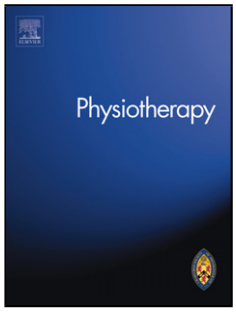

"WALK30X5": A FEASIBILITY STUDY OF A PHYSIOTHERAPY WALKING PROGRAMME FOR PEOPLE WITH MILD TO MODERATE MUSCULOSKELETAL CONDITIONS

Catherine J. Minns Lowe, Paul Kelly, Karen Milton, Charlie Foster, Karen Barker

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"WALK30X5": A FEASIBILITY STUDY OF A PHYSIOTHERAPY WALKING PROGRAMME FOR PEOPLE WITH MILD TO MODERATE MUSCULOSKELETAL CONDITIONS

Author names and affiliations

Dr Catherine J Minns Lowe[1] , Dr Paul Kelly[2] , Dr Karen Milton[3,5] , Prof Charlie Foster[3,6], Prof Karen Barker[1,4]

1. Physiotherapy Research Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Foundation Trust, Windmill Road, Headington, Oxford, OX3 7HE
2. Institute for Sport, Physical Education and Health Sciences (ISPEHS), Moray House School of Education, University of Edinburgh, EH8 8AQ
3. The British Heart Foundation Centre on Population Approaches for Non-Communicable Disease Prevention, Nuffield Department of Population Health, UK
4. Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK

Present addresses

5. Norwich Medical School, Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, NR4 7TJ
6. Centre for Exercise, Nutrition and Health Sciences, School for Policy Studies, University of Bristol, Social Science Complex, 8 Priory Road, Bristol BS8 1TZ

Email addresses

catherine.minnslowe@ouh.nhs.uk
p.kelly@ed.ac.uk
k.milton@uea.ac.uk
charlie.foster@bristol.ac.uk
karen.barker@ouh.nhs.uk

Corresponding Author: Catherine Minns Lowe**,** Physiotherapy Research Unit Nuffield Orthopaedic Centre Oxford University Hospitals NHS Foundation Trust Windmill Road Headington Oxford OX3 7HE**,** Email: catherine.minnslowe@ouh.nhs.uk Telephone: 44 (0) 1865 737424

ABSTRACT

Objectives: To explore the feasibility of delivering and evaluating a web-based walking intervention for people with long term musculoskeletal conditions (LTMCs), to determine its acceptability and the feasibility of conducting a definitive trial.

Design: Prospective randomised feasibility study, with blind outcome assessment at baseline, 3 and 6 months.

Setting: Hospital based physiotherapy service.

Participants: 41 adults referred for assessment and advice for any mild/moderate LTMCs. doing < 120 mins of moderate intensity activity per week.

Interventions: Participants randomised to

1. Usual care: One usual physiotherapy advice and assessment session, including setting a physical activity goal and one follow up session (8 weeks).
2. "Walk30X5": Session one, usual care plus intervention of walking programme. Participants were shown the website and podcasts and practiced how to use them. One follow up session (8 weeks).

Outcome measures: Primary: timed six minute walk test (T6MWT). Secondary: step count, self-reported pain, fatigue, mood, self-efficacy, happiness, objective blood pressure, peak expiratory flow rate, and self-report and accelerometer measured physical activity.

Results: Recruitment target achieved. No adverse events occurred. Adherence was high and the intervention acceptable. Loss to follow up n=3 (7%) at 3 months, n=8 (20%) at 6 months.

T6MWT and step count proved suitable outcomes, unlike accelerometry. Estimated sample size for a definitive trial is 216.

Conclusions: "Walk30X5" is ready for evaluation in a future, appropriately powered (n=216), phase III trial. If effective, the intervention will provide a cheap, highly accessible intervention to enable people with mild/moderate LTMCs to achieve UK physical activity guidelines.

Clinical Trial Registration Number: ISRCTN78581097

Keywords: Musculoskeletal conditions, physical activity, walking programme, feasibility study, web-based intervention

INTRODUCTION

Physical inactivity is a major global healthcare issue, responsible for 13·4 million disability-adjusted life-years worldwide and costing health-care systems at least 53.8 billion international $ in 2013[1]. There is irrefutable evidence of health and psychological benefits from physical activity for both healthy adults and those with disabilities and/or obesity[2]. Current guidance in the United Kingdom (UK) recommends adults undertake a minimum of 150 minutes (2½ hours) of moderate intensity activity, in bouts of 10 minutes or more, each week or 75 minutes of vigorous intensity activity spread across the week or combinations of moderate and vigorous intensity activity[2]. In addition they should undertake at least two sessions of muscle strength training, each week[2].

Musculoskeletal conditions account for the largest cause of disability, and the largest proportion of years lived with a disability in the UK, adversely impacting upon activities of daily living and living independently, in addition to causing symptoms such as pain[3]. Over ten million people in the UK live with long-term musculoskeletal conditions (LTMCs). LTMCs account for 7.5 million days off work and, with indirect costs, cost the UK £24.8 billion for back pain, osteoarthritis and rheumatoid arthritis combined each year[3]. The majority of people with musculoskeletal conditions do not meet physical activity (PA) guidelines and consequently have an increased risk of co-morbidity than their peers[4-6]. The benefits of PA are well demonstrated in the primary and secondary prevention of prevalent chronic diseases and premature death[7-8]. Walking, even at short duration or low volumes, can reduce risk for all-cause mortality and increase health-related fitness[9-10]. Walking is a popular[11], accessible form of PA, across all age ranges that can substantially lower the risk of many chronic diseases[11-12] and benefits mental health[13]. A systematic review of walking interventions in people with chronic musculoskeletal pain indicates walking is associated with significant improvements in pain and self-reported function[14]. However most (19/26) studies involved supervised walking (clinic, hospital, gym) which is considered unfeasible for physiotherapy services in the National Health Service (NHS)[15] to implement and generally the long-term effectiveness of these interventions remains unknown.

Web-based interventions for chronic pain result in small pain reductions, potentially helping people by decreasing treatment costs and side effects[16]. Web-based programmes to increase PA have been popular in the general population, for example the 'Couch to 5K' running programme, but there have been no published web-based programmes to improve PA for people with LTMCs. An internet-mediated study using pedometers to reduce

disability in people with chronic low back pain reported short-term (six months follow up), but not long term (one year follow up), improvements in comparison to enhanced usual care[17]. Poor adherence or declining engagement over time were demonstrated so there is a need for programmes to consider how to keep people active and engaged.

This study aimed to explore the feasibility of delivering and evaluating a web-based walking intervention ("Walk30X5") for people with LTMCs and to determine its acceptability to participants and the feasibility of conducting a definitive trial.

The objectives were to:

1. Evaluate the feasibility of achieving proposed recruitment rates (N=40).
2. Evaluate recruitment and the flow of participants through the study, identifying rates and reasons for attrition and reporting adverse events.
3. Evaluate the fidelity of intervention provision; that participants received their allocated treatment.
4. Evaluate the adherence of participants to "Walk30X5".
5. Evaluate the performance and suitability of outcome measures for use in a definitive trial.
6. Determine the sample size required for a definitive trial.

Semi-structured interviews were carried out with physiotherapists providing the intervention and trial participants to explore the acceptability of the intervention; word count means these data will be presented separately and not included in this paper.

METHODS

Design. A feasibility study and pilot trial at one NHS site.

The Intervention.

"Walk150" (summarised in Table 1) was developed using an iterative consensus process, incorporating the opinions and input of patients with a variety of LTMCs (n=16) and clinical and research physiotherapists (n=15)[18]. A website was commissioned and eight podcasts were scripted (providing audio and musical tempi instructions) (name removed), revised (team) and produced (using a professional sound studio and actor). Podcasts are digital audio files that can be downloaded onto a mobile device such as a smart phone or MP3 player. The podcasts were designed to assist people to begin and increase their amount of moderate-vigorous walking over time (Additional file 1).

Participants: Adults referred for assessment and advice by GPs, physiotherapists or themselves for any mild /moderate/non-severe musculoskeletal conditions affecting PA (eg: chronic back pain, fibromyalgia, lower limb arthritis) with joint pain lasting at least 3 months, and considered physically able (after screening) to undertake the programme. Participants were included if they reported < 120 mins of moderate intensity activity (4X30mins) per week and were able to perform the 6 minute timed walk test (own pace, no walking aid) with non-severe reports of pain (≤ 6/10 verbal rating scale). Exclusion criteria: a recent history of an illness likely to interfere with the ability to undertake the programme safely; serious cardiac or respiratory diagnoses; lower limb fractures (last 12 months); blindness; systemic illness; if they reported that a doctor had advised against exercise; or were pregnant or unable to participate in the intervention. Participants were not included if they were receiving current/additional physiotherapy.

Recruitment: Participants were approached via the Musculoskeletal Interface Service, outpatient physiotherapists and advertisements. Following telephone screening, participants attended a research appointment at the [Name removed to protect anonymity]. Informed consent was obtained and baseline assessment was performed by a research physiotherapist. Baseline assessments started with blood pressure checks and the timed 6 minute walk test, to check eligibility, followed by all outcomes if eligible (referred back for medical care if ineligible). GPs were also sent a letter on the day of baseline assessment to allow them to veto participation. The recruitment target to explore the feasibility of "Walk30X5" and collect data to calculate sample size for a definitive trial[19] was n=40. Randomisation was performed by a mathematician independent of the study using random number tables and transferred to a sequence of sealed, numbered, opaque envelopes used in strict consecutive order. Participants were randomised following baseline assessment.

Participants were randomised to either usual care or "Walk30X5". All interventions were provided by musculoskeletal physiotherapists trained in delivering the interventions by the research team.

Usual care (UC) group protocol: Usual physiotherapy advice and assessment session and one follow up session. In session one participants were asked about their PA levels and advised how they might become more active. Participants set a PA goal (e.g. go swimming 2-3 times per week, walk, cycle) for review at follow up in 8 weeks time.

"Walk30X5" group protocol: Session one included UC and an introduction to the intervention. Participants were shown the website and podcasts and practised how to use them. Participants not owning an MP3 player, or concerned about downloading podcasts,

were provided with an MP3 player with all podcasts installed and ready for immediate use. Any obvious barriers to doing the programme (e.g coping with inclement weather) were discussed and tips and a plan of action agreed. A follow up session was held at 8 weeks. Participants were asked to record their podcast use in a diary (dates used, which level of podcast, and whether it was done in one or two chunks each time) and encouraged to record their comments about their experience of "Walk30X5".

Assessments: Baseline, 3 months and 6 months assessments were held at an outpatient physiotherapy department by a research physiotherapist blinded to group allocation. At baseline assessment demographic data were obtained. At follow up assessments participants were asked to report adverse events, including falls[20]. People who did not attend for follow up were contacted by email or phone (participant preference) after their non attendance and, if no response contacted a further time two weeks later.

Outcomes: The proposed primary outcome for a definitive trial was the timed six minute walk test (T6MWT); an objective measure of aerobic capacity and long distance walking capacity recording the distance (m) covered in a 6-minute walking period over a 10 m walkway in a gymnasium. Participants were instructed to walk as briskly as possible and could pause/rest during the test if needed. T6MWT distance positively correlates with lower limb muscle strength, balance, reduced walking impairment and improved quality of life; it is sensitive to detect change following physical therapy interventions[21].

Secondary Outcomes:

Step count: Step count per day for 7 days after each assessment time point (using Omron HJ-720ITC pedometer[22]). The pedometer was set up for use and demonstrated by the research physiotherapist and written instructions provided. Usable data was defined a minimum of 5 full days data wear.

Numeric Rating Scales (scores 0-10): uni-dimensional numerical rating scales (NRS) measured self-reported pain today and worst pain (intensity), average pain, and fatigue over 7 days[23-24].

Positive and Negative Affect Schedule (PANAS)[25]: a self-report measure of mood, with two scales, positive and negative, each scored between 10-50. A higher score on the positive scale indicates more positive effect, a lower score on the negative score indicates less negative effect.

The General Self-Efficacy Scale[26]: a self-report measure (score 10-40) of self-efficacy; the higher the score, the greater self-efficacy reported.

Happiness: a single question from the short-form health survey (SF-36) with 6 responses varying from ‘all the time’ to ‘never’ which has good internal consistency with the other 4 "mental health" scores and the 4 items from the "vitality" scale of the SF-36[27].

A self-report global health rating question[28].

The British Heart Foundation’s “Daily Activities Questionnaire” (DAQ): adapted from a validated American measure[29] which measures the amount of self-reported PA during the previous 7 days. This measure asks participants to recall the frequency, duration and intensity of 48 physical activities covering: travel to work by cycle, or by walking; activity at work, at home (types of housework), in the garden, other activities around the home (types

of DIY), walking for leisure, outdoor cycling for leisure, stair climbing, sports and recreation plus a global physical activity question.

The Axivity AX3 wrist worn accelerometer: to provide an indirect objective estimate of energy expenditure and measure of longitudinal movement data (total movement counts and average movement counts per hour). How to wear the accelerometer was demonstrated by the researcher and written instructions with photographs provided. The accelerometer was worn for 7 days after each assessment. Usable data was defined as a data file containing a minimum of 5 full days data wear.

Blood Pressure (BP): measured using a GE Medical DINAMAP ® PRO 400 Vital Signs Monitor with a Critikon Dura-Cuf.

Peak expiratory flow rate (PEFR), or peak expiratory flow (PEF): measured using a portable peak flow meter. The highest value from three attempts was recorded (l/min).

Weight: measured in kilograms using calibrated SECA scales.

A trial diary was kept by the research team, recording all written and verbal feedback from participants and physiotherapists during the trial regarding the interventions, outcomes and trial processes to provide additional acceptability information (to supplement the acceptability information provided from the interviews with physiotherapists and participants and checking of physiotherapy treatment notes to ensure participants received their allocated treatment).

Data analyses: Data analyses were undertaken by the team and unblinded. Recruitment, retention numbers, baseline characteristics, adverse events, flow through the trial and trial process evaluations were described. Trial diary data, walking diary data, patient treatment

notes and compliance with interventions and outcomes were evaluated to explore acceptability and adherence: qualitative data underwent content analysis (CML, discussed and checked by team members). Treatment notes were checked to identify whether participants received their allocated intervention. Attendance, walking diary data and treatment note data were described to provide information on engagement and adherence.

Formal statistical hypothesis test results are inappropriate for feasibility trials. Instead the data were described and, where appropriate, group mean/median change scores for outcomes within the two groups were presented. An intention to treat approach was used. For accelerometer data, compliance was reported as the percentage of total wear-time recorded from that expected. The amount of useable data from accelerometers, and the extent to which data agreed with other measures, such as pedometer data, was explored; ordinary least-squares linear regression were used to derive the correlation (validity) coefficient together with the standard error of the estimate to test the association between higher counts per hour scores and higher self-reported scores for pedometer and DAQ. Sample size calculations were undertaken by a senior statistician independent to the study team.

RESULTS

Recruitment: All participants completed baseline assessments with no safety concerns; no GPs vetoed participation in the trial. 89 people were screened to participate and 41 participants recruited. 21 participants did not meet the eligibility criteria, 13 did not reply, 8

participants were undergoing other physiotherapy, 3 were not interested, 1 did not want to travel for treatment, 1 did not have time to participate, and 1 had moved away.

Flow through the study: Four participants withdrew due to medical reasons (2 emergency hospital admissions, one fracture and one ruptured tendon, all unrelated to the trial). Four more participants did not reply to invitations to attend 6 month follow up assessments. There were no adverse events reported. Flow through the trial is presented in Figure 1.

Intervention Fidelity: 36 (88%) sets of treatment notes were available (control n=19, "Walk30X5" n=17) to check whether participants had received their allocated treatment. 33 (80%) participants attended both treatment sessions, 3 (7%) participants (control n= 1, "Walk30X5" n=2) attended the first session only. No protocol violations were reported, all participants received their allocated treatment. Participants spoke of the individualised, flexible progression of treatments. Participants' comments suggested that the UC arm had gone beyond UC, becoming a new goal setting intervention in its own right. UC Participants spoke of the value of spending half an hour with a physiotherapist, discussing activity, the impact of individualised goal setting and the identification of strategies to increase PA. The importance of a follow up session upon implementing changes in activity was emphasized by participants.

Adherence to podcasts: 13 (65%) walking diaries were returned from 20 "Walk30X5" participants. Participants were requested to complete 5 podcasts per week: median number of podcasts reported was 4.88, mean adherence was 4.92 (range 3 – 7 per week). Acceptable adherence was defined for this study as participants doing at least 4 podcasts a week for at least 4 weeks; 11 (out of data from 12 diaries) participants exceeded this amount. Fewer podcasts were reported in week 1 by two participants who started the

programme midweek and diary completion lessened over time to n=10 in week 8 due to missing data and being on holiday (Supplementary file 2). Participants' comments showed that people progressed through podcasts, repeating podcasts if they found them tough, and the majority did the podcasts in one go rather than splitting them into two chunks. Feedback confirmed that 135 bpm promoted fast walking without running. People mentioned missing podcasts due to illness, being away from home, undertaking non podcast walks and other PA such as swimming.

Website: Participants were to be shown the website during their first session of physiotherapy and to have discussed the content with their physiotherapist and future use of the website was monitored. 7 participants reported looking again at the website near the start, but not later on, in the programme.

Performance and suitability of outcome measures.

Baseline characteristics are presented in Table 2: The groups were not statistically different for mean T6MWT at baseline (p=0.13). At six months the "Walk30X5" group mean T6MWT had improved by 97 m compared to 55m in UC (p=0.03). Groups were statistically different at baseline for mean step count (p=0.02); the "Walk30X5" group mean step count was 6543 (SD 3227) and 4390 (SD 2267) for UC. At six months mean step count for the "Walk30X5" group had improved by 1720 steps and UC by 1555 steps. Outcome data for outcomes considered acceptable to participants are presented in Table 3. Both groups reported improved worst pain ratings: the "Walk30X5" group mean rating improved by 2.02 and UC by 0.71. Both groups demonstrated mean weight loss from baseline to six months: 5 kg for the "Walk30X5" groups and 2 Kg for UC. The "Walk30X5" group, unlike UC, also reported improved NRS for pain today (mean improvement 0.75), average pain (mean improvement

1.7) fatigue scores (mean improvement 1.97) and both PANAS scales (mean improvement positive scale 2.78, mean improvement negative scale 2.32).

DAQ: Qualitative data, trial diary comments and feedback from the research physiotherapists indicated that participants found the DAQ to be over lengthy. The majority of participants reported not doing the activities listed in the majority of domains or missed out questions. Since so few data were obtained for the majority of domains they have not been statistically summarised and MET values were not calculated.

Wrist worn accelerometers and pedometers: Six participants reported irritation and/or discomfort whilst wearing accelerometers. Research physiotherapists reported that many more participants stated their dislike at the length of time they needed to wear accelerometers. This was reflected, in addition to software and technological problems, in the amount of useable returned data over time. Usable data required at least 5 days full use of the accelerometer and pedometer for the same worn dates for each participant.

At baseline n=37/41 returned an accelerometer with retrievable data, n=33 met the wear-time criteria of an average of >12 hours per day. Mean wear time was 23.5 hours per day (SD=7.6). At 3 months n=25 returned an accelerometer with retrievable data. N=23 met the wear-time criteria of an average of >12 hours per day. Only n=20 participants (49%) provided usable data at baseline and 3 months. At baseline there were n=33 valid accelerometer cases, n=37 valid pedometer cases and n=31 cases that had valid data from both measures. The positive correlation between Pedometer (mean daily steps) and Accelerometer (movement index) was strong (0.73). At three months there were n=23 valid accelerometer cases, n=33 valid pedometer cases and n=20 cases that had valid data from both measures. The positive correlation between Pedometer (mean daily steps) and

Accelerometer (movement index) was weak (0.27). It is of note that only 14 participants provided usable data for all time points which was insufficient to meaningfully analyse at 6 months (unavailable data for n=27, 66%).

Sample size for a future trial: To detect a difference of 100m in 6MWT at one year with 90% power at the 5% (2-sided) significance level, assuming a standard deviation of 100 (as observed at baseline) requires data on 23 people in each arm. Allowing for 20% loss to follow up, whilst striving for a follow up rate of at least 90%, the estimated sample size for a definitive trial is 58 participants, equivalent of detecting a moderate standardised effect size of 0.5. Calculation for 80% power requires 17 people in each arm (n=34, allowing for 20% drop out n=44).

DISCUSSION

This study achieved the aims of developing a physiotherapy walking programme intervention for use by people with mild/moderate LTMCs and exploring the acceptability of the intervention to patients and the feasibility of conducting a future definitive trial.

Unlike many previous walking programme trials, “Walk30X5” is not condition specific but designed for general use by people with mild to moderate LTMCs and to be feasible for the NHS to implement should it prove an effective intervention. The study included participants with a wide variety of LTMCs, averaging 6-7 years duration and including people with multiple LTMCs (Table 2). All participants were able to participate and there were no adverse events reported. Adherence to “Walk30X5” was high and participants progressed through the podcasts as intended. Adherence to podcast walking was higher than the 50%

adherence level for typical web-based interventions promoting health and changes in health care behaviours[30]. Feedback from "Walk30X5" trial diaries indicated that participants were achieving moderate to vigorous activity. The taxomony techniques included to promote behavioural change appeared appropriate, particularly the beneficial effects of reviewing progress at follow-ups[31]. "Walk30X5" participants provided positive feedback about the website content and it being a well organised, easy to navigate, site. Website use tailed off over time and the majority of people did not engage repeatedly with the website, possibly because participants preferred to be provided with an MP3 player with all podcasts pre-installed so they did not need to download further podcasts. Physiotherapists found some participants preferred to phone with queries as usual rather than log on and message them. Further research is thus required to ascertain the value of the website. The information architecture for the website was designed by users, implementing a sequential fashion to ensure optimal layout and navigation around the site[32]. No changes to "Walk30X5" are considered necessary for a main trial. The UC arm needs to be adapted to appropriately reflect usual UK practice since feedback from participants indicated that UC had gone beyond UC to become a new intervention.

Recruitment, retention and trial procedures: The recruitment target was achieved. Although we report no exclusions at referral and baseline screening phases the number of medical withdrawals was higher than we expected given the age of participants. This may have been by chance or may reflect that many people with LTMCs also have multi-morbidity. Four out of five people with osteoarthritis also have at least one other long term condition and more than three out of ten people aged over 45 years who report a long term

condition (such as cardiovascular disease) also have a LTMC[33]. In response, sample size calculations for a future RCT would allow for a 20% attrition rate, and multi-morbidity will be captured and reported. Trial procedures (randomisation, allocation concealment, blind outcome assessment, receiving the allocated treatment, flow) were shown to be feasible.

Performance of outcomes: There were acceptability and performance issues with the DAQ and wrist worn accelerometers and their use is not recommended in a main trial. We propose to replace the DAQ with the validated 4-item Short International Physical Activity Questionnaire (IPAQ-SF)[34] as a self-report measure of PA which contains far fewer items and less time to complete than the DAQ . The Musculoskeletal Health Questionnaire (MSK-HQ)[35] will also be included to capture PA participation among people with musculoskeletal conditions[36]. The Axivity accelerometers were not acceptable to participants and the amount of useable returned data over time prevented meaningful analysis. This differs from recent research of 103,712 Axivity UK Biobank datasets which reported a high median wear-time (6.9 days) and acceptability to participants[37]. This difference may be due to the face-to-face questioning during assessments about acclerometers in "Walk30X5", compared to returning bands by post[37], plus a minority of Biobank participants (n=106,053, 49%) agreed to wear an accelerometer.

No notable problems with other outcomes were identified. The feasibility study was not powered for hypothesis testing[19] however the data presented in Table 3 are considered justification for a definitive trial. Data for the primary outcome, T6MWT, are promising:

improving by an average of 97.46 meters for "Walk30X5" participants and 54.78 m for UC. Whilst these improvements are less than the estimated minimal clinically important difference for this test for people with fibromyalgia, reported as 156-167m[38], these data were improving over time and the primary endpoint in a future trial would be at least a year. Further research is needed to determine Clinically Meaningful Change Estimates for this test among people with other LTMCs which would be explored in a main trial. It is believed that walking speed is an appropriate outcome for people with LTMCs. Gait speed is positively associated with PA for people with hip and knee osteoarthritis, with evidence (limited by high heterogeneity across studies) that inactivity is a predictor for deterioration of pain and physical function[39-41]. Being less sedentary is related to better physical function in adults with knee osteoarthritis[42]. Slower walking speed is a risk factor for worsening depressing symptoms over time in people with/at high risk of knee osteoarthritis (OA)[43] and anxiety-related responses to pain likewise correlate with gait speed for people with lower limb OA[44]. People with symptomatic knee OA have a higher risk of declining gait speed than those with asymptomatic OA[45]. Walking is also known to be compromised in people with chronic low back pain; pain intensity and distribution significantly impact upon walking speed and walking can have an analgesic effect[46]. Evidence suggests that middle-aged women with fibromyalgia have gaits and walking speeds similar to elderly women[47]. For older people, walking speed is a reliable, valid and responsive Sixth Vital sign: indicative of an individual's general health status and functional capacity, and predictive for a range of outcomes[48]. Step count was also improving over time in both groups (Table 3). In addition to walking speed there were also promising changes observed for the"Walk30X5" group for pain, at six months median improvement for average and worst scores were equal to/above

the minimal clinically important difference of 2 points[49], fatigue and weight loss but no between group comparisons can be made at this time.

The limitations of this study, a single site study, with unblinded data analyses and lack of long term follow up, would be addressed in a main trial now that the feasibility of the intervention has been explored. It is acknowledged that the intervention was provided as part of a research study, it is possible that participants preferred to phone/email the study team directly rather than use the website to comment or raise queries and this may also have contributed to the low use of the website already discussed. The qualitative study exploring acceptability indicates the website content was acceptable, appropriate and understandable, the site easy to use by participants and no changes are required before a main trial.

Conclusions: This research developed an innovative, web-based, podcast delivered, progressive cadence, walking programme designed to help inactive people with long term musculoskeletal conditions to increase their levels of physical activity in order to improve health. The promising findings support its acceptance to patients and the intervention is ready, subject to future funding, for investigation in a main trial to determine the effectiveness of "Walk30X5". Should "Walk30X5" prove effective and cost effectiveness it is designed to be feasible for implementation within the NHS; to be added into routine physiotherapy care and/or, after additional testing, to possibly be added to the NHS website to be freely downloaded by people in the same way as the 'Couch to 5k' running programme.

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ETHICAL APPROVAL: Ethical approval for the study was granted by National Research Ethics Service (Ref: 14/SC/1018).

CONFLICT OF INTERESTS: Professor Karen Barker is an associate editor of Physiotherapy, but had no involvement in the peer review or decision process for this paper.

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Contribution of the Paper statement:

- "Walk 30X5" is a new innovative walking programme intervention designed to help people with long term musculoskeletal conditions to improve their levels of physical activity and promote health.

- “Walk30X5” is a web-based intervention, which includes eight progressive digital audio podcasts, and was developed by people with long term musculoskeletal conditions, researchers and physiotherapy clinicians.
- “Walk 30X5” is feasible, acceptable and ready for evaluation in a definitive trial.

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CONSORT

TRANSPARENT REPORTING of TRIALS

CONSORT

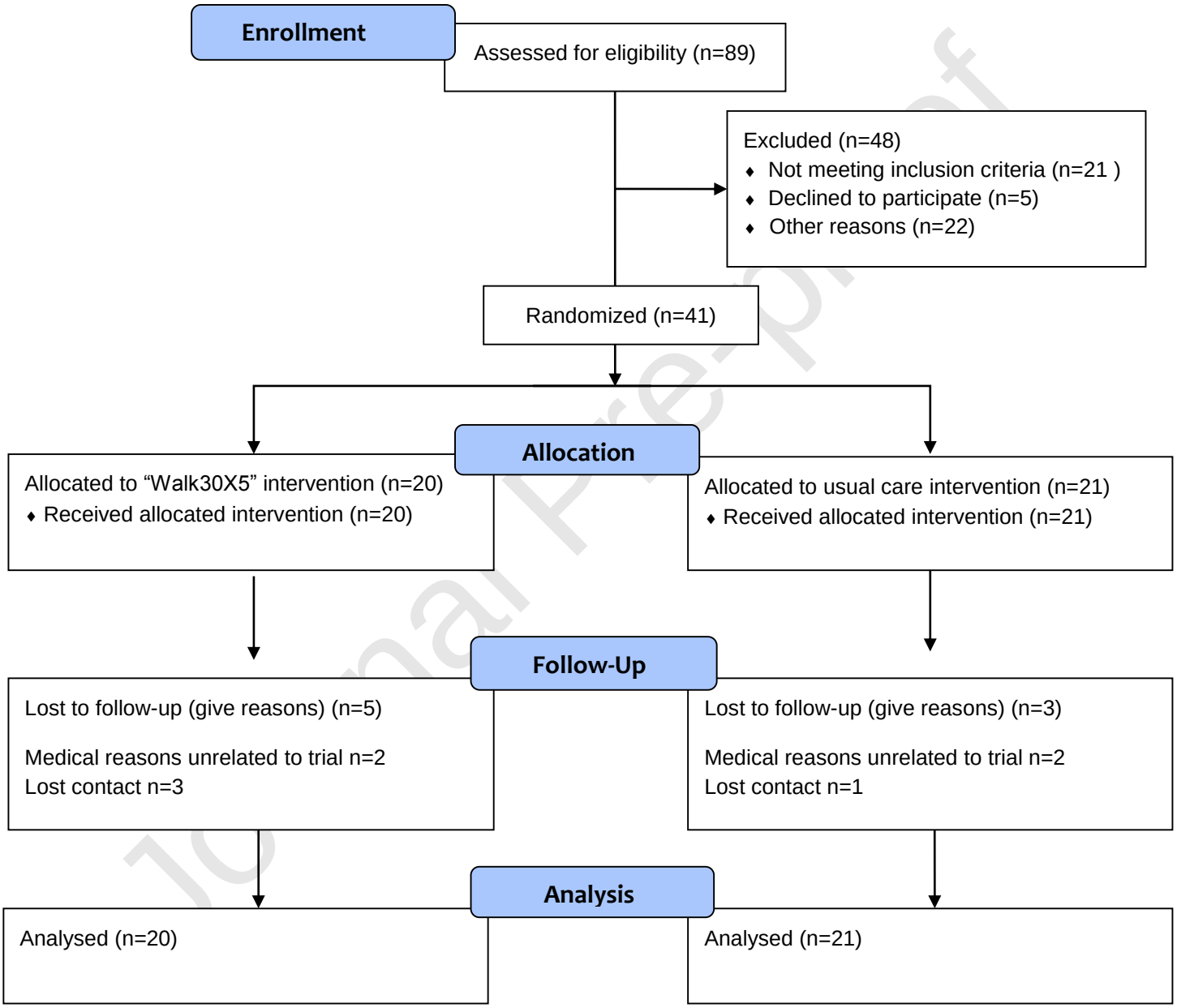

Figure 1. Flow through the feasibility study

Table 1. A summary of the "Walk30X5" Intervention

Component	Content	Techniques included in the intervention to promote behaviour change*
Website: A (non-public) secure website	A home page, introduction, tips on getting ready, motivational information about physical activity, benefits of physical activity, the podcasts, coping with flare ups, how to continue being active after "Walk150" and links to other health and activity sites. Comments could be shared by users &/or the team contacted via the website.	Goal Setting: to achieve 150" moderate/vigorous activity per week. Behaviour Action Planning: Discuss and actively plan how to achieve goal at session 1 and how to maintain activity at session 2. Graded Tasks: Individualised progression (speed, time) through podcasts. Information about health consequences: from physiotherapist and website. Increasing knowledge: from physiotherapist and website. Monitoring by physiotherapist: follow up session, walking diary data. Review of behavioural goals by physiotherapist: at follow up session. Self-monitoring: using a walking diary. Individualised, flexible intervention: discussed and agreed at session 1, flexible progression and modification by participant, discussed and agreed at session 2.
8 Podcasts (PC): These build in intensity. Podcast one lasted 20 minutes and podcast eight lasted 34 minutes.	PCs started and ended with normal (usual pace) walking for warm up/cool down. Early PCs: walking mostly at usual pace with short periods of moderate speed (instructed and encouraged on podcasts to "walk briskly enough for your heart rate to increase and your breathing to quicken, but you should still be able to have a conversation"). Final PC = 30 mins moderate to vigorous walking. Musical tempi; the beats per minute used in background music supported walking speed and progressed through the podcasts: from below normal pace (105 bpm) and slow (115 bpm) in early podcasts to tempo of 135 bpm for moderate/vigorous walking # People requested to do 5 PC/week, progressing at their own pace if/when ready (usually 8 weeks). Progression was flexible and individualised by the participant: people started at PC 1. If too easy, they tried PC 2 on the next walk and progressed until they found the PC where perceived exertion matched the PC. They did this PC for 1week and assessed progress: if ready they progressed PC. If not, they repeated the same PC for a week and then re-assessed. Progress assessed weekly. Flexibility: Each PC could be done all in 1 walk or split into 2 halves (2 walks per day). People could do several PC together (e.g. at weekends) if preferred and symptoms permitted.	

* Michie et al 2013[31] #in accordance with advice from internationally acknowledged expert (Prof Costas Karageorghis).

Table 2. Baseline characteristics of the "Walk30X5" and the Usual Care Groups.

Characteristics at Baseline	"Walk30X5"	Usual Care
Total number of participants randomised to each group	20	21
Gender: males females	5 15	3 18
Mean age in years (SD)	54 (14)	61 (16)
Mean height in cm (SD)	164 (8)	165 (17)
Mean weight in in kg (SD)	80 (23)	78 (14)
Presenting condition/s: Multiple/s Osteoarthritis Fibromyalgia Back pain + weakness Radiating back pain Spinal stenosis Tendinopathy Post Hip replacement Baker's cyst Plantar fasciitis Undiagnosed	 5 1 2 4 3 1 0 1 1 1 1	 7 3 3 2 2 2 1 0 0 0 1
Duration of condition in months: Median (IQR)	81 (63 to 93)	75 (66 to 89)
Location of condition/s: Multiple sites Spine Hip Knee Ankle	 12 3 1 2 2	 15 3 1 1 1
Occupation: In work Not in work Retired Full time carer Unknown	 10 3 5 1 1	 11 2 7 0 1

Table 3. Outcome scores for the "Walk30X5" (WG) and Usual Care (UC) groups at baseline, 3 and 6 months.

Outcome	Baseline		3months		6 months	
	WG	UC	WG	UC	WG	UC
Mean T6MWT in m (SD) 95% CI N=	454.9 (99.5) 408.3, 501.5 (n=20)	407.5 (98.8) 362.7, 452.2 (n=21)	503.9 (111.6) 448.4, 559.4 (n=18)	438.4 (103.1) 388.7, 488.1 (n=19)	552.4 (122.8) 481.4, 559.4 (n=14)	462.3 (102.2) 409.7, 514.9 (n=17)
Median Step Count/Day (IQR) N=	6887 (3254 to 9390) (n=19)	3719 (2722 to 5651) (n=19)	7246 (4338 to 10547) (n=18)	4866 (3024 to 6520) (n=17)	8857 (5565 to 10532) (n=14)	4669* (3713 to 8571) (n=15)
Median NRS Pain Today (IQR) N=	2.5 (1.6 to 4) (n=20)	2 (1 to 4) (n=21)	2* (0 to 5) (n=19)	2 (1 to 3.5)* (n=19)	1 (0 to 3)* (n=15)	2.5 (1 to 4.5) (n=17)
Median NRS Worst Pain (IQR) N=	5.8 (3.6 to 8) (n=20)	6 (2.5 to 7.5)* (n=21)	3 (2 to 8)* (n=19)	5 (4 to 7) (n=19)	3 (1 to 7) (n=15)	4.6 (2.7 to 6.8) (n=17)
Median NRS Average Pain (IQR) N=	3.5 (2.3 to 5) (n=20)	3 (1.8 to 4.5) (n=21)	3 (1 to 5) (n=19)	3 (2 to 4) (n=19)	1.5 (1 to 4)* (n=15)	2 (1.2 to 5) (n=17)
Median NRS Fatigue (IQR) N=	5.5 (3 to 7)* (n=20)	5 to (2 to 6.5)* (n=21)	3 (1.4 to 4) (n=19)	4 (2 to 5) (n=19)	3 (1-4) (n=15)	4 (1.5 to 6.8) (n=17)
Median PANAS positive (IQR) N=	31 (26 to 35) (n=19)	34 (28 to 38) (n=19)	33 (28 to 37) (n=19)	34 (33 to 37)* (n=19)	34 (27 to 39) (n=15)	30 (27 to 35) (n=17)
Mean PANAS negative (SD) 95% CI N=	15 (12 to 27)* (n=20)	13 (11 to 20)* (n=20)	14 (12 to 21)* (n=18)	13 (11 to 15)* (n=19)	15 (12 to 27)* (n=15)	13 (11 to 20)* (n=17)
Median GSES (IQR) N=	27 (28 to 30) (n=20)	30 (27 to 31)	29 (29 to 31)* (n=19)	32 (29 to 35) (n=19)	30 (28-32) (n=15)	31 (28 to 35) (n=17)
Median Happiness (ISQ) N=	4 (4 to 4)* (n=20)	5 (4 to 5)* (n=21)	4 (4 to 4)* (n=19)	5 (4 to 5)* (n=19)	4 (4 to 4)* (n=15)	5 (4 to 5)* (n=17)
Median GRS (IQR) N=	3 (3 to 4)* (n=20)	3 (3 to 4) (N=21)	3 (2 to 4)* (n=19)	3 (2 to 4)* (n=19)	4 (2 to 4)* (n=15)	3 (2 to 4)* (n=17)
Median weight (IQR) N=	75 (66 to 89) (n=20)	81 (63 to 93) (n=21)	73 (66 to 92)* (n=18)	80 (67 to 91)* (n=19)	70 (65 to 79)* (n=14)	78 (65 to 84)* (n=18)
Mean Peak Flow (SD) 95% CI N=	425 (131) 363, 486 (n=20)	353 (108) 304, 402 (n=21)	433 (139) 364, 502 (n-18)	368. (97.) 322, 415 (n=19)	433 (123) 362, 505 (n=14)	371 (100) 321, 421 (n=18)
Median Systolic BP (IQR) N=	126 (116 to 151) (n=20)	127 (112 to 138) (n=21)	136 (118 to 149) (n=18)	127 (112 to 138) (n=18)	127 (119 to 140) (n=14)	130 (114 to 149) (n=18)
Median Diastolic BP (IQR) N=	79 (69 to 89) (n=20)	79 (68 to 81)* (n=21)	79 (69 to 85) (n=18)	74 (69 to 80) (n=18)	74 (69 to 81) (n=14)	77 (67 to 83) (n=18)

* Data not normally distributed for this group at this timepoint

Additional File 1. An overview of the content of the eight "Walk150" podcasts

Podcast Number	Description of amounts of normal pace and brisk walking	Total time Of podcast
1	2 ½ minutes usual (normal) pace (105 bpm music). Then 60 seconds brisk walking (115 bpm music) followed by 90 seconds normal pace (105 bpm music) – repeated 6 times. 2 ½ minutes normal pace (105 bpm music)	20 minutes
2	2 minutes usual pace (105 bpm music). Then 90 seconds brisk walking (115 bpm music) followed by 60 seconds normal pace (105 bpm music) followed by 3 minutes brisk walking (115bpm music) then 2 minutes normal walking (105 bpm): repeat this section 3 times	24 and a half minutes
3	2 minutes usual pace (progressed to 115 bpm music). Then 5 minutes brisk pace (progressed to 125 bpm music) followed by 2 minutes normal walking (115 bpm music: repeated 3 times.	23 minutes
4	2 minutes usual pace (115 bpm music) followed by 8 minutes brisk pace (125 bpm music) followed by 3 minutes of normal walking (115 bpm music) followed by 10 minutes of brisk walking (125 bpm music) ending with 2 minutes usual walking (115 bpm)	25 minutes
5	2 minutes usual pace (115 bpm music). Then 10 minutes brisk pace (125 bpm music) followed by 2 minutes of normal walking (115 bpm music) followed by 15 minutes of brisk walking (125 bpm music) ending with 2 minutes usual walking (115 bpm),	31 minutes
6	2 minutes normal walking (115 bpm music) followed by 20 minutes (125 bpm music) followed by 2 minutes normal walking (115 bpm music) followed by 8 minutes brisk walking (progressed to 135 bpm music), 2 minutes normal walking (115 bpm music)	34 minutes
7	2 minutes normal walking (115 bpm music), 25 minutes brisk walking (135 bpm music), 2 minutes normal walking (115 bpm music)	29 minutes
8	2 minutes normal walking (115 bpm music), 30 minutes brisk walking (135 bpm music), 2 minutes normal walking (115 bpm music)	34 minutes