explore the effects of activity pacing, while implementing the activity pacing
6 framework in a clinically relevant setting, including alongside other coping strategies.
7
8
9
10
11
12
13

14 The generalisability of this study is limited to a sample of predominantly females and
15 white ethnic origin. Recruitment occurred only at one Pain Service and this service
16 had an existing rehabilitation programme for both chronic pain and fatigue. Bias may
17 have arisen through the lead researcher delivering the healthcare professionals'
18 training and undertaking the observations. Further work will test the activity pacing
19 framework and study protocol across other healthcare services and explore
20 feasibility and fidelity over wider geographical locations.
21
22
23
24
25
26
27
28
29
30
31
32

33 It is unknown what potential bias was caused by the attrition rate. However, there
34 were no differences at baseline between those who completed the programme and
35 those who dropped out. It is possible that patients who completed T2 and T3
36 possibly felt greater benefits from the treatment and were more motivated to respond
37 to the follow-up questionnaires. The attrition rate may be reflective of some of the
38 clinical challenges and missed appointments surrounding the complexity of chronic
39 pain/fatigue. Further research could explore whether providing a follow-up treatment
40 session improves commitment to activity pacing.
41
42
43
44
45
46
47
48
49
50
51
52

53 **Modifications for future study**

54
55
56
57
58
59
60

1
2
3 Since more patients completed the T1 questionnaires during the rehabilitation
4 sessions than at home, this may be the preferable mode of distribution of paper
5 questionnaires. To lessen the time taken to complete the questionnaires, the PASS-
6 20 may be considered for exclusion in future study. The whole 20-item PASS scale
7 was included for reliability and validity, but data specifically from the Escape and
8 Avoidance subscale was explored. Modifications to the inclusion criteria may include
9 patients with any chronic spinal pain, including cervical/thoracic pain due to the
10 frequent and similar presentation at rehabilitation services.
11
12
13
14
15
16
17
18
19
20
21
22

23 **Conclusion**

24
25
26
27
28 To the authors' knowledge, this is the first study to explore the clinical utility of a
29 comprehensive activity pacing framework developed for both chronic pain and
30 chronic fatigue. The newly developed activity pacing framework proved feasible to
31 use clinically by healthcare professionals. Patients with both chronic pain and fatigue
32 implemented greater activity pacing strategies following treatment, alongside
33 reporting improvements in quality of life, psychological wellbeing, self-efficacy, pain
34 and fatigue. Physical function and avoidance improved to a lesser extent and for the
35 shorter-term. Future study will use the activity pacing framework in an effectiveness
36 RCT to explore the effects of activity pacing on symptoms.
37
38
39
40
41
42
43
44
45
46
47
48
49
50

51 **ACKNOWLEDGEMENTS**

52
53
54
55
56
57
58
59
60

1
2
3 We would like to acknowledge all of the patients and healthcare professionals who
4 were involved in this study. We would also like to acknowledge our statistical
5 support.
6
7
8
9

10 11 12 **CONFLICT OF INTEREST**

13
14
15
16
17 All authors declare no conflicts of interest
18
19

20 21 **AUTHOR CONTRIBUTIONS**

22
23
24
25
26 DA, AMK, PK, SW and LMc all contributed to the conception and design of the study.
27
28 DA undertook the acquisition of the data. DA, AMK, PK, SW and LMc all contributed
29 to the analysis and interpretation of data. DA, AMK, PK, SW and LMc contributed to
30 drafting the manuscript and revising it critically for important intellectual content and
31
32
33
34
35
36
37 have approved the final version for publication. DA, AMK, PK, SW and LMc are in
38
39
40 agreement to be accountable for all aspects of the work in ensuring that questions
41
42
43
44 related to the accuracy or integrity of any part of the work are appropriately
45
46
47 investigated and resolved.
48
49
50
51
52
53

54 **PATIENT CONSENT FOR PUBLICATION**

55
56
57
58 Not required.
59
60

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.

- 1
2
3 9. Meeus M, Nijs J, Meirleir KD. Chronic musculoskeletal pain in patients with the
4 chronic fatigue syndrome: a systematic review. *Eur J Pain* 2007;11:377-86.
5
6
- 7 10. Tavel ME. Somatic symptom disorders without known physical causes: one
8 disease with many names? *Am J Med* 2015;128:1054-8.
9
- 10 11. Yunus MB. Fibromyalgia and overlapping disorders: the unifying concept of
11 central sensitivity syndromes. *Semin Arthritis Rheum* 2007;36:339-56.
12
- 13 12. Nijs J, Meeus M, Van Oosterwijck J, et al. In the mind or in the brain? Scientific
14 evidence for central sensitisation in chronic fatigue syndrome. *Eur J Clin Invest*
15 2012;42:203-12.
16
- 17 13. Arendt-Nielsen L, Morlion B, Perrot S, et al. Assessment and manifestation of
18 central sensitisation across different chronic pain conditions. *Eur J Pain*
19 2018;22:216-241.
20
- 21 14. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic
22 musculoskeletal pain: a state of the art. *Pain* 2000;85:317-32.
23
- 24 15. Moseley GL. A pain neuromatrix approach to patients with chronic pain. *Man*
25 *Ther* 2003;8:130-40.
26
- 27 16. Ericsson A, Mannerkorpi K. How to manage fatigue in fibromyalgia:
28 nonpharmacological options. *Pain Manag* 2016;6:331-8.
29
- 30 17. British Pain Society. Guidelines for pain management programmes for adults.
31 London: British Pain Society, 2013.
32
- 33 18. Beissner K, Henderson CR, Jr., Papaleontiou M, et al. Physical therapists' use of
34 cognitive-behavioral therapy for older adults with chronic pain: a nationwide survey.
35 *Phys Ther* 2009;89:456-69.
36
- 37 19. Booth J, Moseley GL, Schiltenswolf M, et al. Exercise for chronic musculoskeletal
38 pain: A biopsychosocial approach. *Musculoskeletal Care* 2017;15:413-421.
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 20. Anderson RJ, Hurley RW, Staud R, et al. Cognitive-motivational influences on
4 health behavior change in adults with chronic pain. *Pain Med* 2016;17:1079-1093.
5
6
7 21. Birkholtz M, Aylwin L, Harman RM. Activity pacing in chronic pain management:
8 One aim, but which method? Part one: Introduction and literature review. *British*
9
10
11
12
13
14
15 22. Abonie US, Edwards AM, Hettinga FJ. Optimising activity pacing to promote a
16 physically active lifestyle in medical settings: A narrative review informed by clinical
17 and sports pacing research. *J Sports Sci* 2020;38:590-596.
18
19
20
21 23. Jamieson-Lega K, Berry R, Brown CA. Pacing: A concept analysis of a chronic
22 pain intervention. *Pain Res Manag* 2013;18:207-13.
23
24
25
26 24. Andrews NE, Deen M. Defining Activity Pacing: Is It Time to Jump Off the Merry-
27 Go-Round? *J Pain* 2016;17:1359-1362.
28
29
30
31 25. Andrews NE, Strong J, Meredith PJ. Activity pacing, avoidance, endurance, and
32 associations with patient functioning in chronic pain: a systematic review and meta-
33 analysis. *Arch Phys Med Rehabil* 2012;93:2109-2121 e7.
34
35
36
37 26. Murphy SL, Clauw DJ. Activity pacing: what are we measuring and how does
38 that relate to intervention? *Pain* 2010;149:582-583.
39
40
41
42 27. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex
43 interventions: The new Medical Research Council guidance. *BMJ* 2008;337:a1655.
44
45
46
47 doi: 10.1136/bmj.a1655
48
49 28. Creswell JW, Piano-Clark VL. *Designing and conducting mixed methods*
50
51
52
53
54 29. Antcliff D, Keenan AM, Keeley P, et al. Engaging stakeholders to refine an
55 activity pacing framework for chronic pain/fatigue: A nominal group technique.
56
57
58
59
60

- 1
2
3 30. Racine M, Jensen MP, Harth M, et al. Operant Learning Versus Energy
4 Conservation Activity Pacing Treatments in a Sample of Patients With Fibromyalgia
5 Syndrome: A Pilot Randomized Controlled Trial. *J Pain* 2019;20:420-439.
6
7
8
9
10 31. White PD, Goldsmith KA, Johnson AL, et al. Comparison of adaptive pacing
11 therapy, cognitive behaviour therapy, graded exercise therapy, and specialist
12 medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet*
13 2011;377:823-36.
14
15
16
17
18 32. Lancaster GA and Thabane L. Guidelines for reporting non-randomised pilot and
19 feasibility studies. *Pilot Feasibility Stud* 2019;5:114.
20
21
22
23 33. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement:
24 extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
25
26
27
28 34. Antcliff D, Keenan AM, Keeley P, et al. "Pacing does help you get your life back":
29 The acceptability of a newly developed activity pacing framework for chronic
30 pain/fatigue. *Musculoskeletal Care* 2021 [ePub ahead of print]
31 doi.org/10.1002/msc.1557
32
33
34
35
36
37 35. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in
38 relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301-
39 8.
40
41
42
43
44 36. Antcliff D, Campbell M, Woby S, et al. Assessing the Psychometric Properties of
45 an Activity Pacing Questionnaire for Chronic Pain and Fatigue. *Phys Ther*
46 2015;95:1274-86.
47
48
49
50 37. Jensen MP, Turner JA, Romano JM. What is the maximum number of levels
51 needed in pain intensity measurement? *Pain* 1994;58:387-92.
52
53
54 38. Chalder T, Berelowitz G, Pawlikowska T, et al. Development of a fatigue scale. *J*
55 *Psychosom Res* 1993;37:147-53.
56
57
58
59
60

- 1
2
3 39. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression
4 severity measure. *J Gen Intern Med* 2001;16:606-13.
5
6
7
8 40. Kroenke K, Spitzer RL, Williams JB, et al. The Patient Health Questionnaire
9 Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp*
10 *Psychiatry* 2010;32:345-59.
11
12
13
14 41. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing
15 generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-7.
16
17
18
19 42. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur*
20 *J Pain* 2007;11:153-63.
21
22
23
24 43. McCracken LM, Dhingra L. A short version of the Pain Anxiety Symptoms Scale
25 (PASS-20): preliminary development and validity. *Pain Res Manag* 2002;7:45-50.
26
27
28
29 44. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey:
30 construction of scales and preliminary tests of reliability and validity. *Medical Care*
31 1996;34:220-33.
32
33
34
35 45. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the
36 new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36.
37
38
39
40 46. van Hout B, Janssen MF, Feng Y, et al. Interim Scoring for the EQ-5D-5L:
41 Mapping the EQ-5D-5L to EQ-5D-3L Value Sets. *Value in Health* 2012;15:708 –715.
42
43
44
45 47. Bearne LM, Walsh NE, Jessep S, et al. Feasibility of an exercise-based
46 rehabilitation programme for chronic hip pain. *Musculoskeletal Care* 2011;9:160-8.
47
48
49
50 48. Greenberg J, Lin A, Zale EL, et al. Development And Early Feasibility Testing Of
51 A Mind-Body Physical Activity Program For Patients With Heterogeneous Chronic
52 Pain; The GetActive Study. *J Pain Res* 2019;12:3279-3297.
53
54
55
56 49. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we
57 need to pay attention. *Lancet* 2018;391:2356-67.
58
59
60

1
2
3 50. NICE. Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy).
4
5

6 *NICE Clinical Guideline 53 London 2007.*

7
8 51. Diaz-Arribas MJ, Fernandez-Serrano M, Royuela A, et al. Minimal Clinically
9
10 Important Difference in Quality of Life for Patients With Low Back Pain. *Spine (Phila*
11
12 *Pa 1976)* 2017;42:1908-1916.
13

14
15 52. McClure NS, Sayah FA, Xie F, et al. Instrument-Defined Estimates of the
16
17 Minimally Important Difference for EQ-5D-5L Index Scores. *Value Health*
18
19 2017;20:644-650.
20

21
22 53. Chiarotto A, Vanti C, Cedraschi C, et al. Responsiveness and Minimal Important
23
24 Change of the Pain Self-Efficacy Questionnaire and Short Forms in Patients With
25
26 Chronic Low Back Pain. *J Pain* 2016;17:707-18.
27
28
29

30 31 **FIGURE LEGENDS**

32
33 Figure 1. Activity pacing conceptual model taken from the activity pacing framework

34
35 Figure 2: CONSORT diagram showing the flow of participants through the study

36
37 Figure 3. Participants' written comments following attending the rehabilitation
38
39 programme
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

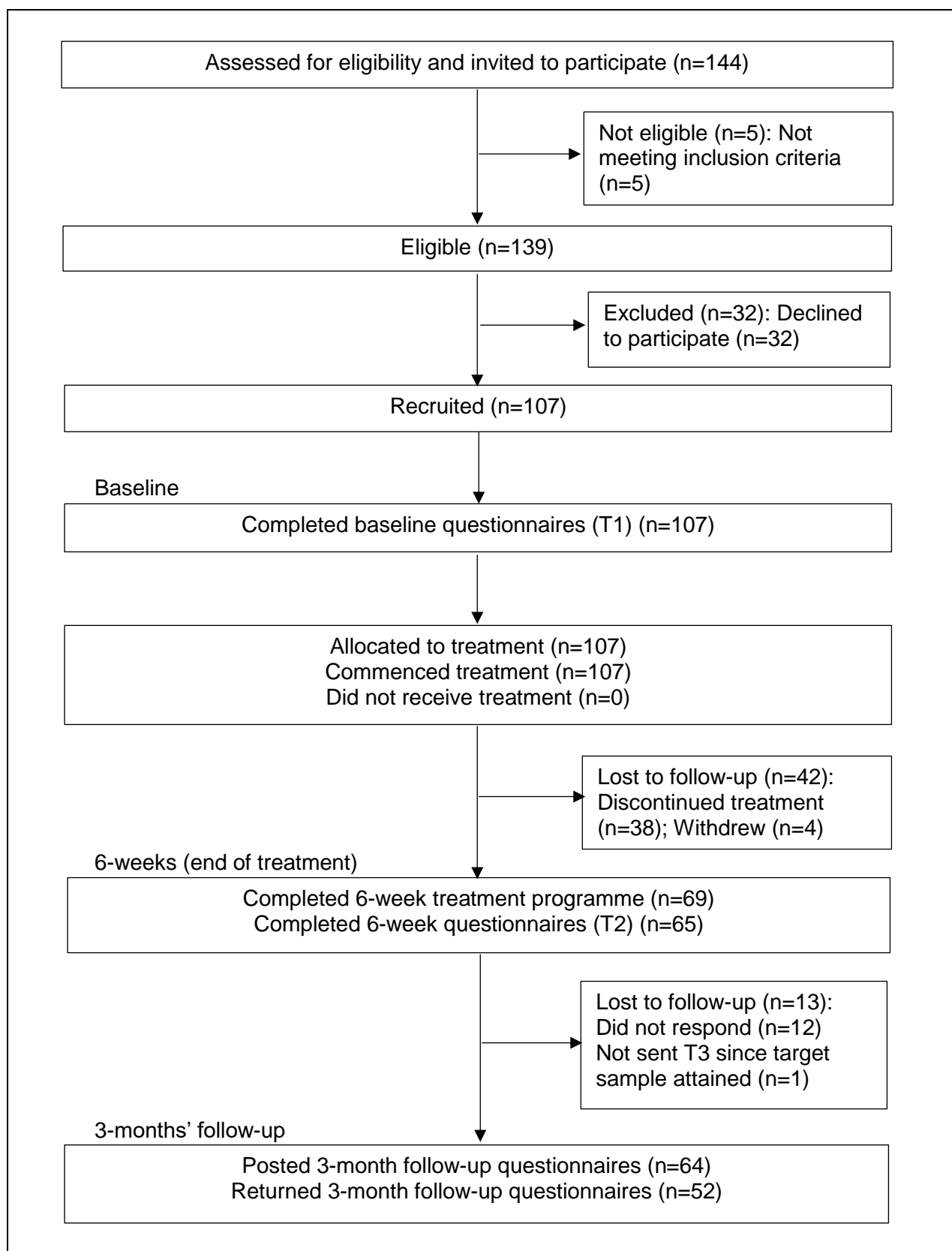


Figure 2: CONSORT diagram showing the flow of participants through the study

1
2
3
4 T2: "The pace and content has been good for me. It has helped me to focus on
5 my belief that I have to own the situation, to be positive and to make use of the
6 tools we have discussed. If I don't take this approach I believe my situation will
7 not improve. There is no magic wand, but I can be the difference." (F070:
8
9

10 *Fibromyalgia*)
11
12

13
14 T3: "I have found pacing really helpful in my everyday life and feel I can achieve
15 more day to day than 12 months ago." (F006: *chronic widespread pain,*
16 *fibromyalgia, chronic fatigue syndrome/myalgic encephalomyelitis*)
17
18

19
20
21 T3: "I found the pain service very helpful and informative. How I view my pain and
22 react to and manage it has improved. Emotionally, I feel more positive as a result
23 of using strategies learned, and also more confident that I can manage my pain
24 and how it makes me feel. Using pacing and realistic goals has enabled me to do
25 some activities that I previously avoided i.e. hoovering, changing the bed. (F068:
26 *fibromyalgia*)
27
28
29
30

31
32
33 T3: "Doing the 6 week course was extremely helpful and gave me some excellent
34 information and resources to work with. The difficulty has been that there has
35 been no follow up or support sessions since. It is great having the info, but then
36 you are battling depression/anxiety it is difficult to apply knowledge without some
37 support, even if that is over the phone every few weeks or maybe a support group
38 facility." (F075: *low back pain, chronic widespread pain*)
39
40
41
42

43
44
45 T3 "I have found 'pacing' a very good way to manage pain and get through the
46 day completing activities" (F105: *low back pain, chronic widespread pain,*
47 *fibromyalgia*)
48
49
50

51
52
53 *Figure 3. Participants' written comments following attending the rehabilitation*
54 *programme*
55
56
57
58
59
60

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

- 1
2
3 Pacing and sleep hygiene
4 Pacing and other strategies
5
6
7 13. Pacing aids
8 Activity diaries
9
10 Goal setting
11
12

B. Appendices and teaching guide*Part 1. Conceptual model of pacing*

15
16
17 Appendix 1. Activity pacing and the fear-avoidance model

18
19 Appendix 2. Pacing as a health behaviour:

20 The Health Action Process Approach (HAPA)

21 The Transtheoretical model
22
23
24

Part 2. Pacing guide for healthcare professionals

25
26
27 Appendix 3. Chronic pain/fatigue cycle

28
29 Appendix 4. Overactivity-underactivity (boom-bust) cycle:

30 Boom-bust, avoidance and excessive persistence behaviours

31
32 Appendix 5. Activity pacing framework model of pacing

33
34 Appendix 6. Facets of pacing:

35 Facets of pacing, explanation/examples and who may benefit

36
37 Appendix 7. Stages of pacing

38
39 Appendix 8. Patient exemplars:

40 Avoidance

41 Excessive persistence

42 Boom-bust

43 Patients who are predominantly bedbound
44
45

46
47 Appendix 9. Questions for healthcare professionals to ask patients:

48 Exploring current patterns of activity

49 Exploring current baselines of activity

50 Exploring possible barriers to pacing

51 Exploring individuals' aims
52
53
54
55
56
57

Part 3. Pacing tools

58
59 Appendix 10. Activity diary:
60

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

For peer review only

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 <i>BMJ Open</i> 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 Supplementary 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.

For peer review only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

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.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

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

1
2
3 Graded exercise (circuit exercises)

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

6
7
8 Goal setting: specific pacing goal
9

10
11
12 **Week 4**

13 Pacing goal review

14 Choice V's demand activities

15 Increasing positive thoughts

16 Work and employment

17 Graded exercise (circuit exercises)

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

20 Goal setting
21
22
23
24
25
26
27
28

29 **Week 5**

30 Goal review

31 Sleep hygiene

32 Medication

33 Graded exercise (circuit exercises)

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

36 Goal setting
37
38
39
40
41
42
43
44

45 **Week 6**

46 Goal review

47 Managing setbacks

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

49 Maintaining progress

50 Signposting to community resources
51
52
53
54
55
56
57
58
59
60

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"