Exercise and Manual therapy Arthritis Research trial (EMPART) for osteoarthritis of the hip: A Multicentre Randomised Controlled trial.

ABSTRACT

Objective: To determine the effectiveness of exercise therapy (ET) compared to ET with adjunctive manual therapy (ET+MT) for people with hip osteoarthritis (OA). A secondary aim was to identify if immediate commencement of ET or ET+MT was more beneficial than a 9 week waiting period for either intervention.

Design: Assessor-blind randomised controlled trial with 9 and 18 week follow-ups.

Setting: Four academic teaching hospitals, Dublin, Ireland.

Participants: 131 patients with hip OA recruited from general practitioners, rheumatologists, orthopaedic surgeons, and other hospital consultants were randomised to one of three groups: ET (n=45), ET+MT (n=43) and wait-list control (n=43).

Interventions: Participants in both ET and ET+ MT groups received up to 8 treatments over 8 weeks. Control group participants were re-randomised into either ET or ET+MT group after 9 week follow-up. Their data were pooled with original treatment group data: ET (n=66) and ET+MT (n=65).

Main Outcome Measures: The primary outcome was the WOMAC physical function (PF) subscale. Secondary outcomes included physical performance, pain, hip range of motion (HROM), anxiety/depression, quality of life, medication usage, patient-perceived change and patient satisfaction.

Results: There was no significant difference in WOMAC PF between ET (n=66) and ET+MT (n=65) groups at 9 weeks (mean diff 0.09 (95% CI -4.41,

5.25)) or at 18 weeks (mean diff 0.42 (95% CI -3.98, 6.83)), or other outcomes, except 'patient satisfaction with outcome' which was higher in the ET+MT group (p=0.02). Improvements in WOMAC, HROM and patient-perceived change occurred in both treatment groups compared with the control group.

Conclusion: Self-reported function, HROM and patient-perceived improvement occurred after an 8 week programme of ET for patients with hip OA MT as an adjunct provided no further benefit, except for higher patient satisfaction.

LIST OF ABBREVIATIONS

ACR	American College of Rheumatology
BMI	Body Mass Index
CONSORT	Consolidated Standards of Reporting Trials
EMPART	Exercise and Manual Physiotherapy Arthritis Research Trial
ET	Exercise Therapy
FABER	Flexion, abduction, external rotation
HADS	Hospital Anxiety and Depression Scale
HEP	Home Exercise Programme
ICC	Intraclass correlation co-efficient
MCID	Minimal Clinically Important Difference
MT	Manual Therapy
NRS	Numerical Rating Scale
NSAID	Non–steroidal Anti-inflammatory Drugs
OA	Osteoarthritis
OR	Odds Ratio
PF	Physical Function
PGA	Patient Global Assessment
POPS	Physiotherapy Out-Patient Survey
RCT	Randomised Controlled Trial
ROM	Range of Motion
SF-36	Short-Form-36
STS	Sit-to-Stand
WOMAC	Western Ontario McMaster Universities Index

Hip osteoarthritis (OA) is a painful and disabling condition which can impact on everyday activities and quality of life [1, 2]. A lifetime prevalence of 25.3% has been reported [3] and this is associated with increasing age. Conservative treatments include exercise therapy (ET) and manual therapy (MT). [4, 5]Although ET has demonstrated beneficial effects for hip OA in recommended core outcomes [6] of pain [7, 8] and patient perceived improvement (patient global assessment-(PGA) [9, 10] in the short and medium term, results for changes in physical function are conflicting. A number of randomised controlled trials (RCTs), some of which have included participants with hip or knee OA, found functional benefits with exercise [9, 11, 12], but a meta-analysis, based on data from participants with hip OA only, found no effect on physical function [7]. The small number of participants (n=204) and inter-study heterogeneity may have influenced this finding. Long-term (>6 months) follow-ups of exercise-based RCTs have found that post-treatment improvements in pain and function were not maintained [13-15], but it is unclear at what point benefits dissipate following treatment and long-term follow-up. There is therefore a need to identify the medium-term effects of physiotherapy for hip OA.

MT, which is the use of hands-on techniques delivered to the joint or soft tissues to modulate pain and improve joint mobility [16], is used for the treatment of pain and disability associated with hip OA [4, 5]. It can be administered as high velocity manipulative techniques or lower grade joint mobilisations [17, 18]. Although clinical guidelines recommend MT as an adjunctive therapy in the management of hip OA [19], the scientific evidence

supporting this recommendation is based on one RCT which compared manual therapy head to head with ET, rather than as an adjunct and found MT superior in pain, function and PGA outcomes [20]. A more recent RCT found no difference in outcomes between ' targeted' hip MT with exercise and 'full kinetic chain' MT with exercise delivered by chiropractors[21]. Neither of these trials included a control group. The aim of this RCT was to determine if the addition of MT to an 8 week programme of ET for hip OA improved function and other clinical outcomes more than ET only at 9 and 18 weeks. A secondary aim was to ascertain if immediate commencement of treatment (ET or ET+MT) resulted in better outcomes compared with a 9 week waiting period for either intervention.

METHODS

Design

The EMPART multicentre randomised controlled trial (RCT) was conducted in four academic teaching hospitals in an urban area in Ireland. The study was approved by each of the hospital's research committees. An initial three group parallel arm trial (allocation ratio 1:1:1) was utilised, with a modified cross-over design, whereby control group participants were crossed over to one of two intervention arms after a 9 week period, thereby ensuring sufficient power to test the primary trial hypothesis. Details of the EMPART protocol are published elsewhere [22].

Participants

The principal investigator (HF) screened all patients for trial eligibility and enrolled participants following receipt of written informed consent. Participants referred from rheumatologists, orthopaedic surgeons, other hospital consultants and general practitioners were recruited from physiotherapy waiting lists. Waiting times for physiotherapy varied from 6 weeks to 6 months across the four trial sites. Participants were included if they had OA of the hip and were aged 40-80 years according to the American College of Rheumatology (ACR) criteria [23]. Exclusion criteria included previous hip arthroplasty, congenital or adolescent hip disease, clinical signs of lumbar spine disease, physiotherapy in the previous 6 months for hip symptoms, pregnancy, hip fracture, contraindications to exercise therapy [24], inflammatory arthritis, on waiting list for hip joint replacement within the next 7 months, intra-articular hip corticosteroid injection in the previous 30 days or insufficient English language to complete questionnaires.

Randomisation

Two computer generated randomisation lists were compiled by an independent statistician. The first list randomised participants into one of the three arms, namely ET, ET+MT or a waiting-list control group. The second list re-randomised control group participants into one of the two intervention groups (ET or ET+MT) after the 9 week follow-up assessment. Both lists were maintained by a member of the research team (TC) who was located offsite from the four trial centres and was

not involved in participant assessment or treatment. Simple randomisation was conducted, following email notification of patient recruitment by the principal investigator. Group allocation was communicated via email by the independent randomiser to the treating therapists in each treatment site

Blinding

A single assessor (HF), blinded to group allocation and measurement data from previous assessment points, carried out all outcome assessments. Patients were requested not to divulge information regarding allocated treatment. Disclosure of group allocation was recorded prospectively by the blinded assessor.

Interventions

The ET and ET+MT interventions were administered by senior grade or clinical specialist physiotherapists (n=23) in the four participating hospitals. Training in the two treatment protocols was provided by the principal investigator (HF) along with a comprehensive written manual to ensure a standardised approach to treatment across the trial centres. All therapists at all sites provided either ET or ET+MT interventions. All participants were treated according to the protocol which is detailed in Appendix 1.

ET

Participants attended six to eight individual 30 minute physiotherapy sessions over eight weeks, which included flexibility and strengthening exercises delivered using a semi-structured protocol. The protocol provided guidance on exercise prescription and progression, but could be tailored to individual patient physical assessment findings. Strengthening focused on low load exercise, commencing in non weight bearing positions and progressing to functional positions. The key target muscles were the gluteal muscles which are commonly atrophied in hip OA [25, 26]. A daily home exercise programme (HEP) supplemented the clinic-based treatment. Adherence to the home programme was measured using a self-report exercise diary. Participants were also encouraged to undertake aerobic exercise such as walking, cycling or swimming for at least 30 minutes, five days a week [27], and were given written and verbal information on the principles of aerobic conditioning such as pacing, gradually progressing intensity and time of exercise and incorporating exercise into daily life.

ET+MT

Participants attended six to eight individual 45 minute physiotherapy sessions over an eight week period, which included 30 minutes of ET as previously described and up to 15 minutes of MT in line with current clinical practice at participating sites. A choice of non-manipulative MT techniques based on pain/ stiffness relationships [17, 18]

and movement restrictions of the affected hip were available, with no more than five MT techniques allowed during an individual session.

Control Group

Participants in the control group remained on the physiotherapy waiting list and completed a follow-up assessment with the blinded outcome assessor at 9 weeks, after which they were re-randomised into either ET or ET+MT group.

All three groups received standardised written information on hip OA[28]. All non-consenting and excluded participants were treated as usual by the physiotherapy department in each trial centre. Participants were asked to avoid all other interventions for the duration of the RCT, apart from routine doctor care and analgesics. Participants with bilateral hip OA received clinic-based treatment for the more symptomatic hip only, but were provided with a home exercise programme for both hips.

Outcomes

Outcomes were chosen according to internationally recommended core outcomes for hip or knee OA [6]. The primary outcome was self-reported physical function as measured by the Western Ontario and McMaster Universities Index physical function subscale for hip OA (WOMAC PF; Likert version) [29]. This has moderate to high validity and reliability [30] with lower scores indicating better functional status. Secondary

outcomes included observed physical function measured with the five times sit-to-stand test [31] and the 50-foot walk test [32] . Active hip range of motion (ROM) was measured using goniometry for flexion, abduction, medial rotation and Thomas test [33]. These scores were combined to give an aggregate ROM score. FABER (combined flexion, abduction and lateral rotation) was measured separately using a measuring tape [34]. ROM and physical performance procedures demonstrated excellent test-retest reliability (ICC>0.90) in a subgroup of people with and without hip OA [35]. Pain severity (with activity and at night) was measured using a numerical rating scale (NRS) and pain medication usage was quantified using the Medication Quantification Scale (MQS) [36]. Other outcomes included general health status (Medical Outcomes Short-Form 36; SF-36) and psychological well-being (Hospital Anxiety and Depression Scale; HADS)[37]. Patient global assessment of change was assessed using a 7-point scale (very much worse to very much better) and the Physiotherapy Out-Patient survey (POPS) assessed patient satisfaction [38].

Sample Size

The WOMAC PF subscale was used to estimate the sample size required. Using a previously ascertained minimal clinically important difference (MCID) of 5.4 (SD=11) on the WOMAC Likert scale [39], with a significance level of 0.05 (2 tailed) and a power of 80%, 67 patients were required per group, based on the final group allocation to ET or ET+MT. This was increased to 74 patients per group to allow for

10% attrition at the 18 week follow-up, thus requiring a total sample of 148 participants.

Statistical Analysis

Analyses were conducted on an intention-to-treat (ITT) basis. Missing data were replaced using multivariate multiple imputation (Stata version 12, Statcorp, Texas, USA). Twenty imputed datasets were generated using a model whereby data were considered missing at random. Imputations were based on baseline demographic variables (age, gender, occupation and body mass index) and predictor variables such as symptom duration, baseline pain, physical function, psychological health and general health status). An overall significance level of $p=0.05$ was set. To address the primary study aim, comparisons were made between the ET and ET+MT groups at baseline, 9 and 18 weeks whereby participants in the control group were analysed according to the intervention received after the 9 week follow-up. Comparisons were made between the control group and the two treatment groups combined (ET and ET+MT) at baseline and 9 weeks to address the secondary study aim. Linear regression modelling was used to examine between-group differences, with adjustment for baseline levels of the outcome. For the two group analysis, baseline WOMAC PF and aggregate ROM were included as co-variates due to baseline differences. Pain medication usage (MQS), aggregate ROM, sit-to-stand and WOMAC PF subscale were added as co-variates for the three group analysis due to baseline differences in these variables.

Quantile regression was used for non-normally distributed outcomes. Patient global assessment ratings were dichotomised as improved (very much better, much better, somewhat better), no change and worse (very much worse, much worse and somewhat worse) and chi-squared analysis was used to test for differences between the groups.

RESULTS

Participants

One hundred and thirty one patients were recruited across the four sites between May 2008 and February 2010. In the initial three group allocation, 43 patients were randomised each to the ET+MT and control groups, and 45 were randomised to the ET group. Figure 1 shows participant flow through the trial. Eight patients (6.1%) withdrew from the trial at 9 weeks, four declined continuation, one had hip surgery, one developed cardiac symptoms, one could not be contacted by the researcher and one withdrew for family reasons. By 18 weeks, a further 11 (8.4%) withdrew, six underwent hip surgery, one could not be contacted and four declined follow-up for personal reasons. This resulted in an overall drop-out rate of 14.5%. Table 1 shows the baseline characteristics as determined by the two group (ET and ET+MT) allocation. Baseline characteristics for the three groups are shown in Table 2.

Success of blinding

Group assignment was disclosed to the outcome assessor by five

participants, who were all in the control group. No treatment disclosure occurred in the two intervention groups.

Outcomes

Two group analysis (ET and ET+MT)

At both 9 and 18 week time points, there was no significant difference between the ET and ET+MT groups for any outcomes (Table 3), with the exception of 'patient satisfaction with outcome' which was higher for the ET+MT group (Table 4).

Three group analysis (Control vs. ET and ET+MT)

At 9 weeks, analysis of data from the initial three group randomisation (Table 5) demonstrated significant improvements in the treatment groups compared to the control group in WOMAC PF, aggregate ROM and PGA. There was no significant difference between the control and two treatment groups in remaining outcomes.

Treatment

Twenty-two physiotherapists treated the patients in the EMPART study. The mean number of treatments for the ET group was 5.62 (SD=1.99) and for the ET+MT group was 5.22 (SD=2.31). Fifty-two of the ET group (78.8%) and 50 (76.9%) of the ET+MT group received at least four of their planned treatments. A total of 38 completed HEP diaries were available for analysis, 22 (40.7%) in the ET+MT group and 16 (28.1%) in the ET group. Mean duration of aerobic exercise per

week undertaken by the ET group was 4.62 hours (+/- 0.91) and for the ET+MT group was 4.1 hours (+/- 0.6). Mean duration of the home exercise programme per week was 2.97 +/- 0.49 hours for the ET group and 3.57 +/- 0.31 hours for the ET+MT group.

Discussion

Primary Research Aim

This assessor-blinded multicentre RCT assessed the effectiveness of the addition of MT to an 8-week ET programme for the treatment of hip OA. There was no significant difference between the ET and ET+MT groups in the majority of outcomes at 9 or 18 weeks, except 'patient satisfaction with outcome'. Due to the number of outcomes assessed in this study, this significant finding of satisfaction may have occurred by chance. Patients reported higher satisfaction with outcome for the ET+MT group, as in other trials of MT intervention for musculoskeletal disorders [40, 41]. This coincides with the higher (although not statistically significant) proportion of participants who reported improvement with ET+MT compared with ET (Table 3). Satisfaction with other aspects of the physiotherapy interactions was comparable, possibly because both interventions were delivered by the same physiotherapists at the same locations.

Comparison with other similar studies is limited as no known studies have evaluated ET with or without MT for hip OA, although a similar trial is underway in New Zealand [42]. A recent study found no differences in 'targeted' versus 'full kinetic chain' MT, both with additive ET for hip OA [21]. Hoeksma

et al, who compared MT head to head rather than as an adjunct to ET, found that MT alone had a superior effect on pain, function and patient global assessment compared to ET [20]. Reasons for these somewhat incongruous results may relate to the dosage of MT provided; Hoeksma et al used high velocity manipulations whereas lower grade mobilisation techniques were utilised [17, 18] in EMPART. The setting in which our RCT was located may affect external validity of these findings. The heterogeneity in clinical severity of the sample may have attenuated the treatment effect and the more severely affected patients may not be representative of those seen in a primary care setting. Although it is possible that treatment effects may differ for patients with varying OA severity, this trial was not powered to examine subgroup effects. Larger multicentre studies are required to identify if effects of ET and MT differ depending on OA severity.

Secondary Aim

Both groups improved in self-reported physical function, aggregate ROM and patient perceived improvement relative to the control group in the short-term (9 weeks). This was a similar finding to other RCTs which evaluated exercise for hip OA such as graded behavioural exercise [10], tai chi and hydrotherapy [43], group-based strengthening [12] and individualised exercise [9, 20]. However, some of these studies included people with hip or knee OA [9, 10, 43], so the evidence regarding the optimal exercise approach for hip OA alone has yet to be identified. A moderate treatment effect on pain for hip OA has been ascertained in two meta-analyses [7, 8] with no significant effect on function, based on five RCTs [7]. The original RCTs which demonstrated a benefit of ET

included data from trials which included participants with hip or knee OA [9, 11, 43] whereas the meta-analysis extracted hip OA data only. This highlights the limitations of including people with hip or knee OA in the same trial and exposing them to similar interventions, as important differential effects may be missed.

The minimal clinically important difference (MCID) for WOMAC PF has previously been determined as 5.4 [39]. In our trial, the mean improvement at 9 weeks was 6.25 for ET+MT and 4.21 for ET (Table 5), which suggests that the clinical significance of the improvement in EMPART is questionable. Deterioration in WOMAC physical function (Table 5) in the control group over such a short timeframe was a surprising outcome. The unblinded status of participants may have influenced these results, introducing cognitive measurement bias which can occur with subjective patient-reported outcomes, where control group participants report negative outcomes due to disappointment at not receiving the target intervention [44]. It may also relate to the inclusion of patients with severe symptoms, compared with other studies which included those with mild/moderate symptoms [9, 12]. The participants in this trial were recruited in a hospital setting where the majority of patients were initially referred from primary care physicians to rheumatology and orthopaedic specialists, and onward to physiotherapy. This care pathway increases the waiting time for patients to receive rehabilitation from the time of onset of symptoms.

The influence of the therapist –patient interaction cannot be outruled as

a reason for improvements in the two intervention groups, compared with the control group. It has been shown that interventions which include a specific therapeutic relationship may contribute to the treatment effect [45].

In EMPART, although self-report physical function improved as a result of both ET and ET+MT interventions, there was no change in physical performance tests. The 50 foot walk may have been too short in distance to detect change as longer walk tests have been shown to be more responsive to change in people with OA [46] and assessment of a range of physical performance tasks may be preferable [9].
Neither intervention in this RCT had a significant impact on psychological status or general health even though reduced quality of life and depression prevail in OA [47]. Similar findings occurred in other RCTs of ET for lower limb OA [9, 10, 43], and suggests that exercise on its own does not impact on the wider psychosocial manifestations of OA. Although the exercise programme in this trial provided information on self-management principles, it did not use behavioural or cognitive approaches to empower participants. Lack of significant change may also have been limited by the outcomes used (SF-36 and HADS), both of which have previously demonstrated lower responsiveness to change than OA-specific measures [48, 49].

This study utilised a rigorous methodology, such as blinding of the outcome assessor, independent central randomisation, allocation

concealment, validated outcome measures, highly reliable physical measures and intention-to-treat analysis using multiple imputation. Simple randomisation was used over block randomisation as the recruitment locations (acute teaching hospitals in an urban area) were comparable. The principal investigator who screened all participants was an experienced musculoskeletal physiotherapist and was able to effectively and systematically screen patients for suitability and ensure that patients with primary lumbar spine pathology were excluded.

Study Limitations

A type II error may have occurred in relation to the two group analysis due to failure to reach the target sample size. Post-hoc power analysis based on the 131 recruited patients and accounting for drop-out rate provided a power of 73.8%, at a significance level of 0.05, resulting in a loss of power of less than 7%. Attrition rate at the 18 week follow-up was higher than the a-priori estimated rate of 10%. No long-term follow up data are presented, thus limiting the interpretation of the results. The lack of blinding of both patients and physiotherapists can also be considered as a limitation, although it is well recognised that blinding is virtually impossible to achieve in non-pharmacological trials [50]. The low return of the completed HEP diaries is also worth noting but may be related to the study design. Participants were asked to return diaries to the treating therapists, to maintain assessor blinding. Due to the high number of treating therapists, this proved difficult to implement successfully.

CONCLUSIONS

This RCT demonstrated that an 8 week programme of ET, with and without adjunctive MT for people with hip OA, showed similar improvements in self report function, ROM and patient global assessment at 9 weeks which were maintained at 18 weeks. However, the clinical meaningfulness of these changes is questionable. Patient satisfaction was higher for those who received adjunctive MT. These findings highlight the benefit of physiotherapy-based exercise for those with hip OA, but no additive benefit from the use of additional manual therapy. More research is required to identify the optimal components of rehabilitation required to target the multifaceted elements of hip OA.

Figure legends

Fig 1: Flow of participants through the trial

Fig 2: CONSORT Checklist

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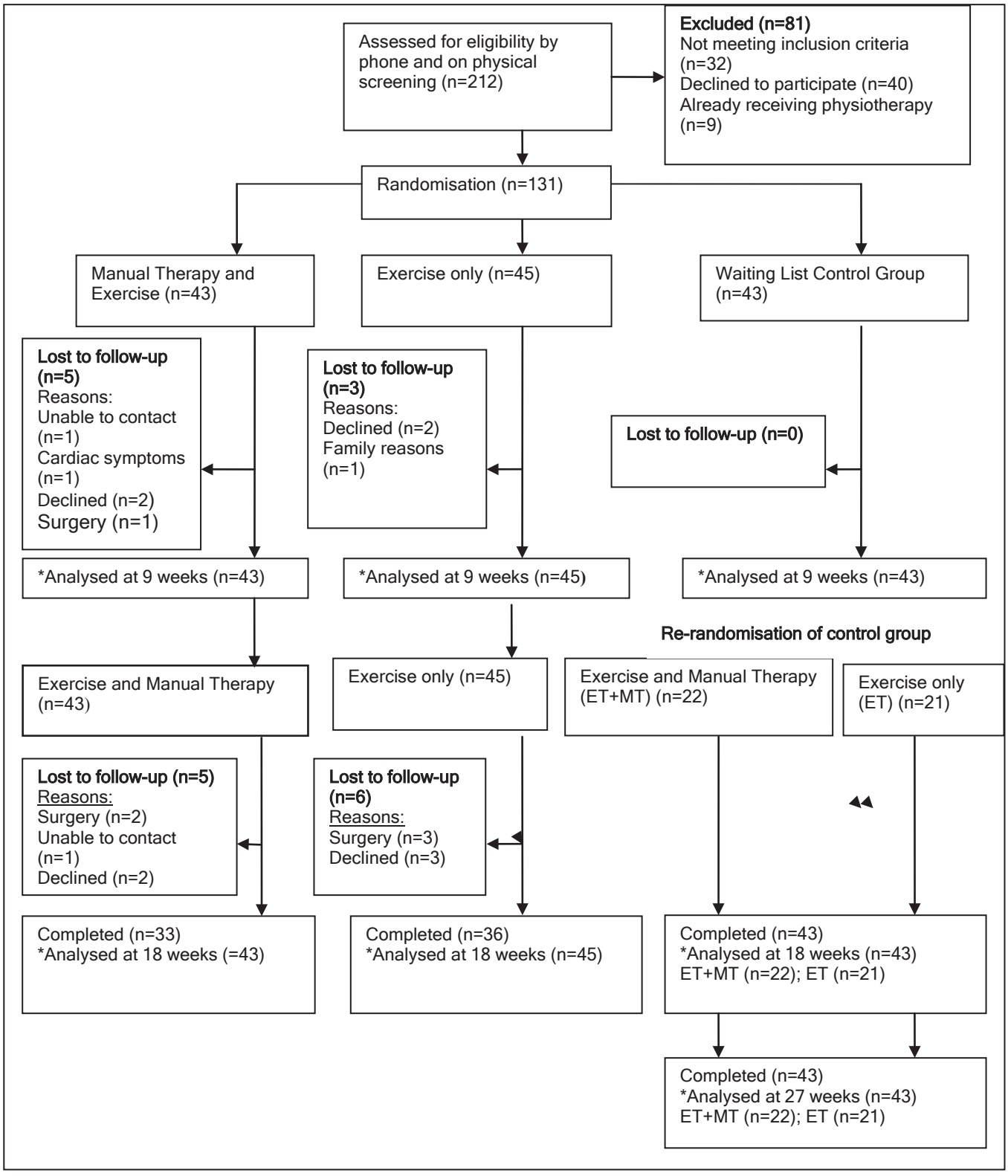

*missing data were imputed using multiple imputation methods

Figure 1: Flow of participants through the trial.

Table 1: Baseline characteristics for the ET and ET+MT groups

		ET (n=66)	ET+MT (n=65)
		Number (% within group)	Number (% within group)
Gender	Female	44 (66.7%)	40 (61.5%)
Body Mass Index	Normal	15 (23.7%)	18 (27.7%)
(kg/m^2)	Overweight/Obese	51 (76.3%)	47 (72.3%)
Referral Source	Orthopaedics	20 (30.3 %)	17 (26.2 %)
	Rheumatology	26 (39.4 %)	37 (56.9 %)
	GP	15 (22.7 %)	7 (10.8 %)
	Other Consultants	5 (7.5%)	4 (6.1%)
Occupation	Retired	24 (36.4 %)	16 (24.6%)
	Homemaker	22 (33.3 %)	20 (30.8%)
	Paid Employment	16 (24.2 %)	23 (35.3%)
	Other	4 (6%)	6 (9.25%)
Pain Medications	No Medication	21 (31.8%)	17 (26.2%)
	Analgesics	37 (56.1%)	39 (60%)
	NSAIDS	24 (36.4%)	21 (32.3%)
Hip Affected	One	55 (73.3%)	45 (69.2%)
	Both	11 (16.7 %)	20 (30.8 %)
		Mean (SD)	Mean (SD)
Age	(years)	62.44 (9.09)	61.43 (10.76)
Symptom Duration	(months)	33.21 (37.77)	36.43 (51.75)
Comorbidities	(number)	1.97 (1.36)	2.38 (1.45)
WOMAC Physical Function		33.48 (14.67)	35.57 (13.57)
HADS Anxiety		6.10 (3.86)	6.17 (4.27)
HADS Depression		4.92 (3.40)	4.50 (3.01)
SF-36 PCS		36.17 (9.42)	34.31 (8.95)
SF-36 MCS		50.99 (12.24)	50.65 (11.02)
Aggregate ROM (degrees)		119.36 (27.62)	125.18 (24.36)
FABER ROM (cm)		30.99 (7.15)	32.09 (6.57)
Sit-to-Stand (seconds)		13.60 (6.18)	14.72 (9.45)
50 foot walk test (seconds)		14.14 (7.20)	14.44 (5.81)
Pain with Activity		5.64 (2.80)	5.88 (2.28)
Pain at Night		5.12 (3.27)	4.59 (3.34)
Pain medication usage (MQS)		6.03 (5.64)	5.84 (4.94)

Cm=centimetres; ET=Exercise Therapy; ET+MT =Exercise therapy and Manual therapy; FABER=Flexion, Abduction, External Rotation; GP= General practitioner; IRQ=Interquartile range; MCS=Mental Component Summary; MQS=Medication Quantification Scale; NSAIDS= Non-Steroidal Anti-Inflammatory Drugs; PCS=Physical Component Summary ROM=range of motion; SD=Standard Deviation; SF-36= Short-Form 36.

Table 2: Baseline characteristics for the ET, ET+MT and control groups

		ET (n= 45)	ET+MT (n= 43)	Control (n= 43)
		Number (% within each group)	Number (% within each group)	Number (% within each group)
Gender	**Male**	11 (24.4%)	16 (37.2%)	20 (46.5%)
	Female	34 (74.5%)	27 (62.8%)	23 (53.5%)
Body Mass Index	**Normal**	13 (28.9%)	9 (20.9%)	7 (16.3%)
(kg/m^2)	**Overweight /Obese**	32 (71.1%)	34 (79.1%)	36 (84.7%)
Pain Medications[†]	**No Medications**	14 (36.8%)	10 (26.3%)	14 (36.8%)
	Analgesics	24 (53.3%)	27 (62.8%)	25 (58.1%)
	NSAIDs	14 (31.1%)	16 (37.2%)	15 (34.9%)
Referral Source	**Orthopaedics**	14 (31.1%)	11 (25.6%)	12 (27.9%)
	Rheumatology	17 (37.8%)	27 (62.8%)	21 (48.8%)
	GP	12 (26.7%)	4 (9.3%)	5 (14.7%)
	Other Consultants	2 (4.4%)	3 (6.6%)	3 (2.7%)
Occupation	**Retired**	16 (35.6%)	16 (35.6%)	15 (34.9%)
	Homemaker	11 (22.4%)	18 (41.9%)	13 (30.2%)
	Paid Employment	16 (35.6%)	13 (30.2%)	11 (25.6%)
	Other	2 (4.5%)	4 (9.3%)	4 (9.3%)
Hip Affected	**Left**	13 (28.95)	8 (18.6%)	9 (23.35)
	Right	23 (51.1%)	20 (46.5%)	26 (60.55)
	Both	9 (20%)	15 (34.9%)	7 (16.35)
Use of Walking Aids	**None**	38 (84.4%)	36 (83.7%)	39 (90.6%)
	Stick for long walk	4 (8.9%)	2 (4.7%)	2 (4.7%)
	Stick most of time	3 (6.7%)	5 (11.6%)	2 (4.7%)
		Mean (SD)	**Mean (SD)**	**Mean (SD)**
Age	**(years)**	61.76 (9.72)	64.83 (9.82)	60.81 (9.73)
Symptom Duration	**(months)**	33(41.56)	37.16 (59.8)	33.3 (30.04)
Co-morbidities		2 (1.26)	2.6 (1.48)	1.86 (1.36)
WOMAC Function		32.29 (12.21)	35.56 (13.39)	32.91 (14.88)
HADS Anxiety		5.80 (3.35)	6.42 (4.68)	5.07 (3.29)
HADS Depression		4.58 (2.95)	4.28 (3.54)	4.37 (2.85)
SF-36 PCS		36.51 (9.87)	35.27 (8.75)	36.60 (9.11)
SF-36 MCS		52.78 (10.75)	50.56 (11.02)	52.82 (11.48)
Aggregate ROM (°)		122.65 (21.62)	121.56 (26.24)	124.87 (24.47)
FABER ROM (cm)		31.36 (5.68)	33.42 (5.84)	29.33 (7.41)
Sit-to-Stand (seconds)		13.18 (4.71)	15.88 (11.20)	14.15 (6.23)
50 foot walk test (seconds)		13.72 (4.37)	15.18 (6.44)	13.52 (5.69)
		Median (IRQ)	**Median (IRQ)**	**Median (IRQ)**
Pain with Activity		6 (4)	6 (3)	5 (4)
Pain at Night		5 (5)	5 (6)	4 (7)
Pain at Rest		3 (5)	4 (5)	3 (5)

ET=Exercise Therapy; ET+MT =Exercise therapy and Manual therapy; FABER=Flexion, abduction, external rotation; IRQ=Interquartile range; ROM=range of motion; SD=Standard Deviation; SF-36= Short-form 36; PCS=Physical Component Summary; MCS=Mental Component Summary; cm=centimetres; °= degrees

Table 3: Primary and secondary outcomes for ET and ET groups at baseline, 9 and 18 weeks

Outcome	Baseline		9 weeks		18 weeks		Difference between groups †	
	Exercise and Manual Therapy (n=65)	Exercise Therapy (n=66)	Exercise and Manual Therapy (n=65)	Exercise Therapy (n=66)	Exercise and Manual Therapy (n=65)	Exercise Therapy (n=66)	9 weeks	18 weeks
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (95% CI)	Mean (95% CI)
↓WOMAC Function (0-68)	35.57 (13.57)	33.48 (14.67)	29.66 (17.16)	29.50 (17.98)	30.53 (19.16)	30.30 (19.33)	0.09 (-2.93, 3.11)	0.42 (-4.41, 5.25)
↓ HADS Anxiety (0-21)	6.17 (4.27)	6.10 (3.86)	6.00 (5.57)	6.48 (4.90)	6.06 (5.76)	6.36 (4.99)	0.60 (-0.86, 2.07)	0.343 (-1.01, 1.86)
↓HADS Depression (0-21)	4.50 (3.01)	4.92 (3.40)	4.80 (4.39)	4.89 (3.82)	4.34 (3.99)	5.16 (4.10)	0.19 (-1.33, 0.95)	0.58 (-0.58, 1.75)
↑SF-36 Physical Summary Score	34.31 (8.95)	36.17(9.42)	35.61 (10.72)	37.50 (11.38)	34.68 (12.27)	36.45 (12.36)	0.77 (-2.20, 3.74)	0.98 (-2.61, 4.57)
↑SF-36 Mental Summary Score	50.65 (11.02)	50.99 (12.24)	49.29 (15.58)	49.33 (13.42)	50.73 (14.68)	47.78 (14.41)	-0.28 (-4.09, 3.53)	-3.43 (-7.38, 0.52)
↑Aggregate ROM (degrees)	125.18 (24.36)	119.36 (27.62)	141.99 (32.66)	132.94 (36.93)	139.24 (41.13)	131.83 (39.79)	-5.40 (-14.29, 3.49)	-4.41 (-15.38, 6.55)
↓FABER ROM (cm)	32.09 (6.57)	30.99 (7.15)	30.03 (8.35)	29.23 (7.93)	30.29 (9.07)	29.79 (8.54)	1.0 (-1.88, 2.06)	0.54 (-1.75, 2.83)
↓Sit to Stand (seconds)	14.72 (9.45)	13.60 (6.18)	13.73 (9.07)	13.17 (7.33)	13.96 (13.93)	12.80 (9.24)	-0.02 (-2.03, 2.09)	-0.02 (-3.03, 3.00)
↓50 foot walk test (seconds)	14.44 (5.81)	14.14(7.20)	14.36 (7.50)	14.70 (10.53)	15.04 (9.49)	15.10 (11.21)	0.50 (-1.59, 2.59)	0.36 (-2.10, 2.82)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (95 % CI IQR)	Mean (95 % CI IQR)
↓Pain severity with activity (NRS)	5.88 (2.28)	5.64 (2.80)	4.32 (3.31)	4.92 (3.46)	4.37 (3.86)	4.67 (3.97)	-0.18 (-1.73, 1.36)	-0.22 (-2.14, 1.71)
↓Night pain severity	5.12 (3.27)	4.59 (3.34)	3.97 (3.86)	3.52 (3.43)	4.65 (4.39)	3.91 (3.78)	0.36	-0.67

(NRS)							(-1.76, 1.05)	(-2.27, 1.71)
↓Pain medication usage (MQS)	5.84 (4.94)	6.03 (5.64)	5.17 (5.07)	5.64 (5.91)	3.97(5.19)	5.49 (6.61)	0.64 (-1.39, 2.67)	1.85 (-0.82, 4.52)

† Adjusted for baseline outcome and the following co-variates: baseline WOMAC and baseline aggregate ROM.
CI=Confidence Interval; FABER=Flexion, Abduction, External Rotation; HADS= Hospital Anxiety and Depression Scale; IQR=Interquartile Range; MQS=medication quantification scale; ROM=range of motion; SF-36= Short-Form 36.

Table 4: Patient satisfaction and global assessment of change outcomes for ET and ET+MT groups

Physiotherapy Outpatient Survey (POPS) at 18 weeks	ET+MT Median (IQR) (n=65)	ET Median (IQR) (n=66)	Median Difference between groups (95%CI)	p-value (between group)†
Expectations (0-5)	3.40 (1.05)	3.60 (1.00)	-0.2 (-0.42,0.40)	0.44
Communication (0-5)	4.5 (0.83)	4.5 (0.83)	0 (-0.34,0.35)	0.27
Therapist (0-5)	4.67 (0.83)	4.31 (0.67)	00.36 (-0.50,0.01)	0.12
Organisation (0-5)	4.29 (0.93)	4.14 (0.71)	0.15 (-0.43,0.16)	0.50
Outcome (0-5)	3.20 (1.20)	2.80 (1.00)	0.40 (00.60,0.00)	**0.02**
Satisfaction (0-5)	4.17 (0.59)	4.25 (0.67)	-0.07 (-0.16,0.16)	1.00
Overall (0-5)	4.01 (0.52)	3.97 (0.56)	-0.04 (0.32,0.06)	0.17
Patient Global Assessment	**Number (%) improved**	**Number (%) improved**	**OR (95% CI)**	**p-value* (between group)**
9 weeks	45 (69.7%)	40 (60.6%)	1.46 (0.72, 2.98)	0.73
18 weeks	33 (50.8%)	28 (42.4%)	1.39 (0.70, 2.76)	0.87

* Chi-squared analysis; † Mann-Whitney U test
ET=Exercise Therapy; ET+MT=Exercise therapy and Manual Therapy; CI=Confidence interval; IRQ=Interquartile range; OR=Odd's Ratio.

Table 5: Outcomes for ET, ET+MT and control groups at 9 weeks

Outcome		Exercise and Manual Therapy (n=43)	Exercise Therapy (n=45)	Control (n=43)	ET+MT and ET vs control (95%CI) †	P-value
		Mean (SD)	Mean (SD)	Mean (SD)	Mean Difference (95% CI)	
WOMAC Function	Baseline	35.56 (13.39)	32.29 (12.21)	32.91 (15.22)	7.76 (2.80, 12.72)	**0.002**
(0-68)	9 weeks	29.31 (17.06)	28.08 (15.48)	36.09 (16.41)		
HADS Anxiety	Baseline	6.42 (4.68*)*	5.80 (*3.35)*	5.07 (3.37)	0.07 (-1.26, 1.41)	0.92
(0-21)	9 weeks	6.31 (5.54*)*	6.74 (*4.27)*	6.14 (3.97)		
HADS Depression	Baseline	4.28 (3.54)	4.58 (2.95)	4.37 (2.92)	-0.67 (-1.85, 0.51)	0.26
(0-21)	9 weeks	4.83 (4.63)	5.02 (3.39)	5.58 (3.45)		
SF-36 Physical	Baseline	35.27(8.75)	36.51 (9.87)	36.60 (9.32)	-1.75 (-0.12, 6.84)	0.06
Summary (0-100)	9 weeks	35.61 (11.22)	37.03 (11.25)	33.82 (9.67)		
SF-36 Mental	Baseline	50.56 (11.02)	52.78 (10.75)	52.82 (11.75)	0.02 (-3.72, 3.69)	0.99
Summary (0-100)	9 weeks	49.92 (15.41)	48.92 (12.50)	48.52 (13.75)		
Aggregate ROM	Baseline	121.56 (26.24)	118.88 (30.16)	124.87 (25.03)	15.85 (6.69, 25.00)	**0.001**
(degrees)	9 weeks	139.98 (31.71)	136.09 (28.86)	123.72 (29.67)		
FABER	Baseline	33.42 (5.84)	31.19 (6.33)	29.24 (7.91)	-1.86 (-3.91, 0.23)	0.07
	9 weeks	31.08 (7.89)	29.67 (6.90)	29.94 (76.03)		
Sit to stand	Baseline	15.88 (11.20)	13.18 (4.71)	14.15 (6.37)	0.07 (-1.98, 2.12)	0.95
(seconds)	9 weeks	15.14 (9.30)	12.94 (5.76)	13.28 (6.67)		
50 foot walk test	Baseline	15.18 (6.44)	13.72 (4.37)	13.30 (4.77)	-0.38 (-2.48, 1.73)	0.72
(seconds)	9 weeks	14.94 (7.68)	14.32 (8.33)	13.94 (8.49)		
		Mean (SD)	Mean (SD)	Mean (SD)	Median Difference (95% CI IQR)	
Pain with activity	Baseline	6.02 (2.23)	5.62 (2.63)	5.65 (2.46)	1.41 (-0.45, 3.28)	0.14
	9 weeks	4.20 (3.42)	4.02 (2.88)	5.62 (2.84)		

Night Pain	**Baseline**	4.97 (3.35)	4.42 (3.24)	4.69 (3.24)	-0.44 (-2.18, 1.31)	0.62
	9 weeks	3.41 (3.67)	3.21 (2.93)	5.13 (3.57)		
Pain Medication	**Baseline**	5.91 (4.64)	5.31(4.87)	5.53 (5.76)	-0.64 (-3.76, 2.47)	0.68
usage Scale (MQS)	**9 weeks**	5.20 (4.77)	4.73 (4.99)	6.49 (6.36)		
Patient Global	**9 weeks**	**Number (%)**	**Number (%)**	**Number (%)**	**ET+MT vs Control OR (95%CI)**	**ET vs Control OR (95%CI)**
Assessment		**Improved**	**Improved**	**Improved**		
		27 (60%)	28 (65.1%)	5 (11.6%)	11.4 (3.8, 34.5)	12.5 (4.1, 38)

† Adjusted for baseline outcome and the following co-variates: baseline WOMAC PF, aggregate ROM, sit-to-stand and MQS
CI=Confidence Interval; FABER=Flexion, Abduction, External Rotation; HADS=Hospital Anxiety and Depression Scale; IQR=Interquartile Range; MQS=Medication Quantification Scale; ROM=range of motion; SF-36= Short-Form 36.