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Synopsis

Gait Rehabilitation for Early rheumatoid Arthritis Trial (GREAT): lessons learnt from a mixed-methods feasibility study and internal pilot trial

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Abstract

Background: People with rheumatoid arthritis experience foot and lower limb pain due to active synovitis, resulting in impaired lower limb function. Earlier intervention may help with prevention of functional decline. The aims of this research were to develop and evaluate a new gait rehabilitation intervention for people with early rheumatoid arthritis, evaluate its feasibility, and to test whether or not gait rehabilitation plus usual care is more clinically and cost-effective than usual care alone.

Design and methods: We undertook a single-arm, repeated-measures, pre- and post-intervention, mixed-methods feasibility study with embedded qualitative components. We planned to undertake a pragmatic, two-arm, multicentre, superiority randomised controlled trial, with health economic evaluation, process evaluation and internal pilot.

Setting and participants: Participants with early rheumatoid arthritis (< 2 years post diagnosis) were identified from early arthritis and rheumatology outpatient clinics and referred for intervention in either podiatry or physiotherapy clinics.

Intervention(s): Participants were randomised to a gait rehabilitation programme (Gait Rehabilitation Early Arthritis Trial Strides) involving a six-task gait circuit. Sessions were underpinned by motivational interviewing to facilitate behaviour change, supported by trained physiotherapists or podiatrists for a minimum of two sessions. Both groups received their normal usual care from the rheumatology multidisciplinary team.

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Main outcome measures: Outcome measures for the feasibility study were intervention acceptability, adherence using the Exercise Adherence Rating Scale and fidelity using the Motivational Interviewing Treatment Integrity Scale. The main outcome measure for the internal pilot/randomised controlled trial was the Foot Function Index disability subscale. Outcomes were measured at baseline, 3 months, 6 months and 12 months. Other outcomes: intervention acceptability questionnaire, Exercise Adherence Rating Scale, exercise treatment beliefs via the Theory of Planned Behaviour Questionnaire, intervention fidelity (Motivational Interviewing Treatment Integrity Scale), health-related quality of life (EuroQol-5 Dimensions, five-level score).

Results: Thirty-five participants were recruited for feasibility and 23 (65.7%) completed 12-week follow-up. Intervention acceptability was excellent: 21/23 were confident that it could help and would recommend it and 22/23 indicated it made sense to them. Adherence was good, with a median (interquartile range) Exercise Adherence Rating Scale score of 17/24 (12.5–22.5). Twelve participants' and nine therapists' interviews confirmed intervention acceptability, identified perceptions of benefit, but highlighted some barriers to completion. Motivational Interviewing Treatment Integrity Scale scores demonstrated good fidelity. The trial did not progress from internal pilot to full main trial as a result of low recruitment and high attrition, after 53 participants were recruited from 9 sites over 12 months. Process evaluation confirmed good intervention acceptability and adherence, and fair fidelity. Evaluation of clinical and cost-effectiveness was not possible.

Limitations: Significant delays were experienced with the impact of coronavirus disease 2019, regulatory approvals, contracts and site readiness, resulting in few sites opening in time and low recruitment capacity. Foot and/or ankle pain prevalence was lower than anticipated, resulting in a low potential participant pool and a low conversion rate from screening to enrolment.

Conclusions: The Gait Rehabilitation Early Arthritis Trial Strides intervention was acceptable to people with early rheumatoid arthritis and intervention clinicians, safe, with good levels of adherence by participants, and fair intervention fidelity. The randomised controlled trial stopped early following failure to meet recruitment targets. Gait Rehabilitation Early Arthritis Trial Strides is a promising intervention that could be adapted for future evaluations. A definitive trial of the Gait Rehabilitation Early Arthritis Trial Strides gait rehabilitation intervention still needs to be done.

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Introduction

This report describes the work done to explore the clinical and cost-effectiveness of a gait rehabilitation intervention as an addition to usual care in patients recently diagnosed with rheumatoid arthritis (RA) of the foot or ankle. The project arose from a call commissioned by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme. This call requested development of a gait rehabilitation intervention for people with early RA, a feasibility study to standardise and manualise the intervention and test its fidelity, and a randomised controlled trial (RCT) of its clinical and cost-effectiveness with an internal pilot phase. The emergence of this call was based upon the unmet need for care of foot and lower limb problems in RA, in the context of good evidence supporting the effectiveness of gait rehabilitation in neurological conditions, and its conceptually appealing nature for improving gait in people with early RA.[1–7] The National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guidelines Network clinical guidelines for the management of RA both recommend lower limb exercises to enhance joint flexibility, muscle strength and address functional impairments in RA,[8,9] but guidelines do not mention anything specifically about gait rehabilitation.

In this synopsis, we bring together the findings of our research which sought to evaluate the feasibility of a newly developed novel gait rehabilitation intervention [Gait Rehabilitation Early Arthritis Trial (GREAT) Strides] and a future trial, and the internal pilot phase of a full RCT, which sought to determine recruitment and retention rates of eligible participants. We did not progress to the full RCT due to failure to meet recruitment targets within the specified time period for the internal pilot phase. The aims of this synopsis are to provide a high-level summary of the findings of the GREAT research project, explore the reasons for non-progression to a full RCT and make recommendations for future research.

Background

There are an estimated 700,000 people with RA in the UK, and the current literature suggests that almost all of them will experience foot and/or ankle synovitis and associated mobility problems over the course of their disease.[10–12] During the early post-diagnosis stage, around 65% of patients experience foot pain and swelling and 60% report walking-related disability.[13] With the introduction of first-line disease-modifying antirheumatic drugs (DMARDs), the prevalence of

walking disability decreases to approximately 40% at 1 year post diagnosis and thereafter.[13] Self-reported walking disability at 2 years post diagnosis is the main predictor of persistent walking disability.[14] This suggests that there may be a therapeutic 'window of opportunity' for prevention of persistent walking disability during the first 2 years of RA.[15]

People with RA exhibit slow and unsteady gait patterns characterised by decreased walking speed, cadence, ankle power, step length and increased double limb support time.[16–18] They also take fewer steps, are more sedentary and are less physically active.[19–22] These sedentary characteristics are associated with poor body composition (increasing fat, decreasing lean muscle), elevated cardiovascular disease risk and need for ongoing care.[23–26] A progressive deterioration of gait in RA occurs due to a complex cycle of physical deconditioning which is negatively influenced by fear avoidance of activities.[15,27–29]

People with RA commonly express safety concerns about undertaking exercise and physical activity.[26,30–32] However, there is strong evidence to suggest that weight-bearing exercises are safe and do not cause disease exacerbations or joint damage.[21] Avoidance of painful movements and activities appears to be the key contributor to functional decline in RA.[33,34] Resultant lower limb muscle weakness and poor muscle endurance are common and are associated with reduced walking speed and impaired physical function.[17,18,35–40] Proprioception and postural stability are also commonly impaired in those with foot involvement, manifesting as balance problems during everyday activities such as walking and stair climbing.[41] There is an increased risk of falls in RA, and impaired balance and fear of falling are associated with reduced functional capacity.[41–44]

The current medical approach to managing early RA involves early use of DMARDs and/or biologic drugs to maximise disease control (aiming for disease remission) and preserve function.[44] Improvements in disease activity following first-line medical management in early RA are well recognised,[45–47] and lower limb function and walking ability generally improve for some patients.[13,48,49] People with RA who experience ongoing problems may be referred to physiotherapy and podiatry for the provision of muscle stretching/strengthening exercises, physical activity recommendations, footwear advice and foot orthoses as required, in line with clinical practice guidelines.[8,9] However, foot pain, gait problems and walking disability persist throughout the disease course for a significant proportion of patients.[13,48,50]

Gait rehabilitation

Gait rehabilitation is a treatment strategy employed for improving independent walking capacity in neurological disorders such as stroke.[1–5] Gait rehabilitation is largely considered to be the repetitive practice of gait cycles in order to improve walking ability, occasionally with the utilisation of electro-mechanical assistance (robotics) and functional electrical stimulation.[4] There is good evidence that gait patterns can be improved as a result of gait rehabilitation in neurological disorders.[1–5] In RA, two small studies demonstrated benefits in walking ability and physical function in participants with established disease who underwent rehabilitation involving repetitive walking tasks without electro-mechanical assistance.[6,7] Gait rehabilitation is not currently recommended in clinical guidelines nor is it recognised as a usual care intervention for early RA, and evidence of efficacy and clinical protocols are lacking.

Gait Rehabilitation Early Arthritis Trial Strides

Gait Rehabilitation Early Arthritis Trial Strides is a theoretically underpinned psychologically informed home-based 12-week gait rehabilitation programme for people with early RA (< 2 years post diagnosis), delivered initially and supported by trained podiatrists or physiotherapists for a minimum of two and a maximum of six (refined to two to four sessions following feasibility) intervention sessions. GREAT Strides is comprised of six repetitive walking tasks which have been adopted previously in established RA as part of a walking circuit[6] and the Otago Exercise Programme for falls prevention in older adults,[7] which were selected to target main lower limb muscle groups utilised during gait to improve key therapeutic targets including muscle strength, endurance and balance/proprioception.

Gait Rehabilitation Early Arthritis Trial Strides was designed for a simple home-based set-up for completion after initial assessment, support and dose prescription by GREAT Strides intervention therapists. The intervention included a psychological component based on motivational interviewing (MI) and behaviour change techniques (BCTs) to support participants and to facilitate translation of intentions into action. GREAT Strides was coproduced by people with RA, rheumatology specialist physiotherapists and podiatrists, health psychologists and clinical academics. Full descriptions of the original GREAT Strides intervention are provided in the feasibility study article,[51] and details of the refined (post-feasibility phase) GREAT Strides intervention are provided in the pilot trial protocol.[52] Associated intervention support materials are provided in *Report Supplementary Material 1* and *Report Supplementary Material 2*.

Clinical uncertainty

Prior to evaluation of clinical and cost-effectiveness via a full trial, our goal was to assess whether the newly designed GREAT Strides gait rehabilitation programme would be safe and well-tolerated by individuals with early RA. We also sought to evaluate whether NHS podiatrists and physiotherapists, responsible for its implementation, would find the programme acceptable and if it could be administered as intended. Before conducting a RCT, we needed to resolve uncertainties about the optimal and most practical outcome measure for detecting changes as the primary endpoint. Uncertainty also existed concerning the feasibility of a main trial in terms of recruitment and retention rates relative to sample size requirements.

Feasibility

We published the findings of the feasibility study in *BMC Pilot and Feasibility Studies*,[51] which described the development of the new GREAT Strides gait rehabilitation intervention for people with RA, and its feasibility in terms of intervention acceptability, safety, intervention training acceptability, fidelity and adherence. We also sought to evaluate the feasibility of a future main trial by evaluating the measurement properties of several candidate primary outcome measures and monitoring rates of recruitment and retention. Eleven therapists across three centres across Scotland and England participated in GREAT Strides training (8 hours across 2 days, delivered face-to-face, 2 weeks apart). In this non-randomised, single-arm, repeated-measures study with an embedded qualitative component, 35 people with early RA (< 2 years post-diagnosis disease duration) were recruited to receive the GREAT Strides intervention and 23 (65.7%) completed the 12-week follow-up, between June 2018 and March 2019 (a monthly recruitment rate of 3.5). Twelve participants and nine therapists participated in qualitative study interviews. The project including the feasibility study, internal pilot and main RCT was prospectively registered with the International Standard Randomised Controlled Trial Number (ISRCTN) registry as ISRCTN14277030.

Intervention acceptability, evaluated using a three-item questionnaire,[53] was excellent, with the majority of participants indicating that they were confident the treatment could help the problem (n = 21, 91.3%) and that they would recommend it to a friend with a similar problem (n = 21, 91.3%), and that the treatment was logical and made sense to them (n = 22, 95.7%). Intervention adherence, evaluated using the Exercise Adherence Rating Scale (EARS),[54] was good with a median score [interquartile range (IQR)] of 17.5 (12.5–22.5). These results were corroborated by interview findings, which suggested positive attitudes towards motivation to change behaviours and perceived effectiveness. However, key barriers to continuation were suitable space at home to complete the programme and disruption due to major life events and responsibilities. One participant reported mild transient post-exercise soreness, and one serious adverse event (a fall in public prior to enrolment resulting in a fractured ankle which required hospitalisation for surgery) was reported but deemed unrelated to the intervention or study participation. The participant was unable to participate in the study because of their injury.

Intervention fidelity was evaluated using a sample of GREAT Strides consultations (n = 55) between 6 therapists and 28 participants, assessed by 2 trained independent raters using the Motivational Interviewing Treatment Integrity (MITI) Scale 4.2.1[55] and a bespoke checklist for mandatory session components and BCTs. MITI scores demonstrated that relational and technical aspects of MI were delivered with proficiency, and six core BCTs were delivered with high treatment fidelity. GREAT Strides training was received positively by clinicians who commented in interviews on the supportive training environment, role-play activities and its comprehensiveness but stressed that the time requirement to attend two face-to-face sessions was problematic for clinicians in context of busy caseloads.

Outcome measures evaluated as potential use as the primary outcome for the future main RCT were the Foot Function Index (FFI) disability subscale, the Patient Reported Outcomes Measurement Information System Physical Function 20-item form (PROMIS-PF-20), the Recent-Onset Arthritis Disability lower extremity subscale (ROADles) and the 10-minute walk test (10MWT).[56–58] We observed similar measurement properties (responsiveness and theoretical consistency) for all measures except ROADles which did not behave in a theoretically consistent fashion. The selection of the primary outcome measure for the main trial (FFI disability subscale) was based upon practicalities and relative simplicity of completion and scoring.

Lessons learnt from the feasibility study

The feasibility study met 5/5 a priori specified decision rules (identification of a suitable primary outcome measure, intervention acceptability, adherence, fidelity and safety) for progression from the feasibility study to the internal pilot phase of the RCT. However, the feasibility study identified important potential future challenges with recruitment, leading to a lower than anticipated sample size (35 recruited of 42 planned), a lower monthly recruitment rate (3.5 participants per month over

10 months vs. an anticipated 7 participants per month over 6 months) and a higher attrition rate at 12 weeks (34.4% vs. an anticipated 20%). Lower than anticipated recruitment rates observed during the feasibility study led to amended inclusion criteria for the internal pilot where confirmation of the American College of Rheumatology 2010 classification criteria[59] (a key reason for not meeting eligibility in the feasibility study) was amended to a clinician diagnosis of RA. Additionally, in the context of the lower than anticipated foot and/or ankle disease prevalence observed from screening logs, our recruitment strategy for the internal pilot was enhanced to target more recruitment sites (10 vs. 5 sites originally planned) and the addition of a mailshot approach to invite more potentially eligible participants. The sampling frame was expanded from exclusively 'early arthritis' clinics to include rheumatology outpatient clinics in order to identify people with early RA who had been routinely transferred from early arthritis clinics at 1 year post diagnosis to RA follow-up clinics. Reasons for high attrition were unclear. However, the removal of outcome measures used in the feasibility phase which necessitated in-person follow-ups (i.e. 10MWT) meant that data could then be collected remotely (by post, online or over the telephone) for the internal pilot, and so improved attrition rates were anticipated. Only one participant received intervention sessions 5 and 6; therefore, the intervention sessions for the pilot were reduced to two compulsory plus a further two optional sessions to lessen the burden on participants and practitioners/NHS services and potentially improve attrition rates.

We concluded that GREAT Strides was an acceptable and safe intervention that could be delivered mostly as intended, with good patient adherence. Refinement of the intervention, follow-up procedures and eligibility criteria were undertaken with the intent to improve recruitment and retention rates for the pilot phase of the RCT.

Project timeline drift prior to the coronavirus disease 2019 pandemic

Delays for regulatory approvals [local research and development (R&D) approvals and site agreements] resulted in a 6-month delay to the start of the feasibility-phase recruitment period. The final patient final visit for the feasibility phase was completed in March 2019 (month 18 of the total of 60), resulting in revised timelines for the internal pilot phase. The planned target for ethical/Health Research Authority (HRA) approvals and starting the recruitment period for the internal pilot phase of the RCT was originally April 2019 and May 2019, respectively (months 19 and 20 of 60). Following timeline revision, ethical/HRA approvals were obtained in December 2019 and January 2020 (months 27 and 28), respectively. Recruitment to the pilot phase of the RCT was due to commence in March 2020 but was halted due to the emergence of the coronavirus disease 2019 (COVID-19) pandemic.

Impact of coronavirus disease 2019 pandemic

National and local COVID-19 lockdowns that took place between late March 2020 and July 2021 had a significant impact on the progression of the pilot trial phase. By March 2020, local approvals were obtained for one site and were being sought for six sites. Intervention training was complete for three sites, and was scheduled for an additional four sites between 17 March and 26 April 2020. Intervention training for these sites was postponed due to the COVID-19 national lockdown. As the true extent of the impact of COVID-19 became clear, all local approval processes were halted and the project was officially paused on the 20 May 2020. During this time, the intervention and training procedures were adapted for remote delivery, and the protocol amended to include updates to intervention delivery and contingency planning for COVID-19. The project officially re-started in September 2021, when local R&D approval processes restarted and revised intervention training was delivered remotely for all participating site intervention therapists. Four sites could no longer host the trial due to changes in local site personnel and site staff capacity. One site (site 3) that had initially withdrawn from the trial subsequently hosted the trial at a later date once the local service capacity issues had resolved. A summary of the timetable for local site approval and 'green for go' status for recruitment is provided in *Table 1*. A total of nine sites opened and started recruitment between February 2022 and January 2023. After 8 weeks of recruitment, site 2 could not continue due to staff capacity. The time taken for R&D set-up and approvals ranged from 4 to 11 months. Delays of 1–4 months were observed for several sites between both local approvals being obtained and first patient first visit (FPFV). There were 27 live site recruitment months combined across all sites (n = 7) over the 8 months recruitment period for the internal pilot phase of the RCT. There were 56 live site recruitment months combined across all sites (n = 9) over the 12 months extended recruitment period.

Trial protocol

Full details of the proposed study protocol for the internal pilot and main RCT phases are available via open access research repository.[52] The planned protocol manuscript was not submitted for publication due to the project being stopped early.

TABLE 1 Summary of timelines for local approvals, start of recruitment for each site and recruitment time contribution (months) from each site

Site	R&D set-up requested	Local approval	Contract	Green for go	FPFV	Site recruitment months (8 months)[a]	Site recruitment months (12 months)[b]
Site 1	May 2021	October 2021	October 2021	January 2022	February 2022	8	12
Site 2	May 2021	November 2021	November 2021	January 2022	March 2022	2	2
Site 3[c]	January 2020	March 2022	March 2022	May 2022	July 2022	3	7
Site 4	December 2021	March 2022	March 2022	May 2022	July 2022	3	7
Site 5	May 2021	April 2022	April 2022	April 2022	May 2022	5	9
Site 6	May 2021	April 2022	April 2022	April 2022	June 2022	4	8
Site 7	October 2021	June 2022	June 2022	June 2022	August 2022	2	6
Site 8	August 2022	November 2022	November 2022	November 2022	November 2022	0	3
Site 9	August 2022	November 2022	November 2022	November 2022	December 2022	0	2
					Total	27	56

a Original internal pilot recruitment period (8 months).
b Extended internal pilot recruitment period (12 months).
c Local approvals were initially granted in January 2021 before being suspended due to lack of intervention staff capacity. Local approvals were restarted for this site and obtained in March 2022.

Design

This study was designed as a pragmatic, two-arm, multicentre, superiority RCT with blinded outcome assessment and statistical analysis, with concurrent health economic evaluation, mixed-methods process evaluation and internal pilot phase.

Recruitment and retention targets

The internal pilot phase aimed to assess recruitment and retention rates based on the first 76 participants recruited over an 8-month period. The progression criteria at the end of this internal pilot were based on recruitment and retention. We specified at least 80% recruited as planned to proceed to the main RCT, or at least 70% of the recruitment target to develop and initiate a rescue plan. A retention rate of > 80% at 3-month follow-up was required to proceed to the main RCT, or > 70% to develop and initiate a rescue plan. Extension of the pilot recruitment period by 4 months from 8 to 12 months was granted by the NIHR while a contract variation request for a funded extension was being considered. This request was ultimately rejected in January 2023 and subsequently recruitment was halted.

Process evaluation

The internal pilot included a process evaluation that was originally planned to run for the duration of the main RCT. The aims of the process evaluation were to evaluate intervention acceptability, intervention adherence, intervention fidelity, exercise treatment beliefs, and to monitor and describe usual care. Process evaluation data were limited to all 3- and 6-month follow-ups for participants enrolled in the internal pilot at the time of stopping recruitment, and 12-month follow-up data already obtained at the time of stopping. Intervention acceptability was evaluated using an eight-item intervention acceptability questionnaire (IAQ) developed using the theoretical framework of acceptability (TFA).[60–62] The IAQ is adaptable to specific intervention contexts and the eight items cover seven TFA constructs of affective attitude, burden, perceived effectiveness, intervention coherence, self-efficacy, and opportunity costs, ethicality, and one general acceptability item.[59] Intervention adherence was examined using the EARS, a valid and reliable six-item self-reported measure of adherence to prescribed exercise therapies.[54] For intervention fidelity, one trained assessor rated a 10% randomly selected sample of audio-recorded intervention sessions to assess the extent to which the mandatory session components and BCTs were delivered as intended. High treatment fidelity was achieved if at least 80% of mandatory components were fully or partially delivered in 80% of the sampled sessions. Randomly selected 20-minute segments of the sampled intervention sessions were rated for MI

relational proficiency (3.5 on a 5-point scale indicates fair interpersonal style) and technical proficiency (a score of 3 on a 5-point scale indicates fair technique) using the MITI scale.[55] Exercise treatment beliefs at 3-month follow-up (attitude, subjective norms, perceived behavioural control, intentions) were evaluated using an adapted 12-item version of the Theory of Planned Behaviour (TPB) Questionnaire [score for each construct, 3–18 (18 indicates best)].[63] Within this questionnaire, participants were asked to respond to specific questions concerning their personal views on the following advice:

> *It is recommended that all adults, including people with rheumatoid arthritis and other musculoskeletal conditions, complete at least 150 minutes of moderate aerobic exercise a week and strengthening exercises on two or more days a week. This can include things like walking, or any prescribed exercises. These targets can be met by doing several short bouts of exercise, each lasting at least 10 minutes, or longer sessions.*

Participants' usual care at 6-month follow-up was recorded using a customised resource use questionnaire (RUQ).

Embedded qualitative component (participants with early rheumatoid arthritis)

Within the GREAT trial, a qualitative study was undertaken to explore the lived experiences of individuals with early RA receiving the intervention. This aspect of the research was key to evaluating the delivery and acceptability of the programme from the patients' perspective, providing an in-depth understanding of how the intervention aligns with their day-to-day experiences and the broader context of their lives. Through this, the study sought to discern the nuanced perceptions of programme delivery and its acceptability, aiming to ensure that the intervention is both patient-centred and effective in real-world settings. The interview topic guide was developed by the research team, drawing on the principles of the COM-B model of behaviour change, which encompasses capability, opportunity and motivation.[64] This theoretical framework informed the development of targeted questions aimed at elucidating the multifaceted aspects of intervention acceptability. Additionally, the guides incorporated a series of questions designed to broadly gauge the general acceptability of the GREAT Strides intervention among participants with early RA. The interviews were conducted by independent researchers not involved in the intervention's design, training or delivery. All interviews were audio-recorded and transcribed verbatim. To ensure accuracy and enhance the credibility of the data, participants were given the opportunity to review their transcription. The data analysis was performed using the thematic analysis method by two researchers to enhance confirmability and credibility of findings.

Embedded qualitative component (intervention therapists)

In order to understand the experiences of GREAT Strides clinicians and explore the feasibility and acceptability of both training for and delivery of the GREAT Strides intervention, an embedded semistructured interview study was conducted. The topic guide was informed by the TFA.[60–62] All clinicians who received training were eligible and invited for interviews. The interviews were conducted by independent researchers not involved in the intervention's design, training or delivery. All interviews were audio-recorded and transcribed verbatim. Inductive thematic analysis was conducted on the verbatim transcripts of the interviews. Member checking was used to confirm the accuracy of transcripts.

Economic evaluation

The original aim of the economic analysis for the GREAT intervention was to determine the cost-effectiveness of adding the gait rehabilitation intervention to usual care compared to usual care alone. Following the unavoidable impacts of the COVID-19 pandemic, which resulted in the early stopping of the RCT, the planned economic evaluation was adapted. Due to the small number of participants with both cost and utility data at baseline and 6-month follow-up (n = 37 : 19 gait rehabilitation; 18 usual care), a descriptive analysis with an emphasis on data quality/completion rates was conducted.

Both costs and utilities were the primary outcomes for the economic evaluation. Data were collected at baseline, 3-month follow-up (resource use only) and 6-month follow-up. Estimates of the resources used in providing the GREAT Strides intervention were obtained from discussion with the Principal Investigator. Health state utility values were calculated based on responses to the EuroQol-5 Dimensions, five-level score (EQ-5D-5L) questionnaire. EQ-5D-5L measures patient's self-reported health-related quality of life in five domains: mobility, usual activities, self-care, pain/discomfort and anxiety/depression. Values were calculated using the Policy Research Unit – Economic Methods of Evaluation in Health and Care Interventions Decision Support Unit (EEPRU DSU) crosswalk, a statistical mapping approach for estimating utility values for the 5L system based on the 3L value set.[65] Utility scores were derived from responses to understand the magnitude and variability of changes in perceived health [using EuroQol visual analogue scale (EQ-VAS)] and health-related quality of life (using utility scores). Mean change scores were

reported with estimates of precision [standard deviation (SD), minimum and maximum scores].

Information on healthcare resource use was collected via a self-completed questionnaire using a RUQ developed for this study. The RUQ provided a standardised method of collecting information on contacts with primary and secondary care, medications, equipment and contacts with allied health professionals. Binary yes/no questions were used to collect service use information, and if 'yes' the frequency of use was collected. For reporting of medications participants were asked to write down the name of the medication, the dosage prescribed and how often they have to take the medication. Patients were also asked to record personal expenditure on use of private health care and over-the-counter medications and/or equipment.

Results

Recruitment and retention

Recruitment ran from February 2022 to January 2023, and 6-month follow-ups were completed by August 2023. A total of 1460 patients were pre-screened for early RA, and from those, 221 patients were identified as potentially eligible and subsequently screened for eligibility (*Figure 1*). A total of 53/76 (70%) participants were identified as eligible and enrolled (*Figure 2*). Retention at the 3-month follow-up was 42/53 participants (79%), dropping to 39/53 participants (74%) at the 6-month follow-up. Recruitment at the end of the internal pilot trial 8-month recruitment period was 39/76 participants (51%), at a rate of 1.44 participants recruited per live site recruitment month (39/27). Recruitment at the end of the extended internal pilot recruitment period at 12 months was 53/76 (70%), a rate of 0.95 participants recruited per live site recruitment month (53/56). Retention at the 3-month follow-up was 42/53 (79%). Screening log data were incomplete for several sites, and thus reasons for exclusion following eligibility screening remain largely unknown.

Participant characteristics

Of the 53 participants enrolled and randomised, 36 (67.9%) were female. The mean age of participants was 57.0 years (SD 15.5) and the mean disease duration from the point of diagnosis was 8.5 months (SD 7.1). Participants were typically overweight [body mass index (BMI) 28.0, SD 6.0], and the majority were either retired due to age (n = 18, 34%) or currently in full-time employment (n = 16, 30.2%). Participants were typically in moderate disease activity [mean disease activity score 28 (DAS28) 3.7, SD (1.0) and foot disease activity states mean Rheumatoid Arthritis Foot Disease Activity Index-5 (RADAI-F5) score 4.7, SD 2.3], and all were in receipt of either DMARD or biologic therapies. Most participants had at least one comorbid condition (66.6%). Baseline characteristics were similar between groups (*Tables 2* and *3*).

Intervention acceptability

Nineteen participants (70%) completed the IAQ at the 3-month follow-up (*Table 4*). The GREAT Strides intervention appeared to have good acceptability with a mean (SD) summary score of 20.3 (3.2) from a possible 32 (completely acceptable). Intervention acceptability was good at the item level for 8/8 items: 74% liked or strongly liked the recommended exercises; 63% agreed or strongly agreed that the exercises improved their walking ability; 79% disagreed or strongly disagreed that the exercises interfered with other priorities; 79% felt confident or very confident about completing the exercises; 84% agreed or strongly agreed that the exercises would help their walking ability; 63% felt it was fair or very fair to receive information about exercises to improve walking ability; and 95% found the exercises acceptable or completely acceptable. For item 2 (burden perception), 68% of participants felt the exercises required little or no effort.

Intervention acceptability (embedded qualitative study: participants)

From a total of 16 participants who initially consented to be interviewed from the intervention arm, 6 participants (3 males; 3 females) took part in semistructured, telephone-based interviews. The analysis revealed four primary themes with some overlap: 'Adapting and Overcoming', which highlighted participants' resilience in tailoring exercises to their needs; 'Physical and Emotional Empowerment', suggesting participants experienced improved mobility and well-being, feeling more in control of their health; 'Integration into Daily Life and Routines', illustrating the practicality of the intervention; and 'Support and Engagement', emphasising the role of personal and external support systems in facilitating consistent engagement with the intervention. The motivation and commitment of participants were bolstered by support from their social and healthcare networks.

The findings indicate that the GREAT Strides intervention was positively received and considered beneficial, as reflected in the physical and emotional advantages participants reported (*Table 5*). The ability for participants to personalise and integrate exercises into their daily routines was key to the intervention's acceptability. The delivery of the gait exercises was considered to be well supported by instructional materials, effective programme facilitation and the ability to involve personal support

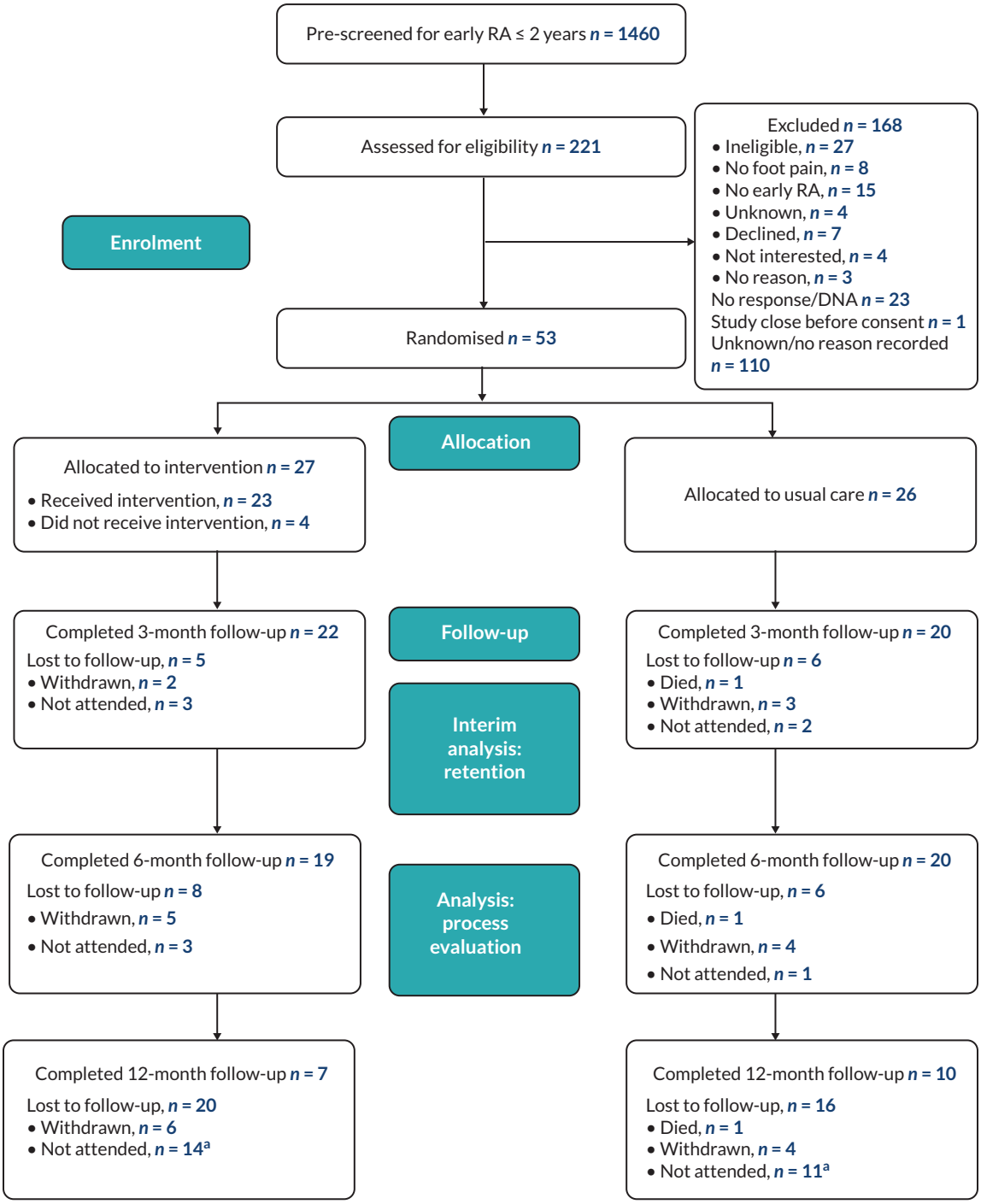

FIGURE 1 Trial flow chart. a, All cases 'not attended' at 12-month follow-up were due to study closure prior to reaching end of visit window.

systems within the home-based environment. However, a larger, more diverse sample could have captured a broader spectrum of experiences, providing a more comprehensive understanding of the intervention's impact and delivery.

Intervention acceptability (embedded qualitative study: gait rehabilitation early arthritis trial strides clinicians)

Nine clinicians (podiatrists *n* = 5, physiotherapists *n* = 4) who received training face-to-face as part of the feasibility study (six of whom delivered the intervention) and another six clinicians (podiatrists *n* = 5, physiotherapist *n* = 1) who received training remotely as part of the pilot phase of the RCT (five of whom delivered the intervention) were interviewed. Some therapists expressed limited familiarity with psychologically informed practice, which influenced their perceptions of training and delivering GREAT Strides (*Table 6*). Three themes: 'training length and format, skill development-supported clinical practice, time delay between training and delivery' suggested GREAT Strides

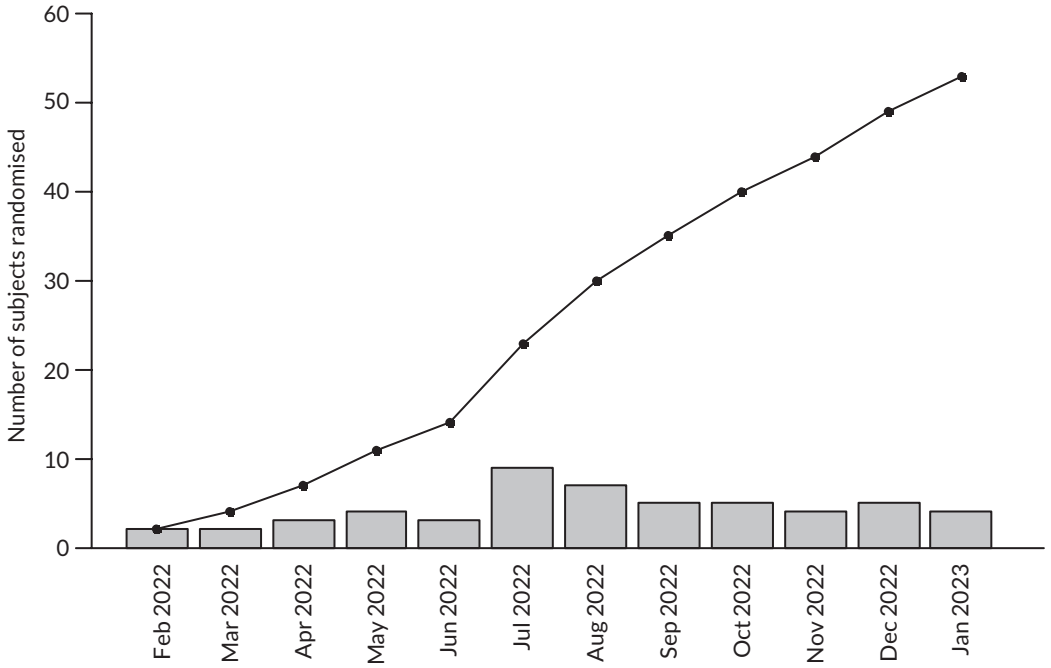

FIGURE 2 Absolute and cumulative number of participants randomised across the internal pilot trial recruitment period.

TABLE 2 Baseline demographics

Variable	Summary statistic	All randomised (*N* = 53)	Usual care (*N* = 26)	Gait rehabilitation (*N* = 27)
Age, in years	Mean (SD)	57.0 (15.5)	57.4 (16.0)	56.5 (15.3)
	Median (IQR)	59.6 (48.0–67.0)	58.0 (51.0–67.3)	60.0 (47.5–67.0)
	(Min–max)	(20.3–85.1)	(20.3–85.1)	(30.9–78.7)
Gender	*N* (%) Male	17 (32.1%)	8 (30.8%)	9 (33.3%)
	N (%) Female	36 (67.9%)	18 (69.2%)	18 (66.7%)
Primary employment status	*N* (%) Employed full-time	16 (30.2%)	9 (34.6%)	7 (25.9%)
	N (%) Employed part-time	6 (11.3%)	3 (11.5%)	3 (11.1%)
	N (%) Unemployed	1 (1.9%)	0 (0.0%)	1 (3.7%)
	N (%) Self-employed	5 (9.4%)	0 (0.0%)	5 (18.5%)
	N (%) Retired (because of age)	18 (34.0%)	9 (34.6%)	9 (33.3%)
	N (%) Retired (because of ill health)	6 (11.3%)	4 (15.4%)	2 (7.4%)
	N (%) Student	1 (1.9%)	1 (3.8%)	0 (0.0%)
	N (%) Housewife/husband	0 (0.0%)	0 (0.0%)	0 (0.0%)
	N (%) Other	0 (0.0%)	0 (0.0%)	0 (0.0%)
BMI, in kg/m^2	Mean (SD)	28.0 (6.0)	28.9 (6.0)	27.1 (6.0)
	Median (IQR)	26.5 (23.8–31.4)	26.7 (24.1–33.0)	26.3 (22.7–29.6)
	(Min–max)	(19.4–48.6)	(20.5–40.8)	(19.4–48.6)

TABLE 2 Baseline demographics (*continued*)

Variable	Summary statistic	All randomised (*N* = 53)	Usual care (*N* = 26)	Gait rehabilitation (*N* = 27)
Ethnicity	*N* (%) White	41 (77.4%)	20 (76.9%)	21 (77.8%)
	N (%) Mixed	3 (5.7%)	2 (7.7%)	1 (3.7%)
	N (%) Asian or Asian British	5 (9.4%)	3 (11.5%)	2 (7.4%)
	N (%) Black or Black British	4 (7.5%)	1 (3.8%)	3 (11.1%)
	N (%) Chinese or other ethnic group	0 (0.0%)	0 (0.0%)	0 (0.0%)

Max, maximum; min, minimum.

TABLE 3 Baseline clinical characteristics

Variable	Summary statistic	All randomised (*N* = 53)	Usual care (*N* = 26)	Gait rehabilitation (*N* = 27)
Currently taking DMARDs	*N* (%) Yes	48 (90.6%)	23 (88.5%)	25 (92.6%)
Currently taking biologic drugs	*N* (%) Yes	7 (13.2%)	3 (11.5%)	4 (14.8%)
DAS28 type recorded	*N* (%) DAS ESR	11 (20.8%)	5 (19.2%)	6 (22.2%)
	N (%) DAS CRP	10 (18.9%)	4 (15.4%)	6 (22.2%)
	N (%) Not available	32 (60.4%)	17 (65.4%)	15 (55.6%)
DAS28	Mean (SD)	3.7 (1.0)	3.8 (1.3)	3.6 (0.8)
	Median (IQR)	3.8 (3.0–4.3)	4.2 (3.8–4.8)	3.4 (3.0–4.1)
	(Min–max)	(1.7–5.3)	(1.7–5.3)	(2.7–5.0)
Disease duration, in months	Mean (SD)	8.5 (7.1)	10.4 (7.5)	6.7 (6.3)
	Median (IQR)	6.4 (2.4–15.2)	11.1 (3.0–16.6)	4.5 (2.0–10.2)
	(Min–max)	(−0.0 to 22.6)	(0.2–22.6)	(−0.0 to 22.2)
Comorbidities	*N* (%) None	23 (43.4%)	9 (34.6%)	14 (51.9%)
	N (%) Cardiology	8 (15.1%)	5 (19.2%)	3 (11.1%)
	N (%) Immunology	1 (1.9%)	1 (3.8%)	0 (0.0%)
	N (%) Neurology	2 (3.8%)	1 (3.8%)	1 (3.7%)
	N (%) Oncology	2 (3.8%)	0 (0.0%)	2 (7.4%)
	N (%) Respiratory	12 (22.6%)	7 (26.9%)	5 (18.5%)
	N (%) Other	22 (41.5%)	13 (50.0%)	9 (33.3%)
FFI-DS	Mean (SD)	34.5 (24.2)	35.7 (27.0)	33.5 (21.6)
	Median (IQR)	32.0 (12.0–54.0)	35.5 (10.0–55.5)	29.0 (20.0–52.5)
	(Min–max)	(0.0–82.0)	(0.0–82.0)	(1.0–74.0)
RADAI-F5 score	Mean (SD)	4.7 (2.3)	4.5 (2.3)	4.8 (2.3)
	Median (IQR)	4.4 (3.0–6.4)	4.0 (2.9–6.3)	5.6 (3.1–6.4)
	(Min–max)	(0.4–9.2)	(1.0–9.2)	(0.4–9.0)

CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; FFI-DS, Foot Function Index disability score; Max, maximum; Min, minimum.

TABLE 4 Intervention acceptability questionnaire item-level responses at the 3-month follow-up

Variable	Summary statistic	Gait rehabilitation (*N* = 19/27)
1. Did you like or dislike completing the recommended exercises?	*N* (%) Strongly disliked	0 (0.0%)
	N (%) Disliked	2 (10.5%)
	N (%) No opinion	3 (15.8%)
	N (%) Liked	12 (63.2%)
	N (%) Strongly liked	2 (10.5%)
2. How much effort did it take to complete the recommended exercises?	*N* (%) No effort at all	2 (10.5%)
	N (%) A little effort	11 (57.9%)
	N (%) No opinion	1 (5.3%)
	N (%) A lot of effort	4 (21.1%)
	N (%) Huge effort	1 (5.3%)
3. To what extent do you agree with this statement? 'The recommend exercises have improved my walking ability'	*N* (%) Strongly disagree	0 (0.0%)
	N (%) Disagree	0 (0.0%)
	N (%) No opinion	7 (36.8%)
	N (%) Agree	9 (47.4%)
	N (%) Strongly agree	3 (15.8%)
4. To what extent do you agree with this statement? 'Completing the recommended exercises interfered with my other priorities'	*N* (%) Strongly disagree	1 (5.3%)
	N (%) Disagree	14 (73.7%)
	N (%) No opinion	2 (10.5%)
	N (%) Agree	1 (5.3%)
	N (%) Strongly agree	1 (5.3%)
5. How confident did you feel about completing the recommended exercises?	*N* (%) Very unconfident	2 (10.5%)
	N (%) Unconfident	1 (5.3%)
	N (%) No opinion	1 (5.3%)
	N (%) Confident	8 (42.1%)
	N (%) Very confident	7 (36.8%)
6. To what extent do you agree with this statement? 'It is clear to me how completing the recommend exercises will help my walking ability'	*N* (%) Strongly disagree	1 (5.3%)
	N (%) Disagree	0 (0.0%)
	N (%) No opinion	2 (10.5%)
	N (%) Agree	9 (47.4%)
	N (%) Strongly agree	7 (36.8%)
7. How fair is a system where people with RA receive information on completing recommended exercises to improve walking ability?	*N* (%) Very unfair	1 (5.3%)
	N (%) Unfair	2 (10.5%)
	N (%) No opinion	4 (21.1%)
	N (%) Fair	8 (42.1%)
	N (%) Very fair	4 (21.1%)
8. To what extent did you find the recommended exercises acceptable?	*N* (%) Completely unacceptable	0 (0.0%)
	N (%) Unacceptable	0 (0.0%)
	N (%) No opinion	1 (5.3%)
	N (%) Acceptable	11 (57.9%)
	N (%) Completely acceptable	7 (36.8%)

TABLE 5 Example quotes from GREAT Strides participants

'Well, what I felt was, actually the exercises you could actually combine just into everyday living. You didn't need to just sit and do them. I found that if I just kind of brought them into, if I was working in the kitchen, if I just kind of moved about in that direction and done, you know, the kind of circle of eights and whatever. As I was doing things, I found I could combine them, you know, just with my everyday living if I thought about it'. (01)
'…you know if you if you if you're new to er the condition, you're new to rheumatoid, erm it it it is it really does hit you hard and erm you you're thinking this is this is the end you know this is the active the activity er the erm the movement that I had has gone and it'll never be back. Because it hits you like that. Erm but something like this combined with the medication er you you see the benefits and you start to believe it will it will improve you can you can get a better life out of it. Yeah yeah'. (06)
'Going through the different exercises whilst they were telling me how I can go about things without having to go to hospital all the time. I did a lot I did a lot of the exercises in my garden'. (03)
'Well my my er my idea was that it would have allowed me to do it and fit in with my schedule. I didn't have to set a given time. Whereas if I had an appointment to go somewhere I had to work my schedule around it er to go to there so being able to do it at home it suited me erm and I could do it every day if I wanted to or maybe twice a day or or whatever. Erm I wasn't I wasn't having to wait for a session to come up to go and do it'. (04)
'Erm no I tried to kind of push myself. You know some of the exercises you were to do on your toes and things like that you know erm to improve the difficulty and things. I tried to do that as much as I could erm on my kind of days where my my erm my feet because it's mainly my feet that I was having the most problems with and that's where I do still get some of the pain so so erm I tried to kind of push myself to do that a wee bit harder kind of things on your toes and things like that so erm. No and I think it did help. It did improve'. (05)
'Erm I think the I I just got into a process I'd I put the kettle on in the morning when I come down erm and I've got space at home to do it er and I do those exercises then I I obviously reboil the kettle and and go and have a cup of tea and watch the television or something. Erm so I sort of tried to get into a routine'. (06)
'Yeah, because in the beginning I was really, really miserable, never kind of felt like that before, so as obviously my mobility and less pain, just everything becomes much easier and your, your mood is a lot better as well. You're just not in that pain constantly'. (02)

TABLE 6 Example quotes from GREAT Strides-trained clinicians

'For all of us I would say, that attended the training, it was the motivating interviewing that was quite a new technique. We did tend to just be, here is your treatment, this is what you've got to do, I'll see you in 8 weeks, do you know, sort of thing?'
'The practical sessions were great. I don't like doing them and doing them in front of people but actually completing the MI techniques with somebody helped me because I'd not been involved in that sort of thing before'.
'I liked the (clinician) manual, I thought it was very easy to understand. It was brilliant because we'd got some ideas of examples of what phrases to use, what questions to ask, so you got a bit stuck it was good. And also, the fact that it gave you some ideas about how to progress the exercises as well'.
'I'm a wee bit worried now about actually going in to do it because it's been so long in-between it. I think it's just from my point of view just a wee bit frustrating in that not being able to kind of follow it up and get a chance at it because it's, and now I'm at the stage I'm thinking 'am I going to be able to do this now?' you know, because it's been so long in-between'.
'Now I've got two, now I've got three underneath me belt, it's not as, I'm not as scared. The first initial one does sort of give me a little bit of an heebie-jeebies because it's the first time you're meeting the patient, you're not quite sure how engaging the patient will be, how engaging they'll be with you, how receptive they'll be'.
'We had a problem with getting enough room with space here within the unit, so there was quite a lot of running around sometimes when patients came in because the rooms were already booked elsewhere by other people and you needed a space to be able to record it, otherwise you've got lots of other things going on. So that was, space and accommodation was an issue here. And some of the participants didn't have room in their own home to set up'.
'I think it'll help them manage things quite a lot because it just gets them moving and gets them concentrating. They find that oh yeah, I'm getting a bit more better at that and that's the one that I think is the really, it's the balance aspect of things and I think as you get older and from a foot perspective, the feet muscles have to work so much harder when you're doing the balance, then that will help in itself, just getting those muscles as tight and as strong as they should be that will help with walking and their symptoms will stop'.
'I mean, If I can just tell you from the patients I saw, absolutely. The ones that committed to it and did it, they were, they were thrilled at how quickly they started to pick it up and they could see the changes in themselves, so yeah definitely. Definitely for the ones who committed and did it, yes'.

training was largely perceived as a positive experience by clinicians. The training delivered over two separate sessions was appropriate and necessary, and participants felt that skills learnt were widely applicable to clinical practice. They also highlighted drawbacks and benefits of each modality, such as virtual training and resources being more easily accessible. However, participants felt that training in key psychological skills, like MI, was best delivered face-to-face. The time delay between training and intervention delivery was raised as an issue across training modalities.

Four themes: 'confidence in delivering the intervention, challenges of delivery, patient engagement, implementation within clinical practice' highlighted positive aspects, as well as challenges clinicians faced with delivery. Participants stated that their confidence improved with practice and that they found the techniques useful in clinical practice, for example, employing MI techniques with all patients with chronic conditions. There were also positive perceptions of patients' adherence to exercise and progress following the intervention if they engaged with it fully. The challenges described included the time the training and intervention took, particularly in relation to the constraints and pressures of high workloads. Perceived complications concerning logistics, such as finding space and the organisation of clinics and appointments, were also a concern.

The findings suggest that a blended approach to training may be the most appropriate for GREAT Strides and future RCTs, as there is an access–interaction trade-off. In addition, reducing the time frame between intervention training and delivery and providing refresher training or support where needed, especially for clinicians who are less experienced with psychologically informed treatment approaches, could be beneficial. Clinicians suggested that beneficial aspects of taking part included learning useful new skills that could be applied elsewhere and seeing benefits for patients, but that the challenges of fitting research into busy clinical practice also need to be further considered when developing interventions.

Intervention adherence

Twenty participants completed the EARS at 3-month follow-up, 18 at 6-month and 7 at 12-month (*Table 7*). At 3-month follow-up, a mean (SD) score of 16.4 (4.7) represents good adherence, which improved slightly to 17.3 (5.0) at 6-month and then reduced to 13.3 (5.5) at 12-month follow-up.

At the item level (*Table 8*), there were positive responses by the majority of participants for 5/6 items: 65% disagreed that they forgot to do their exercises; 60% disagreed that they did less exercise than recommended; 60% agreed that they fitted exercises into their regular routines; 70% disagreed that they did not get around to doing their exercises; and 60% agreed that they did most or all of their exercises. For item 1, 45% agreed that they did their exercises as often as recommended.

Intervention fidelity

Sixteen randomly selected intervention sessions, delivered by seven therapists, were rated for intervention fidelity and MI proficiency. High fidelity of delivery of mandatory session components was not achieved in any session. Fair relational MI proficiency was achieved in session 1 (3.5 on a scale of 5) and session 3 (3.8 on a scale of 5) but not session 2. Fair technical MI proficiency was achieved in all sessions (3.2–3.7 on a scale of 5) (*Table 9*).

Exercise treatment beliefs

At 12-week follow-up, exercise treatment beliefs scores were largely similar for both the usual care and gait rehabilitation intervention groups, but marginally and consistently higher across all four domains and items for the intervention group (*Tables 10* and *11*). The largest between group difference observed was for the intentions construct [mean (SD) 16.4 (1.7) vs. 13.5 (5.0)] involving a greater proportion of higher responses to items 4, 7 and 10, concerning goals to do the recommended exercises, intention to do the recommended exercises and planning to do the recommended exercises.

Intervention safety

A total of 21 expected adverse events of interest occurred (n = 12 intervention arm, n = 9 usual care arm), the majority of which were mild to moderate [n = 18 (85.7%)], the most common of which was transient post-exercise soreness (n = 7, n = 6 intervention arm vs. n = 1 standard care arm). A shorter duration of adverse event onset from randomisation was noted in the intervention arm [mean (SD) 71.3 (43.2) days vs. 118.1 (88.3) days]. The majority of adverse events in the intervention arm resolved [8/12 (66.7%)] compared to the standard care arm [2/9 (22.2%)].

Two serious adverse events were recorded for the standard care arm (1 – COVID-19 pneumonitis, hospital admission, resulted in death; 2 – severe headache, hospital admission, recovered) but were deemed unrelated to the intervention or study participation. Full safety reporting analyses are provided in *Appendix 1*.

Economic evaluation

The delivery of GREAT Strides in clinical practice primarily depends upon the initial training of clinicians (physiotherapists and podiatrists) in MI to support patient

TABLE 7 Exercise Adherence Rating Scale

Variable	Summary statistic	Gait rehabilitation (*N* = 27)
Attended Week 12 visit	*N* (%) Yes	22 (81.5%)
EARS score at Week 12	*N* (*N* missing)	20 (2)
	Mean (SD)	16.4 (4.7)
	Median (IQR)	16.0 (12.0–20.0)
	(Min–max)	(8.0–24.0)
Attended Week 26 visit	*N* (%) Yes	19 (70.4%)
EARS score at Week 26	*N* (*N* missing)	18 (1)
	Mean (SD)	17.3 (5.2)
	Median (IQR)	17.0 (13.2–22.8)
	(Min–max)	(10.0–24.0)
Change in EARS score at Week 26	*N* (*N* missing)	17 (2)
	Mean (SD)	0.5 (4.3)
	Median (IQR)	0.0 (−2.0 to 2.0)
	(Min–max)	(−6.0 to 12.0)
Attended Week 52 visit	*N* (%) Yes	7 (25.9%)
EARS score at Week 52	*N* (*N* missing)	7 (0)
	Mean (SD)	13.3 (5.5)
	Median (IQR)	12.0 (10.5–12.5)
	(Min–max)	(0.0–17.0)
Change in EARS score at Week 52	*N* (*N* missing)	7 (0)
	Mean (SD)	−1.9 (3.5)
	Median (IQR)	−2.0 (−5.0 to 0.0)
	(Min–max)	(−5.0 to 4.0)

Max, maximum; min, minimum.

Note
Total item score (0 = best adherence; 24 = worst adherence)

adherence to their rehabilitation activities and additional clinical activity to supervise and support patients completing the prescribed gait circuit. For participants, support materials are provided for patients to continue at home (*Table 12*).

Healthcare resource use

At baseline, 47 (88.7%) participants reported attendance at outpatient appointments during the previous 3 months. During the study, participants' self-reported appointments for RA largely involved hospital outpatient appointments, and appointments with either a general practitioner (GP) or practice nurse at the local surgery/community clinic (*Table 13*). Appointments with allied health professionals were less frequently observed, most commonly with physiotherapists and podiatrists at the hospital or community clinic. Some care-seeking behaviour might have been interrupted by lockdowns during the COVID-19 pandemic. Further details on all of the resource use and EuroQol-5 Dimensions data reported by participants are included in *Appendix 2*.

Health-related quality of life

Information for 53 participants was available at baseline: 27 in the 'gait rehabilitation plus usual care' and 26 in the 'usual care only' arm. Insufficient data (i.e. EQ-5D-5L not completed) excluded 16 participants (30%) at 6-month follow-up. Mean scores are reported in *Table 14*.

TABLE 8 Exercise Adherence Rating Scale item-level responses

Variable	Summary statistic	Gait rehabilitation (*N* = 27)
Attended Week 12 visit	*N* (%) Yes	22/27 (81.5%)
Completed questionnaire at Week 12 visit	*N* (%) Yes	20/27 (74.1%)
1. I do my exercises as often as recommended	*N* (%) 0 – completely agree	4 (20.0%)
	N (%) 1	5 (25.0%)
	N (%) 2	4 (20.0%)
	N (%) 3	6 (30.0%)
	N (%) 4 – completely disagree	1 (5.0%)
2. I forget to do my exercises	*N* (%) 0 – completely agree	1 (5.0%)
	N (%) 1	3 (15.0%)
	N (%) 2	3 (15.0%)
	N (%) 3	3 (15.0%)
	N (%) 4 – completely disagree	10 (50.0%)
3. I do less exercise than recommended by my healthcare professional	*N* (%) 0 – completely agree	3 (15.0%)
	N (%) 1	2 (10.0%)
	N (%) 2	3 (15.0%)
	N (%) 3	5 (25.0%)
	N (%) 4 – completely disagree	7 (35.0%)
4. I fit my exercises into my regular routine	*N* (%) 0 – completely agree	11 (55.0%)
	N (%) 1	1 (5.0%)
	N (%) 2	1 (5.0%)
	N (%) 3	6 (30.0%)
	N (%) 4 – completely disagree	1 (5.0%)
5. I do not get around to doing my exercises	*N* (%) 0 – completely agree	0 (0.0%)
	N (%) 1	1 (5.0%)
	N (%) 2	5 (25.0%)
	N (%) 3	4 (20.0%)
	N (%) 4 – completely disagree	10 (50.0%)
6. I do most, or all, of my exercises	*N* (%) 0 – completely agree	9 (45.0%)
	N (%) 1	3 (15.0%)
	N (%) 2	2 (10.0%)
	N (%) 3	6 (30.0%)
	N (%) 4 – completely disagree	0 (0.0%)

TABLE 9 Fidelity of delivery of core session components and MI proficiency

Session	Number of core components and BCTs to deliver per session	Number (%) of sampled sessions in which ≥ 80% core components and BCTs were delivered[a]	MI relational proficiency[b]	MI technical proficiency[b]
1	13	5/7 sessions (71%)	3.5 (meets recommended 'fair' proficiency)	3.2 (meets recommended 'fair' proficiency)
2	9	2/6 sessions (33%)	3.4 (does not meet recommended 'fair' proficiency of 3.5)	3.4 (meets recommend 'fair' proficiency)
3	5	1/3 sessions (33%)	3.8 (meets recommended 'fair' proficiency of 3.5)	3.7 (meets recommended fair proficiency)

a Assessed by bespoke checklist.
b Assessed using MI treatment integrity coding manual v4.2.1.[55]

Note
MI relational proficiency: 3.5 = fair, 4 = good; MI technical proficiency: 3 = fair, 4 = good.

TABLE 10 Theory of Planned Behaviour Questionnaire construct summary scores at 12 weeks

Variable	Summary statistic	Usual care (*N* = 26)	Gait rehabilitation (*N* = 27)
Attended Week 12 visit	*N* (%) Yes	20 (76.9%)	22 (81.5%)
Completed questionnaire at Week 12	*N* (%) Yes	16/26 (61.6%)	19/27 (70.4%)
Construct 1 score (range 0–18) at Week 12	Mean (SD)	12.2 (3.1)	13.4 (3.2)
	Median (IQR)	12.0 (10.0–15.0)	13.0 (12.0–15.5)
	(Min–max)	(6.0–17.0)	(6.0–18.0)
Construct 2 score (range 0–18)[a] at Week 12	Mean (SD)	14.1 (4.1)	14.8 (3.2)
	Median (IQR)	16.0 (10.0–18.0)	15.0 (11.5–18.0)
	(Min–max)	(8.0–18.0)	(9.0–18.0)
Construct 3 score (range 0–18) at Week 12	Mean (SD)	12.3 (3.7)	13.9 (3.5)
	Median (IQR)	12.0 (9.0–15.0)	15.0 (11.0–17.0)
	(Min–max)	(6.0–18.0)	(9.0–18.0)
Construct 4 score (range 0–18) at Week 12	Mean (SD)	13.5 (5.0)	16.4 (1.7)
	Median (IQR)	14.0 (10.8–18.0)	17.0 (15.5–18.0)
	(Min–max)	(0.0–18.0)	(12.0–18.0)

Max, maximum; min, minimum.
a For item 3 (construct 2), participants were asked to respond if the question was applicable: 12/16 (usual care) and 14/19 (gait rehabilitation) reported the question as applicable, the remaining 4/16 and 5/19 had a possible score of 0–12 for construct 2.

Note
Construct 1 = attitude towards behaviour (items 2, 5, 12); construct 2 = subjective norms (items 1, 3[a], 6); construct 3 = perceived behavioural control (items 8, 9, 11); construct 4 = intention (items 4, 7, 10).

Discussion/interpretation

Feasibility-phase principal findings

The feasibility phase of this project confirmed that the GREAT Strides gait rehabilitation intervention was viewed as acceptable by patients and therapists, with high intervention fidelity, good patient adherence and no safety concerns. All progression criteria were met as required in order to proceed to the internal pilot RCT phase. Important lessons were learnt from the feasibility phase, including the need for strategies to improve recruitment and retention due to a lower than anticipated pool of eligible participants.

TABLE 11 Item-level responses to the TPB Questionnaire

Variable	Summary statistic	Usual care (*n* = 26)	Gait rehabilitation (*N* = 27)
Attended Week 12 visit	*N* (%) Yes	20/26 (76.9%)	22/27 (81.5%)
Completed questionnaire at Week 12	*N* (%) Yes	16/26 (61.6%)	19/27 (70.4%)
Item 1: Most people who are important to me think that I should do the recommended exercises.	*N* (%) 1 – completely disagree	0 (0.0%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	0 (0.0%)	0 (0.0%)
	N (%) 4 – neither agree nor disagree	3 (18.8%)	0 (0.0%)
	N (%) 5	1 (6.2%)	1 (5.3%)
	N (%) 6	4 (25.0%)	5 (26.3%)
	N (%) 7 – completely agree	8 (50.0%)	13 (68.4%)
Item 2: For me to do the recommended exercises would be …	*N* (%) 1 – unpleasant	0 (0.0%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3 – somewhat unpleasant	1 (6.2%)	1 (5.3%)
	N (%) 4 – neither agree nor disagree	6 (37.5%)	4 (21.1%)
	N (%) 5 – somewhat pleasant	4 (25.0%)	7 (36.8%)
	N (%) 6	3 (18.8%)	3 (15.8%)
	N (%)–7 – pleasant	2 (12.5%)	4 (21.1%)
Item 3: My spouse/significant other approves of me doing the recommended walking exercise.[a]	*N* (%)–1 – completely disagree	0 (0.0%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	0 (0.0%)	0 (0.0%)
	N (%) 4 – neither agree nor disagree	2 (16.7%)	1 (7.1%)
	N (%) 5	0 (0.0%)	0 (0.0%)
	N (%) 6	2 (16.7%)	4 (28.6%)
	N (%) 7 – completely agree	8 (66.7%)	9 (64.3%)
Item 4: My goal is to do the recommended exercises.	*N* (%) 1 – completely disagree	1 (6.2%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	1 (6.2%)	0 (0.0%)
	N (%) 4 – neither agree nor disagree	3 (18.8%)	0 (0.0%)
	N (%) 5	2 (12.5%)	1 (5.3%)
	N (%) 6	3 (18.8%)	5 (26.3%)
	N (%) 7 – completely agree	6 (37.5%)	13 (68.4%)

TABLE 11 Item-level responses to the Theory of Planned Behaviour Questionnaire (*continued*)

Variable	Summary statistic	Usual care (*n* = 26)	Gait rehabilitation (*N* = 27)
Item 5: Doing the recommended exercises would be ...	*N* (%) 1 – enjoyable	2 (12.5%)	4 (21.1%)
	N (%) 2	4 (25.0%)	5 (26.3%)
	N (%) 3	2 (12.5%)	2 (10.5%)
	N (%) 4 – neither enjoyable nor unenjoyable	5 (31.2%)	4 (21.1%)
	N (%) 5	2 (12.5%)	1 (5.3%)
	N (%) 6	0 (0.0%)	2 (10.5%)
	N (%) 7 – unenjoyable	1 (6.2%)	1 (5.3%)
Item 6: My closest friend or family member (other than my spouse/significant other) approves of me doing the recommended exercises.	*N* (%) 1 – completely disagree	0 (0.0%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	0 (0.0%)	0 (0.0%)
	N (%) 4 – neither agree nor disagree	2 (12.5%)	3 (15.8%)
	N (%) 5	2 (12.5%)	0 (0.0%)
	N (%) 6	5 (31.2%)	8 (42.1%)
	N (%) 7 – completely agree	7 (43.8%)	8 (42.1%)
Item 7: I intend to do the recommended exercises.	*N* (%) 1 – completely disagree	1 (6.2%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	0 (0.0%)	0 (0.0%)
	N (%) 4 – neither agree nor disagree	3 (18.8%)	0 (0.0%)
	N (%) 5	4 (25.0%)	1 (5.3%)
	N (%) 6	1 (6.2%)	8 (42.1%)
	N (%) 7 – completely agree	7 (43.8%)	10 (52.6%)
Item 8: How much personal control do you believe you have over whether or not you do the recommended exercises?	*N* (%) 1 – complete control	6 (37.5%)	9 (47.4%)
	N (%) 2	2 (12.5%)	2 (10.5%)
	N (%) 3	2 (12.5%)	1 (5.3%)
	N (%) 4	1 (6.2%)	2 (10.5%)
	N (%) 5	5 (31.2%)	1 (5.3%)
	N (%) 6	0 (0.0%)	4 (21.1%)
	N (%) 7 – absolutely no control	0 (0.0%)	0 (0.0%)
Item 9: How much do you feel that whether you do the recommended exercises is beyond your control?	*N* (%) 1 – completely beyond my control	1 (6.2%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	1 (6.2%)	3 (15.8%)
	N (%) 4	3 (18.8%)	1 (5.3%)
	N (%) 5	3 (18.8%)	0 (0.0%)
	N (%) 6	3 (18.8%)	6 (31.6%)
	N (%) 7 – completely within my control	5 (31.2%)	9 (47.4%)

continued

TABLE 11 Item-level responses to the Theory of Planned Behaviour Questionnaire (*continued*)

Variable	Summary statistic	Usual care (*n* = 26)	Gait rehabilitation (*N* = 27)
Item 10: Do you plan to do the recommended exercises?	*N* (%) 1 – definitely not	1 (6.2%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	0 (0.0%)	0 (0.0%)
	N (%) 4	2 (12.5%)	0 (0.0%)
	N (%) 5	4 (25.0%)	3 (15.8%)
	N (%) 6	2 (12.5%)	7 (36.8%)
	N (%) 7 – definitely so	7 (43.8%)	9 (47.4%)
Item 11: How confident are you that you will be able to do the recommended exercises?	*N* (%) 1 – completely unsure	1 (6.2%)	0 (0.0%)
	N (%) 2	1 (6.2%)	0 (0.0%)
	N (%) 3	1 (6.2%)	1 (5.3%)
	N (%) 4	5 (31.2%)	1 (5.3%)
	N (%) 5	0 (0.0%)	4 (21.1%)
	N (%) 6	4 (25.0%)	8 (42.1%)
	N (%) 7 – completely sure	4 (25.0%)	5 (26.3%)
Item 12: For me to do the recommended exercises would be …	*N* (%) 1 – harmful	1 (6.2%)	0 (0.0%)
	N (%) 2	0 (0.0%)	0 (0.0%)
	N (%) 3	0 (0.0%)	1 (5.3%)
	N (%) 4 – neither harmful nor beneficial	2 (12.5%)	1 (5.3%)
	N (%) 5	2 (12.5%)	1 (5.3%)
	N (%) 6	6 (37.5%)	5 (26.3%)
	N (%) 7 – beneficial	5 (31.2%)	11 (57.9%)

a For item 3 (construct 2), participants were asked to respond if the question was applicable: 12/16 (usual care) and 14/19 (gait rehabilitation) reported the question as applicable.

Internal pilot randomised controlled trial process evaluation principal findings

The principal findings of the internal pilot RCT in relation to a priori specified progression criteria were that recruitment at 8 months was *n* = 39, 51% of target (*n* = 76 participants), and significantly lower than the minimum requirement for proposal of a rescue plan (*n* ≥ 60 participants). This ultimately was the primary reason for the early stopping of the RCT. After 12 months of recruitment (extended recruitment period while a request for a costed extension was being reviewed by the funder), 53 participants had been randomised, representing 70% of target. Retention at 3-month follow-up was 42/53 (79%) and was within the acceptable range (70–80%) for the proposal of a rescue plan in order to progress to the main RCT. Attrition rate at 3 months had improved from that observed in the feasibility study following the refinement of follow-up procedures where face-to-face contact was not required.

Secondary findings from the embedded process evaluation of the internal pilot RCT phase largely confirmed and corroborated positive findings concerning intervention acceptability from the feasibility study. However, the small sample size and poor precision of estimates necessitate some degree of caution with the interpretation of these findings. The embedded process evaluation was an important step following the refinement of intervention training procedures, adaptation of the intervention for online delivery and refinement of eligibility criteria. Intervention acceptability among participants and clinicians appeared to be largely excellent. Intervention adherence was good but marginally lower among participants in the internal pilot phase of the RCT

TABLE 12 Estimated costs of GREAT rehabilitation intervention

Item	Assumption for units used in calculations	Unit cost (per hour or item)	Time (hours)	Total cost (£, 2022 prices)
Preparation for delivery of GREAT ***intervention***				
Training facilities	Pre-COVID-19 pandemic, training was conducted in-person and involved two sessions face-to-face followed by two online sessions with additional training materials including pre-recorded video examples. All sessions were delivered online during the pandemic			Not costed
Time spent training the multidisciplinary team member to ensure fidelity to GREAT (senior trial researcher)	Online training involves one trainer for up to three clinicians. Based on 2 hours per training session for a AfC Band 8a equivalent	75.00	2.0	150.00
Clinical time backfilled (podiatrist specialist or physiotherapist specialist) for attendance at training in psychologically based MI	Based on 2 hours per training session for a AfC Band 6	54.00	2	108.00
Course materials – GREAT trainer manual, online video footage	Administration costs may be incurred			Not costed
Secure website for access to DVD content online	Future delivery models will require to consider resourcing			Not costed
Time of additional in-clinic activity				
First session (compulsory for intervention delivery), face-to-face	Conducted face-to-face (time taken 45–60 minutes). Based on 60 minutes for a AfC Band 6	54.00	1.0	54.00
Second session (compulsory for intervention delivery), face-to-face	Conducted face-to-face (time taken 30–45 minutes). Based on 45 minutes for a AfC Band 6	54.00	0.75	40.50
Optional further sessions (maximum four)	Conducted by telephone, although could be face-to-face (time taken 15–30 minutes). Based on 30 minutes for a AfC Band 6	54.00	0.5	27.00
Clinical space for delivery of GREAT session (which offers sufficient room and appropriate privacy)	Usual consulting rooms were adequate and used for GREAT sessions. Future trials will wish to consider potential displacement of other patient appointments			Not costed
Cost of support materials for set-up and completion of the gait circuit at home				
DVD	Educational material and step-by-step demonstrations of gait circuit home set-up and task completion			Not costed
Participant booklet	High-quality, illustrated educational 28-page booklet, printed and supplied in hard copy			Not costed
Trial-specific activity (unlikely to continue in practice)				
Adherence diary for participants	One page printed and supplied in hard copy, incorporated within patient booklet			Not costed

AfC, Agenda for Change; DVD, digital video disc.

Note
All costs in 2022 GBP prices.
Sources for unit costs: Personal Social Services Research Unit:[66] Table 12.3.1 physiotherapists, Table 12.3.4 chiropodists/podiatrists; trial records.

compared to those in the feasibility phase. Results on exercise treatment beliefs suggest that participants in the intervention arm were more amenable to changing their behaviours concerning exercise than those randomised to usual care. Albeit these findings require cautious interpretation due to collection of TPB Questionnaire data at a single discrete time point only. An interesting finding was that intervention fidelity was scored as 'fair', which was lower in the pilot RCT than the feasibility study. The main reason for this may be the online delivery of training,

TABLE 13 Hospital-based and community-based healthcare consultations for RA in the last 3 months, recorded at 3-and 6-month follow-up

Variable	Summary statistic	0–3 months (*n* = 39)	3–6 months (*N* = 39)
No appointments	*N* (%) Yes	5	10
Appointments			
Hospital outpatient appointment	*N* (%) Yes	24 (61.5%)	20 (51.3%)
Hospital outpatient appointment – number of times	Count (range)	46 (1–6)	31 (1–9)
GP appointment at the surgery	*N* (%) Yes	5 (12.8%)	9 (23.1%)
GP appointment at the surgery – number of times	Count (range)	10 (1–5)	16 (1–4)
Practice nurse appointment at the surgery	*N* (%) Yes	11 (28.2%)	8 (20.5%)
Practice nurse appointment at the surgery – number of times	Count (range)	30 (1–5)	13 (1–2)
Allied health professional appointments			
Podiatrist at the hospital	*N* (%) Yes	1 (2.6%)	4 (10.3%)
Podiatrist at the hospital – number of times	Count (range)	2 (1)	7 (1–4)
Podiatrist at the local community clinic	*N* (%) Yes	3 (7.7%)	2 (5.1%)
Podiatrist at the local community clinic – number of times	Count (range)	4 (1)	2 (1)
Physiotherapist at the hospital	*N* (%) Yes	6 (15.4%)	3 (7.7%)
Physiotherapist at the hospital – number of times	Count (range)	7 (1)	3 (1)
Physiotherapist at the local community clinic	*N* (%) Yes	4 (10.3%)	2 (5.1%)
Physiotherapist at the local community clinic – number of times	Count (range)	5 (1)	3 (1)
Occupational therapist at the hospital	*N* (%) Yes	3 (7.7%)	2 (5.1%)
Occupational therapist at the hospital – number of times	Count (range)	3 (1)	2 (1)
Orthotist at the local community clinic	*N* (%) Yes	1 (2.6%)	0 (0.0%)
Orthotist at the local community clinic – number of times	Count (range)	1 (1)	0

which became a necessity following the COVID-19 pandemic and removed some opportunities for in-person demonstrations, practice and provision of feedback in real time. Overall, the GREAT Strides intervention appears to be promising as a safe intervention which patients and clinicians find acceptable and perceive to be potentially effective.

Challenges: lessons to be learnt

The GREAT project experienced challenges that were largely beyond the control of the project team. Primarily, significant time delays were observed for obtaining local R&D approvals, securing of contracts, and organisation of local site personnel capacity and readiness for commencement of recruitment, both before (feasibility phase) and after (internal pilot) the COVID-19 pandemic. The initial delays with the commencement of the feasibility phase resulted in revised timelines and study drift of around 8 months in the period leading up to the internal pilot RCT phase. Subsequently, the catastrophic effect of the COVID-19 pandemic, which necessitated an official project pause (for 15 months), subsequent revision, and the restarting of intervention training, R&D approvals and site set-ups, significantly and negatively affected progress. This resulted in the need for a funded extension request due to additional time commitments beyond the funded period by essential members of the project team, and fixed-term research posts essential to the delivery of the project coming to an end. Ultimately, this request was rejected due to low recruitment rates and failure to meet the recruitment target progression criterion [39/76 participants (51%) by 8 months]. Similar delays have been highlighted in other multicentre trials and have similarly resulted in early discontinuation.[67,68]

TABLE 14 EuroQol-5 Dimensions, five-level score utilities[a] and self-reported health (EQ-VAS) of GREAT trial participants at baseline and at 6-month follow-up, including change in score between time points

		n (missing)	Mean	SD
All				
Utility	0 month	53 (0)	0.62	0.19
	6 months	37 (16)	0.66	0.24
	Change	37 (16)	0.04	0.19
Self-reported health	0 month	53 (0)	69.3	17.1
	6 months	37 (16)	67.8	17.4
	Change	37 (16)	−1.5	17.5
Gait rehabilitation				
Utility	0 month	27 (0)	0.59	0.21
	6 months	19 (6)	0.63	0.27
	Change	19 (6)	0.04	0.23
Self-reported health	0 month	27 (0)	69.3	17.2
	6 months	19 (6)	65.4	21.6
	Change	19 (6)	−4.5	20.2
Standard care				
Utility	0 month	26 (0)	0.66	0.17
	6 months	18 (8)	0.70	0.19
	Change	18 (8)	0.04	0.13
Self-reported health	0 month	26 (0)	69.3	17.3
	6 months	18 (8)	70.3	11.8
	Change	18 (8)	1.6	14.0

a Calculated using DSU EEPRU EQ-5D-5L calculator.[65]

The main impact of delays from the point of seeking R&D approval and commencement of recruitment at sites observed in this pilot RCT was an inefficient staggered recruitment approach where consecutive sites opened to recruitment slowly over a 10-month period. As a result, the time duration each site spent recruiting was suboptimal for achieving the desired recruitment target. Based upon the number of sites targeted (n = 9) to achieve the sample size of n = 76 and the specified recruitment period (8 months), in the first 8 months of the trial recruitment period, we were only at approximately one-third (37.5%) of the desired recruitment capacity for sites at the time of stopping (27 site recruitment months vs. a desired/optimum 72). Similarly, over the 12-month recruitment period prior to early stopping, we were only at approximately half (51.8%) of the desired recruitment capacity (56 site recruitment months vs. a desired/optimum 108).

There is often an urgency among researchers to commence recruitment as early as possible as a key milestone and marker of progress that can be reported back to the funder. However, the impact of starting the clock on recruitment at suboptimal capacity, as observed here, appeared to be the main reason for not meeting key progression criteria targets for recruitment. Conversely, a delay in the commencement of recruitment has a similar effect in terms of study drift in relation to timelines, with similar cost implications. However, the latter at least permits more robust indications of whether or not recruitment rates can be achieved when recruitment capacity is closer to optimal/full capacity. At present, the current model leaves projects vulnerable to external factors largely beyond their control. The key take-home messages are that care should be taken by researchers when specifying progression criteria targets for an internal pilot for progression to a main RCT. Specifically, we would

urge (1) more emphasis on participating sites' recruitment capacity, in terms of the number of sites open and ready to recruit before the anticipated start date for recruitment; (2) realistic timescales for project teams to set up a sufficient number of sites prior to recruitment commencing, in the context of lengthy delays observed from initiating R&D approval processes to FPFV; and (3) realistic funding for several project team members to simultaneously undertake and coordinate site set-up and liaison tasks. Similar suggestions have been made by the Clinical Trials Transformation Initiative concerning recruitment planning for trials research.[69]

In spite of the challenges experienced with site set-up, participant recruitment at the site level was lower than anticipated in both the feasibility study and the internal pilot trial. Refinement of eligibility criteria between the feasibility study and internal pilot trial did not appear to result in noticeable benefits to recruitment rates. However, attrition rates did appear to improve between the feasibility study and internal pilot, most likely due to the addition of remote follow-up options. Nevertheless, attrition rates of 79%, while in the acceptable range for progression to the main trial, would require additional attention and implementation of strategies to boost attrition rates for the main trial to > 80%. Of those screened for eligibility, < 25% of patients were eligible for inclusion, far fewer than originally anticipated during the project planning stage. The most common reasons cited for exclusion were patients with disease duration > 2 years (i.e. not early RA), no foot pain, and patients declining without giving a reason and/or having no interest in participation.

Recruitment of people with early RA within 2 years of diagnosis proved to be a significant challenge. People with early RA are generally managed in outpatient early arthritis clinics (predominantly RA) in the first year from diagnosis. Once medication, disease activity and symptoms stabilise, they typically transfer to general rheumatology outpatient clinics that are populated by patients with largely heterogeneous diagnoses. This resulted in increased time demands on limited resources in terms of site recruitment staff needing to have a presence in clinics running on different days of the week. Therefore, both finding and making initial contact with people with early RA were time consuming.

Anecdotally, local site personnel suggested many people with early RA were not ready to engage with research and/or an exercise and behaviour change intervention in the context of their recent life-changing diagnosis, current demands on their time from seeking care, and severity of ongoing symptoms. Indeed, similar barriers to enrolment in research have been identified previously in rheumatology patients.[70] A key question then is whether or not this trial should have been limited to people with early RA as specified in the commissioning brief. While earlier intervention with gait rehabilitation to prevent deteriorations in lower limb function is conceptually appealing, there is little evidence to suggest that the GREAT Strides intervention would not be potentially beneficial for people with a disease duration of RA > 2 years. Future trials involving exercise and/or BCTs may benefit from recruiting people with RA at early and later times from diagnosis.

In both the feasibility study and internal pilot RCT, foot pain seemed far less prevalent than has been previously reported in the literature. The best available evidence suggests that foot pain is an almost ubiquitous feature of RA, affecting approximately 90% of patients.[11,12,50] The reasons for the apparent lower prevalence of foot pain observed during this project are unclear. This provided a significant unforeseen challenge to the project team, such that the pool of potentially eligible participants was far smaller than anticipated. The results of this were twofold, including lower recruitment rates and signs of recruitment fatigue emerging relatively early, after approximately 6 months at each site. As such, robust estimates of the prevalence of characteristics under consideration for inclusion criteria should be subject to significant scrutiny at trial planning stages to avoid basing inclusion criteria upon inaccurate prevalence data reported in the literature.

Screening log completion was largely insufficient to draw specific meaningful conclusions about reasons for the apparent lack of interest among patients for participation in the feasibility study and pilot RCT. However, broadly similar findings have been observed in other studies involving behaviour change and exercise-based interventions[71] and may be explained at least partially by the traditional barriers to physical activity and exercise.[72] The ratio of patients screened to participants enrolled in our pilot RCT was significantly lower than the rates observed for drug trials in early RA.[73,74] This may be due in part to the passive nature of drug interventions being preferred by patients, and generally greater interest in and support/facilitation of such trials among local site rheumatologists and rheumatology nurse specialists.

Patient and public involvement

Patient and public involvement aims

In the pre-funding stage of the project, the primary aim of patient and public involvement (PPI) activity was to coproduce a new gait rehabilitation intervention with

people who had RA (including early RA). In the post-funding stage of the project, our PPI activity aims were: (1) evaluation of all patient-facing materials, including the participant information sheets and intervention support materials for all separate study phases; (2) evaluation of acceptability of the changes to the gait rehabilitation intervention following the feasibility study and prior to testing via the internal pilot; and (3) development of the dissemination strategy upon successful completion of the project.

Patient and public involvement methods

In the pre-funding phase of the project, 14 people with RA were invited by local charity organisations (Arthritis Care Scotland and the Glasgow branch of the National Rheumatoid Arthritis Society) to participate in an evening workshop facilitated by two clinical academics (one podiatrist and one physiotherapist). The facilitators delivered a presentation and practical demonstration of a variety of exercises designed to target lower limb function. Facilitated round-table discussion involved selection and ranking of preferred individual exercises and discussion of exercise programme format and delivery. The workshop was not audio recorded, but informal detailed field notes were recorded.

During the funded period of the project, two PPI representatives joined the project team. Prior to submission for regulatory approval, PPI representatives reviewed all patient-facing documentation being submitted for ethical approval for readability, comprehension and perception of burden/time to complete. Representatives read all documentation and provided written and verbal feedback to the project team (for both the feasibility and internal pilot phases).

Following the feasibility study, two PPI representatives were invited to review the main changes to the GREAT Strides intervention following refinement informed by the results of the feasibility study, and the main changes in proposed methodology between the original funding application and the protocol for the full main trial (including the internal pilot). Both representatives met with the project PPI lead (GJH) and research fellow (AP), who presented the main changes being proposed with justification from the feasibility study results. Representatives were then asked to comment on their perceptions of the acceptability of the proposed changes. Detailed field notes were recorded.

Patient and public involvement outcomes

Our patient representatives generally preferred walking-based tasks over static stretching/strengthening exercises, with additional preference for simple set-up which did not require any additional equipment (such as elastic resistance bands). There was a preference for home-based exercises in the early stages of RA post-diagnosis as opposed to the need for group classes on a face-to-face basis. The main outcome from the pre-funding phase PPI activities was a coproduced 'prototype' intervention that was ready for manualisation prior to initial evaluation via the feasibility study.

Patient representatives provided helpful feedback for the reduction of patient-facing documentation to a manageable level, which was initially considered lengthy, burdensome and time consuming to read and complete. For the feasibility phase, which involved the completion of three questionnaires that were candidate primary outcome measures, we omitted one lengthy questionnaire (TPB) to reduce participant burden, opting to include it in the internal pilot once the best primary outcome measure had been identified. Participant information sheets were revised in order to simplify wording and reduce the length and, therefore, time required to read.

Following intervention refinement informed by the feasibility study, patient representatives reviewed and approved changes to the intervention (training materials for therapists) and internal pilot study methods. Representatives recognised that these changes to the internal pilot trial protocol were largely designed to minimise participant burden and improve intervention adherence, recruitment and attrition rates.

Patient and public involvement discussion and conclusion

The PPI activities in this project successfully led to coproduction and refinement of the GREAT Strides gait rehabilitation intervention. Representatives' input has potentially maximised participants' largely positive perceptions of intervention acceptability and adherence across both feasibility and internal pilot phases. During the funded period of the project, PPI input was integral to reducing participant burden with contributions to strategies to maximise adherence and attrition rates during the internal pilot.

Equality, diversity and inclusion

Inclusion criteria for this study were maximally inclusive and based on both clinical characteristics (early RA, foot pain) and ability and willingness to participate. However, given the dialogue-based nature of the MI component of the GREAT Strides intervention, participants who

were unable to speak English were not able to take part. The project team considered the use of interpreters for non-English-speaking populations who were otherwise eligible to participate. However, several obstacles to MI treatment fidelity such as a loss of control and spontaneity in interviews, misunderstandings and a lack of trust between the parties necessary for effective communication have been previously reported with the use of interpreters in this context.[75,76] The use of translators for the intervention arm would have provided additional training considerations for intervention therapists and cost and coordination implications. While these issues were not addressed in our project, we see no reason why they could not be explored in a future feasibility study with sufficient planning and appropriate funding. However, at present, there is uncertainty concerning the fidelity of the GREAT Strides intervention for those who do not speak English. There did not appear to be any intervention accessibility barriers, nor barriers to participation among any participants, including non-white minority ethnic groups who were able to speak English.

We enrolled 53 participants in the GREAT internal pilot trial from 9 rheumatology centres in Scotland (North East, Central, South West) and England (Central, South, South East), representing a wide geographical diversity of rheumatology units. A total of 23% of participants were from non-white ethnic groups, while 77% were from white ethnic groups. From the UK Biobank data on RA between 2006 and 2010 (n > 500,000), 96% of people with RA were from a white ethnic background,[77] suggesting that the participants recruited were broadly representative of the wider RA population. However, a recently published review has identified that trials of exercise-based interventions commonly exclude potential participants based on at least one equity factor such as place of residence, personal characteristics (e.g. age), language, sex, social capital, time-dependent factors or features of relationship factors, without sufficient justification.[78] While our eligibility criteria were maximally inclusive, the intervention was not suitable for those unable to speak English. Two-thirds of the sample were female, as expected. There was insufficient data to explore the effects of the intervention in specific subgroups.

Following feedback from local site personnel based in pilot trial sites in London, it became apparent that eligible participants who had provided indications of willingness to participate, and who were largely from non-white ethnic groups, were not returning signed consent forms via post following initial contact about the study via telephone. Subsequently, an option for remote consent has been added to the protocol in an attempt to facilitate recruitment in context of fewer face-to-face clinic appointments (due to COVID-19). Every attempt was made to minimise participant burden including adaptation of the GREAT Strides intervention and follow-up procedures to allow for remote intervention delivery [preferred method of contact including telephone and videoconference call via Zoom (Zoom Video Communications, San Jose, CA, USA) or Microsoft Teams (Microsoft Corporation, Redmond, WA, USA)]. Similar amendments have resulted in improved recruitment and retention rates in other trials.[79]

Impact and learning

This project has resulted in the first manualised gait rehabilitation intervention incorporating BCTs for people with early RA, which is safe, appears to have adequate fidelity when training and intervention sessions are delivered face-to-face (such as in the feasibility study), has high patient and clinician acceptability, and exhibits good adherence and perceptions of efficacy. The training programme content, clinician intervention manual and all support materials, including website content, digital video disc (DVD) content and illustrated patient booklet, are available upon request to any bona fide researchers or clinical services who are interested in undertaking further evaluations of the intervention in the future. Given the excellent intervention acceptability and positive findings concerning levels of adherence, it is clear that the GREAT Strides intervention has significant promise and is worthy of further comparative effectiveness research evaluation, not just for an early RA population, but potentially for those with more established RA and indeed other inflammatory/degenerative joint diseases, such as psoriatic arthritis, osteoarthritis and spondyloarthritis. We recommend further fidelity assessment with the use of translators for non-native speakers and/or training of bilingual therapists from underserved communities, as well as cross-cultural adaptation evaluations of GREAT Strides to maximise accessibility. The primary reasons for the early stopping of the trial were largely driven by delays with regulatory approvals, local site set-up driven by local clinical research infrastructure and resources, a lower than expected number of potential participants and the impact of the COVID-19 pandemic, and not by issues related to the feasibility of the GREAT Strides intervention. Given the current problems with UK clinical research, and in light of the problems experienced in this project, further investigations/evaluations within the UK are not likely to fundable. However, GREAT Strides could have a future as a mainstream intervention with adaptation for evaluation and/or use in other countries.

Given the early stopping of the trial, it is difficult to predict longer-term future impact. However, with excellent acceptability characteristics, GREAT Strides requires evaluation via a full main trial to determine whether it would be an effective addition to usual care within rheumatology multidisciplinary teams. Confirmation of effectiveness and subsequent updates could provide new training opportunities for physiotherapists and podiatrists, and further referral options for rheumatology consultants and new adjunct care pathways for people with inflammatory joint disease. The potential impact of this research will depend upon whether or not there is further evaluation and uptake of the GREAT Strides intervention in other countries. There remains a significant unmet need for therapeutic intervention in order to improve, maintain and/or prevent the deterioration of walking abilities of people with RA and other inflammatory joint diseases.

The main learning from this project is concerned with the planning and efficiency of seeking regulatory approvals and local site set-up for recruitment in the NHS. Robust estimates are required for the prevalence of key patient characteristics that influence eligibility for inclusion. These estimates should not be limited to those cited in the literature but should be informed through liaison with clinical personnel and, where possible, analysis of existing data sources. Moreover, liaison with clinical personnel should include key operational considerations of fitting of the sampling frame, patient identification and recruitment methods, and any potential barriers to efficient recruitment.

Considerable time and resources should be allocated by research teams to allow for significant delays in regulatory approvals and local site set-up. The delays experienced in this project necessitated formal requests for time and funding extensions. A revised approach to costing future grant applications may be prudent where project team staff costs are forecasted and reduced accordingly for anticipated periods of relative quiescence during lengthy waiting times for approvals and local site agreements to be signed. During such periods, staff costs for specific members of the team who are involved in local site liaison and set-up should be increased to allow for simultaneous site set-up to facilitate readiness to recruit at a sufficient number of sites converging on a common start date for recruitment. Greater emphasis should be directed towards collective sites' readiness to recruit, in order to ensure sufficient capacity to meet recruitment targets within an adequate duration.

Rheumatoid arthritis is a relatively uncommon non-communicable disease. The commissioning brief for this project specifically required an early disease focus with disease affecting the foot and/or ankle. Several difficulties were encountered at the point of initial contact with people with early RA who were still coming to terms with their life-changing diagnosis, in moderate–high disease activity states, attending frequent clinical appointments, and on new and sometimes unstable medications that were causing unpleasant side effects. As such, while conceptually appealing from a prevention of functional decline perspective, it was not clear whether the early disease stage (< 2 years post diagnosis) was the optimum time for recruitment of patients to a trial of an intervention with no known benefit. This was largely reflected in low conversion rates from eligibility screening to enrolment.

Implications for decision-makers

We are unable to make any recommendations for future practice in this area because of a lack of trial results concerning the clinical and cost-effectiveness of the GREAT Strides intervention. The positive results concerning intervention acceptability, fidelity (when training and intervention sessions are delivered face-to-face), safety and adherence are encouraging but only warrant further investigation of the intervention in a definitive trial before recommendations can be provided concerning future uptake for delivery in NHS clinical practice.

The delays in site set-up resulted in a suboptimal recruitment effort that did not achieve full recruitment capacity at any point throughout the pilot trial recruitment period. Nevertheless, the pool of eligible participants and enrolment rates following eligibility screening was significantly lower than originally estimated. A future trial would benefit from consideration of broader inclusion criteria, longer time period for site set-up and recruitment and an increased number of clinical sites.

Walking disability is common throughout the RA disease course and while early intervention is conceptually appealing and feasible, the early RA inclusion criterion dictated by the commissioning brief was restrictive and provided significant recruitment challenges. Many people with different inflammatory joint diseases and at different (non-early) disease stages experience lower limb pain and walking disability and could feasibly and potentially be relevant participants in a future trial of the GREAT Strides gait rehabilitation intervention.

This synopsis should be referenced as follows:
Hendry GJ, Bearne L, Fenocchi L, Foster NE, Gates S, Godfrey E, *et al.* Gait Rehabilitation for Early rheumatoid Arthritis Trial (GREAT): lessons learnt from a mixed-methods feasibility study and internal pilot trial [published online ahead of print March 26 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/XBDJ8546

Research recommendations

We have identified the following questions for future research:

1. Cross-cultural adaptability

Can GREAT Strides be adapted for use with minority ethnic groups to enhance its effectiveness within specific populations with inflammatory joint diseases?

2. Intervention fidelity for non-native language speakers using an interpreter

Can GREAT Strides be delivered as intended with use of an interpreter where the patient is a non-native language speaker with an inflammatory joint disease?

3. Clinical and cost-effectiveness

Is GREAT Strides clinically and cost-effective for maintenance and/or improvement of lower limb function in people with inflammatory joint diseases?

Conclusions

The GREAT Strides intervention was acceptable to people with early RA and intervention clinicians (podiatrists and physiotherapists), safe, with good levels of adherence by participants, and fair intervention fidelity by clinicians. The RCT stopped early following a failure to meet recruitment targets for progression to the main RCT during the internal pilot phase. The project was hampered by delays in site set-up and contracting and by the impact of the COVID-19 pandemic. GREAT Strides is a promising intervention that could be adapted for future evaluations involving people with established RA and other inflammatory joint diseases beyond the UK. A definitive trial of the GREAT Strides gait rehabilitation intervention still needs to be conducted.

Additional information

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review.

Ethics statement

Ethical approval for the feasibility study was granted by the West of Scotland Research Ethics Committee 3 (17/WS/0264) in January 2017.

Ethical approval for the main trial and internal pilot was granted by the West of Scotland Research Ethics Committee 5 (19/WS/0189) in December 2019.

Information governance statement

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Disclosure of interests

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Catherine Sackley has served on the board of the HS&DR from January 2012 to March 2017.

Martijn PM Steultjens currently serves as Vice-Chair of the Board of Trustees for versus Arthritis. Martijn PM Steultjens has served as a member of the Data Monitoring Committee for NIHR HTA-funded project PROP-OA.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Publications

Hendry GJ, Bearne L, Foster N, Godfrey E, Hider S, Jolly L, *et al*. Gait rehabilitation for foot and ankle impairments in early rheumatoid arthritis: a feasibility study of a new gait rehabilitation programme (GREAT Strides). *Pilot Feasibility Stud* 2022;**8**:115.

Conference papers

Hendry GJ, Bearne L, Foster N, Godfrey E, Hider S, van der Leeden M, *et al*. A mixed methods feasibility study of a gait rehabilitation programme for people with early rheumatoid arthritis and foot pain. *Rheumatology* 2020;**59**:keaa111.120.

Hendry GJ, Bearne L, Foster N, Godfrey E, Hider S, Leeden MV, *et al*. Feasibility of a new gait rehabilitation programme for people with early RA. *Scott Med J* 2022;**67**.

Sekhon M, Godfrey E, Hendry G, Foster NE, Hider S, van der Leeden M, *et al*. Therapists acceptability of delivering a psychologically informed gait rehabilitation intervention in early rheumatoid arthritis (GREAT): a qualitative interview study. *Rheumatology* 2020;**59**:keaa111.103.

Sekhon M, Godfrey E, Hendry G, Foster NE, Hider S, van der Leeden M, *et al*. Treatment fidelity in the Gait Rehabilitation in Early Rheumatoid Arthritis Trial (GREAT) feasibility study. *Rheumatology* 2020;**59**:keaa111.216.

Sekhon M, Godfrey E, Amirova A, Hendry G, Foster N, Hider S, *et al*. *Applying a Theoretical Framework to Assess the Acceptability of Therapist Training and Delivery of the Gait Rehabilitation in Early Rheumatoid Arthritis Trial intervention (*GREAT *Strides): A Qualitative Analysis*. Interdisciplinary behavioural medicine: systems, networks & interventions 16th International Congress of Behavioural Medicine (ICBM), 07–11 June 2021.

Sekhon M, Godfrey E, Amirova A, Hendry G, Foster N, Hider SH, *et al*. Acceptability of therapist training and delivery of a psychological informed gait rehabilitation intervention for people with early rheumatoid arthritis. *Physiotherapy* 2022;**114**:E120–1.

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List of supplementary material

Report Supplementary Material 1
GREAT patient manual

Report Supplementary Material 2
GREAT research clinician manual

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/XBDJ8546).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

10MWT	10-minute walk test
AFC	Agenda for Change
BCTS	behaviour change techniques
BMI	body mass index
COVID-19	coronavirus disease 2019
DAS28	disease activity score 28
DMARD	disease-modifying antirheumatic drugs
DVD	digital video disc
EARS	Exercise Adherence Rating Scale
EEPRU DSU	Economic Methods of Evaluation in Health and Care Interventions Decision Support Unit
EQ-5D-5L	EuroQol-5 Dimensions, five-level score
EQ-VAS	EuroQol visual analogue scale
FFI	Foot Function Index
FPFV	first patient first visit
GP	general practitioner
GREAT	Gait Rehabilitation Early Arthritis Trial
HRA	Health Research Authority
HTA	Health Technology Assessment
IAQ	intervention acceptability questionnaire
ISRCTN	International Standard Randomised Controlled Trial Number
MI	motivational interviewing
MITI	Motivational Interviewing Treatment Integrity Scale
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
PPI	patient and public involvement
RA	rheumatoid arthritis
RADAI-F5	Rheumatoid Arthritis Foot Disease Activity Index-5
RCT	randomised controlled trial
R&D	research and development
ROADLES	Recent Onset Arthritis Disability lower extremity subscale
RUQ	resource use questionnaire

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TFA	theoretical framework of acceptability
TPB	Theory of Planned Behaviour

References

1. Mehrholz J, Kugler J, Storch A, Pohl M, Hirsch K, Elsner B. Treadmill training for patients with Parkinson's disease. *Cochrane Database Syst Rev* 2015;**8**:CD007830.
2. Mehrholz J, Pohl M, Elsner B. Treadmill training and body weight support for walking after stroke. *Cochrane Database Syst Rev* 2014;**1**:CD002840. https://doi.org/10.1002/14651858.CD002840.pub3
3. Mehrholz J, Thomas S, Werner C, Kugler J, Pohl M, Elsner B. Electromechanical-assisted training for walking after stroke. *Cochrane Database Syst Rev* 2013;**7**:CD006185. https://doi.org/10.1002/14651858.CD006185.pub3
4. Mehrholz J, Kugler J, Pohl M. Locomotor training for walking after spinal cord injury. *Cochrane Database Syst Rev* 2012;**11**:CD006676.
5. Mehrholz J, Friis R, Kugler J, Twork S, Storch A, Pohl M. Treadmill training for patients with Parkinson's disease. *Cochrane Database Syst Rev* 2010;**8**:CD007830.
6. da Silva KNG, de Paiva Teixeira LEP, Imoto AM, Atallah AN, Peccin MS, Trevisani VFM. Effectiveness of sensorimotor training in patients with rheumatoid arthritis: a randomized controlled trial. *Rheumatol Int* 2012;**33**:2269–75.
7. Williams SB, Brand CA, Hill KD, Hunt SB, Moran H. Feasibility and outcomes of a homebased exercise program on improving balance and gait stability in women with lower-limb osteoarthritis or rheumatoid arthritis: a pilot study. *Arch Phys Med Rehabil* 2010;**91**:106–14.
8. National Institute for Health and Care Excellence. *Rheumatoid Arthritis in Adults: Management*. 2018. URL: www.nice.org.uk/guidance/ng100/chapter/recommendations (accessed September 2024).
9. SIGN. *Management of Early Rheumatoid Arthritis*. 2011. URL:www.sign.ac.uk/our-guidelines/management-of-early-rheumatoid-arthritis/ (accessed September 2024).
10. National Audit Office. *Services for People with Rheumatoid Arthritis*. Report by the comptroller and auditor general. 2009. URL: www.nao.org.uk/reports/services-for-people-with-rheumatoid-arthritis/#downloads (accessed 26 February 2025).
11. Grondal L, Tengstrand B, Nordmark B, Wretenberg P, Stark A. The foot: still the most important reason for walking incapacity in rheumatoid arthritis: distribution of symptomatic joints in 1000 RA patients. *Acta Orthop* 2008;**79**:257–61.
12. Michelson J, Easley M, Wigley FM, Hellma D. Foot and ankle problems in rheumatoid arthritis. *Foot Ankle Int* 1994;**15**:608–13.
13. van der Leeden M, Steultjens MP, Ursum J, Dahmen R, Roorda LD, Schaardenburg DV, Dekker J. Prevalence and course of forefoot impairments and walking disability in the first eight years of rheumatoid arthritis. *Arthritis Rheum* 2008;**59**:1596–602.
14. van der Leeden M, Dahmen R, Ursum J, Roorda LD, van Schaardenburg D, Knol DL, *et al*. Prediction of walking disability by disease-related factors in patients with rheumatoid arthritis. *J Rehabil Med* 2010;**42**:506–10.
15. Woodburn J, Hennessy K, Steultjens MPM, McInnes IB, Turner DE. Looking through the 'window of opportunity': is there a new paradigm of podiatry care on the horizon in early rheumatoid arthritis? *J Foot Ankle Res* 2010;**3**:8.
16. Carrol M, Parmar P, Dalbeth N, Boocock M, Rome K. Gait characteristics associated with the foot and ankle in inflammatory arthritis: a systematic review and meta-analysis. *BMC Musculoskelet Disord* 2015;**16**:134.
17. Baan H, Dubbeldam R, Nene AV, van de Laar MA. Gait analysis of the lower limb in patients with rheumatoid arthritis: a systematic review. *Semin Arthritis Rheum* 2012;**41**:768–88.e8.
18. Weiss RJ, Wretenberg P, Stark A, Palmblad K, Larsson P, Grondal L, Brostrom E. Gait pattern in rheumatoid arthritis. *Gait Posture* 2008;**28**:229–34.
19. Paul L, Rafferty D, Marshall-McKenna R, Gill JMR, McInnes I, Porter D, Woodburn J. Oxygen cost of walking, physical activity and sedentary behaviours in rheumatoid arthritis. *Scand J Rheumatol* 2014;**43**:28–34.
20. Piva SR, Almeida GJM, Wasko MCM. Association of physical function and physical activity in women with rheumatoid arthritis. *Arthritis Care Res* 2010;**62**:1144–51.
21. Lemmey AB, Marcora SM, Chester K, Wilson S, Casanova F, Maddison PJ. Effects of high intensity resistance training in patients with rheumatoid arthritis: a randomized controlled trial. *Arthritis Rheum* 2009;**61**:1726–34.
22. Tourinho TF, Capp E, Brenol JC, Stein A. Physical activity prevents bone loss in premenopausal women with rheumatoid arthritis: a cohort study. *Rheumatol Int* 2008;**28**:1001–7.
23. Metsios GS, Stavropoulos-Kalinoglou A, Panoulas VF, Wilson M, Nevill AM, Koutedakis Y, Kitas GD. Association of physical inactivity with increased cardiovascular risk in patients with rheumatoid arthritis. *Eur J Cardiovasc Prev Rehabil* 2009;**16**:188–94.

24. Turesson C, Matteson EL. Cardiovascular risk factors, fitness and physical activity in rheumatic diseases. *Curr Opin Rheumatol* 2007;**19**:190–6.

25. Sattar N, McInnes IB. Vascular comorbidity in rheumatoid arthritis: potential mechanisms and solutions. *Curr Opin Rheumatol* 2005;**17**:286–92.

26. Veldhuijzen van Zanten JJ, Rouse PC, Hale ED, Ntoumanis N, Metsios GS, Duda JL, Kitas GD. Perceived barriers, facilitators and benefits for regular physical activity and exercise in patients with rheumatoid arthritis: a review of the literature. *Sports Med* 2015;**45**:1401–12.

27. Nordgren B, Friden C, Demmelmaier I, Opava CH. Who makes it to the base? Selection procedure for a physical activity trial targeting people with rheumatoid arthritis. *Arthritis Care Res* 2014;**66**:662–70.

28. Brenton-Rule A, D'Almeida S, Bassett S, Carroll M, Dalbeth N, Rome K. The effects of sandals on postural stability in patients with rheumatoid arthritis: an exploratory study. *Clin Biomech* 2014;**29**:350–3.

29. Turner DE, Helliwell PS, Emery P, Woodburn J. The impact of rheumatoid arthritis on foot function in the early stages of disease: a clinical case series. *BMC Musculoskelet Disord* 2006;**7**:102.

30. Vervloesem N, Van Gils N, Ovaere L, Westhovens R, Van Assche D. Are personal characteristics associated with exercise participation in patients with rheumatoid arthritis? A cross-sectional explorative survey. *Musculoskelet Care* 2012;**10**:90–100.

31. Crowley L, Kennedy N. Barriers to exercise in rheumatoid arthritis – a focus group study. *Physiother Pract Res* 2009;**30**:27–33.

32. Wilcox S, Der AC, Abbott J, Vrazel J, Ramsey C, Sharpe PA, Brady T. Perceived exercise barriers, enablers, and benefits among exercising and non exercising adults with arthritis: results from a qualitative study. *Arthritis Rheum* 2006;**55**:616–27.

33. Bearne LM, Scott DL, Hurley MV. Exercise can reverse quadriceps sensorimotor dysfunction that is associated with rheumatoid arthritis without exacerbating disease activity. *Rheumatology* 2002;**41**:157–66.

34. Hakkinen A, Sokka T, Kotaniemi A, Hannonen P. A randomized two-year study of the effects of dynamic strength training on muscle strength, disease activity, functional capacity, and bone mineral density in early rheumatoid arthritis. *Arthritis Rheum* 2001;**44**:515–22.

35. Wilkinson TJ, Lemmey AB, Jones JG, Sheikh F, Ahmad YA, Chitale S, *et al*. Can creatine supplementation improve body composition and objective physical function in rheumatoid arthritis patients? A randomised controlled trial. *Arthritis Care Res* 2016;**68**:729–37.

36. Challal S, Minichiello E, Boissier MC, Semerano L. Cachexia and adiposity in rheumatoid arthritis. Relevance for disease management and clinical outcomes. *Joint Bone Spine* 2016;**83**:127–33.

37. Lusa AL, Amigues I, Kramer HR, Dam TT, Giles JT. Indicators of walking speed in rheumatoid arthritis: relative influence of articular, psychosocial, and body composition characteristics. *Arthritis Care Res* 2015;**67**:21–31.

38. Kramer HR, Fontaine KR, Bathon JM, Giles JT. Muscle density in rheumatoid arthritis: associations with disease features and functional outcomes. *Arthritis Rheum* 2012;**64**:2438–50.

39. Giles JT, Bartlett SJ, Fontaine KR, Bathon JM. Association of body composition with disability in rheumatoid arthritis: impact of appendicular fat and lean tissue mass. *Arthritis Rheum* 2008;**59**:1407–15.

40. Marcora SM, Chester KR, Mittal G, Lemmey AB, Maddison PJ. Randomized phase 2 trial of anti-tumor necrosis factor therapy for cachexia in patients with early rheumatoid arthritis. *Am J Clin Nutr* 2006;**84**:1463–72.

41. Rome K, Dixon J, Gray M, Woodley R. Evaluation of static and dynamic postural stability in established rheumatoid arthritis: exploratory study. *Clin Biomech* 2009;**24**:524–6.

42. Morpeth T, Brenton-Rule A, Carroll M, Frecklington M, Rome K. Fear of falling and foot pain, impairment and disability in rheumatoid arthritis: a case-control study. *Clin Rheumatol* 2015;**35**:887–91. https://doi.org/10.1007/s10067-015-3124-6

43. Stanmore EK, Oldham J, Skelton DA, O'Neill T, Pilling M, Campbell AJ, Todd C. Risk factors for falls in adults with rheumatoid arthritis: a prospective study. *Arthritis Care Res* 2013;**65**:1251–8.

44. Hayashibara M, Hagino H, Katagiri T, Okano T, Okada J, Teshima R. Incidence and risk factors of falling in ambulatory patients with rheumatoid arthritis: a prospective 1-year study. *Osteoporos Int* 2010;**21**:1825–33.

45. Smolen JS, Landewe R, Breeveld FC, Dougados M, Emery P, Gaujoux-Viala C, *et al*. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. *Ann Rheum Dis* 2010;**69**:964–75.

46. McInnes I, O'Dell JR. State-of-the-art: rheumatoid arthritis. *Ann Rheum Dis* 2010;**69**:1898–906.

47. Smolen JS, Landewé RBM, Bergstra SA, Kerschbaumer A, Sepriano A, Aletaha D, *et al*. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying

antirheumatic drugs: 2022 update. *Ann Rheum Dis* 2023;**82**:3–18.

48. Broström EW, Esbjörnsson AC, von Heideken J, Larsson P, Wretenberg P, Iversen M. Change in gait deviation index after anti-tumour necrosis factor-α treatment in individuals with rheumatoid arthritis: a pilot study. *Scand J Rheumatol* 2013;**42**:356–61.
49. Hamilton J, Brydson G, Fraser S, Grant M. Walking ability as a measure of treatment effect in early rheumatoid arthritis. *Clin Rehabil* 2001;**15**:142–7.
50. Otter SJ, Lucas K, Springett K, Moore A, Davies K, Young A, Walker-Bone K. Comparison of foot pain and foot care among rheumatoid arthritis patients taking and not taking anti- TNFα therapy: an epidemiological study. *Rheumatol Int* 2010;**31**:1515–9.
51. Hendry GJ, Bearne L, Foster N, Godfrey E, Hider S, Jolly L, *et al*. Gait rehabilitation for foot and ankle impairments in early rheumatoid arthritis: a feasibility study of a new gait rehabilitation programme (GREAT Strides). *Pilot Feasibility Stud* 2022;**8**:115.
52. GREAT. *Trial Protocol*. 2024. URL: https://researchonline.gcu.ac.uk/ws/portalfiles/portal/82481410/GREAT_PilotMain_protocol_V5.0_15th_Jun_23-_clean.pdf (accessed September 2024).
53. Foster NE, Thomas E, Barlas P, Hill JC, Young J, Mason E, Hay EM. Acupuncture as an adjunct to exercise based physiotherapy for osteoarthritis of the knee: randomised controlled trial. *BMJ* 2007;**335**:436.
54. Newman-Beinart NA, Norton S, Dowling D, Gavriloff D, Vari C, Weinman JA, Godfrey EL. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the exercise adherence rating scale (EARS). *Physiotherapy* 2017;**103**:180–5.
55. Moyers TB, Martin T, Manuel JK, Hendrickson SML, Miller WR. Assessing competence in the use of motivational interviewing. *J Subst Abuse Treat* 2005;**28**:19–26.
56. Budiman-Mak E, Conrad KJ, Roach KE. The foot function index: a measure of foot pain and disability. *J Clin Epidemiol* 1991;**44**:561–70.
57. Hays RD, Spritzer KL, Fries JF, Krishnan E. Responsiveness and minimally important difference for the Patient-Reported Outcomes Measurement and Information System (PROMIS®) 20-item physical functioning short form in a prospective observational study of rheumatoid arthritis. *Ann Rheum Dis* 2015;**74**:104–7.
58. Salaffi F, Stancati A, Neri R, Grassi W, Bombardieri S. Measuring functional disability in early rheumatoid arthritis: the validity, reliability and responsiveness of the Recent-Onset Arthritis Disability (ROAD) index. *Clin Exp Rheumatol* 2005;**23**:S31–42.
59. Aletaha D, Neogi T, Silman AJ, Funovits J, Felson DT, Bingham CO, *et al*. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum* 2010;**62**:2569–81.
60. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;**17**:88.
61. Sekhon M, Cartwright M, Francis JJ. Acceptability of health care interventions: a theoretical framework and proposed research agenda. *Br J Health Psychol* 2018;**23**:519–31.
62. Sekhon M, Cartwright M, Francis JJ. Development of a theory-informed questionnaire to assess the acceptability of healthcare interventions. *BMC Health Serv Res* 2022;**22**:279.
63. Ajzen I. *Constructing a Theory of Planned Behaviour Questionnaire: Conceptual and Methodological Considerations*. 2006. URL: http://people.umass.edu/aizen/pdf/tpb.measurement.pdf (accessed February 2024).
64. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;**6**:42. https://doi.org/10.1186/1748-5908-6-42
65. Hernández Alava M, Pudney S, Wailoo A. Estimating the relationship between EQ-5D-5L and EQ-5D-3L: results from a UK population study. *PharmacoEconomics* 2023;**41**:199–207. https://doi.org/10.1007/s40273-022-01218-7
66. Jones KC, Weatherly H, Birch S, Castelli A, Chalkley M, Dargan A, *et al*. *Unit Costs of Health and Social Care 2022 Manual*. Technical report. Personal Social Services Research Unit (University of Kent) & Centre for Health Economics (University of York), Kent, UK; 2023. https://doi.org/10.22024/UniKent/01.02.100519
67. Williams NH, Jenkins A, Goulden N, Hoare Z, Hughes DA, Wood E, *et al*. Lessons learnt from a discontinued randomised controlled trial: adalimumab injection compared with placebo for patients receiving physiotherapy treatment for sciatica (Subcutaneous Injection of Adalimumab Trial compared with Control: SCIATiC). *Trials* 2018;**19**:408. https://doi.org/10.1186/s13063-018-2801-6
68. Carlisle B, Kimmelman J, Ramsay T, MacKinnon N. Unsuccessful trial accrual and human subjects

protections: an empirical analysis of recently closed trials. *Clin Trials* 2015;**12**:77–83. https://doi.org/10.1177/1740774514558307

69. Huang GD, Bull J, Johnston McKee K, Mahon E, Harper B, Roberts JN; CTTI Recruitment Project Team. CTTI Recruitment Project Team. Clinical trials recruitment planning: a proposed framework from the Clinical Trials Transformation Initiative. *Contemp Clin Trials* 2018;**66**:74–9. https://doi.org/10.1016/j.cct.2018.01.003
70. Sandhu VK, Duro T, Kamboj A, Salto L, Chiruvolu N. Barriers to enrolment in rheumatology research: who, what, where, when, and why? *Cureus* 2022;**14**:e2. https://doi.org/10.7759/cureus.27235
71. Garner S, Fenton T, Martin L, Creaser C, Johns C, Barnabe C. Personalized diet and exercise recommendations in early rheumatoid arthritis: a feasibility trial. *Musculoskeletal Care* 2018;**16**:167–72.
72. Bell K, Conde M, Hendry G, Rafferty D, Steultjens M. Barriers and facilitators to physical activity in people with an inflammatory joint disease: a mixed methods study. *BMC Musculoskelet Disord* 2022;**23**:897. https://doi.org/10.1186/s12891-022-05847-z
73. van Vollenhoven R, Takeuchi T, Pangan AL, Friedman A, Mohamed MF, Chen S, *et al*. Efficacy and safety of upadacitinib monotherapy in methotrexate-naive patients with moderately-to-severely active rheumatoid arthritis (SELECT-EARLY): a multicenter, multi-country, randomized, double-blind, active comparator-controlled trial. *Arthritis Rheumatol* 2020;**72**:1607–20. https://doi.org/10.1002/art.41384
74. Hetland ML, Haavardsholm EA, Rudin A, Nordstram D, Nurmohamed M, Gudbjornsson B, *et al*. Active conventional treatment and three different biological treatments in early rheumatoid arthritis: phase IV investigator initiated, randomised, observer blinded clinical trial. *BMJ* 2020;**371**:m4328. https://doi.org/10.1136/bmj.m4328
75. Plumridge G, Redwood S, Greenfield S, Akhter N, Chowdhury R, Khalade A, Gill P. Involving interpreters in research studies. *J Health Serv Res Policy* 2012;**17**:190–2.
76. Williams A, Manias E, Cross W, Crawford K. Motivational interviewing to explore culturally and linguistically diverse people's comorbidity medication self-efficacy. *J Clin Nurs* 2015;**24**:1269–79.
77. Siebert S, Lyall DM, Mackay DF, Porter D, McInnes IB, Sattar N, Pell JP. Characteristics of rheumatoid arthritis and its association with major comorbid conditions: cross-sectional study of 502 649 UK Biobank participants. *RMD Open* 2016;**2**:e000267. https://doi.org/10.1136/rmdopen-2016-000267
78. Jenkins N, Jhundoo N, Rainbow P, Sheehan KJ, Bearne LM. Inequity in exercise-based interventions for adults with rheumatoid arthritis: a systematic review. *Rheumatol Adv Pract* 2023;**7**:rkac095. https://doi.org/10.1093/rap/rkac095
79. Ho EK, Ferreira ML, Hodges P, Halliday M, Maka K, Ceprnja D, *et al*. Developing resilient clinical trials: lessons learned from rolling out the get back to healthy trial during a pandemic. *Contemp Clin Trials* 2023;**133**:107330.
80. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.

Appendix 1 Safety reporting

TABLE 15 Events of interest, summarised by event for the randomised population overall and by treatment actually received. Between-group comparisons assessed using the Fisher's exact test for categorical variables and the Wilcoxon Mann–Whitney test for continuous variables

Variable	Summary statistic	All events (*N* = 21)	Standard care (*N* = 9)	Gait rehabilitation (*N* = 12)	*p*-value
Type of adverse event	*N* ($N_{missing}$)	21 (0)	9 (0)	12 (0)	*p* = 0.184
	N (%) Transient post-exercise soreness	7 (33.3%)	1 (11.1%)	6 (50.0%)	
	N (%) Post-exercise stiffness	3 (14.3%)	2 (22.2%)	1 (8.3%)	
	N (%) Post-exercise fatigue	1 (4.8%)	1 (11.1%)	0 (0.0%)	
	N (%) Post-exercise trips, slips and/or falls	2 (9.5%)	0 (0.0%)	2 (16.7%)	
	N (%) Temporary exacerbation of disease-related inflammatory pain during exercises	4 (19.0%)	3 (33.3%)	1 (8.3%)	
	N (%) Trips/slips/falls during circuit set-up, exercises or when clearing away	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	N (%) Temporary musculoskeletal pain from set-up of circuit at home	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	N (%) Perceived instance of disease flare after undertaking gait rehabilitation circuit	4 (19.0%)	2 (22.2%)	2 (16.7%)	
Time from randomisation until AE onset, in days	*N* ($N_{missing}$)	21 (0)	9 (0)	12 (0)	*p* = 0.240
	Mean (SD)	91.4 (68.6)	118.1 (88.3)	71.3 (43.2)	
	Median (IQR)	77.0 (61.0–112.0)	106.0 (72.0–106.0)	66.0 (51.0–112.8)	
	(Min–max)	(0.0–348.0)	(64.0–348.0)	(0.0–134.0)	
Severity	*N* ($N_{missing}$)	21 (0)	9 (0)	12 (0)	*p* = 0.336
	N (%) Mild	12 (57.1%)	6 (66.7%)	6 (50.0%)	
	N (%) Moderate	6 (28.6%)	1 (11.1%)	5 (41.7%)	
	N (%) Severe	3 (14.3%)	2 (22.2%)	1 (8.3%)	
Outcome	*N* ($N_{missing}$)	21 (0)	9 (0)	12 (0)	*p* = 0.080
	N (%) Resolved	10 (47.6%)	2 (22.2%)	8 (66.7%)	
	N (%) Ongoing	11 (52.4%)	7 (77.8%)	4 (33.3%)	
Serious	*N* ($N_{missing}$)	21 (0)	9 (0)	12 (0)	*p* = 1.000
	N (%) Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	N (%) No	21 (100.0%)	9 (100.0%)	12 (100.0%)	
Medication required	*N* ($N_{missing}$)	21 (0)	9 (0)	12 (0)	*p* = 1.000
	N (%) Yes	8 (38.1%)	3 (33.3%)	5 (41.7%)	
	N (%) No	13 (61.9%)	6 (66.7%)	7 (58.3%)	
AE duration, in days (if resolved)	*N* ($N_{missing}$)	10 (0)	2 (0)	8 (0)	*p* = 0.895
	Mean (SD)	32.9 (29.6)	39.0 (5.7)	31.4 (33.3)	
	Median (IQR)	35.5 (3.0–54.2)	39.0 (37.0–41.0)	24.0 (0.0–58.5)	
	(Min–max)	(0.0–85.0)	(35.0–43.0)	(0.0–85.0)	

AE, adverse event; max, maximum; min, minimum.
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TABLE 16 Adverse events of interest, summarised by subject for the randomised population overall and by treatment actually received. Between-group comparisons assessed using the Fisher's exact test for categorical variables and the Wilcoxon Mann–Whitney test for continuous variables

Variable	Summary statistic	All randomised (*N* = 53)	Standard care (*N* = 27)	Gait rehabilitation (*N* = 26)	*p*-value
Experienced at least one AE	*N* ($N_{missing}$)	53 (0)	27 (0)	26 (0)	*p* = 0.327
	N (%) Yes	11 (20.8%)	4 (14.8%)	7 (26.9%)	
	N (%) No	42 (79.2%)	23 (85.2%)	19 (73.1%)	
Time from randomisation until onset of first AE, in days	*N* ($N_{missing}$)	11 (0)	4 (0)	7 (0)	*p* = 0.315
	Mean (SD)	63.1 (36.6)	81.2 (22.5)	52.7 (40.4)	
	Median (IQR)	70.0 (47.0–80.5)	73.5 (68.5–86.2)	55.0 (23.5–77.5)	
	(Min–max)	(0.0–114.0)	(64.0–114.0)	(0.0–112.0)	
Highest severity of AEs experienced	*N* ($N_{missing}$)	11 (0)	4 (0)	7 (0)	*p* = 0.309
	N (%) Mild	4 (36.4%)	2 (50.0%)	2 (28.6%)	
	N (%) Moderate	4 (36.4%)	0 (0.0%)	4 (57.1%)	
	N (%) Severe	3 (27.3%)	2 (50.0%)	1 (14.3%)	
Experienced at least one AE of the following types:	*N* ($N_{missing}$)	53 (0)	27 (0)	26 (0)	
Transient post-exercise soreness	*N* (%) Yes	5 (9.4%)	1 (3.7%)	4 (15.4%)	*p* = 0.192
Post-exercise stiffness	*N* (%) Yes	3 (5.7%)	2 (7.4%)	1 (3.8%)	*p* = 1.000
Post-exercise fatigue	*N* (%) Yes	1 (1.9%)	1 (3.7%)	0 (0.0%)	*p* = 1.000
Post-exercise trips, slips and/or falls	*N* (%) Yes	1 (1.9%)	0 (0.0%)	1 (3.8%)	*p* = 0.491
Temporary exacerbation of disease-related inflammatory pain during exercises	*N* (%) Yes	3 (5.7%)	2 (7.4%)	1 (3.8%)	*p* = 1.000
Trips/slips/falls during circuit set-up, exercises or when clearing away	*N* (%) Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	*p* = 1.000
Temporary musculoskeletal pain from set-up of circuit at home	*N* (%) Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	*p* = 1.000
Perceived instance of disease flare after undertaking gait rehabilitation circuit	*N* (%) Yes	4 (7.5%)	2 (7.4%)	2 (7.7%)	*p* = 1.000

AE, adverse event; max, maximum; min, minimum.
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TABLE 17 Serious adverse events, summarised by event for the randomised population overall and by treatment actually received

Variable	Summary statistic	All events (*N* = 2)	Standard care (*N* = 2)	Gait rehabilitation (*N* = 0)	*p*-value
Outcome	*N* ($N_{missing}$)	2 (0)	2 (0)	0 (0)	–
	N (%) Recovered	1 (50.0%)	1 (50.0%)	0 (–%)	
	N (%) Recovered with sequelae	0 (0.0%)	0 (0.0%)	0 (–%)	
	N (%) Recovering	0 (0.0%)	0 (0.0%)	0 (–%)	
	N (%) Not recovered	0 (0.0%)	0 (0.0%)	0 (–%)	
	N (%) Unknown	0 (0.0%)	0 (0.0%)	0 (–%)	
	N (%) Fatal	1 (50.0%)	1 (50.0%)	0 (–%)	
Severity	*N* ($N_{missing}$)	2 (0)	2 (0)	0 (0)	–
	N (%) Mild	0 (0.0%)	0 (0.0%)	0 (–%)	
	N (%) Moderate	0 (0.0%)	0 (0.0%)	0 (–%)	
	N (%) Severe	2 (100.0%)	2 (100.0%)	0 (–%)	
Serious adverse event duration, in days (if recovered)	*N* ($N_{missing}$)	1 (0)	1 (0)	0 (0)	–
	Mean (SD)	2.0 (–)	2.0 (–)	– (–)	
	Median (IQR)	2.0 (2.0–2.0)	2.0 (2.0–2.0)	– (–,–)	
	(Min–max)	(2.0–2.0)	(2.0–2.0)	(–,–)	
Length of hospital stay, in days (if hospitalised)	*N* ($N_{missing}$)	1 (0)	1 (0)	0 (0)	–
	Mean (SD)	2.0 (–)	2.0 (–)	– (–)	
	Median (IQR)	2.0 (2.0–2.0)	2.0 (2.0–2.0)	– (–,–)	
	(Min–max)	(2.0–2.0)	(2.0–2.0)	(–,–)	
Is the event suspected to be related to the intervention?	*N* ($N_{missing}$)	2 (0)	2 (0)	0 (0)	–
	N (%) Yes	0 (0.0%)	0 (0.0%)	– (–%)	
	N (%) No	2 (100.0%)	2 (100.0%)	– (–%)	
If related to the intervention, was reaction expected?	*N* ($N_{missing}$)	0 (0)	0 (0)	0 (0)	–
	N (%) Yes	– (–%)	– (–%)	– (–%)	
	N (%) No	– (–%)	– (–%)	– (–%)	
Suspected unexpected serious adverse reaction (SUSAR)	*N* ($N_{missing}$)	2 (0)	2 (0)	0 (0)	–
	N (%) Yes	0 (0.0%)	0 (0.0%)	– (–%)	
Seriousness criteria:	*N* ($N_{missing}$)	2 (0)	2 (0)	0 (0)	
Resulted in death	*N* (%) Yes	1 (50.0%)	1 (50.0%)	0 (–%)	–
Life-threatening	*N* (%) Yes	0 (0.0%)	0 (0.0%)	0 (–%)	–
Persistent/significant disability/ incapacity	*N* (%) Yes	0 (0.0%)	0 (0.0%)	0 (–%)	–
Congenital anomaly/birth defect	*N* (%) Yes	0 (0.0%)	0 (0.0%)	0 (–%)	–
Hospitalisation/prolongation of hospitalisation	*N* (%) Yes	1 (50.0%)	1 (50.0%)	0 (–%)	–
Other important medical event	*N* (%) Yes	0 (0.0%)	0 (0.0%)	0 (–%)	–

Max, maximum; min, minimum.

TABLE 18 Patients with at least one serious adverse event in the randomised population

	All (*N* = 53)	Treatment	
		Gait rehabilitation (*N* = 26)	Standard care (*N* = 27)
	N (%)	*N* (%)	*N* (%)
Any event			
Any event	2 (3.8%)	0 (0.0%)	2 (7.4%)
Infections and infestations			
Any event	1 (1.9%)	0 (0.0%)	1 (3.7%)
COVID-19 pneumonia	1 (1.9%)	0 (0.0%)	1 (3.7%)
Nervous system disorders			
Any event	1 (1.9%)	0 (0.0%)	1 (3.7%)
Headache	1 (1.9%)	0 (0.0%)	1 (3.7%)

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TABLE 19 Patients with at least one serious adverse event, at least possibly related to the study treatment, in the randomised population

All (*N* = 53) *N* (%)	Treatment	
	Gait rehabilitation (*N* = 26) *N* (%)	Standard care (*N* = 27) *N* (%)
No events of this type observed		

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TABLE 20 Patients with at least one serious adverse event that is also a suspected unexpected serious adverse reaction in the randomised population

All (*N* = 53) *N* (%)	Treatment	
	Gait rehabilitation (*N* = 26) *N* (%)	Standard care (*N* = 27) *N* (%)
No events of this type observed		

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TABLE 21 Patients with at least one fatal serious adverse event in the randomised population

	All (*N* = 53)	Treatment	
		Gait rehabilitation (*N* = 26)	Standard care (*N* = 27)
	N (%)	*N* (%)	*N* (%)
Any event			
Any event	1 (1.9%)	0 (0.0%)	1 (3.7%)
Infections and infestations			
Any event	1 (1.9%)	0 (0.0%)	1 (3.7%)
COVID-19 pneumonia	1 (1.9%)	0 (0.0%)	1 (3.7%)

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TABLE 22 Listing of serious adverse events (1/2)

Patient ID	Date and time of randomisation	Age	Sex	Randomised treatment	Actual treatment received
3003	30 June 2022 09 : 04 : 23	85.1	Male	Standard care	Standard care
Serious adverse reaction (SAR)				No	
Suspected unexpected serious adverse reaction (SUSAR)				No	
Outcome				Fatal	
Date event became serious				23 September 2022	
Hospital admission date				–	
Hospital discharge date				–	
Date of recovery				–	
Date of death				29 September 2022	
Severity				Severe	
Diagnosis				COVID-19 pneumonitis	
System Organ Class (SOC)				Infections and infestations	
Preferred Term (PT)				COVID-19 pneumonia	
Lower Level Term (LLT)				COVID-19 pneumonitis	
Seriousness criteria				Yes	
Resulted in death				No	
Life-threatening				No	
Persistent/significant disability/incapacity				No	
Congenital anomaly/birth defect				No	
Hospitalisation/prolongation of hospitalisation				No	
Other important medical event					
Event suspected to be related to the intervention				No	
If related to the intervention, reaction was expected				–	
Narrative				Patient presented to accident and emergency 22 September 2022 with a 3-day history of shortness of breath, worsening. COVID positive with high C-reactive protein, low lymphocytes and extensive shadowing on CXR. Received standard treatment including tazocin, tocilizumab dexamethasone and respiratory support including optiflow/continuous positive airway pressure. He agreed that he did not want to be intubated and ventilated, and when he continued to deteriorate he received palliative treatment to keep him comfortable. He died on 29 September 2022. Death certificate: Date/time of death 29 September 2022 15 : 36 1 COVID-19 pneumonitis 2 Rheumatoid arthritis with interstitial lung disease, heart failure, hypertension	
Cause of death				COVID-19 pneumonitis	

Project: GREAT | Output created by program: GREAT_FinalAnalysis_v1_2_hardlock20231101.R | Last run on Mon Feb 05 14 : 21 : 13 2024

TABLE 23 Listing of serious adverse events (2/2)

Patient ID	Date and time of randomisation	Age	Sex	Randomised treatment	Actual treatment received
10005	24 January 2023 12 : 15 : 02	76.9	Female	Standard care	Standard care
Serious adverse reaction (SAR)				No	
Suspected unexpected serious adverse reaction (SUSAR)				No	
Outcome				Recovered	
Date event became serious				17 April 2023	
Hospital admission date				17 April 2023	
Hospital discharge date				18 April 2023	
Date of recovery				18 April 2023	
Date of death				–	
Severity				Severe	
Diagnosis				Severe headache	
System Organ Class (SOC)				Nervous system disorders	
Preferred Term (PT)				Headache	
Lower Level Term (LLT)				Headache	
Seriousness criteria				No	
Resulted in death				No	
Life-threatening				No	
Persistent/significant disability/incapacity				No	
Congenital anomaly/birth defect				Yes	
Hospitalisation/prolongation of hospitalisation				No	
Other important medical event					
Event suspected to be related to the intervention				No	
If related to the intervention, reaction was expected				–	
Narrative				Had a severe headache on 16 April 2023 and saw GP on 17 April 2023 who sent to hospital. Had CT scan and lumbar puncture which were normal.	
Cause of death				–	

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Appendix 2 Economic evaluation

Gait rehabilitation early arthritis trial strides, gait rehabilitation for foot and ankle impairments in early rheumatoid arthritis: economic evaluation

Aims and objectives of economic analysis

The aim of the economic analysis for the GREAT intervention was to determine the cost-effectiveness of adding the gait rehabilitation intervention to usual care compared to usual care alone.

Given the early close down of the trial, it was not possible to complete the cost–utility analysis as planned. Descriptive statistics of resource use associated with participants RA and for other health conditions were calculated and reported along with health-related quality of life measured using the EQ-5D-5L.

Methods

Data collection

Both costs and utilities were the primary outcomes for the economic evaluation. Data were collected at baseline, 3-month follow-up (resource use only) and 6-month follow-up. Due to an early stop to research, collection of 12-month follow-up data was not completed for all participants.

Estimation of costs of the rehabilitation intervention

The GREAT intervention is a set of individually tailored physical actions that are designed to improve independent walking ability of adults who have a clinician diagnosis of RA, with a disease duration of < 2 years, and who also have disease-related foot impairments (either foot pain or synovitis). As an addition to usual medical and health care, members of the multidisciplinary team [physiotherapist or podiatrist, minimum Agenda for Change (AfC) band 6] supervise sessions of an adapted set of six task-specific, bodyweight resistance-only, functional walking exercises. Support materials are provided for patients to practice at home. No specialist equipment is required. Patients attend between two and six supervised clinic sessions over a 12-week period. At a minimum, sessions 1 and 2 are delivered face-to-face in clinic. Following these first two supervised sessions, patients may choose telephone-based sessions for the remaining time. Estimates of the resources used in providing the treatment were obtained from discussions with the Principal Investigator.

Health-related quality of life

Utilities were calculated on the basis of responses to the EQ-5D-5L questionnaire.[80] EQ-5D-5L measures patient's self-reported health-related quality of life in five domains: mobility, usual activities, self-care, pain/discomfort and anxiety/depression and is scored using the DSU EEPRU crosswalk.[65] Utility scores were derived from responses to understand the magnitude and variability of changes in perceived health (using EQ-VAS) and health-related quality of life (using utility scores). Mean change scores were reported with estimates of precision (SD, minimum and maximum scores).

Estimation of resource use

Information on healthcare resource use was collected via a self-completed questionnaire using a RUQ developed for this study. The RUQ provided a standardised method of collecting information on contacts with primary and secondary care, medications, equipment and contacts with allied health professionals. Binary yes/no questions were used to collect service use information, and if 'yes' the frequency of use was collected. For reporting medications, participants were asked to write down the name of the medication, the dosage prescribed and how often they have to take the medication. Patients were also asked to record personal expenditure on the use of private health care and over the counter medications and/or equipment.

Results

Resources for delivery of intervention

Delivery of GREAT in practice primarily depends upon the initial training of the clinical team (physiotherapists and podiatrists) in MI to support patient adherence to the rehabilitation activities, and additional clinical activity to supervise and support patients completing the prescribed gait circuit. For participants, support materials are provided for patients to continue at home (see *Table 1*).

TABLE 24 Estimated costs of GREAT rehabilitation intervention

Item	Assumption for units used in calculations	Unit cost (per hour or item)	Time (hours)	Total cost (£, 2022 prices)
Preparation for delivery of GREAT ***intervention***				
Training facilities	Pre-COVID-19 pandemic, training was conducted in-person and involved two sessions face-to-face followed by two online sessions with additional training materials including pre-recorded video examples. All sessions were delivered online during the pandemic			Not costed
Time spent training the multidisciplinary team member to ensure fidelity to GREAT (senior trial researcher)	Online training involves one trainer for up to three clinicians. Based on 2 hours per training session for a AfC Band 8a equivalent	75.00	2.0	150.00
Clinical time backfilled (podiatrist specialist or physiotherapist specialist) for attendance at training in psychologically based MI	Based on 2 hours per training session for a AfC Band 6.	54.00	2	108.00
Course materials – GREAT trainer manual, online video footage	Administration costs may be incurred			Not costed
Secure website for access to DVD content online	Future delivery models will require to consider resourcing			Not costed
Time of additional in-clinic activity				
First session (compulsory for intervention delivery), face-to-face	Conducted face-to-face (time taken 45–60 minutes). Based on 60 minutes for a AfC Band 6	54.00	1.0	54.00
Second session (compulsory for intervention delivery), face-to-face	Conducted face-to-face (time taken 30–45 minutes). Based on 45 minutes for a AfC Band 6	54.00	0.75	40.50
Optional further sessions (maximum four)	Conducted by telephone, although could be face-to-face (time taken 15–30 minutes). Based on 30 minutes for a AfC Band 6	54.00	0.5	27.00
Clinical space for delivery of GREAT session (which offers sufficient room and appropriate privacy)	Usual consulting rooms were adequate and used for GREAT sessions. Future trials will wish to consider potential displacement of other patient appointments			Not costed
Cost of support materials for set-up and completion of the gait circuit at home				
DVD	Educational material and step-by-step demonstrations of gait circuit home set-up and task completion			Not costed
Participant booklet	High-quality, illustrated educational 28-page booklet, printed and supplied in hard copy			Not costed
Trial-specific activity (unlikely to continue in practice)				
Adherence diary for participants	One page printed and supplied in hard copy, incorporated within patient booklet			Not costed

Note
All costs in 2022 GBP prices.
Sources for unit costs: Personal Social Services Research Unit:[66] Table 12.3.1 physiotherapists, Table 12.3.4 chiropodists/podiatrists; trial records.

Health-related quality of life

Information for 53 participants was available at baseline for economic analysis: 27 in the 'gait rehabilitation plus usual care' and 26 in the 'usual care only' arm. Insufficient data (i.e. EQ-5D-5L not completed) excluded five participants (14%) at the 6-month follow-up. Mean scores are reported in *Table 2*. No statistical difference was observed between groups at baseline or 6-month follow-up.

TABLE 25 EuroQol-5 Dimensions, five-level score utilities and self-reported health (EQ-VAS) of GREAT trial participants at baseline and at 6-month follow-up, including change in score between time points

		n (Missing)	Mean	SD
All				
Utility	0 month	53 (0)	0.624	0.189
	6 months	37 (5)	0.66	0.235
	Change	37	0.039	0.187
Self-reported health	0 month	53 (0)	69.3	17.1
	6 months	37 (5)	67.8	17.4
	Change	37	−1.5	17.5
Gait rehabilitation				
Utility	0 month	27 (0)	0.592	0.205
	6 months	19 (2)	0.627	0.274
	Change	19	0.043	0.233
Self-reported health	0 month	27 (0)	69.3	17.2
	6 months	19 (2)	65.4	21.6
	Change	19	−4.5	20.2
Standard care				
Utility	0 month	26 (0)	0.658	0.168
	6 months	18 (3)	0.696	0.185
	Change	18	0.035	0.13
Self-reported health	0 month	26 (0)	69.3	17.3
	6 months	18 (3)	70.3	11.8
	Change	18	1.6	14.0

Assessment of levels of impairment chosen at baseline and at 6-month follow-up, by trial arm, indicated that the domains of mobility and pain/discomfort were most bothersome for participants, as would be expected for foot and ankle impairments from RA (see *Table 3*). The very small sample size precluded any further meaningful analysis.

Health service resource use

There were no important differences in healthcare resources used during the follow-up period between the two arms.

At baseline, all participants (*n* = 53, 100%) reported taking medication, including 48 participants reporting DMARDs (*n* = 48, 90.5%) or biologics (*n* = 7, 13.2%) prescribed for RA. All participants continued to report medication prescriptions at each time point, with largely no change in dosage of DMARDs or biologics and occasional small variability observed for other medications. Of a total of 793 items reported across all data collection points using the RUQ (see *Table 4*), no items were unidentifiable through the *British National Formulary*, and therefore it would be plausible for a future trial to identify unit costs.

In terms of the use of healthcare services, at baseline 47 (88.7%) patients had used hospital-based healthcare services during the previous 3 months (see *Table 5*). These were reported as mainly outpatient appointments, with 84.9% (*n* = 45) of patients attending an average of two appointments during the time period. A small number reported being seen by a podiatrist (*n* = 8, 15.1%) or a

TABLE 26 Distribution of EQ-5D-5L dimension responses at baseline and at 6-month follow-up (GREAT Strides trial, *n* = 37). Most frequent reported levels highlighted

	Intervention				Usual care				
	Baseline		6-month follow-up		Baseline		6-month follow-up		*p*-value
Dimension	*n*	%	*n*	%	*n*	%	*n*	%	
Mobility									
Level 1 (no problems)	6	22	6	32	8	31	6	33	
Level 2 (slight problems)	10	37	8	42	11	42	6	33	
Level 3 (moderate problems)	10	37	4	21	6	23	5	28	
Level 4 (severe problems)	1	4	1	5	1	4	1	6	
Level 5 (unable to walk about)	0	0	0	0	0	0	0	0	
Self-care									
Level 1 (no problems)	13	48	11	58	13	50	10	56	
Level 2 (slight problems)	7	26	4	21	7	27	7	39	
Level 3 (moderate problems)	6	22	1	5	6	23	1	6	
Level 4 (severe problems)	1	4	3	16	0	0	0	0	
Level 5 (unable to wash or dress)	0	0	0	0	0	0	0	0	
Usual activities									
Level 1 (no problems)	4	15	7	37	6	23	6	33	
Level 2 (slight problems)	11	41	5	26	14	54	7	39	
Level 3 (moderate problems)	10	37	5	26	4	15	5	28	
Level 4 (severe problems)	1	4	2	11	1	4	0	0	
Level 5 (unable to do usual activities)	1	4	0	0	1	4	0	0	
Pain/discomfort									
Level 1 (no pain/discomfort)	2	7	2	11	3	12	2	11	
Level 2 (slight pain/discomfort)	8	30	8	42	11	42	9	50	
Level 3 (moderate pain/discomfort)	13	48	6	32	11	42	6	33	
Level 4 (severe pain/discomfort)	4	15	3	16	1	4	1	6	
Level 5 (extreme pain/discomfort)	0	0	0	0	0	0	0	0	
Anxiety/depression									
Level 1 (not anxious/depressed)	11	41	10	53	12	46	12	67	
Level 2 (slightly anxious/depressed)	12	44	6	32	8	31	6	33	
Level 3 (moderately anxious/depressed)	4	15	2	11	6	23	0	0	
Level 4 (severely anxious/depressed)	0	0	1	5	0	0	0	0	
Level 5 (extremely anxious/depressed)	0	0	0	0	0	0	0	0	
Missing data	0	0	2	10	0	0	3	14	

TABLE 27 Completion rates and data volume for prescribed medications

	Participants completing medication data, *n*	Items reported, *n*	DMARDs[a] reported, *n* (instances)	Biologics reported, *n* (instances)	Other medications reported, *n* (instances)
Baseline	53	283	9 (68)	2 (6)	78 (209)
3 months	36	198	4 (46)	1 (4)	64 (148)
6 months	36	204	4 (40)	12 (16)	72 (148)
12 months	17	108	4 (23)	5 (9)	48 (76)

a DMARDs reported by participants: adalimumab, amoxicillin, carbamazepine, celecoxib, certolizumab pegol, etanercept, folic acid, hydroxychloroquine sulfate, leflunomide, mebeverine hydrochloride, meloxicam, methotrexate, mirtazapine, naproxen, omeprazole, phenoxymethylpenicillin, prednisolone, sulfasalazine, tocilizumab.

TABLE 28 Numbers of participants reporting use of healthcare services for RA in the last 3 months, by time point and item

	Gait rehabilitation			Standard care		
Item	Baseline (*n* = 26)	3 months (*n* = 20)	6 months (*n* = 19)	Baseline (*n* = 27)	3 months (*n* = 19)	6 months (*n* = 20)
Hospital-based healthcare services						
• Been to accident and emergency (casualty)	1	0	0	0	0	0
• Stayed in hospital overnight	0	0	0	0	0	0
• Had a hospital outpatient appointment	23	15	7	22	9	13
• Seen a podiatrist at a hospital	4	2	2	4	2	3
• Seen by a physiotherapist at a hospital	2	4	1	2	2	2
• Seen an occupational therapist at a hospital	3	1	0	3	2	2
Community-based healthcare services						
• GP at the surgery	12	2	6	9	3	3
• GP at your home	1	1	0	0	1	0
• Practice nurse at the surgery	9	4	2	7	7	6
• Practice nurse at home	0	1	0	0	1	0
• Home visit from district nurse	1	0	0	0	0	0
• Podiatrist at the local community clinic	0	2	1	1	1	1
• Physiotherapist at the local community clinic	1	2	2	0	2	0
• Occupational therapist at the local community clinic	0	0	0	1	0	0
• Orthotist at the local community clinic	0	0	0	1	1	0
Nil healthcare use reported	1	1	6	2	4	4

physiotherapist (*n* = 4, 7.5%) in a hospital setting. Very few appointments occurred in the community setting excepting GP and practice nurse appointments at GP surgery premises.

The same patterns (participants reporting mainly hospital outpatient appointments and GP (or practice nurse) surgery appointments) were observed for the use of healthcare services for other health conditions (see *Table 6*).

Costs incurred by patients

Additional costs incurred by RA were reported by 27 participants (50.9%: GR *n* = 15, 58%; SC *n* = 12, 44%) between baseline and 6-month follow-up. Funding was generally met by patients (self-funded or by a family member) (see *Table 7*). With the exception of one participant who had used NHS patient transport services in addition to self-funded bus travel, all other participants reported self-funded transport costs comprising parking charges or taxi fares to and from hospital settings. Special equipment purchases were self-funded and ranged from aids such as grab bars in bathrooms, compression gloves and ergonomic tools (kitchen, computer) to self-funded over-the-counter medications and devices (including supplements, orthotics, adapted footwear, wrist supports, splints). Participant-reported additional costs incurred as a result of RA included private osteopathy services, leisure centre membership specifically for use of facilities aiding joint pain relief, engagement of a gardener or purchase of smaller and lighter tools, and purchase and installation of a stairway handrail. Adaptations funded by the public sector tended to be of higher cost and included a home move to accommodate stair-free access and the purchase of a suitable student study equipment package, including an adapted desk and technology kit.

Conclusion

The gait rehabilitation intervention is additional to standard care and as such incurs additional costs. For it to be cost-effective, robust data about outcomes

TABLE 29 Numbers of participants reporting use of healthcare services for other health problems in the last 3 months, by time point and item

Item	Gait rehabilitation			Standard care		
	Baseline (*n* = 26)	3 months (*n* = 20)	6 months (*n* = 19)	Baseline (*n* = 27)	3 months (*n* = 19)	6 months (*n* = 20)
Hospital-based healthcare services						
• Been to accident and emergency (casualty)	3	1	1	0	0	1
• Stayed in hospital overnight	0	0	0	0	1	1
• Had a hospital outpatient appointment	8	6	1	10	1	1
• Seen a podiatrist at a hospital	0	0	0	1	0	0
• Seen by a physiotherapist at a hospital	0	2	0	1	1	1
• Seen an occupational therapist at a hospital	0	0	0	0	1	0
Community-based healthcare services						
• GP at the surgery	7	3	8	6	7	7
• GP at your home	0	0	0	0	1	2
• Practice nurse at the surgery	6	3	2	7	5	2
• Practice nurse at home	1	0	0	0	0	0
• Home visit from district nurse	0	0	0	0	0	0
• Podiatrist at the local community clinic	0	0	1	1	0	0
• Physiotherapist at the local community clinic	1	0	0	2	1	1
• Occupational therapist at the local community clinic	0	0	0	0	0	0
Nil healthcare use reported	14	10	9	13	8	9

TABLE 30 Participant-reported payments made for their RA over time in response to questions at baseline, 3-month follow-up and 6-month follow-up, asking about costs incurred in the 3 months prior to data collection point (*N* = 27)

Item	No. of participants (GR, SC)	Self-funded	Range (per 3 months), £	Public funded	Range (per 3 months), £
Employing extra help (e.g. childcare or cleaning)	4 (3, 1)	3	200–2340	1	6000–10,000
Transport to get health care (e.g. to go to your GP surgery or hospital)	18 (10, 8)	17	2–800	1	10–4200
Changes to your home (e.g. moving bathroom downstairs, stairlift)	5 (2, 3)	4	20–8000	1	0–1000
Special equipment	15 (8, 7)	12	6–5000	3	17–3000
Other costs	14 (5, 9)	14	Unknown	0	0

GR, gait rehabilitation; SC, standard care.

would be required to determine whether the additional cost is outweighed by superior benefits following the intervention, potentially including changes in other healthcare resource use. Due to the stop of the trial, it was not powered to achieve statistical significance on outcomes. Data collection of economic evaluation primary outcomes using a bespoke RUQ to collect costs and the EQ-5D-5L to calculate utilities was feasible; however, the small numbers of participants moving through the study dictated a descriptive analysis of the data. The resources required to deliver the intervention, including training in preparation for the intervention and delivery and support of the intervention itself, have been detailed for the use of future research to evaluate the gait rehabilitation intervention.