Exercise-Based Upper Limb Rehabilitation In Rheumatoid Arthritis

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EXERCISE-BASED UPPER LIMB REHABILITATION IN RHEUMATOID ARTHRITIS

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Abstract

Background: Rheumatoid arthritis (RA) is a chronic, systemic, disabling disease which reduces independence, quality of life, and longevity. Upper limb impairment causes considerable disability, contributes to work incapacity, and has substantial monetary and non-monetary, personal and societal consequences.

Objectives: The studies in this thesis focus on the development and evaluation of a novel exercise programme for the rehabilitation of global upper limb disability in people with RA. It explores participants' experiences and the factors influencing their uptake and maintenance of the programme. It evaluates the physical activity (PA) levels of adults with rheumatic diseases against PA guidelines, and assesses the proportion of respondents who report ever receiving PA advice from a healthcare professional (HCP).

Methods: Following development of a global upper limb home exercise programme, supplemented by four supervised group education, self-management, and exercise sessions (the EXTRA programme), 108 people with RA of less than 5 years duration were randomly allocated to receive either the EXTRA programme or usual care. Self-reported disability, upper limb functional performance, strength, self-efficacy, quality of life (QOL), and disease activity were assessed at baseline, 12, and 36 weeks. Participants were interviewed to evaluate their experiences of the EXTRA programme. Physical activity participation, recommendation, and preferences were surveyed among 508 adults with a range of rheumatic diseases.

Results: Following the EXTRA programme, there were significant improvements to upper limb disability, function, strength, and self-efficacy, but not QOL, and no adverse effects on disease activity or pain. Participants perceived the EXTRA programme to be effective and acceptable. Sixty-one percent of respondents met PA guidelines, although 27% were inactive. Forty-three percent of respondents reported receiving PA advice from a HCP. Walking was the most preferred PA (65%)

Conclusions: The EXTRA programme improves upper limb disability, function, strength, and self-efficacy, with no adverse effects on disease activity or pain, in people with RA. Many people with rheumatic diseases are inactive and more than half have never discussed PA with a HCP. Recommending exercise and regular PA should be integral to rheumatic disease management.

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Symbols and Abbreviations

ACR	American College of Rheumatology
ACSM	American College of Sports Medicine
ADL	Activities of Daily Living
AIMS	Arthritis Impact Measurement Scale
ARUK	Arthritis Research UK
AS	Ankylosing Spondylitis
ASES	Arthritis Self-Efficacy Scale
ASMP	The Arthritis Self-Management Programme
ANOVA	Analysis of Variance
BMI	Body Mass Index
CDAI	Clinical Disease Activity Index
CI	Confidence Interval
CRP	C-Reactive Protein
CVD	Cardiovascular Disease
d	Cohen's *d*
d	Difference
$\bar{d}$	Mean of the Difference
DAS28	28 Joint Disease Activity Score
DASH	Disability of the Arm, Shoulder, and Hand Questionnaire
df	Degrees of Freedom
DMARD	Disease Modifying Anti-Rheumatic Drug
DOM	Dominant
EDC	Extensor Digitorum Communis
ESCAPE	Enabling Self-management and Coping with Arthritic Knee Pain through Exercise
ESR	Erythrocyte Sedimentation Rate
EULAR	European League Against Rheumatism
EXTRA	Education, self-management, and eXercise Training in Rheumatoid Arthritis
FIT-HaNSA	Function Impairment Test-Hand, and Neck, Shoulder, Arm
FMS	Fibromyalgia Syndrome
GAT	Grip Ability Test
GSTH	Guy's and St. Thomas' Hospital NHS Foundation Trust
HAQ	Health Assessment Questionnaire
HCP	Healthcare Professional
HGD	Hand Grip Dynamometer
HHD	Hand Held Dynamometer
ICC	Intra-Class Correlation
ICF	International Classification of Functioning, Disability, and Health
IgG	Immunoglobulin-Gamma
IL	Interleukin
IPAQ	International Physical Activity Questionnaire
IPA	Interpretive Phenomenological Analysis
IQR	Interquartile Range
JTT	Jebsen-Taylor Hand Function Test
K	Kurtosis
KCH	King's College Hospital NHS Foundation Trust
KCL	King's College London
LB	Lindsay Bearne (Chief Investigator)
LOA	Limits of Agreement

LN	Natural Logarithm
MACTAR	McMaster Toronto Arthritis Patient Preference Disability Questionnaire
MCAR	Missing Completely at Random
MCID	Minimal Clinically Important Difference
MCP	Metacarpophalangeal
MET	Metabolic Equivalent of Task
MH	Michael Hurley (Research Team Member)
MHAQ	Modified Health Assessment Questionnaire
MHQ	Michigan Hand Function Questionnaire
MI	Multiple Imputation
MNAR	Missing Not at Random
MRC	Medical Research Council
N	Newtons
NDOM	Non-Dominant
NG	Nadine Geddes (Qualitative Researcher)
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NNT	Number Needed to Treat
NSAID	Non-Steroidal Anti-Inflammatory Drug
nSJ	Number of Swollen Joints
nTJ	Number of Tender Joints
σ	The standard deviation in a population of scores
OA	Osteoarthritis
P_0	Minimally acceptable level of reliability
P_1	Minimally acceptable level of reliability (null hypothesis)
PA	Physical Activity
PADA	Patient's Assessment of Disease Activity
PI	Principal Investigator
PIP	Proximal Interphalangeal
PO_2	Plasma Oxygen Partial Pressure
PRT	Progressive Resistance Training
PSA	Psoriatic Arthritis
PT	Physiotherapist
QOL	Quality of Life
QWB-SA	Quality of Wellbeing Scale
r	Pearson's product moment correlation coefficient
R^2	Coefficient of determination
RA	Rheumatoid Arthritis
ReA	Reactive Arthritis
RAQoL	Rheumatoid Arthritis Quality of Life Questionnaire
RC	Repeatability Coefficient
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
Reps	Repetitions
ROM	Range of Movement
RM	Repetition Maximum
RPE	Rating of Perceived Exertion
S	Skewness
SCT	Social Cognitive Theory
SD	Standard Deviation
SD_{diff}	Standard Deviation of the Difference
SE	Standard Error
SF-12	Medical Outcomes Study Short Form-12 Health Survey
SF-36	Medical Outcomes Study Short Form-36 Health Survey
SLE	Systemic Lupus Erythematosis
SMART	Specific, Measurable, Achievable, Relevant, Timed
SODA	Sequential Occupational Dexterity Assessment
SPADI	Shoulder Pain and Disability Index

TNF-α	Tumor Necrosis Factor-Alpha
TPB	Theory of Planned Behaviour
TRA	Theory of Reasoned Action
μ	The mean of a population of scores
UHL	University Hospital Lewisham NHS Foundation Trust
VAS	Visual Analogue Scale
VM	Victoria Manning (Author and Principal Investigator)
VO_{2max}	Maximal Oxygen Consumption
WHO	World Health Organization
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
χ^2	Chi square test statistic

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1 Introduction

1.1 RHEUMATIC DISEASE

Rheumatic diseases comprise a wide range of disease states and syndromes that involve the articular structures. They include, but are not limited to, regional pain syndromes (e.g. tendonitis), systemic inflammatory diseases (e.g. rheumatoid arthritis (RA)), infections involving the joints and periarticular structures, and diseases in which joints are secondarily involved [1]. Rheumatic diseases are among the most prevalent chronic conditions, accounting for a large proportion of disability, lost productivity, reduction in quality of life (QOL), and increased healthcare usage worldwide [2-3]. Rheumatoid arthritis is the second most prevalent rheumatic disease after osteoarthritis (OA) [2], and imposes the greatest personal and societal burden [4].

1.2 RHEUMATOID ARTHRITIS

1.2.1 Definition

Rheumatoid arthritis is a chronic autoimmune disease associated with articular, extra-articular, and systemic effects [5] (Figure 1.1 [6]). The small joints of the hands and feet are typically affected early in the disease [7].

Figure 1.1 Common clinical features of rheumatoid arthritis

Articular features:

- Symmetrical polyarthritis
- Progressive joint erosions
- Presence of rheumatoid factor or anti-citrullinated protein antibodies

Extra-articular features:

- ***Skin:*** subcutaneous nodules, ulcers, vasculitis, palmar erythema
- ***Neuropathy:*** compressive or vasculitic
- ***Lung:*** interstitial lung disease, pleural effusions, nodules
- ***Ocular:*** scleritis, episcleritis, sicca syndrome, scleromalacia
- ***Cardiac:*** pericarditis, cardiomyopathy
- ***Gastrointestinal:*** splenomegaly, abnormal liver function tests
- ***Haematological:*** Felty's syndrome, anaemia of chronic disease

1.2.2 Prevalence and Incidence

An estimated 0.5-1.0% of adults in the UK are affected by RA [3], and RA is 2 to 3 times more prevalent among women than men [8]. Annual incidence rates are 14/100 000 and 36/100 000 for UK men and women, respectively [9]. In men, RA rarely occurs under the age of 45 years and prevalence and incidence increases with age [9]. Among women, the prevalence and incidence of RA increases up to the age of 45 years, remains steady until the age of 75 years, and falls thereafter [9].

1.2.3 Aetiology and Risk Factors

The underlying cause of RA is unknown but there is evidence that a combination of genetic [10] and environmental factors, such as exposure to traffic pollution [11] and cigarette smoking [12], may influence the development, rate of progression, and severity of RA.

1.2.4 Articular Pathophysiology

Autoimmunity is the immune response to autologous antigens. Autoimmune diseases (such as RA) result from the pathological effects of this response on one or more organ(s). Whilst many specific cells and pathways have been defined, no one unified mechanism controlling the pathophysiology of RA has been identified.

The autoimmune response is activated by autologous antigens, which are presented to T-lymphocytes (T-cells) by dendritic cells, macrophages, and B-lymphocytes (B-cells) [5]. Activated T-cells infiltrate the synovial membrane producing cytokines and chemokines (proteins that mediate cell to cell communication) leading to the further T-cell, B-cell, and macrophage interactions [5]. In addition to antigen presentation, B-cells produce antibodies, autoantibodies (particularly rheumatoid factor (the immunoglobulin directed against the Fc portion of immunoglobulin-Gamma (IgG) and found in ~80% of people with RA [1]), and anti-cyclic citrullinated protein antibodies), and cytokines, which amplify the pro-inflammatory cytokine cascade [5].

Macrophages are responsible for the majority of cytokine production, including tumor necrosis factor-alpha (TNF-α), interleukin-6 (IL-6), and interleukin-1 (IL-1) [5]. IL-6 is particularly important in the pathogenesis of RA [5], acting upon local and distant cells by trans-signalling mechanisms. Trans-signalling promotes T-cell recruitment by regulating chemokine secretion and B-cell development [5]. IL-6 contributes to neutrophil recruitment, responsible for the secretion of proteolytic enzymes and reactive oxygen intermediates, precipitating joint inflammation and cartilage destruction [5]. IL-6, IL-1, and TNF-α also activate synoviocytes and chondrocytes, resulting in the secretion of matrix metalloproteinases in synovial fluid and cartilage, promoting bone and cartilage degradation [5].

Vascular endothelial growth factor plays a central role in angiogenesis, integral to the formation and maintenance of pannus, facilitating macrophage driven osteoclastogenesis [5]. Osteoclasts, the primary mediators of bone destruction, populate the synovial membrane polarized on bone, concentrated in pannus [5]. The joint synovial lining becomes hyperplastic, and the synovial membrane expands and forms villi [5]. Destruction of the articular cartilage, subchondral cyst formation, and bony erosions around periarticular structures, precipitate joint dysfunction and disability. TNF-α and Il-1 inhibit matrix synthesis, preventing repair.

Pro-inflammatory cytokines, particularly IL-6, also affect plasma concentrations of acute-phase proteins, such as C-reactive protein (CRP) [5]. Increased levels of CRP exacerbate disease-related tissue damage, and

facilitate the development of comorbid complications, such as cardiovascular disease (CVD) [5].

1.2.5 Extra-Articular and Systemic Pathophysiology

Approximately 50% of people with RA experience at least one extra-articular feature (Figure 1.1) or systemic manifestation, such as anaemia, CVD, osteoporosis, fatigue, depression, and rheumatoid cachexia [13]. The incidence of CVD in people with RA is greater than three times that of the general population [14] and is associated with increased rates of mortality [15]. The etiology of the systemic effects of RA are multifactorial, but are related to the unregulated production of pro-inflammatory cytokines [16-17] and lifestyle factors, such as physical inactivity.

Release of TNF-α, IL-6, and IL-1 from synovial tissue alters the function of adipose tissue, skeletal muscle, liver, and the vascular endothelium, resulting in insulin resistance, dyslipidaemia, increased global oxidative activity, and endothelial dysfunction [5]. Fatigue, dysthymia, irritability, and depression, frequently reported by people with RA, are associated with cytokine (TNF-α, IL-6, and IL-1) mediated dysregulation of the hypothalamic-pituitary-adrenal axis [5].

Rheumatoid cachexia, or loss of muscle mass accompanied by stable or increasing fat mass, is observed without any evidence of malabsorption or impaired renal or liver function [16]. People with RA typically lose an average of 13-15% muscle mass [16]; a loss of 5% muscle mass is associated with reduced muscular strength, altered energy metabolism, greater susceptibility to infections, and increased mortality rates compared to the general

population [16]. Sarcoactive cytokines thought to be involved in the pathogenesis of rheumatoid cachexia include TNF-α, IL-6, IL-1, transforming growth factor-β, and interferon-ɣ [16-18].

1.2.6 Diagnosis and Clinical Features

The classification of RA was previously based on the 1987 American College of Rheumatology (ACR) revised classification criteria [19] (Figure 1.2 [19]).

Figure 1.2 The 1987 American College of Rheumatology Classification Criteria for Rheumatoid Arthritis

Patients must have four of the seven criteria:

1) **Morning stiffness lasting at least one hour***
2) **Swelling in three or more joints***
3) **Swelling in hand joints***
4) **Symmetric joint swelling***
5) **Erosions of decalcification on x-ray of hand**
6) **Rheumatoid nodules**
7) **Abnormal serum rheumatoid factor**

*Must be present for at least six weeks

However, to improve diagnostic sensitivity in early disease, the ACR and European League Against Rheumatism (EULAR) published new classification criteria in 2010 [20] (Figure 1.3 [20]).

The onset of RA is usually insidious, although a small proportion of people experience an acute onset of symptoms which develop over a few days. Persistent joint inflammation is central to the diagnostic features of RA, and systemic features of ill-health such as weight loss, malaise, and fever often accompany early synovitis [21].

Figure 1.3 The 2010 American College of Rheumatology and European League Against Rheumatism Classification Criteria for Rheumatoid Arthritis

Target population (Who should be tested?): Patients who:
1) Have at least 1 joint with definite clinical synovitis (swelling)
2) With synovitis not better explained by another disease

Classification criteria for RA
(Score-based algorithm: add score of categories A–D; a score of ≥6/10 is needed for classification of a patient as having definite RA):

A. Joint involvement (swollen or tender)	**Score**
• 1 large joint	**0**
• 2-10 large joints	**1**
• 1-3 small joints (with or without involvement of large joints)	**2**
• 4-10 small joints (with or without involvement of large joints)	**3**
• ≥10 joints (at least 1 small joint)	**5**
B. Serology (at least 1 test result is needed for classification)	
• Negative RF and negative ACPA	**0**
• Low-positive RF or low-positive ACPA	**2**
• High-positive RF or high-positive ACPA	**3**
C. Acute-phase reactants (at least 1 test result is needed for classification)	
• Normal CRP and normal ESR	**0**
• Abnormal CRP or abnormal ESR	**1**
D. Duration of symptoms	
• <6 weeks	**0**
• ≥6 weeks	**1**

Later in the disease, typical features include morning stiffness, pain, fatigue, and multi-joint inflammation. The symptoms may exacerbate and remit, characterising disease flares. Clinically, disease activity is monitored by a core data set selected on the basis of construct, face, content, criterion, and discriminant validity [22-25] (Figure 1.4 [22, 24-25]).

Figure 1.4 Core data set for assessing RA disease activity

1) **Number of swollen joints**
2) **Number of tender joints**
3) **Patient's assessment of pain**
4) **Patient's global assessment of disease activity**
5) **Assessor's global assessment of disease activity**
6) **Laboratory evaluation of acute-phase reactant (erythrocyte sedimentation rate, C-reactive protein, or equivalent)**
7) **Patient's assessment of physical function***

*Any self-assessed measure which is valid, reliable, and sensitive to change in an RA population

Joint damage can occur within a few months of symptom onset, and rate of progression is highest in the early stages of the disease [26-27] leading to considerable disability, dysfunction, and in some cases, joint deformity, such as characteristic 'Swan neck' and 'Boutonnieres' deformities of the fingers.

1.2.7 Disability

Disability is the 'difficulty performing activities of daily living (ADL)' [28]. Whilst disability rates in RA are declining (2% per annum) as a result of earlier, more aggressive, pharmacological therapy and the introduction of biological agents [29], 30% of people with RA are severely disabled within 10 years of diagnosis [7].

The causes of disability in RA are multifactorial. In addition to joint inflammation and articular damage [30-34], disability is associated with pain [35-36], sensorimotor dysfunction [31, 34, 37], and reduced muscle mass [38]. As 50% of people with RA are of working age at the time of diagnosis [9, 39], over half of the total cost of RA results from disability related work

incapacity [4, 39-47], and the progression of disability in early RA predicts long-term costs [48]. Therefore, addressing dysfunction and disability in RA are key management aims.

1.2.8 Upper Limb Disability

The upper limbs are involved in 80% to 90% of people with RA [30, 49], often from the early stages of the disease [50-51], resulting in decreased strength [37], reduced proprioceptive acuity [37, 52], and impaired range of movement (ROM) [53]. Effective upper limb function requires good proximal muscle control to stabilize the upper limb and place the hand for manual dexterity, and upper limb and hand grip weakness [30-31, 37, 53-55] and impaired wrist and shoulder joint ROM [31, 53, 56] are associated with upper limb disability. Disuse muscular atrophy [57] and rheumatoid cachexia [18, 58] account for as much as one third of upper limb weakness in RA, independent of joint pain or deformity [58].

Upper limb function deteriorates with disease progression [30, 59], and impairs work capacity [60]. Nearly half of employed people with RA perceive not being able to use their hands as a persistent threat to their continued employment [61], and costs due to work incapacity are augmented by poor hand function [45]. Consequently the effective management of upper limb dysfunction in people with RA is vital.

1.2.9 Assessment of Disability

The World Health Organizations' (WHO) International Classification of Functioning, Disability, and Health (ICF) Core Set for RA [62-63] (Figure 1.5

[62]) (formerly the International Classification of Impairment, Disability, and Handicap [64]) provides a valid means of understanding function in people with RA [65-66]. It is recommended that functional outcome measures are selected on the basis of ICF categories [63, 67].

1.2.9.1 Self-Reported Global Disability

Self-report measures of overall function and disability in people with RA include the ‘Health Assessment Questionnaire’ (HAQ) [68], the ‘Arthritis Impact Measurement Scale’ (AIMS) [69], the ‘Quality of Well-Being Scale’ (QWB-SA) [70], the ‘Medical Outcomes Study Short Form-36/12 Health Survey’ (SF-36/12) [71], and the ‘McMaster Toronto Arthritis Patient Preference Disability Questionnaire’ (MACTAR) [72].

Among people with RA, the HAQ correlates well with disease activity [73] and other self report measures of disability (e.g. ‘Disabilities of the Arm, Shoulder, and Hand Questionnaire’ (DASH)) [74], is reliable (over 2 weeks; intraclass correlation coefficient (ICC) >0.9 [73]), and demonstrates good internal consistency (Cronbach's alpha >0.9) [73], however the association between the HAQ and objective measures of upper limb function (e.g. Sollerman Hand Function Test and Sequential Occupational Dexterity Assessment (SODA)) is weak [75] and, among patients with early disease, compared to other self-report (e.g. ‘Michigan Hand Function Questionnaire’ (MHQ)) and objective measures (e.g. hand grip strength) of upper limb disability, the HAQ shows poor responsiveness to change in wrist and hand function [76].

Figure 1.5 International Classification of Functioning, Disability, and Health (ICF) categories included in the Brief ICF Core Set for Rheumatoid Arthritis

ICF Component	ICF Category Title
Body Functions	• Sensation of pain • Mobility of joint functions • Muscle power functions • Exercise tolerance functions • Sensations related to muscles and movement functions • Gait pattern functions • Sleep functions • Muscle endurance functions
Body Structures	• Structure of lower extremity • Structure of upper extremity • Structure of head and neck region • Structure of shoulder region • Structure of areas of skin • Structure of trunk • Eye, ear, and related structures, unspecified
Activities and Participation	• Walking • Remunerative employment • Fine hand use • Changing basic body position • Hand and arm use • Carrying out daily routines • Lifting and carrying objects • Using transportation • Dressing • Washing oneself • Recreation and leisure • Intimate relationships • Work and employment, other specified, and unspecified • Eating
Environmental Factors	• Immediate family • Health services, systems and policies • Health professionals • Products and technology for personal use in daily living • Social security services, systems and policies • Design, construction and building products and technology of buildings for private use • Transportation services, systems and policies • Products and technology for personal indoor and outdoor mobility and transportation • Products or substances for personal consumption • Design, construction and building products and technology of buildings for public use

The AIMS is an arthritis-specific questionnaire containing a component for hand and finger, but not arm, function. The subsequent AIMS2 (comprising 57 items) contains 5 items for arm, and 5 items for hand and finger function. Among people with RA, the AIMS2 correlates well with other general disability measures (e.g. MHAQ, SF-36), and is similarly responsive to changes in disease activity [77]. In a cohort of 45 participants, test-retest reliability over 3 weeks was satisfactory (ICC 0.78-0.94), however the sample was small, and comprised people with OA as well as RA; therefore the AIMS2 may require further evaluation in an RA population [78].

The QWB-SA correlates well with the AIMS, and may be valid for use [70], but to date has had limited application among patients with RA and other rheumatic conditions.

The SF-36 and SF-12 are 36 and 12 item questionnaires, respectively, designed to assess 8 aspects of health ranging from physical limitations to general perceptions of vitality and mental well-being. Test-retest reliability of the questionnaires is satisfactory to poor (ICC 0.71-0.81) [79], and whilst scores correlate with other self-report disability measures (e.g. HAQ [71], MHAQ [79]) and disease activity [71], they may be unresponsive to improvement in people with RA [79]. Nevertheless, missing responses were high among more disabled respondents, thus limiting the generalizability of findings to more able individuals with RA [79].

The MACTAR is an arthritis-specific, individualized questionnaire which enables patients to identify activities and functional problems which are particularly pertinent to them. The MACTAR is responsive to change

(receiver-operating characteristics (ROC) curve = 0.9 [80], standardized response mean = 2.2 [72]), and outcomes correlate well with other self-report functional indices (e.g. 'Western Ontario and McMaster Universities Osteoarthritis Index' (WOMAC), SF-36, HAQ) and disease activity [72, 80]. However, not all impaired activities identified by respondents were represented by other functional indices, limiting conclusions as to MACTAR validity [72, 80] and, in one study, results were from a cohort of participants with knee or hip OA, likely unrepresentative of people with RA, particularly those with upper limb impairments [80]. Moreover, the MACTAR requires trained interviewers and thus may be less feasible and more time consuming than simpler, self-completed questionnaires.

1.2.9.2 Self-Reported Upper Limb Disability

Self-report measures specific to upper limb disability include the 'Michigan Hand Function Questionnaire' (MHQ) [81-82], the 'Shoulder Pain and Disability Index' (SPADI) [83-84], and the 'Disabilities of the Arm, Shoulder, and Hand Questionnaire' (DASH) [74].

The MHQ correlates well with self-report measures of overall disability (e.g. AIMS2, SF-12) [81-82] but not objective measures of upper limb function (e.g. 'Jebsen-Taylor Hand Function Test' (JTT)) [85], demonstrates good internal consistency (Cronbach's alphas 0.79 to 0.97 [81-82]), is responsive to change [86], and analysis with Spearman's correlation coefficient indicates good test-retest association [81-82]. However, retest response rate was low in one study (49%), potentially producing a biased sample [86], and further analysis with ICC is required to verify repeatability,

rather than association [87]. Moreover, given that current studies include people with a range of hand disorders [81, 85-86], and only one study exclusively enrolled participants with RA, and only those with severe subluxation of the metacarpophalangeal joints [82], it is unclear whether findings would be replicated, or if they are generalizable to all individuals with RA.

Among those with general shoulder discomfort, the SPADI demonstrates good construct validity, correlating well with overall (e.g. HAQ, SF-20) [84] and upper limb specific (e.g. DASH) [83] disability measures, is reliable (ICC >0.9 [83]), and responsiveness to change [84], but the SPADI has not been investigated among patients with RA.

The DASH is the only self report measure of global upper limb function, developed according to the WHO ICF taxonomy [88-89]. The DASH demonstrates good internal consistency (Cronbach's alpha 0.97 [74]) and, whilst test-retest reliability is high (ICC >0.9) [74, 90], in one study retesting was conducted after only 2 days [74], and in another participants had general upper limb dysfunction as opposed to RA [90], thus limiting conclusions as to the longer-term reliability of the DASH in people with RA. A number of large studies utilizing robust statistical methodologies indicate that the DASH correlates well with self-report measures of overall (e.g. HAQ, SF-36) [74], upper limb (e.g. SPADI) [90], and disease specific (e.g. AIMS2) [74] disability, as well as objectively measured hand function (e.g. ‘Grip Ability Test’ (GAT)) [31]. However, whilst clinical measures, such as hand grip

strength [31] and disease activity [91], correlate well with the DASH in some studies, these associations are not always replicated [74].

Whilst the ability of the DASH to assess meaningful clinical change among people with RA is not currently known, both small (n=21) and large (n=104) studies among people undergoing surgery for subacromial impingement, carpal tunnel syndrome, and elbow dysfunction, report clinically important changes, 6 months post-operatively, equivalent to 10 DASH points [92-93]. Importantly, a large review of 71 studies assessing four shoulder disability scales, including the DASH and SPADI, found that the DASH was able to effectively differentiate between different populations and disability levels [83], and one statistically robust study among a large cohort of 172 respondents with general upper limb dysfunction demonstrated that the DASH was more responsive to change than other joint specific upper limb measures (e.g. SPADI) [90].

1.2.9.3 Objective Upper Limb Disability

Objective measures of upper limb function and disability, which involve achievement-rating or timing participants' speed in completing an activity or task, include the 'Jebsen-Taylor Hand Function Test' (JTT) [85], the 'Functional Impairment Test – Hand, and Neck, Shoulder, Arm' (FIT-HaNSA) [94], and the 'Grip Ability Test' (GAT) [31].

The JTT assesses a broad range of hand functions via 7 activities including writing a 24-letter sentence and stacking checkers; an overall score is determined by the time taken to complete each activity with both the dominant (DOM) and non-dominant (NDOM) hand. Thus, the test is time

consuming, and biased scores may be achieved where participants' perform poorly on their unaffected NDOM side. Among people (n=111) with a range of musculoskeletal conditions (RA, OA, carpal tunnel syndrome, and distal radius fractures), the JTT demonstrates poor construct validity and responsiveness to change when compared to self-report measures of upper limb disability (e.g. MHQ) [85]. Whilst only a small number of people with RA (n=37) were evaluated and disease specificity is important when comparing objective with patient reported measures of disability and function, this study employed robust, well described statistical analyses and findings concur with previous research in people with RA [95].

The FIT-HaNSA assesses shoulder function via 3 timed subtasks, including: 1) moving objects to waist-height shelves, 2) moving objects to eye-level shelves, and 3) sustained manipulation of overhead nuts/bolts. A maximum score is achieved if the participant can maintain each subtask for 5 minutes. Among people with shoulder impingement, all tasks were highly reliable (test re-test ICCs >0.84), tasks 2 and 3 demonstrated good discriminate validity to age-gender matched healthy controls and people with milder shoulder pathologies, and subtasks 1 and 2 correlated well with the DASH and SPADI respectively [94]. However, reliability testing was conducted among only 10 individuals, and it is unclear over what time period [94]. Similarly, validity was assessed in a small, young (mean age 32 years) sample, of whom only 5 had severe shoulder pathology, and therefore it is unclear whether the findings may be generalized to an older, more disabled population [94]. Moreover, the psychometric properties of the FIT-HaNSA

among people with RA have not been investigated, and clinical application may be limited by the time and equipment required to conduct the test.

The GAT was specifically designed to assess hand function in people with RA [96]. It comprises 3 tasks; the time taken to complete each task is weighted and summed to generate a GAT score (Section 3.3.1). Demonstrated among large cohorts of people with RA, the GAT correlates well with other self-report (e.g. HAQ) and objective (e.g. grip strength, wrist mobility) disability measures, effectively discriminates between those with RA and healthy controls, is responsive to change following a hand exercise training program, and demonstrates good test-retest (intra- and inter-rater) reliability (r >0.9) and internal consistency [59, 96]. However, only a small sub-cohort (n=24) completed the hand training programme, thus limiting conclusions on the responsiveness of the GAT, and further work is required to confirm GAT reliability, as r is a measure of association rather than repeatability (future studies should describe limits of agreement or report ICC [87]) [59, 96]. Moreover, the majority of participants were mildly disabled, and it is unclear how generalizable the findings would be to more severely disabled individuals [59, 96]. Whilst there are limitations to the psychometric testing of this outcome measure, it provides a quick and easy, disease specific objective test of hand function for clinicians and researchers.

1.3 THE CLINICAL MANAGEMENT OF RHEUMATOID ARTHRITIS

1.3.1 Management by a Multidisciplinary Team

The National Institute of Health and Clinical Excellence (NICE) clinical guideline for the management and treatment of adults with RA recommends that people with RA have access to a multidisciplinary team (including rheumatology physicians and specialist nurses, physiotherapists, occupational therapists, psychotherapists, and podiatrists) to help manage their condition and provide periodic disease and health status review [7]. This multidisciplinary approach aims to alleviate symptoms, minimize disease activity, inhibit articular damage, extra-articular, and systemic effects, reduce treatment complications (e.g. vasculitis), and improve patient QOL [3, 7].

1.3.2 Pharmacological Management

The target of pharmacological management is disease remission [7], and early pharmacological intervention improves long-term outcomes [6]. Analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) contribute toward symptomatic relief [6]. Disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate, sulphasalazine, and leflunomide, prescribed individually or in combination, reduce symptoms and the acute systemic inflammatory response, limiting joint damage [6]. Corticosteroids also rapidly reduce disease activity [6]. Biological agents (introduced in 1999), including anti-TNF, rituximab, and etanercept, specifically, and with high affinity, target, bind to, and neutralize pro-inflammatory cytokines (TNF-α, IL-6, and IL-1) involved in RA pathogenesis [6].

1.3.3 Surgical Management

Total joint arthroplasty, soft tissue surgery, and joint reconstruction reduce pain and restore function [97]. Over the last decade surgical intervention rates have decreased, reflecting improvements in disease management and outcomes for people with RA [98-99].

1.3.4 Physical Management

Exercise therapy is the cornerstone of the physical management of RA [100-101]. Exercise aims to reduce pain and disability by increasing or maintaining sensorimotor function and aerobic fitness [100]. In people with RA, exercise-induced improvements to sensorimotor and cardio-respiratory parameters are equivalent to age and gender matched 'healthy' individuals, irrespective of disease duration [102].

Exercise may be prescribed independently, or in combination with other physical therapies, including: *thermotherapy* (e.g. hot and cold packs, paraffin and wax baths, and infrared) [103], *electrotherapy* (e.g. transcutaneous electrical nerve stimulation [104], interferential therapy [105], ultrasound [106], and laser therapy [107]), *manual therapy* (e.g. mobilisations and myofascial release [108-109]), *provision of assistive devices* (e.g. walking aids, splints, orthoses, and insoles) [110], and *education and advice* (e.g. promoting a healthy lifestyle, self-management techniques, and joint protection) [111].

1.4 PHYSICAL ACTIVITY AND EXERCISE THERAPY IN RHEUMATOID ARTHRITIS

Physical activity (PA) is ‘any bodily movement produced by skeletal muscles which results in energy expenditure’ [112], and incorporates activity performed for recreation, at work, at home, or for transportation. Current UK and US PA guidelines recommend that all adults participate in at least 150 minutes of moderate-intensity PA or 75 minutes of vigorous-intensity PA, or an equivalent combination of moderate- and vigorous-intensity PA, in bouts of at least 10 minutes, per week [113-114]. However, similar to the general population [115], low levels of PA are reported by people with rheumatic diseases [116-118].

Exercise is a subset of PA which involves planned, structured, and repetitive bodily movement to improve or maintain physical performance [112, 119], including flexibility, aerobic, balance, and strengthening exercise, performed on land or in water (hydrotherapy) [120]. To be effective, exercise needs to be sufficiently intense, and specific to the target outcomes [121].

1.4.1 The Safety of Exercise in RA

Traditionally, RA was managed with rest, flexibility, or non-weight bearing *isometric* (i.e. muscle contraction without change in muscle length) strengthening exercises [122-125], due to fears that *dynamic* exercise (i.e. muscle contraction with muscle shortening (*concentric* contraction) or lengthening (*eccentric* contraction)) would exacerbate disease activity and increase joint destruction [126].

These fears were reinforced by a series of studies in which increases in intra-articular pressure, reductions in capillary perfusion pressure, and reductions in synovial fluid $p0_2$ were observed following prolonged (2 minutes) isometric contractions of the quadriceps, in full knee extension, in chronically inflamed knee joints. Post-exercise, capillary perfusion pressure returned to supra-basal levels, accompanied by significant increases in synovial $p0_2$, resulting in oxidative damage to lipids and IgG [126]. The researchers concluded that persistence of synovial inflammation, in inflammatory conditions, was facilitated by exercise-induced hypoxic reperfusion injury. Crucially, the exercises employed in these studies do not reflect current clinical practice, and dynamic exercise may benefit chronically inflamed joints by increasing the rate of synovial blood flow, preventing chronic synovial ischemia [127], and reducing the levels of inflammatory markers (e.g. CRP, IL-6) [128]. Plasma concentrations of pro-inflammatory cytokines (TNF-α, IL-1, and IL-6) were no different 6 months after 5 weeks (twice-weekly) of progressive isometric and dynamic functional lower-limb exercises in people with stable RA, and there was a tendency toward reduced cytokine concentrations immediately post-exercise, suggesting that exercise is safe in people with stable disease [129]. These results are reflected in those with active [130-131] and early RA [132-133] following short-term exercise programmes.

Furthermore, no difference in radiographic joint damage was noted following 2 years of combined high-intensity dynamic aerobic and whole-body resistance exercise compared to usual care in people with RA [134]. Whilst subsequent sub-group analysis revealed that a small number of people with

extensive large joint damage at baseline had an elevated rate of exercise-induced joint destruction [135], these changes were no longer observed at 18-months, confirming the safety of long-term dynamic exercise in RA [136].

1.4.2 Flexibility Exercise

In ‘healthy’ individuals, flexibility (*or ROM*) exercises improve muscle and connective tissue elasticity and joint ROM [137-139], function [139-141], and attenuate eccentric exercise-induced muscle damage in the short term [142]. For passive (i.e. against a fixed object, held by another part of the body, etc.) or active (i.e. utilising the agonist muscle groups to facilitate the stretch) stretching to be effective, a muscle needs to be extended to its maximum length, so extrafusal muscle fibres are fully elongated, causing intrafusal fibres (muscle spindle fibres, or stretch proprioceptors) to habituate, inhibiting the myotatic reflex (or muscle contraction) and triggering golgi tendon organ (stretch proprioceptors) mediated autogenic inhibition (or muscle relaxation). Static stretching (i.e. no muscle contraction causing change in muscle length during the stretch) may be more efficacious for increasing ROM than dynamic stretching (i.e. muscle contraction causing change in muscle length during the stretch) in the short-term [143], although many ROM assessment methods (e.g. goniometry) show poor reliability [144-146], and the long-term effects of stretching exercise on joint mobility are unclear [147].

There is conflicting evidence for the clinical effectiveness of flexibility exercise in people with RA. Whilst some studies report improvements to finger ROM following flexibility exercises alone [148-149], 12 weeks of

flexibility and non-weight bearing isometric exercises, performed (twice-weekly) supervised in a group, individually, or unsupervised at home, were ineffective at improving joint ROM compared to high-intensity combined aerobic and whole-body dynamic resistance exercise (3 times/weekly) [150].

1.4.3 Aerobic Exercise

Short- and long-term aerobic exercise improves cardio-respiratory fitness (assessed with a maximal or submaximal ergometer test to measure or estimate maximal oxygen consumption (VO_{2max}, in ml/kg/min)), function, strength, and body composition in people with RA [101].

Twelve weeks of moderate-intensity aerobic exercise (3 times/weekly) performed under supervision (n=102) or at home (unsupervised) (n=103) improved function (walk time, grip strength) compared to usual care (n=105), in people with RA [151]. Whilst a large number of participants were lost to follow-up, potentially biasing the findings toward highly motivated participants, these findings are consistent with other studies. For example, improvements to cardio-respiratory fitness, strength, and fat mass, and tendencies toward improvements to function and disease activity, were observed among 20 people with RA following six months of combined aerobic and whole-body dynamic resistance exercise (twice-weekly), compared to a usual care control group (n=20) [152].

Aerobic exercises are sometimes completed in water, yet whilst hydrotherapy has high patient satisfaction [153], land-based exercise [154-156] is superior to hydrotherapy [156-157] for increasing cardio-respiratory

fitness in the short-term [101] although its long-term clinical effectiveness is unclear [101].

1.4.4 Balance Exercise

Balance exercises apply visual and auditory input to stimulate mechanoreceptors in and around the joints, eliciting improvements to postural control, joint position sense, and dynamic joint stability. There is limited evidence to support the use of balance exercise in people with RA [158].

1.4.5 Strengthening Exercise

Isometric (or *static*) exercises are traditionally prescribed for people with RA, and remain the preferred mode of exercise among patients and healthcare professionals (HCP) [159]. Dynamic exercises can be performed *isotonically* (constant force generation) or *isokinetically* (changing force generation throughout ROM). Theoretically, isokinetic exercise activates the greatest number of motor units [160], and is most applicable to functional exercise and ADL.

In untrained individuals, increases in motor performance are easily attained [121] as strength gains achieved during the initial stages of training are predominantly due to neural pathway adaptations (i.e. increased motor unit recruitment and firing rate), and improved agonist activation and antagonist and synergist co-activation [121]. Subsequently, muscular hypertrophy contributes to strength increments [121]. Motor performance can

be determined by measuring maximal isometric or isokinetic strength with fixed or hand held dynamometers [161-162].

In people with RA, dynamic progressive resistance training (PRT) improves strength [102, 130, 132-133, 163-165], function [57, 102, 130], and body composition (increases lean mass and reduces fat mass) [163, 166-167]. Following 21-weeks of supervised combined dynamic high-intensity PRT and aerobic exercise (3 times/week), comparable significant improvements in strength, functional performance (walking speed), and cardio-respiratory fitness (VO_{2max}) were observed between women with stable early (n=12) and longstanding RA (n=11), and healthy controls (n=12) [102]. Whilst this study had a small sample limiting the generalizability of the results, a subsequent larger study (employing a similar 21-week combined dynamic PRT and aerobic exercise intervention) confirmed these findings; comparable increases in strength and cardio-respiratory fitness (VO_{2max}), accompanied by increases in lean body mass (and reductions in fat mass), were observed among women with RA (n=23) and matched healthy controls (n=12) [163]. These findings were replicated following short-term supervised high-intensity dynamic PRT in people with stable [57, 150], early [132], and active RA [130-131].

Increases in lean mass (accompanied by reductions in fat mass) were also reported in a small (n=20), non-randomised, pilot study following 12 weeks of whole-body supervised (twice-weekly) high-intensity dynamic PRT in people with stable RA [167]. These effects were confirmed by a subsequent small randomised controlled trial (RCT), in which significant

increases in lean body mass, strength, and objective functional performance (walk time, chair stands) were observed among 13 people with longstanding, stable RA following 24 weeks of whole-body supervised (twice-weekly) high-intensity dynamic PRT, compared to a ROM exercise control group (n=15) [166]. Whilst PRT participants remained significantly leaner, and retained functional improvements compared to controls, the PRT-induced changes to lean body mass and strength were completely lost 3 years after cessation of the programme [168].

1.4.6 Upper Limb Exercise

Many studies demonstrate the beneficial effects of lower limb or whole-body exercise on function [57, 130, 133, 152, 166], strength [57, 129-130, 132-133, 152, 164-166], ROM [150], and lean body mass [152, 166-167], as well as pain and fatigue [57, 130] in people with RA. However, when attempting to identify clinically acceptable upper limb exercise regimens to improve function and disability, there is limited evidence, and upper limb exercises incorporated into whole-body interventions are often poorly described [132, 151, 164-165].

Only five studies evaluating whole-body programmes provide clear descriptions of the upper limb exercise included [102, 130-131, 133, 169], and in two of these studies, upper limb motor performance outcome measures were limited to hand grip strength [131, 133]. The remaining three studies report significant improvements to upper limb strength (‘chest press’ [102, 130], elbow extension [169], and elbow flexion [130, 169]) but not global subjective function (e.g. HAQ) following short-term moderate- or high-

intensity dynamic PRT [130] or combined aerobic exercise and PRT [102, 169], but are limited by small sample sizes.

1.4.7 Upper Limb Exercise Programmes

Studies specifically investigating the effects of upper limb exercise frequently focus on the hands [148-149, 170-176] or shoulders [177-178] in isolation, ignoring the contribution of other joints in effective upper limb function [148-149, 170-180] (Table 1.1). Whilst specific upper limb exercise improves strength [170, 174, 179], mobility [148-149, 172, 176, 178], pain [172, 175, 177], and function [172, 174-175, 178, 180], with no adverse disease effects, similar to whole-body or lower limb only exercise programmes, many are limited by small sample sizes [148, 170-171, 173, 177-178, 181], heterogeneous treatment groups [149, 174], lack of assessor blinding [148-149, 171, 175, 178, 181], similarities in treatment received by intervention and control groups [175, 177], and exercise interventions incorporating other physical therapies, thereby rendering it impossible to distinguish the effects of exercise from other modalities [172, 182].

Conclusions are further limited by inadequate detail of trial protocols and interventions by omission of recruitment and sampling strategies [181], control treatments [149, 178], or the exercises or exercise principles employed [173]. Of the six studies incorporating resistance exercises into interventions [171-172, 174-175, 177-178], only one adequately quantifies the training intensity [177].

Furthermore, there is substantial variability in exercise type, frequency, and volume, as well as outcome assessment methods and length

of follow-up; only two small studies assess the long-term effects of upper limb exercise in RA [170, 174].

Thus, the clinical effectiveness of short- and long-term global upper limb exercise, and appropriate upper limb exercises and exercise principles, for improving function and strength in people with RA remains unclear.

Table 1.1 Studies evaluating specific upper limb exercise regimens in people with rheumatoid arthritis

Study	Design	Subjects and Duration	Delivery	Frequency and Volume	Intensity and Equipment	Exercise Type	Assessments and Outcome Measures	Significant Results and Comments
Byers, 1985 [148]	Within subject 1. Evening and morning exercise 2. Morning exercise only	n=30 2 consecutive mornings and evenings	Registered nurses; home-based	Morning: *ROM A* 10 reps, *ROM B* 5 reps Evening: *ROM B* 4 reps	None	*ROM A:* finger flexion, extension (right 2nd MCP joint) *ROM B:* whole-body (neck, shoulders, elbow, wrist, back, hip, knee, ankle, feet and hand)	Pre- and post-treatment (mornings) - Finger ROM - Objective finger stiffness - Subjective finger stiffness	All groups: > Finger ROM < Objective stiffness 1: < Subjective stiffness *Lack of assessor blinding
Hawkes, 1986 [173]	Assessor blinded; randomized groups 1. Exercise and wax bath 2. Exercise and ultrasound 3. Exercise and ultrasound and faradic baths	n=30 3 weeks	Physiotherapist; hospital-based	5 days/week	Unspecified	Unspecified	Baseline 1 week (1w) 2 weeks (2w) 3 weeks (3w) - Finger ROM - Hand grip strength - PIP joint size - Global pain - Hand joint pain - Objective upper limb function	All groups: > All measures (1w, 2w, 3w) *Multiple treatment groups
Dellhag, 1992 [149]	RCT 1. Exercise* and wax bath 2. Exercise* 3. Wax bath 4. Control *Supplemented by written instructions	n=52 4 weeks	Occupational therapist; hospital-based	3 days/week; 5 reps	Gentle Soft exercise dough	*Resistance:* finger flexion, extension; radial and ulnar deviation; wrist dorsal and palmar flexion, thumb opposition and abduction *ROM:* shoulder rotation, flexion, abduction	Baseline 4 weeks (4w) - Finger ROM - Hand grip strength - Hand stiffness - Hand pain with resisted motion - Hand pain with nonresisted motion - Objective hand grip function (Sollerman test)	1: > Finger ROM < Hand stiffness < Hand pain > Hand grip function§ 2: > Finger ROM§ < Hand stiffness§ < Nonresisted hand pain§ 3: < Hand stiffness < Pain *Lack of assessor blinding; control treatment poorly described; multiple treatment groups

Study	Design	Subjects and Duration	Delivery	Frequency and Volume	Intensity and Equipment	Exercise Type	Assessments and Outcome Measures	Significant Results and Comments
Brighton, 1993 [170]	Assessor blinded RCT 1. Exercise 2. Usual care	n=44; erosive joint damage in hands 4 years	Unspecified; home-based; reassessed every 6 months	Daily; ROM 10 reps; functional 5 reps	None	*ROM:* finger flexion and extension; MCP and PIP joint flexion and extension *Functional:* place hands flat on a table and extend each finger; roll and unroll a crepe bandage; roll and unroll a bath towel; grip a piece of paper between the thumb and alternately each finger and try to pull the paper out	Baseline Reassessed every 6 months Final assessment at 4 years - MCP and PIP ROM - Hand grip and pincer grip strength	All groups: < MCP extension ROM > PIP extension ROM 1: > Strength 2: < Strength *No measure of function; between group differences not assessed
Hoenig 1993 [176]	1. ROM exercise 2. Resistance exercise 3. ROM and resistance exercise 4. Usual care	n=57 3 months					Baseline 3 months - Grip strength - MCP and PIP ROM - Hand joint index - Joint circumference - Ulnar deviation deformities - Dexterity - Stiffness - Pain	All groups: > Grip strength 1: > Articular index 2: > ROM 3: > Dexterity * All exercise demonstrated to all participants; multiple treatment groups
Bromley, 1994 [171]	1. Wax baths 2. Ultrasound 3. Wax baths and ultrasound 4. Exercise	n=18 6 weeks	Physiotherapist; hospital-based	2 days/week	Gentle 'Soft rubber objects'	*ROM:* passive finger flexion and extension Resistance: hand grip *Functional:* 'precision handling'	Pre- and post-treatment - Objective MCP stiffness	4: < MCP stiffness *Lack of assessor blinding; not randomized groups; inclusion/exclusion criteria not described; multiple treatment groups

Study	Design	Subjects and Duration	Delivery	Frequency and Volume	Intensity and Equipment	Exercise Type	Assessments and Outcome Measures	Significant Results and Comments
Mannerkorpi 1994 [178]	Cross-over RCT 1. Exercise 2. Control	n=35; female 8 weeks	Authors; home-based; one 1:1 appointment	3 days/week; *ROM A* 10 reps, *ROM B* 3 reps, resistance 1-3 sets of 10-30 reps	'Pain free' Assisted pulley and therapy band	*ROM A:* shoulder elevation and depression, retraction, flexion and abduction *ROM B:* trapezius, levator scapulae *Resistance:* external shoulder rotation	Baseline 8 weeks - ROM - Static endurance - Pain - Objective function	1: > ROM§ > Endurance§ < Pain§ > Objective function *Lack of assessor blinding
Bostrom 1998 [177]	Assessor blinded RCT 1. Static exercise 2. Progressive dynamic exercise	n=45; female 10 weeks	3 physiotherapists; gym-based; reassessed every 3 weeks	3 days/week; 3 sets of 30 reps, 30 s rest	30% maximum voluntary isometric strength Pulley apparatus with wristband	*Resistance:* internal and external shoulder rotation Contraction times: Static = 3s isometric Dynamic = 2s concentric, 2s eccentric	Baseline 10 weeks (10w) 20 weeks (20w) - Max isometric strength - Disease activity - Swollen joints - Pain - Subjective disability -Objective function	All groups: < Swollen joints (10w, 20w) < Pain (10w, 20w) 2: < Disability (10w, 20w)§
Buljina 2001 [172]	Assessor blinded cross-over RCT 1. Thermal therapy and exercise 2. Usual care	n=100 3 weeks	Physiotherapist	Daily; 5 reps, 20s rest	Unspecified Therapy putty	*ROM:* finger flexion, extension, radial and ulnar deviation; thumb opposition and abduction; wrist dorsal and palmar flexion *Resistance:* finger abduction and adduction; hand grip Contraction time: Isometric 3-5s	Baseline 3 weeks - ROM - Hand grip, tip-to-tip, palmar, key pinch strength - Disease activity - Pain - Objective function	1: > ROM > Strength < Joint tenderness < Pain > Objective function *Multiple treatments; between group differences not assessed

Study	Design	Subjects and Duration	Delivery	Frequency and Volume	Intensity and Equipment	Exercise Type	Assessments and Outcome Measures	Significant Results and Comments
O'Brien 2006 [174]	Assessor blinded RCT 1. Joint protection leaflet 2. Joint protection leaflet and ROM 3. Joint protection leaflet and ROM and progressive resistance exercise (RT)	n=73 6 months	Musculoskeletal therapist; home-based; two 1:1 appointments	Twice daily; baseline 5 reps; 1 month 10 reps; 3 months 20 reps	Unspecified Towel and therapy band	*ROM:* finger flexion, abduction, radial deviation; thumb opposition, interphalangeal flexion; wrist flexion, extension, circumduction, pronation, supination *Resistance:* finger pinch grip, wrist extension	Baseline 3 months 6 months - ROM - Hand grip strength - Finger pinch strength - Disease activity - Swollen joints - Tender joints - Subjective function (AIMS2) - Objective function	1: < Function§ 2: < Function§ 3: > Grip strength > Function§ *No adjustment for multiple testing
Ronningen 2008 [175]	RCT 1. Intensive exercise 2. Conservative exercise	n=60 14 weeks	Occupational therapist; hospital-based until discharge; home-based thereafter; diary	1: Hospital daily; home 5 days/week; 10 reps 2: Hospital daily; home as usual; 3 reps	Unspecified Soft dough	1: *ROM:* thumb flexion; hand pronation, supination; wrist palmar, dorsi flexion *Resistance:* finger flexion, extension, radial finger walking; thumb abduction, opposition; wrist ulnar deviation 2: *ROM:* as above plus+ thumb opposition *Resistance:* as above plus+ finger tip-to-tip and rolling 'ball' on table with palm minus- thumb opposition	Baseline 2 weeks (2w) 14 weeks (14w) - ROM (finger, wrist) - Hand grip strength - Finger pinch strength - Disease activity - Pain - Objective grip function (GAT) - Subjective function (MHAQ)	All groups: > ROM > Objective function (2w) 1: > Hand strength (2w, 14w) < Pain (2w, 14w) > Objective function (2w, 14w) > Subjective function (14w) *Lack of assessor blinding; intention to treat analysis using baseline, worst, and mean values; not randomized groups

Study	Design	Subjects and Duration	Delivery	Frequency and Volume	Intensity and Equipment	Exercise Type	Assessments and Outcome Measures	Significant Results and Comments
Brorsson 2009 [180]	1. Exercise in RA 2. Exercise in healthy	n=20; early RA n=20; healthy controls 12 weeks	Unspecified; home-based; diary	5 days/week 10 reps, 20s rest	Therapy putty (intensity selected by participants)	*Resistance*: hand grip; putty roll on table surface from wrist to finger tips and back again; finger extension; finger pinch Contraction time: isometric 10s	Baseline (1 & 2) 6 weeks (6w) 12 weeks (12w) - Finger extension strength - Finger flexion strength - Objective function (GAT) - Subjective function (DASH) - EDC muscle cross-sectional area - EDC thickness - EDC pennation angle - EDC contraction pattern	All groups: > Extension and flexion strength (6w, 12w) > Objective function (6w, 12w) > EDC cross sectional area (12w) > EDC contraction pattern 1: > Subjective function (12w) > EDC cross sectional area (6w) 2: > EDC thickness (6w) *Lack of assessor blinding; not randomized groups
Speed 2012 [179]	1. Exercise in RA 2. Exercise in healthy	n=14; stable RA n=14; healthy controls 12 weeks	Unspecified; home-based; 1st appointment 1:1; contacted weekly in weeks 1 and 2	Weeks 1-6: daily Weeks 7-12: twice daily 10 reps, 60s rest	Rubber ball (medium compressibility)	Right hand only *Resistance*: hand grip Contraction time: isometric 10s	Baseline 3 weeks (3w) 6 weeks (6w) 12 weeks (12w) - Hand grip strength - Joint count - CRP - Pain - Local disease severity - ROM - Volumetric analysis of right forearm	1: > Strength 2: > Hand grip strength > Muscle volume *Lack of assessor blinding; not randomized groups

RA = rheumatoid arthritis; RCT = randomized controlled trial; MCP = metacarpophalangeal; PIP = proximal interphalangeal; EDC = extensor digitorum communis; ROM = range of movement; AIMS2 = Arthritis Impact Measurement Scale 2; MHAQ = Modified Health Assessment Questionnaire; DASH = Disabilities of the Arm, Shoulder, and Hand Questionnaire; GAT = Grip Ability Test ; reps = repetitions; s = seconds; w = weeks; § = significant between group difference

1.5 EXERCISE ADHERENCE

In order to sustain the benefits of exercise, continued exercise participation is required [136, 183]. In 21 people with early RA, significant strength gains following 6 months of supervised individualized whole-body twice-weekly PRT were lost 3.5 years after cessation of the programme, although lack of assessor blinding and greater baseline strength among PRT participants (compared to control participants receiving usual care (n=18)) may have biased conclusions [183]. Strength gains attained following 2 years of supervised (twice-weekly) combined high-intensity dynamic PRT and aerobic exercise among people with stable RA, compared to usual care [184], were only maintained at 18-months follow-up by participants who had continued exercising [136].

Whilst long term exercise regimens are costly [185] and not readily transferable into clinical practice due to resource limitations, home-based exercise programmes are cost-effective, promote self-management, and are associated with improvements in pain, sensorimotor function, disability, psychological wellbeing, and QOL in people with arthritis [151, 186-188].

Sustained improvements in subjective function were reported 1 year following a short (4 weeks) home-based whole-body resistance and flexibility exercise programme (5 times/weekly), supplemented by weekly phone calls from the research team to ensure adherence [187]. Similarly, improvements to strength and function were maintained in people with early RA 3 years after completing 2-years of home-based (twice-weekly) moderate-intensity dynamic PRT and aerobic exercise, supplemented with regular follow-up

appointments [189-190]. However, without follow-up from HCPs, sustained PA and exercise participation is poor [115, 118].

1.5.1 Exercise Barriers and Facilitators

Increasing uptake and maintenance of exercise is challenging and understanding and addressing the factors which facilitate and impede exercise participation is vital. External variables, such as social support [191-193], environmental [194], lifestyle [195], and socioeconomic factors (such as cost and level of education) [195-196], and internal variables, such as enjoyment and motivation [197-198], exercise knowledge [199], self-efficacy (i.e. one's confidence in their ability to exercise) [200-203], and outcome expectations [199, 204-207], influence PA and exercise behaviour. In people with RA and other chronic conditions, disease-related factors, such as disability [208-209], pain and fatigue [207, 210-211], disease duration [212-214], and psychosocial aspects of pathology including fear, isolation, and perceived control [215-216], further influence uptake and adherence of exercise.

1.5.2 Health Beliefs

Psycho-behavioural interventions underpinned by conceptual health belief models which address: 1) strengthening intention to act, 2) enabling translation of intention into action (uptake), and 3) facilitating maintenance of action [217] are associated with short- and long-term behaviour change as well as improvements in physical and psychological health status [213-214, 218-223].

There are a number of health belief models, including *Social Cognitive Theory* (SCT) [224], the *Theory of Reasoned Action* (TRA) [225-226], the *Theory of Planned Behaviour* (TPB) [227-232], the *Health Belief Model* [233-235], *Protection Motivation Theory* [236-237], the *Relapse Prevention Model* [238-239], and *Self Determination Theory* [240-241], which are all founded on the shared metatheory that psychosocial factors contribute to health behaviour. Thus, whilst each theory is unique, they contain many overlapping concepts [204]. *Social Cognitive Theory* [224] is most frequently applied to interventions which aim to increase self-management and exercise participation [242-244] in people with arthritis [169, 245], such as the successful 'Arthritis Self-Management Programme' (ASMP) [218, 246-251] and the integrated self-management and exercise programme for chronic knee pain - Enabling Self-management and Coping with Arthritic knee Pain through Exercise (ESCAPE-knee pain) [252].

1.5.2.1 Social Cognitive Theory

Social Cognitive Theory (1986) [224], formerly *Social Learning Theory* (1977) [253], explains health behaviour by a three-way reciprocal model, in which personal factors, environmental influences, and behaviour interact. It comprises five core constructs [204]:

1) *Knowledge* of the risks and benefits of a given health behaviour.
2) *Perceived self-efficacy,* or confidence in one's ability to carry out a specific behaviour under variable circumstances.
3) *Outcome expectations,* or the expected costs and benefits of a health habit.

4) *Self-regulation methods*, such as goals and the plans for achieving the behaviour.
5) Perceived barriers and facilitators.

Social Cognitive Theory proposes that knowledge is the precondition for change [204], suggesting that without sufficient knowledge of the benefits of a health behaviour, it is unlikely that individuals will alter detrimental habits [204]. Outcome expectations, (physical, social (e.g. others' approval or disapproval), or self-evaluative (e.g. feeling of self-satisfaction and worth), self-regulation strategies, and barriers and facilitators provide direction and alter the incentive to perform a behaviour [204]. Primary (short-term) outcome expectations are particularly relevant to exercise intention and uptake [254-255].

Self-Efficacy

According to SCT, perceived self-efficacy is the most fundamental construct to health behaviour because it is influential both directly and indirectly by altering other determinants [204]; people with high self-efficacy expect more favourable outcomes, set higher goals, and view barriers as surmountable with perseverance [204].

Self-efficacy is learned and developed through four primary mechanisms [256-257]:

1) *Performance accomplishments* - task achievement and mastery as a result of personal experience and practice. Performance accomplishments may be the strongest source of self-efficacy, if

attributed to personal skill or ability, rather than chance, temporary, or external factors [254].

2) *Verbal persuasion* - receipt of external encouragement regarding personal achievement.
3) *Vicarious experience* - observation of others' success or progress in carrying out a behaviour.
4) *Physiological state or cues* - receipt of positive internal and external physiological feedback resulting from a behaviour.

Self-efficacy is positively associated with exercise behaviour, and exercise interventions which include self-efficacy enhancing strategies report higher adherence rates. For example, a large (n=177) observational study, in which inactive older adults were randomized to participate in either 12 months of group walking or flexibility, toning and balance exercise found that self-efficacy predicted class attendance [258]. However, it is unclear whether differences were observed between the exercise interventions, and thus whether the importance of self-efficacy differed according to exercise modality [259-260]. Similarly, an observational study of 16 people with multiple sclerosis found that exercise self-efficacy was predictive of objectively (accelerometer) measured activity [261], however the sample size was small limiting conclusions. Nevertheless, a RCT among patients post-cardiac rehabilitation also reported increased exercise participation among participants randomized to receive a home-based upper-body resistance exercise programme, supplemented by an exercise manual, which enhanced self-efficacy, compared to those who received standard exercise recommendations [262]. However, adherence was measured with a log book,

associated with potential involuntary and voluntary error (e.g. through poor memory and social desirability).

In one study among people with neurological pathologies, activity levels did not change following a 4-week (twice weekly) expert-led group education and exercise programme (developed to facilitate performance accomplishment, verbal persuasion, vicarious experiences, and physiological cues), despite improvements to exercise self-efficacy [263]. However, self-efficacy was measured with an unpublished scale with unknown psychometric properties, and activity was self-reported using a tool which may have been unresponsive to change [263]. Therefore, it is likely that targeting self-efficacy is a key strategy for increasing uptake and maintenance of exercise.

1.5.2.2 The Theory of Reasoned Action and the Theory of Planned Behaviour

The Theory of Reasoned Action [225-226] suggests that one's attitudes and perceptions of the subjective norm (expectation that others value a behaviour) determine health behaviour [225-226]. According to the TRA, attitudes relate to personal beliefs and outcome evaluations, whilst the influence of the subjective norm is dependent upon an individual's motivation to comply with the beliefs of others [264].

The Theory of Planned Behaviour [227-232] is an extension of the TRA which includes perceived behavioural control (self-efficacy), dependent upon one's perception of control beliefs (barriers and facilitators) and the power of those beliefs to impede or facilitate behaviour.

Both the TRA and TPB have been applied to exercise behaviour [265-272], but whilst useful for increasing intentions to initiate and maintain exercise, these models fail to address the translation from ‘intention’ to ‘action’ [264].

1.5.3 Exercise Knowledge

Educational interventions and the provision of verbal or written advice (i.e. pamphlets and information sheets) focus on the transfer of knowledge and specific skills, rather than the mechanisms underpinning behaviour change. Whilst they increase exercise knowledge and adherence to exercise [207, 273], as well as health outcomes such as function and pain [222, 274-277] in people with RA, these effects are short-term and not sustained in the long-term [214, 278-280]. However, many studies are small and low in quality [279].

1.5.4 Social Support

Social support influences adherence to exercise [191-193], and people with arthritis value peer feedback and encouragement [207] as well as advice [281-283] and support [207, 284-286] received from HCPs. However, long-term social support can foster dependence [204], and sustained autonomous exercise participation requires appropriate social support to facilitate self-efficacy for exercise [204].

1.5.5 Integrated Education, Self-Management, and Exercise Programmes

Minimising disability, improving function, particularly of the upper limbs, and facilitating self-management in people with RA requires appropriate education, exercise prescription, and sustained behaviour change. Theoretically, the individual effects of education and exercise are additive [287], and if combined and underpinned by a theoretically driven behavioural change strategy, long-term exercise participation and the benefits of exercise could be maximised.

The ESCAPE programme is a cost effective [288] integrated education, self-management, and exercise programme, which produced clinically meaningful improvements in function, pain, and psychosocial measures [252] for up to 30 months in people with knee OA, compared to the usual care [289]. This pragmatic programme comprised 6 weeks of simple, supervised (twice-weekly) group education, self-management, and exercise sessions in a community hospital, and could be adapted to other conditions.

To date, only one small study (n=19) has evaluated an integrated education, self-management, and exercise programme in RA, reporting improvements to cardio-respiratory fitness and strength, but not self-efficacy or health status, 22 weeks following an 8-week (3 times/weekly) supervised multidisciplinary education and whole-body moderate-intensity combined aerobic and resistance exercise programme [169].

Consequently a large trial evaluating an integrated education, self-management, and exercise programme to address global upper limb

functional impairments in RA, which occur early in the disease, is required, and if underpinned by theoretically driven behavioural change strategies, may result in sustained improvements to physical performance and QOL.

2 *Aims of the Thesis*

The aims of this thesis are:

1) To develop an integrated Education, self-management, and eXercise Training programme to improve global upper limb disability in people with early Rheumatoid Arthritis (the EXTRA programme).
2) To evaluate the clinical effectiveness of an integrated Education, self-management, and eXercise Training programme (the EXTRA programme) for improving global upper limb disability, function, strength, self-efficacy, and quality of life in people with early rheumatoid arthritis.
3) To investigate participants' experiences of an integrated Education, self-management, and eXercise Training programme (the EXTRA programme) and explore the factors which affect uptake and maintenance of the programme in people with early rheumatoid arthritis.
4) To evaluate physical activity participation, healthcare professional recommendation, and physical activity preferences among people with a range of rheumatic diseases.

3 General Methodology

3.1 INTRODUCTION

When evaluating the clinical effectiveness of physical interventions, valid and reliable outcome measures which assess a range of motor, disease, and psychosocial parameters are required [290-291]. The outcome measures utilised to assess the clinical effectiveness of a global upper limb education, self-management, and exercise programme for people with RA, developed (Chapter 4) and evaluated (Chapter 5) in this thesis, are described below.

3.2 ASSESSMENT OF UPPER LIMB DISABILITY

Disability was evaluated with the 'Disabilities of the Arm, Shoulder and Hand Questionnaire' [88-89] (Appendix A). This brief, self-administered measure of global upper limb symptoms and physical function [90] is valid and reliable in an early RA population [74, 292] (Section 1.2.9.2).

The DASH comprises three separately scored modules: 'disability and symptoms' (30 questions), 'work' (optional; 4 questions), and 'sports and performing arts' (optional; 4 questions). Questions are answered on a Likert

scale ranging from 1 (‘no difficulty’) to 5 (‘unable’). Each module is scored according to Equation 1:

$$\text{DASH Score} = \frac{(\text{sum of responses}) - 1}{n} \times 25$$

n=the number of completed responses

Equation 1 Disabilities of the Arm, Shoulder, and Hand Score

Where more than 3 responses are missing, a ‘disability and symptoms’ module score may not be calculated. All questions must be answered to calculate the optional module scores (‘work’ and ‘sports and performing arts’). A high DASH score (range: 0-100) indicates greater disability. A 10-point change in mean DASH score may be considered a minimal clinically important difference (MCID) [93].

3.3 ASSESSMENT OF OBJECTIVE UPPER LIMB FUNCTION

3.3.1 Grip Ability Test

The Grip Ability Test is a valid and reliable measure of hand function in people with RA [96] (Section 1.2.9.3). It comprises of 3 tasks representing 4 common hand grip types: pulp pinch, lateral pinch, five finger pinch, and transverse volar grip. All standardized tasks are performed with the participant seated at a table, starting with their hands placed on the table beside predetermined markers (Figure 3.1).

Figure 3.1 Standardized protocols for completing the Grip Ability Test

Task		Equipment	Verbal Instruction to Participants
1	**Pouring water from a jug to a cup**	Plastic water jug with handle filled with water (1 litre) and cup (2 decilitre)	Take the water jug with your dominant hand, lift the jug, fill the cup with water, and put the water jug back on the table - the time is taken from the word “start” until you place the water jug back on the table
2	**Putting a paper clip on an envelope**	Metal paper clip (30 x 10 mm) and letter envelope (11.5 x 16.0 cm)	Pick up the paper clip from the table - you are not allowed to pull it over the edge of the table - put the paper clip anywhere on the envelope and put the envelope back on the table - the time is taken from the word “start” until you place the envelope back on the table
3	**Putting a flexi-grip stocking over the non dominant hand**	Elasticized tubular bandage (25cm): size D (7.5cm width) for women, size F (10cm width) for men	Take the flexigrip stocking on the table in front of you with your dominant hand and pull it like a glove over your other hand until all fingertips, including the thumb, are shown under it - the time is taken from the word “start” until all your fingertips are visible

To minimize intra and inter-assessment learning effect each task was repeated consecutively three times [293], and the fastest time for each task is weighted and used to generate a GAT score (Equation 2).

$$\text{GAT Score} = (1.8 \times \text{task 1}) + (1.0 \times \text{task 2}) + (1.8 \times \text{task 3})$$

Equation 2 Grip Ability Test Score

If more than 60 seconds are required to perform any one task, this is taken as the maximum time [96]. A high GAT score is indicative of reduced hand function; a GAT score below 20 represents normal hand function [96].

3.3.2 Global Upper Limb Function

The time (seconds) taken to complete 2 common ADL, dressing and eating, were used to estimate global upper limb function [37]. Both activities were performed according to standardized protocols (Figure 3.2).

Figure 3.2 Standardized protocols to evaluate two upper limb activities of daily living

Activity		Equipment	Starting Position	Verbal Instruction to Participants
1	**Dressing - putting on a shirt and fastening 3 buttons**	Sleeveless shirt (men's, extra large)	Participant standing in front of a table, hands by their side; shirt placed on the table on predetermined markers	Take the shirt, put it on, and fasten three buttons as quickly as you can - the time is taken from the word "start" until the third button is fastened
2	**Eating – cutting a piece of putty in half using a knife and fork**	Tubular putty (1.5 cm diameter x 10 cm length) and knife and fork	Participant seated at a table, hands placed on the table beside predetermined markers; equipment placed on the table according to a standard place setting on predetermined markers	Take the cutlery and cut the putty in half as quickly as you can - the time is taken from the word "start" until the cutlery is returned to its original position

To minimize intra and inter-assessment learning effect each activity was repeated consecutively three times [293], and the fastest time for each activity was used for analysis. A faster time represents better global upper limb function.

3.3.3 Intra-Rater Reliability of Upper Limb Functional Measures

3.3.3.1 Methods

Aim and Design

The intra-instrument and intra-rater reliability of the GAT and two ADL (dressing and eating) for assessing upper limb function in people with arthritis was assessed following ethical and research governance approval from King's College Hospital NHS Foundation Trust (KCH) and the London (Dulwich) Research Ethic Committee (REC) (08/H0808/118) (Appendix B).

Participants

Patients were recruited from the rheumatology outpatient department of KCH between February 2009 and September 2010.

Inclusion criteria were: 1) ≥18 years of age; 2) diagnosed with arthritis affecting the upper limbs according to the ACR classification criteria [19, 294]. The *exclusion criterion* was: unable to provide written informed consent.

Protocol

Each participant attended for one assessment, during which the upper limb functional assessments (Sections 3.3.1 and 3.3.2) were conducted twice, 20 minutes apart to minimize fatigue.

Sample Size

Sample size was calculated *a priori* by a standard power calculation [295]. Based on a significance level of $\alpha=0.05$, $\beta=0.2$, a minimal acceptable

level of reliability of P_1=0.9, P_0=0.7, and 2 observations, 18 participants were required to establish intra-rater reliability based on ICC.

Data Analysis

Two analyses were used to assess intra-rater reliability: ICC and Bland and Altman tests [87, 296-297]:

ICC coefficients were calculated with SPSS Statistics for Windows version 17.0 (*IBM*), using a two-way random effects model for absolute agreement. An ICC of 1 indicates perfect reliability with no measurement error and 0 indicates no reliability [87].

Bland and Altman test statistics which provide estimates of the magnitude of disagreement between measurements were calculated [296-297] with Microsoft Excel 2007:

1) Mean of time 1, time 2 difference ($\bar{d}$).
2) Standard deviation of time 1, time 2 difference (SD_{diff}).
3) 95% repeatability coefficient (95% RC, Equation 3).

$$95\%\ RC = 1.96 \times SD_{diff}$$

Equation 3 95% Repeatability Coefficient

4) 95% limits of agreement (95% LOA, Equation 4).

$$95\%\ LOA = \bar{d} + (1.96 \times SD_{diff})$$

Equation 4 95% Limits of Agreement

5) Standard error of 95% LOA (SE of 95% LOA, Equation 5).

$$\text{SE of 95\% LOA} = \sqrt{3 \times SD_{diff}^2/n}$$

Equation 5 Standard Error of 95% Limits of Agreement

6) 95% confidence interval of 95% LOA (95% CI of 95% LOA, Equation 6).

$$\text{95\% CI of 95\% LOA} = 1.96 \times \text{SE of LOA}$$

Equation 6 95% Confidence Interval for 95% Limits of Agreement

3.3.3.2 Results

Eighteen patients with RA and 1 patient with OA (4 male, 15 female, (mean (SD)), aged 56 (12) years, body mass index (BMI) 30 (8), disease duration 49 (49) months) participated in this study.

Two outliers (participants) were omitted from analysis of the GAT ($\bar{d}$ (SD_{diff})=30.80 (12.36)), and one outlier was omitted from analysis of timed dressing (d=-20.34) [296].

Intra-rater reliability was high for all upper limb functional tests (Table 3.1).

Table 3.1 Intra-rater reliability of the Grip Ability Test and two upper limb activities of daily living for assessing objective upper limb function in people with early arthritis

	Bland and Altman Test Statistics*					Intra-Class Correlation	
	$\bar{d}$ (SD_{diff})	95% RC	95% LOA	SE of LOA	95% CI for LOA	ICC coefficient	95% CI of ICC coefficient
GAT	1.00 (2.26)	4.43	-3.43 to 5.42	0.95	1.86	0.97	0.93 to 0.99
Dressing	0.39 (3.03)	5.94	-5.55 to 6.33	1.24	2.42	0.88	0.69 to 0.95
Eating	0.31 (0.90)	1.77	-1.46 to 2.08	0.36	0.70	0.97	0.92 to 0.99

$\bar{d}$ = mean of difference; SD_{diff} = standard deviation of difference; 95% RC = 95% repeatability coefficient; 95% LOA = 95% limits of agreement; SE = standard error; 95% CI = 95% confidence interval; ICC = intra-class correlation
*GAT values are given in weighted seconds, dressing and eating values are given in seconds

3.4 ASSESSMENT OF DISEASE ACTIVITY

The seven EULAR [25] and ACR core data set measures of RA disease activity were assessed, incorporating the 28 joint 'Disease Activity Score' (DAS28) [24] (Figure 1.4).

3.4.1 Disease Activity Score

The DAS28 (range: 0.14-9.3; smallest detectable difference (SDD) = 1.3 (14%) [298]), is a simple, standard measure of RA disease activity which, in several large robust studies, including a 3-year longitudinal analysis among people with early disease [299], a cross-sectional study of over 2800 individuals [300], and a 24-week observational study including 735 participants [301], was found to correlate well with other indices of disease activity (including erythrocyte sedimentation rate (ESR) [299], the Clinical Disease Activity Index (CDAI) [300], the ACR 66 and 68 joint counts for pain and swelling [301], and the HAQ [299-300]), distinguish effectively between

high, moderate, low disease activity, and remission [299-300], and demonstrate satisfactory test-retest reliability [298], assessed appropriately by ICC (>0.85) and reinforced by Bland and Altman statistics (i.e. SDD) [296].

The DAS28 incorporates the 28 swollen and tender joint counts (SDD: swollen = 3.5 (13%), tender = 4.8 (17%) [298]), patient's assessment of disease activity (PADA; visual analogue scale (VAS): 100-mm: anchors 'not active at all' and 'extremely active'; SDD = 26.2 (26%) [298]), and ESR (mm/hr, recorded in routine clinical practice (obtained from medical notes); SDD = 8.0 (8%) [298]) (Appendix C, Appendix D). DAS28 score is calculated according to Equation 7:

$$\text{DAS28 Score} = \left(0.56 \times \sqrt{\text{n TJ}}\right) + \left(0.28 \times \sqrt{\text{n SJ}}\right) + (0.7 \times \text{LN of ESR}) + (0.014 \times \text{PADA})$$

n TJ = number of tender joints
n SJ = number of swollen joints
LN = natural logarithm

Equation 7 28 Joint Disease Activity Score

A DAS28 score ≥5.1 indicates highly active RA, 3.3 to 5.0 = moderately active RA, ≤3.2 = low disease activity, and <2.6 = disease remission [302].

3.4.2 Pain

Patient's assessment of pain was determined using a VAS (100-mm: anchors 'no pain' and 'pain as bad as it could be'). VAS effectively distinguished between moderate and severe post-operative pain (assessed

against a 4 point Likert scale: none, mild, moderate and severe) among a large cohort of 736 patients [303], however these findings may not be generalizable to the assessment of chronic pain such as that experienced by people with RA. One study found the test-retest reliability of VAS for measuring pain in people with RA acceptable (ICC >0.88; SDD = 22.3 (22.3%)) [298], however the sample size was small and respondents had stable disease, thus limiting the generalizability of findings to those with active disease.

3.4.3 Fatigue

Patient's assessment of fatigue was determined using a VAS (100-mm: anchors 'no fatigue' and 'fatigue as bad as it could be'). A large systematic review of 50 studies utilizing 23 different VAS for measuring fatigue in RA reported correlations with pain, poor sleep, low mood, and disability (r >0.31) and the ability of the scales to effectively discriminate between healthy individuals, those with RA, and other rheumatic conditions [304]. However, validation data was limited, and lack of an internationally agreed definition of RA fatigue meant that, potentially, studies contributing validation data were missed [304]; thus the responsiveness and reliability of VAS for measuring fatigue in RA is unclear.

3.4.4 Morning Stiffness

Patient's assessment of morning stiffness was estimated by recording mean minutes of morning stiffness in the last week.

3.4.5 Assessor's Assessment of Disease Activity

Assessor's assessment of global disease activity was determined using a 5-point Likert scale (range: 1 ('asymptomatic') to 5 ('very severe').

3.5 ASSESSMENT OF UPPER LIMB STRENGTH

3.5.1 Maximum Isometric Upper Limb Strength

3.5.1.1 Equipment

Maximum isometric voluntary strength of the shoulder, elbow, and wrist extensors and flexors were measured in Newtons (N; to the nearest 0.1N) using a digital hand held dynamometer (HHD; *Hoggan Health Industries USA, microFET2;* Figure 3.3).

Figure 3.3 Hoggan Health Industries USA, microFET2 digital hand held dynamometer

3.5.1.2 Calibration of Hand Held Dynamometer

The HHD was calibrated at the beginning and end of the study by vertically loading to the centre of the dynamometer with known weights

(range 5 to 30 N) and recording deflection. The equation of line was calculated (Equations 8 and 9), and found to be y = 1.0x + 0.8.

$$y = mx + c$$

y = the vertical axis
x = the horizontal axis
m = the gradient (Equation 8)
c = the y intercept

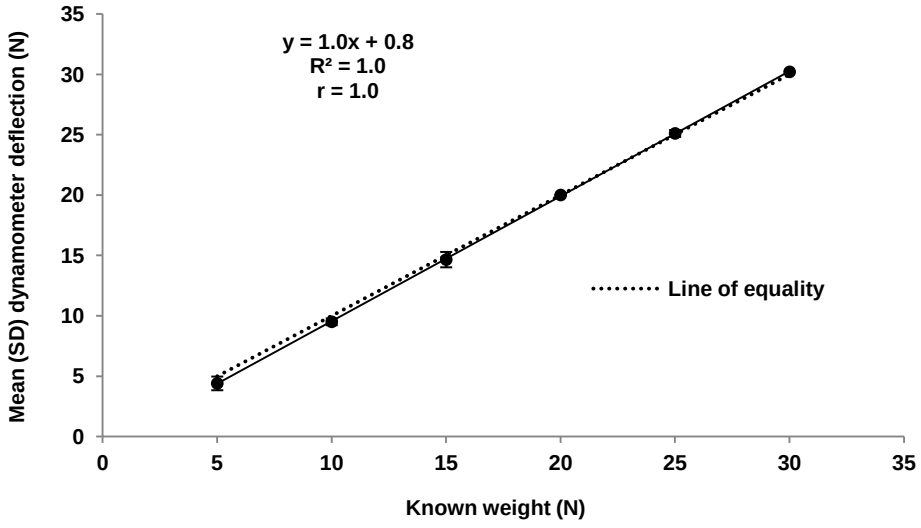
Equation 8 Equation of a Straight Line

$$m = \frac{\text{change in y}}{\text{change in x}}$$

Equation 9 Gradient of a Straight Line

There was no deviation from the equation of line on repeated testing (Figure 3.4).

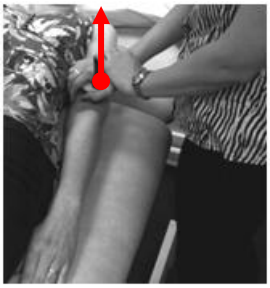
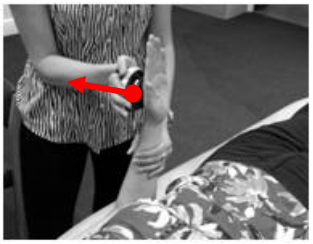
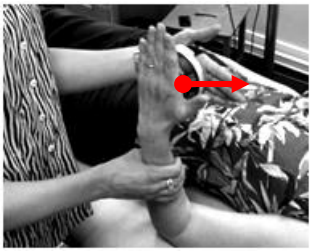
Figure 3.4 Calibration of hand held dynamometer using known weights



3.5.1.3 Upper Limb Strength Testing Protocol

Participants were assessed lying supine according to standardized protocols (Figure 3.5) [305]. Participants were instructed to push against the HHD, “as hard as possible” for 4 seconds to achieve maximal force production [162], during which time vigorous verbal encouragement was provided. To minimize intra and inter-assessment learning effect each muscle group was tested 3 times [306-307], on alternate sides to reduce fatigue, and the peak force produced by each DOM and NDOM muscle group was used for analysis.

Figure 3.5 Standard protocols for measuring the strength of upper limb muscle groups using hand held dynamometry

Muscle group	Subject Position	Dynamometer Position	Action
Shoulder Extensors	Supine, shoulder adducted and neutrally rotated, shoulder and elbow in 90° flexion, forearm supinated	Posterior aspect, proximal to elbow joint, just proximal to the humeral epicondyles	
Shoulder Flexors	Supine, shoulder adducted, neutrally rotated and extended, elbow extended, forearm pronated	Anterior aspect, proximal to elbow joint, just proximal to the humeral epicondyles	
Elbow Extensors	Supine, shoulder adducted and neutrally rotated, elbow in 90° flexion, forearm in neutral position	Medial aspect, proximal to wrist joint, just proximal to ulna styloid process	
Elbow Flexors	Supine, shoulder adducted and neutrally rotated, elbow in 90° flexion, forearm supinated	Lateral aspect, proximal to wrist joint, just proximal to radius styloid process	
Wrist Extensors	Supine, shoulder adducted and neutrally rotated, elbow in 90° flexion, forearm and wrist in neutral position, fingers flexed	Posterior aspect, distal to wrist joint, just proximal to heads of metacarpals	
Wrist Flexors	Supine, shoulder adducted and neutrally rotated, elbow in 90° flexion and supported on coach, forearm and wrist in neutral position, fingers extended	Anterior aspect, distal to wrist joint, just proximal to heads of metacarpals	

3.5.2 Maximum Isometric Hand Grip Strength

3.5.2.1 Equipment

Maximum isometric voluntary hand grip strength was measured in kilograms (kg; force measured to the nearest 1kg) using a hand grip dynamometer (HGD; *Lafayette USA Instrument 6, Jamar J00105;* Figure 3.6).

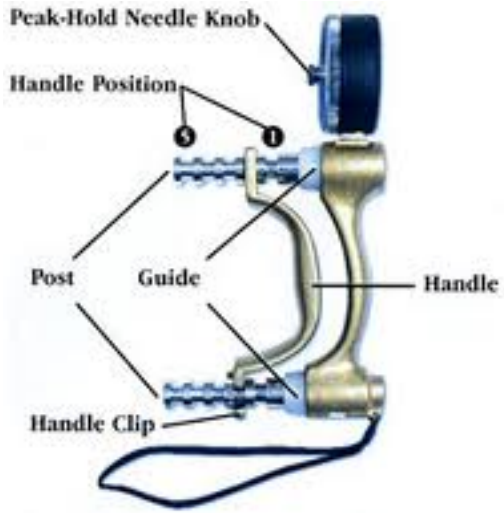
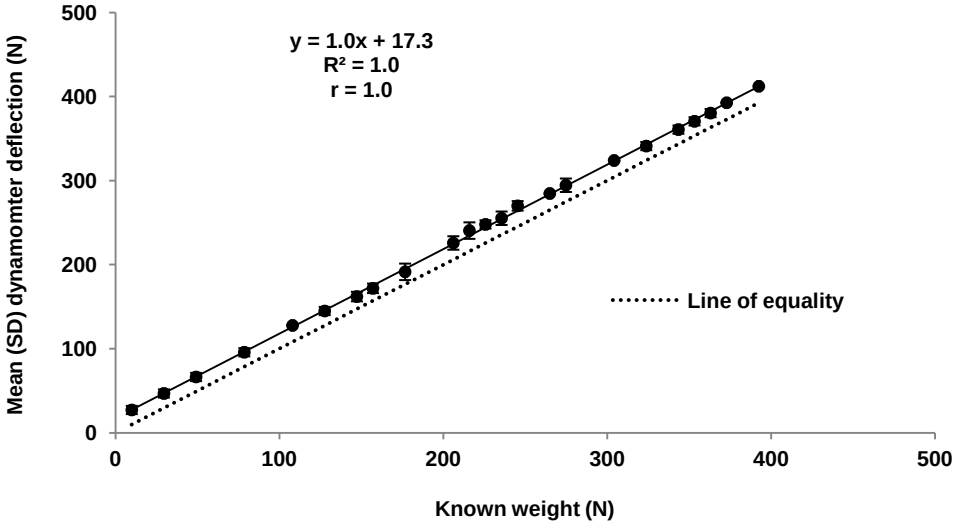


Figure 3.6 Lafayette USA Instrument 6, Jamar J00105 Hand grip dynamometer

3.5.2.2 Calibration of the Hand Grip Dynamometer

The HGD was calibrated at regular intervals (4 times) during the study by loading the dynamometer with known weights (range 10 to 392 N). The equation of line was calculated (Equations 8 and 9) and found to be y = 1x + 17.3. There was no deviation from the equation of line on repeated testing (Figure 3.7).

Figure 3.7 Calibration of hand grip dynamometer using known weights



3.5.2.3 Hand Grip Strength Testing Protocol

Participants were seated with their shoulder in approximately 30° flexion, elbow flexed, forearm in mid supination supported on a table, and their hand unsupported (Figure 3.8). This position is adapted from the published protocol recommended by the American Society for Hand Therapists [308], as people with RA who have proximal upper limb pain and weakness are unable to support the weight of a Jamar HGD. The HGD handle position was adjusted for each participant at baseline assessment (default position = 2, range 1 to 5) according to participant preference, and this was replicated in each subsequent assessment.

Participants were instructed to squeeze the HGD “as hard as possible” for 4 seconds to achieve maximum force [162], during which time vigorous verbal encouragement was provided. To minimize intra and inter-assessment learning effect DOM and NDOM muscle groups were tested 3 times [306-

307], on alternate sides to reduce fatigue, and the peak force produced by each hand used for analysis [54, 309].

Figure 3.8 Hand grip strength testing using a hand grip dynamometer

3.5.3 Intra-Rater Reliability of Upper Limb Strength Measures

3.5.3.1 Methods

Aim and Design

The intra-instrument and intra-rater reliability of the HHD and HGD for assessing upper limb strength in people with arthritis was assessed following ethical and research governance approval from KCH and the London (Dulwich) REC (08/H0808/118) (Appendix B).

Participants

Patients were recruited from the rheumatology outpatient department of KCH between February 2009 and September 2010.

Inclusion criteria were: 1) ≥18 years of age; 2) diagnosed with arthritis affecting the upper limbs according to the ACR classification criteria [19, 294]. The *exclusion criterion* was: unable to provide written informed consent.

Protocol

Each participant attended for one assessment, during which upper limb strength assessments (Sections 3.5.1 and 3.5.2) were conducted twice, 20 minutes apart to minimize fatigue.

Sample Size

Sample size was calculated *a priori* by a standard power calculation (Section 3.3.3) [295].

Data Analysis

Two analyses were used to assess intra-rater reliability: ICC and Bland and Altman tests (Section 3.3.3) [87, 296-297].

3.5.3.2 Results

Hand Held Dynamometry

Nineteen patients with RA and 1 patient with OA affecting the upper limbs (4 male, 16 female, (mean (SD)), aged 56 (12) years, BMI 30 (8), disease duration 50 (48) months) participated in this study.

One outlier (participant) was omitted from analysis of shoulder flexion strength (d=-87.20), one outlier was omitted from analysis of elbow extension strength (d=54.70), one outlier was omitted from analysis of elbow flexion

strength (d=-47.60), and one outlier was omitted from analysis of strength of all muscle groups collectively (d=-87.20) [296].

Intra-rater reliability was high, with an overall (all muscle groups) ICC coefficient of 0.98 (0.97 to 0.99) and 95% RC of 30.0 N (Table 3.2).

Table 3.2 Intra-rater reliability of hand held dynamometry for assessing shoulder, elbow, and wrist flexor and extensor strength in people with early arthritis

	Bland and Altman					Intra-Class Correlation	
	$\bar{d}$ (SD_{diff}) (N)	95% RC (N)	95% LOA (N)	SE of LOA (N)	95% CI for LOA (N)	ICC coefficient	95% CI of ICC coefficient
Shoulder Extension	-1.6 (20.5)	40.1	-41.7 to 38.5	7.9	15.5	0.98	0.95 to 0.99
Shoulder Flexion	1.8 (13.3)	26.1	-24.3 to 27.9	5.3	10.4	0.97	0.92 to 0.99
Elbow Extension	1.5 (11.9)	23.2	-21.7 to 24.8	4.7	9.2	0.97	0.93 to 0.99
Elbow Flexion	-0.6 (14.5)	28.5	-29.1 to 27.9	5.8	11.3	0.98	0.94 to 0.99
Wrist Extension	0.8 (11.8)	23.0	-22.2 to 23.8	4.6	8.9	0.97	0.93 to 0.99
Wrist Flexion	-1.3 (10.4)	20.4	-21.8 to 19.1	4.0	7.9	0.96	0.91 to 0.99
All Muscle Groups	**0.2 (15.3)**	**30.0**	**-29.9 to 30.1**	**2.4**	**4.8**	**0.98**	**0.97 to 0.99**

$\bar{d}$ = mean of difference; SD_{diff} = standard deviation of difference; 95% RC = 95% repeatability coefficient; 95% LOA = 95% limits of agreement; SE = standard error; 95% CI = 95% confidence interval; ICC = intra-class correlation

Hand Grip Dynamometry

Twenty-one patients with RA and 1 patient with OA affecting the upper limbs (5 male, 17 female, (mean (SD)), aged 57 (13) years, BMI 31 (7), disease duration 47 (46) months) participated in assessing the intra-rater reliability of the HGD.

One outlier (participant) was omitted from analysis (d=-58.8) [296]. Intra-rater reliability was found to be high (Table 3.3).

Table 3.3 Intra-rater reliability of hand grip dynamometry for assessing hand grip strength in people with early arthritis

Bland and Altman					Intra-Class Correlation	
$\bar{d}$ (SD_{diff}) (N)	95% RC (N)	95% LOA (N)	SE of LOA (N)	95% CI for LOA (N)	ICC coefficient	95% CI of ICC coefficient
-4.7 (13.7)	26.9	-31.6 to 22.3	5.2	10.2	0.99	0.98 to 1.00

$\bar{d}$ = mean of difference; SD_{diff} = standard deviation of difference; 95% RC = 95% repeatability coefficient; 95% LOA = 95% limits of agreement; SE = standard error; 95% CI = 95% confidence interval; ICC = intra-class correlation

3.6 ASSESSMENT OF PSYCHOSOCIAL PARAMETERS

3.6.1 Health-Related Quality of Life

The Rheumatoid Arthritis Quality of Life Questionnaire (RAQoL) is a self-completed, 30-item disease specific questionnaire (Appendix E) [310]. The content of the RAQoL was developed from interviews with people with RA, and (where possible) items were constructed utilizing participants' own words. Face and content validity of the RAQoL was judged to be good by respondents asked to report items that were inappropriate, difficult to answer, or not fully understood, however, whilst participants represented a wide range of disease severities, the sample was small (n=15) and biased toward those with short or moderate disease duration, and thus the applicability of the RAQoL to those with long-term RA is less clear [310].

The RAQoL has been robustly evaluated in a number of studies, with large sample sizes utilizing appropriate methodologies and data analyses, indicating that scores, whilst less responsive to change in pain than the SF-36 [73], correlate well with other measures of QOL (RAND 36-Item Health Survey 1.0), functional status (e.g. HAQ, walk test, grip strength), and disease activity [311], are internally consistent (Cronbach's alpha coefficient > 0.90 [73, 310-311]), able to discriminate well between different levels of disease activity and patient reported health status [73, 310], and reliable (Spearman rank correlation coefficient >0.90 [73, 310]). Thus, the RAQoL is a suitable assessment of QOL for RA patients with relatively recently diagnosed disease.

Each item is answered "yes" (scored 1) or "no" (scored 0) and the responses from all items are summed to give a total score ranging from 0 (good QOL) to 30 (poor QOL). Where up to 20% of data is missing, the total score is calculated according to Equation 10:

$$\text{RAQoL Score} = \left(\frac{T}{30 - M}\right) \times 30$$

T = the item summation score
M = the number of missing items

Equation 10 Rheumatoid Arthritis Quality of Life Score

Where more than 20% of responses are missing, no score is calculated.

3.6.2 Arthritis Self-Efficacy

The Arthritis Self-Efficacy Scale (ASES) estimates the degree of confidence people with arthritis have in their ability to influence their disease symptoms and daily activities (Appendix F) [312]. The questionnaire has 3 subscales: ‘pain’, ‘function’, and ‘other symptoms’, comprising of 5, 9, and 6 items, respectively. Each item is scored on a VAS scale (10-100-mm: anchors ‘very uncertain’ (10) and ‘very certain’ (100)). Subscales are scored separately by calculating the subscale mean; a low score indicates poor self-efficacy. If more than 25% of the responses are missing, no score can be calculated.

A systematic review of 74 studies found the ASES to correlate with pain, fatigue, disease severity, and disability in people with RA, and be responsive to change following educational and cognitive behavioural therapy (e.g. the ASMP), however, many studies included only a small number of participants with RA, who were mostly well educated women thereby limiting the generalizability of the results, and the 12 randomized trials used to assess responsiveness lacked control groups, limiting conclusions [313]. In a series of larger studies, individual subscales demonstrated acceptable internal consistency (Cronbach’s alpha coefficient > 0.75) and test-retest reliability (r >0.85) [312], however participants had a range of arthritis and r is not recommended as an appropriate measure of repeatability [87]. Thus, whilst the ASES is the most widely used measure of self-efficacy in people with RA [313], future studies are required to confirm

the psychometric properties in this population, particularly among individuals of a low socioeconomic status.

3.7 CONCLUSIONS

- There are a range of valid and reliable outcome measures for evaluating upper limb disability (DASH), disease activity (EULAR and ACR Core data set), quality of life (RAQoL), and self-efficacy for disease self-management (ASES) in people with RA.
- The Grip Ability Test and two upper limb activities of daily living for the assessment of objective upper limb function have high intra-rater reliability.
- Hand held dynamometry and hand grip dynamometry for the assessment of upper limb and hand grip strength have high intra-rater reliability.

4 *Development of an Upper Limb Education, Self-Management, and Exercise Training Programme for People with Early Rheumatoid Arthritis (the EXTRA Programme)*

4.1 INTRODUCTION

Whilst advances in the pharmacological therapy such as more aggressive treatment (triple DMARD therapy) and the introduction of biological agents have improved the prognosis for people with RA [6, 314], upper limb impairments occur early in over 80% of cases [315], causing global upper limb disability and dysfunction [30-31, 37, 53-56]. Exercise therapy is a key component in upper limb rehabilitation (Chapter 1), however the clinical effectiveness of global upper limb exercise and self-management in RA is unclear. Studies investigating the effects of upper limb exercise frequently concentrate on the hands [148-149, 170-176] or shoulders [177-178] in isolation, ignoring the contribution of other joints for effective global upper limb function.

For exercise benefits to be obtained, exercise has to be increased and sustained [136, 183], and both of these steps in behaviour change are likely to be challenging. To be effective, rehabilitation programmes need to be socioeconomically and culturally appropriate [194, 203], and accommodate the strengths and skills of the target population and HCP [316]. A key factor in the uptake and maintenance of exercise is self-efficacy [202, 256-257, 317]) (Chapter 1), but few upper limb rehabilitation programmes incorporate behavioural change strategies to enhance exercise participation and self-management of RA, and there is a need for acceptable exercise and self-management interventions, which are individually tailored and targeted, to successfully maintain and improve global upper limb function in people with early RA.

Therefore, informed by the Medical Research Council's (MRC) framework for developing complex healthcare interventions [291] and NICE guidance for developing behaviour change interventions [316], this study aims to develop and assess the acceptability of a global upper limb exercise and self-management rehabilitation programme for people with early RA.

4.2 AIMS OF RESEARCH

This study aims to develop a global upper limb education, self-management, and exercise rehabilitation programme to improve upper limb function and disability in people with early RA.

4.3 METHODS

The upper limb 'Education, self-management, and eXercise Training in early Rheumatoid Arthritis' programme (the EXTRA programme) was developed through an iterative process consisting of seven key phases (Figure 4.1).

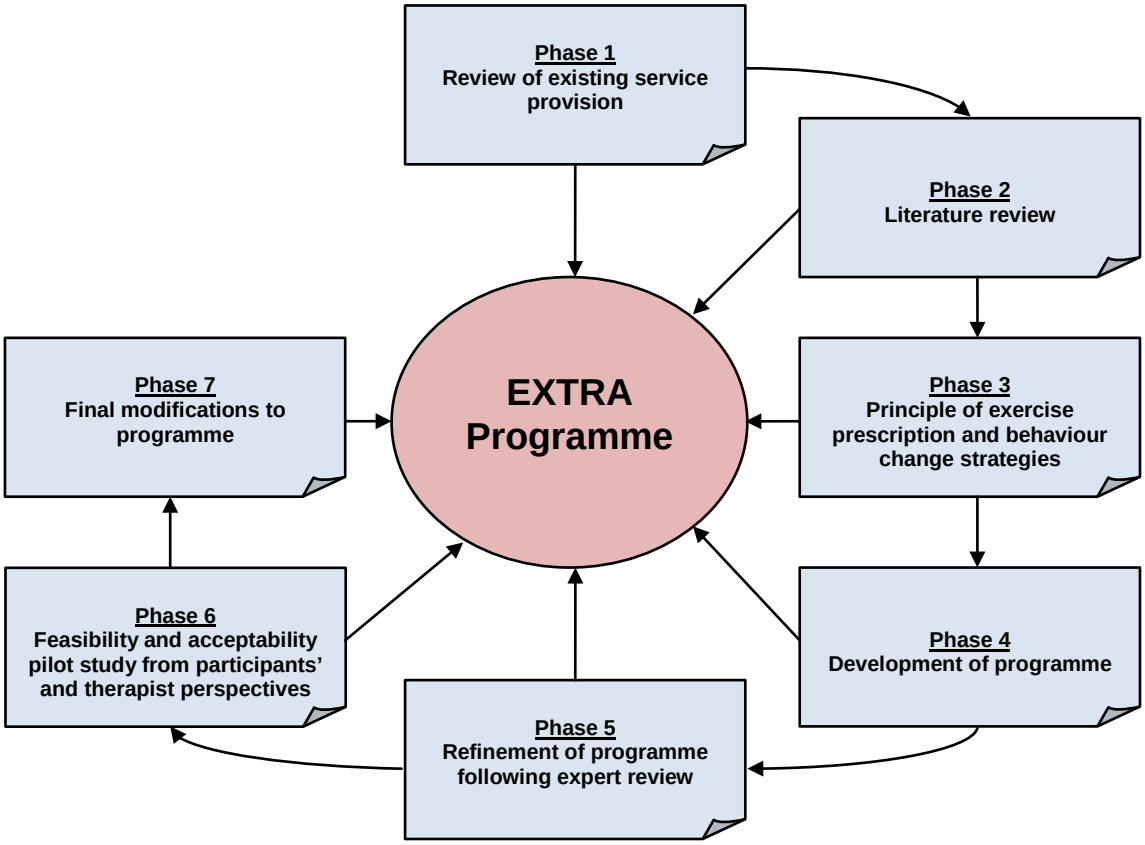


Figure 4.1 Development of a global upper limb exercise and self-management rehabilitation programme to improve upper limb function and disability in people with early RA

4.3.1 Phase 1: Review of Existing Service Provision

Between October and December 2008, existing local (south-east London) secondary care (KCH and Guy's and St. Thomas' NHS Foundation

Trust (GSTH)) services for addressing upper limb disability and self-management in people with RA were reviewed with two aims:

1) To understand current, typical practice and provide context for the programme under development.
2) To explore realistic formats for programme delivery (such as home versus hospital-based, supervised versus unsupervised, 'one to one' versus group delivery).

Rheumatology clinicians (physicians, nurse specialists, physiotherapists, and occupational therapists) were consulted informally and observed in clinical practice. Detailed notes were taken and reviewed by the research team.

Hand therapy was routinely prescribed for people with early RA. Typically, this comprised 4 to 6 'one to one' hospital-based sessions with an occupational therapist in which exercises, education, splints, and/or assistive devices were provided, in addition to unsupervised home exercise. Education for RA self-management was available to patients (optional) through a single (approximately 1 hour) hospital-based group session delivered by members of the RA multidisciplinary team (rheumatology nurse specialists, physiotherapists, occupational therapists). Physiotherapy was prescribed following referral from a physician.

4.3.2 Phase 2: Literature Review

Between October and December 2008, a scoping exercise to identify existing literature was completed. This aimed to:

1) Assess and identify appropriate exercise strategies and principles for the effective and safe rehabilitation of upper limb disability and dysfunction in people with early RA.
2) Explore behavioural change strategies applied to exercise uptake and maintenance.

Scientific publications were identified using Wed of Science, Medline, and Cochrane databases and reviewed by the researcher (VM) (Appendix O and M). Search terms included:

1) ‘rheumatoid arthritis’ or ‘rheumatoid’ or ‘rheumatic’ combined with ‘finger’ or ‘thumb’ or ‘hand’ or ‘wrist’ or ‘elbow’ or ‘shoulder’ combined with ‘exercise’ or ‘strengthening’ or ‘resistance training’.
2) ‘adherence’ or ‘uptake’ or ‘maintenance’ combined with ‘exercise’ or ‘physical activity’.

The reference lists of retrieved articles were also reviewed.

Eleven studies were identified with descriptions of targeted exercise programmes for the rehabilitation of upper limb disability in RA [148-149, 170-178] (Chapter 1). All focussed on sensorimotor deficits in the hands [148-149, 170-176] or shoulders [177-178] in isolation to the rest of the upper limb.

Three studies evaluating whole body exercise interventions provided detailed descriptions of the upper limb exercises incorporated [102, 131, 133] (Chapter 1).

No studies were found which integrated behavioural change strategies with exercise interventions specifically for people with RA. Two theoretically underpinned self-management programmes incorporating behavioural change strategies with exercise for people with OA and other rheumatic conditions were indentified; including the ASMP [218, 246-247, 250-251, 318-319] and ESCAPE [287] (Chapter 1).

4.3.3 Phase 3: Principles of Exercise Prescription and Behavioural Change Strategies

4.3.3.1 Principles of Exercise Prescription

General exercise principles of warm up, cool down, specificity, and overload were reviewed [119, 121].

Warm Up and Cool Down

Warm up facilitates the transition from rest to exercise by mobilising joints, stretching muscles, and increasing blood flow, body temperature, and metabolic rate to meet exercise requirements [119, 320-321]. A warm up may also reduce the risk of musculoskeletal injury by increasing connective tissue extensibility, improve joint ROM and thus function, and enhance muscular performance [322-325]. Conversely, *cool down* facilitates the attenuation of heart rate and blood pressure to resting values reducing the likelihood of post-exercise hypotension and dizziness, and assists the dissipation of body heat and removal of lactic acid [119, 326-327].

Guidelines for warm up and cool down recommend 5 to 10 minutes of low-intensity (large muscle group) aerobic exercise, in addition to mobility

and static stretching exercises (to tightness at the end of ROM but no pain; 15 to 30 seconds hold) [119, 321, 328].

Specificity

The principle of *specificity* states that physical adaptations resulting from exercise are specific to the exercises performed and muscles involved [119]. Thus, an exercise programme which incorporates a variety of major muscle groups, and focuses on the complex interplay of cognitive, perceptual, and motor functions involved in the performance of daily tasks, is more likely to result in physical adaptations transferable toward ADL [119, 329], and therefore tailoring an exercise programme to an individual's requirements is essential [330].

Overload

The principle of *overload* states that muscular adaptations, such as increases in strength and mass, are achieved by exposing muscles to stimuli greater than those to which they are normally accustomed [119]. The intensity of exercise can be modified by altering load, volume (i.e. number of sets and repetitions), contraction speed, rest intervals, and frequency [119], and should be progressive to prevent plateauing or reversal of training effects [183]. Thus, high-intensity resistance exercise (approximately 60 to 85% of 1 repetition maximum (1RM)) and multiple, as opposed to single, sets of between 8 to 12 repetitions are more efficacious for eliciting muscular hypertrophy [331-332] and maximal strength gains [333-335], respectively.

Strength training guidelines for people with RA recommend 8 to 10 dynamic progressive resistance exercises performed at 50 to 80% of an individual's 1RM, in 1 to 2 sets of 8 to 12 repetitions, at moderate contraction speeds (3 seconds concentric, 2 seconds isometric, 3 seconds eccentric), 2 to 3 days per week [119, 336].

4.3.3.2 Behavioural Change Strategies

Successful programmes should incorporate behavioural change strategies to increase uptake and adherence to exercise and self-management [262, 337] (Chapter 1). Bandura's (1986) *Social Cognitive Theory* [224] has successfully underpinned self-management programmes incorporating exercise for people with arthritis [218, 246-247, 252].

Social Cognitive Theory considers *knowledge* a precondition for change [204], and *outcome expectations*, *self-regulation methods*, and *barriers and facilitators* as providing the direction and altering the incentive to change [204]. Therefore, provision of knowledge, goal setting, relapse prevention strategies, and problem solving are key features of self-management programmes underpinned by SCT [218, 246-247, 252].

Bandura (2004) suggests that *perceived self-efficacy* is most fundamental to behavioural change [204] and can be learned and developed through four primary mechanisms: 1) *performance accomplishments*, 2) *verbal persuasion*, 3) *vicarious experience*, and 4) *physiological state or cues* [256-257] (Chapter 1). Performance accomplishments may be the strongest source of self-efficacy, however only if attributed to personal skill or ability, rather than mere chance, temporary, or external factors [254].

4.3.4 Phase 4: Development of a Global Upper Limb Education, Self-Management, and Exercise Programme for People with Early RA (the EXTRA Programme)

4.3.4.1 Exercises

Warm Up and Cool Down

A 5 to 10 minute exercise warm up and cool down were incorporated into the initial EXTRA programme, comprising low-intensity aerobic and upper limb mobility and static stretching exercises (Table 4.1), in accordance with the American College of Sports Medicine (ACSM) and American College of Rheumatology (ACR) recommendations [119, 336, 338].

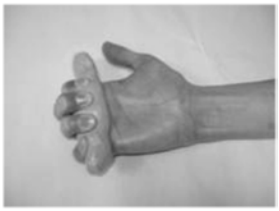
Table 4.1 Mobility, stretching, and aerobic exercises incorporated into the global upper limb exercise programme warm up and cool down

Mobility (slow and controlled)	**Static Stretching** (20 second hold each)
Fingers and Hands: • Make a fist and stretch the fingers out ('Stars') • Finger abduction and adduction • Finger flexion and extension • Thumb abduction and flexion to finger tips **Wrists:** • Ulnar and radial deviation • Flexion and extension **Elbows:** • Flexion and extension **Shoulders:** • Rotation: Elevation, retraction, depression and protraction • Arm circles: Small to large (In 90° abduction) **Spine:** • Cervical half-circles (Chin drawn in to chest) • Lateral flexion and extension	**Triceps:** • With one arm, reach up as much as possible. Now bend arm and ease elbow up and back (Head up) **Chest:** • Reach back (Thumbs up) **Mid/Lower Back:** • Reach up with one arm (rest other hand on hip) and lean to contralateral side (If this is not possible, with hands by the side, lean as if trying to reach hand to ipsilateral knee) **Upper Back:** • Reach forwards **Neck:** • Ear to shoulder (Reach down with contralateral arm)
Cardiovascular March on the spot / Mini-squats / Chair sit-to-stand	

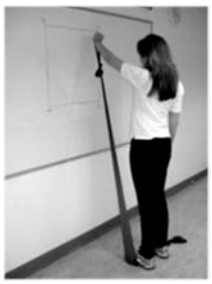
Functional Exercises

Upper limb exercises were chosen to reflect common ADL involving the use of the upper limb, such as cutting food with a knife and fork, carrying a shopping bag, cleaning windows, or placing an object on an overhead shelf (Table 4.2), in accordance with the principle of specificity (Section 4.3.3).

Table 4.2 Functional exercises included in the initial upper limb rehabilitation programme

Exercise			Action	Primary Muscles Involved
1	**Hand Grip**		Spherical volar hand grip	Flexor digitorum superficialis, Flexor digitorum profundus, Flexor pollicis longus
2	**Finger Tip Pinch**		Pulp finger pinch	Flexor digitorum superficialis, Flexor digitorum profundus, Flexor pollicis longus
3	**Finger Flexion**		Finger flexion	Flexor digitorum superficialis, Flexor digitorum profundus
4	**Knife and Fork Putty Cutting**		Involving diagonal volar hand grip; (Tripod finger pinch)	Flexor digitorum superficialis, Flexor digitorum profundus, Flexor pollicis longus
5	**Paper Clip and Envelope Challenge**		Involving lateral and pulp finger pinch; Extension hand grip	Flexor digitorum superficialis, Flexor digitorum profundus, Flexor pollicis longus

6	**Wrist Extension**		Wrist extension	Extensor carpi radialis longus, Extensor carpi ulnaris, Extensor carpi radialis brevis
7	**Wrist Flexion**		Wrist flexion	Flexor carpi radialis, Palmaris longus, Flexor carpi ulnaris
8	**Arm Extension**		Elbow extension	Triceps brachii, Flexor carpi radialis, Palmaris longus, Flexor carpi ulnaris
9	**Triceps Press Out of Chair**		Elbow extension	Triceps brachii
10	**Arm Curl**		Elbow flexion	Biceps brachii, Brachialis, Flexor carpi radialis, Palmaris longus, Flexor carpi ulnaris

11	**Upright Row**		Shoulder abduction; Shoulder elevation; (Elbow flexion)	Trapezius, Levator scapulae, Deltoid, Supraspinatus
12	**Reach Back**		Shoulder retraction, Lateral shoulder rotation	Trapezius, Rhomboids
13	**Lateral Shoulder Raise**		Shoulder abduction	Deltoid, Supraspinatus
14	**Shoulder Press Squares**		Shoulder flexion; Lateral shoulder rotation; Medial shoulder rotation	Deltoid, Supraspinatus, Pectoralis major, Pectoralis minor, Serratus anterior, Teres minor, Teres major
15	**Chest Press**		Shoulder adduction; Shoulder protraction; Elbow extension	Pectoralis major, Pectoralis minor, Serratus anterior, Triceps brachii

16	**Shoulder Rotation**		Lateral shoulder rotation	Deltoid, Infraspinatus, Teres minor
17	**Shoulder Press**		Shoulder flexion; Elbow extension	Deltoid, Supraspinatus, Triceps brachii

Exercise Principles

Exercises were developed to be performed progressively, at 50 to 80% of an individual's 1RM, in 1 to 3 sets of 8 to 12 repetitions, at moderate contraction speeds (3 seconds concentric, 2 seconds isometric, 3 seconds eccentric), 3 days per week, in accordance with the principle of overload (Section 4.3.3) and ACSM and ACR recommendations for resistance training in RA [119, 336] (Table 4.3). All participants were prescribed 8 exercises.

Table 4.3 Exercise principles applied to the initial upper limb rehabilitation programme

Exercise	Frequency	Intensity	Sets	Repetitions	Contraction Speed	Rest	Progression	Regression
Hand Grip	3 days per week	50-80% maximal exertion (1RM)	1-3	8-12	3 seconds concentric, 2 seconds isometric, 3 seconds eccentric	30 seconds between sets	• Increase load (e.g. 'double over' therapy band) • Increase number of sets • Increase isometric contraction time to 4 seconds *(where applicable)* • Perform standing not seated *(where applicable)*	• Reduce load (e.g. 'slacken' therapy band tension, perform assisted repetitions, etc.) • Reduce number of sets • Reduce number of repetitions • Increase rest (i.e. between sets and repetitions)
Finger Tip Pinch								
Finger Flexion								
Wrist Lift								
Wrist Curl								
Arm Extension								
Triceps Press Out of Chair								
Arm Curl								
Upright Row								
Reach Back								
Lateral Shoulder Raise								
Shoulder Press Squares								
Chest Press								
Shoulder Rotation								
Shoulder Press								
Knife and Fork Putty Cutting	3 days per week	50-80% maximal exertion (1RM)	1-3	As many as possible in 30 seconds	As quickly as possible	30 seconds between sets	• Increase number of sets • Increase number of repetitions (i.e. as many as possible in 60 seconds)	• Reduce number of sets
Paper Clip and Envelope Challenge								

4.3.4.2 Behavioural Change Strategies

Modelled on previous successful self-management interventions for people with arthritis [218, 246-247, 252], the initial EXTRA programme was developed to incorporate exercise and RA self-management knowledge, goal setting, relapse prevention strategies, and problem solving through group educational seminars (Table 4.4) and supplementary written materials, including information sheets, written and pictorial exercise descriptions, and a weekly goal and exercise diary.

Table 4.4 Education and self-management topics incorporated into the initial rehabilitation programme through group educational seminars

- **Aims and objectives of the programme**
- **Exercise tips (e.g. posture)**
- **Coping with pain**
- **Coping with tiredness**
- **Personal objectives and goal setting**
- **Managing flare ups**
- **Exercise progression**

Underpinned by SCT, supplementary supervised group sessions and a self-evaluative goal and exercise diary were developed, in order to facilitate verbal persuasion from others (peers and physiotherapist), exposure to vicarious experience, skills mastery, and an awareness of physiological state before and after exercise [224]. Self-management educational seminars were designed to be interactive and largely patient-led, to facilitate discussion, learning, and support between peers. Moreover, exercises were performed within a group setting, to enable observation of peers' exercise abilities and

achievements. The goal and exercise diary was developed to enable participants to record their accomplishments (i.e. sets and repetitions per exercise), experiences (i.e. difficulty, intensity), and short- and long-term goals.

4.3.4.3 Summary of Initial EXTRA Programme

Table 4.5 provides a summary of the initial EXTRA programme following review of existing service provision and literature.

Table 4.5 The initial upper limb education, self-management, and exercise programme following review of existing service provision and current literature

Upper Limb Exercises:

- **Warm up:** 5 to 10 minutes incorporating low-intensity cardiovascular, mobility, and static stretching exercises
- **17 functional exercises** from which 8 individually prescribed
- Participants provided with exercise **therapy putty and graded therapy bands**
- **Exercise principles:**
  - Frequency: 1 to 3 sets, 8 to 12 repetitions
  - Intensity: 50 to 80% 1RM, moderate contraction speeds
  - Time: 3 days per week
  - Type: progressive (monitored by participants)
- **Cool down:** 5 to 10 minutes incorporating low-intensity cardiovascular, mobility, and static stretching exercises

Self-Management/Education:

- **Informed by Social Cognitive Theory**
- **Educational seminars covering:**
  - Aims and objectives of the programme
  - Exercise tips
  - Pain, fatigue, and flare management
  - Personal objectives and goal setting
  - Exercise progression
- **Written materials including:**
  - Information sheets (supplementary to educational seminars)
  - Written and pictorial exercise descriptions
  - Weekly goal and exercise diary

Format and Delivery:

- **Home-based** exercise regimen
- **4 to 6 supervised group sessions** (1 hour duration) incorporating educational seminars (patient led) and exercise

4.3.5 Phase 5: Programme Refinement Following Expert Review

Following initial development of the EXTRA programme (Phase 4), rheumatology clinicians (physicians, nurse specialists, physiotherapists, and occupational therapists (KCH)) and specialist academics (King's College London (KCL)) were consulted formally, via 'one to one' interviews, and informally through email or telephone correspondence, depending on the commitment of the expert. A topic guide was developed to structure consultations (Table 4.6). Views were collated and the research team reviewed and incorporated suggestions iteratively.

Table 4.6 Topic guide for consultation with experts

1) **Exercise specifications** (exercises for inclusion in the intervention, number of prescribed exercises per person, exercise intensity, strategies for exercise progression and regression, etc.).

2) **Educational specifications** (topics for inclusion in the educational seminars, delivery of the educational seminars, etc.).

3) **Handbook specifications** (content, appearance, and acceptability of the programme handbook).

4) **Format and delivery** (home versus hospital based, clinical feasibility and acceptability, number of supervised sessions, timing, patient numbers, materials, cost, format, etc.).

Clinicians and experts suggested that the supervised group sessions would be most appropriately led by an experienced physiotherapist (band 6) within a hospital setting.

Physiotherapists advised a 'circuit training' exercise format to aid delivery of the supervised sessions. They suggested provision of 'therapist notes' to supplement class delivery, including a session timeline (Table 4.8),

points for discussion during the educational seminars, and details of each exercise and the equipment required. To facilitate session preparation, physiotherapists recommended provision of an ‘equipment box’ containing all materials required for programme delivery.

Specialist academics recommended that exercises be prescribed on a daily basis to facilitate development of an exercise habit [339], and that it would more feasible for each participant to be prescribed 6 rather than 8 exercises [252]. They advised that, where possible, exercises be given ‘functional’ names to facilitate participants’ learning, memory, and functional outcome expectations (Table 4.7).

Table 4.7 Refined upper limb exercise names following expert review

1	**Putty Ball Squeeze**
2	Finger Tip Pinch
3	**Finger Hook and Squeeze**
4	Knife and Fork Putty Cutting
5	Paper Clip and Envelope Challenge
6	Wrist Lift
7	Wrist Curl
8	**Back Scrub**
9	**Up and Out of Chair**
10	Arm Curl
11	Upright Row
12	Reach Back
13	**Side Raise**
14	**Wall Wash Squares**
15	**Door Push**
16	Shoulder Rotation
17	**Reach to Shelf**

N.B. Refined names indicated by bold script

On the basis of previous experience of intervention implementation [252], academics suggested that no more than six people be included in each

class cohort to ensure sufficient ‘one to one’ time with the physiotherapist (to address individual concerns and questions) in preparation for unsupervised home-based exercise. It was considered realistic and appropriate that 4 supervised sessions be delivered twice weekly for 2 weeks. It was proposed that the educational seminars be delivered within the first 15 minutes of the supervised sessions (Table 4.8), and the proposed topics, identified from previous integrated exercise and self-management programmes [218, 247, 252] were discussed and structured within the 4 supervised sessions (Table 4.9).

Table 4.8 Supervised session timeline following expert review

Time (minutes)	
Arrival	**Class register**
0	Educational seminar
15	Exercise warm up
25	Individually prescribed exercises
50	Exercise cool down
60	**End**

To ensure practicality, ‘ease of use’, and utility of the written materials, it was recommended that participants be provided with a complete ring bound handbook containing all of the supplementary written materials, rather than handouts distributed individually at each session. It was suggested that the handbook be aesthetically pleasing (i.e. pictures, large font, etc), and use lay language to encourage and facilitate use and understanding.

4.3.5.1 Summary of the EXTRA Programme Following Expert Review

Table 4.9 provides a summary of the EXTRA programme following review by experts.

Table 4.9 Upper limb education, self-management, and exercise programme following expert review

Upper Limb Exercises:

- Warm up: 5 to 10 minutes incorporating low-intensity cardiovascular, mobility, and static stretching exercises
- 17 functional exercises from which **6 individually prescribed**
- **Functional names (Table 4.7)**
- Participants provided with exercise therapy putty and graded therapy bands
- Exercise principles:
  - Frequency: 1 to 3 sets, 8 to 12 repetitions
  - Intensity: 50 to 80% 1RM, moderate contraction speeds
  - **Time: daily**
  - Type: progressive (monitored by participants)
- Cool down: 5 to 10 minutes incorporating low-intensity cardiovascular, mobility, and static stretching exercises

Self-Management/Education:

- Informed by Social Cognitive Theory
- Educational seminars:
  - **Seminar 1: Aims and objectives of the programme and exercise tips**
  - **Seminar 2: Pain and fatigue management**
  - **Seminar 3: Personal objectives and goal setting**
  - **Seminar 4: Flare management and exercise progression**
- **Programme handbook (ring bound, aesthetically pleasing, lay language)** containing:
  - Information sheets (supplementary to educational seminars)
  - Written and pictorial exercise descriptions
  - Weekly goal and exercise diary

Format and Delivery:

- Home-based exercise
- **4 supervised group sessions:**
  - 1 hour duration
  - **Delivered twice weekly for 2 weeks**
  - **Hospital-based regimen**
  - **Delivered by physiotherapist (experienced, band 6) provided with 'therapist notes' (session schedule, education seminar discussion points, exercise details) and 'equipment box' (containing materials required for delivery)**
  - **4 to 6 participants per cohort**
  - Incorporating educational seminars (patient led, **15 minutes duration**) and exercise **(circuit training' format)**

*Refinements indicated by bold script

4.3.6 Phase 6: Feasibility and Acceptability of the Programme

4.3.6.1 Methods

Aim and Design

To explore the participants' and therapist's experiences of the EXTRA programme, and inform further adaptation and refinement, a preliminary feasibility and acceptability study of the intervention with qualitative analysis was conducted. Ethical and research governance approval was obtained from KCH and the London (Dulwich) REC (08/H0808/118) (Appendix B).

Participants

Between October and December 2008, patients were recruited from the rheumatology outpatient department of KCH to participate in a pilot study evaluating the experience of the EXTRA programme.

Inclusion criteria were: 1) ≥18 years of age; 2) diagnosed with arthritis affecting the upper limbs according to the ACR classification criteria [19, 294]. The *exclusion criterion* was: unable to provide written informed consent.

Participant Characteristics

Socio-demographic data (gender, age, height, weight, BMI, disease duration, ethnicity, and marital status) were obtained, and upper limb disability (DASH [88-89]), hand grip strength, QOL (RAQoL [311, 340]), and self-efficacy (ASES [312, 341]) were assessed (Chapter 3) before participation in the pilot of the EXTRA programme.

The EXTRA Programme

Following assessment, participants received an individually tailored global upper limb exercise programme to complete at home for 4 weeks, supplemented by 4 supervised (experienced physiotherapist (band 6)), hospital-based group education, self-management, and exercise sessions (delivered twice a week for 2 weeks) and an exercise handbook (Table 4.9).

Therapist Training

The physiotherapist (PT) received 2 hours of training by a member of the research team (VM) on the aims of the programme, content of the 4 supervised sessions, and strategies to facilitate discussion during the interactive educational seminars. The therapist was also provided with notes to support programme delivery.

Treatment Fidelity

Pilot sessions were attended by two members of the research team (VM and LB) to monitor treatment fidelity.

Field Notes

Members of the research team (VM and LB) kept detailed field notes during the pilot study, recording informal feedback provided by patients or the physiotherapist, in order to inform the focus group and protocol review.

Focus Group

Following the intervention, a focus group including participants, the physiotherapist, and academics monitoring the fidelity of the intervention (VM and MH) was conducted at an academic research facility (Rehabilitation Research Unit, Dulwich Community Hospital), led by the principal investigator (PI) (VM).

A semi-structured discussion schedule was constructed to facilitate reflection on experiences of the intervention (Table 4.10). The PI (VM) used prompts/probes to encourage further detail and, where necessary, relayed participants' opinions or statements for validation. The focus group was audio recorded and transcribed verbatim (Appendix G).

Table 4.10 Focus group interview discussion schedule

1) **Tell us about your overall impressions/experiences of the rehabilitation programme?**

2) **What did you think about the supervised sessions?**
Probes: What about the structure, number, frequency?

3) **What did you think about the educational seminars?**
Probes: What did you think about the topics that were covered? What additional topics, if any, should have been included, omitted?

4) **What did you think about the exercises?**
Probes: What about the warm up/cool down exercises, your individual exercises?

5) **What did you think about the exercise handbook?**
Probes: What was it like to use? What additional sections, if any, should be included, omitted?

6) **Tell us about your experiences of exercising at home.**
Probes: What were the positives, negatives? What helped or hindered you?

7) **What, if anything, would you change about the programme?**

8) **Is there anything we have not talked about that anyone would like to add?**

Data Analysis

The focus group transcript was analysed by the PI (VM) using NVivo 9 (*QSR International Pty Ltd.*). The transcript was first read and reread to provide familiarity with the material. Thematic Content Analysis was used to develop themes and organize and understand the data [342].

4.3.6.2 Results

Participants

Three patients participated in the feasibility study (Table 4.11).

Table 4.11 Characteristics of participants completing a feasibility study of the upper limb 'Education, self-management, and eXercise Training programme for people with early Rheumatoid Arthritis' (the EXTRA programme)

Variable	P1	P2	P3
Gender (n)	Female	Male	Female
Age (years)	63	73	73
Height (cm)	168	178	158
Weight (kg)	75	111	100
BMI	27	35	40
Rheumatic Diagnosis	RA	OA	RA
Disease Duration (months)*	204	36	24
Ethnicity	White	White	White
Marital Status	Married	Married	Married
DASH Symptoms (0-100 scale)	43	40	58
Hand Grip Strength (Newtons):			
DOM	49	373	157
NDOM	79	275	186
Arthritis Self-efficacy (10-100 scale):			
Pain	54	54	X
Function	70	54	66
Symptoms	80	68	62
Quality of Life (0-30 scale)	8	19	14

BMI = body mass index; RA = rheumatoid arthritis; OA = osteoarthritis; DASH = Disability of the Arm, Shoulder, and Hand Questionnaire; DOM = dominant; NDOM = non dominant; X = missing data; P1 = participant 1; P2 = participant 2; P3 = participant 3

Focus Group

Overall, the participants and the physiotherapist found the programme acceptable, and a positive experience. Six themes emerged, relevant to the participants' and therapist's experiences of the intervention, reflecting key components of the programme: 1) Exercises suited to individual needs, 2) Educational seminars confirmed and extended knowledge, 3) Supervised sessions were intensive, 4) Working in a group provided peer support, 5) Location, location, location, and 6) Written materials facilitate learning.

Exercises Suited to Individual Needs

Participants felt that their exercises were well suited to their own individual needs:

P3: "I didn't know I had weaknesses in my two little fingers. It wasn't until the exercise you gave me...that I realized that those were weak as well...That's why I felt those first two exercises were really for me personally."

They found their exercises challenging, but viewed this positively:

P1: "The push ups from the chair were quite challenging, but then, on the other hand, I needed that challenge."

One participant reflected that she had experienced shoulder pain following the first supervised session, but once her exercises were appropriately adjusted by the physiotherapist, she experienced no further aggravation and her exercise outcome expectations improved:

P3: "I think, when you modified them, which was on the second day...then it started to, I feel uh, do a bit of good...and today, I feel quite good after."

Educational Seminars Confirmed and Extended Knowledge

Participants felt that the educational seminars emphasized and confirmed their knowledge of RA self-management, and were beneficial:

P1: "...just to bring that awareness to the forefront I thought was very good...[You know], "Oh yes I've heard that before""

They felt that the seminars should have included more information on arthritis pathophysiology and the role of exercise, symptom relief, and nutrition:

P3: "I would have liked, p...perhaps, I know it's not your field, but any other, just, are there any massage, heat treatments, that could be recommended for people like us, so, you know."

P3: "...that would be useful, nutrition, yeah."

Participants reflected on their need for expert support and instruction when learning to perform their exercises:

P3: "...I really needed [PT] to take me through...because I got confused, what I'd done and what I hadn't done."

The Supervised Sessions were Intensive

Some participants liked the intensive twice weekly format of the supervised sessions, but felt that it would have been difficult to maintain for more than two weeks:

P3: "I think we, we perfectly managed this alright but if it was...go....ongoing...any longer then...it would have been more difficult...and then we'd be saying, 'well I can do that session, but I can't do that', and then you're messing people around."

Another participant reported that she would have preferred the programme to continue for more than two weeks.

MH: What about things you'd want to add in? What would you think?
P1: More sessions.

Participants discussed their experiences of performing their exercises in a timed circuit. Whilst one participant found this confusing, she also felt that a circuit approach provided valuable rest between exercises:

P3: "But that was good because it gave a rest for the uh, the muscles before you go back...so it was beneficial, it's just confusing to begin with."

Another participant was motivated by the circuit format, and reflected that it helped him achieve more:

P2: "Well, well I, I quite enjoyed the...the timing...because I was...because I felt I was achieving more each time."

Participants valued feeling a sense of control over their exercises during the supervised sessions:

P3: "And I think if you can be given that choice of doing, like you did today...which do you want to do first?"

The physiotherapist supported participants' autonomy:

PT: "[P2] might have liked to do wrist-wrist...shoulder-shoulder exercises, and you might have liked to go through one at a time...and then you have a particular order as well, which makes you remember them...So, hopefully, the class structure we did today, facilitates being able to do them...how you might do them at home."

Working in a Group Provided Peer Support

Participants reflected on how peer support contributed toward their experience of the programme:

P2: "Oh, I thought it was friendly...I thought it was all a very friendly atmosphere when we came in."

Location, Location, Location

One participant remarked that the class location was poorly accessible:

P3: "I think they need a new lift, but never mind that...so, but I mean here, it doesn't hurt, I come, find difficulty in getting up the stairs, but I can walk down the stairs quite easily."

Written Materials Facilitate Learning

Participants reflected that the pictorial exercise descriptions were helpful when learning and remembering how to perform their exercises, particularly when at home.

They discussed their experiences of keeping an exercise diary. They suggested writing the exercise names, as opposed to numbers, at the start of the diary:

P1: "When I take my blank sheet home, I actually think to write in more [inaudible]...'cause I forgot the numbers."

The physiotherapist noted that participants were confused by the diary 'example day', incorrectly perceiving this as a target for achievement (i.e. sets and repetitions).

PT: The other question I noted down, that you mentioned [P1] was there was a bar across the top which had an example of sort of sets and repetitions and...you just kind of mentioned that you felt it was, perhaps a suggestion of...how many reps..."
P3: "Yeah, I agree with [P1] there, yeah."
PT: "Maybe a b...bit misleading, maybe."

One participant commented that inadequate space was provided to record comments and feelings, and suggested using numbers to rate exercise experience:

P3: "Yeah, could have a little more room...to put the comments down...or put uh, perhaps numbers..."

Field Notes

Exercises Suited to Individual Needs

It was noted that participants struggled to perform the 'Wrist Curl' exercise, and they found the distinction between 'Wrist Curl' and 'Wrist Lift' confusing. One participant discussed the possibility of integrating these two exercises into one exercise. She described an exercise she had been taught in an 'over 50's' exercise group called the 'Ankle Alphabet', performed by writing the alphabet with the foot.

It was noted that participants found some of the exercise names ('Upright Row' and 'Side Raise') difficult to translate into the actions required and understand in terms of functional outcome expectations.

Educational Seminars Confirmed and Extended Knowledge

Participants were concerned about the negative effects of exercise on arthritis symptoms, such as pain and fatigue.

The physiotherapist noted that it was not always possible, during the educational seminars, to cover all of the points listed in the therapist's notes. Thus, they suggested that key points, or 'take home messages', be provided.

The Supervised Sessions Were Intensive

It was noted that participants required additional time to enable them to learn their exercises in the first two classes.

Written Materials Facilitate Learning

Participants particularly valued the exercise pictures, but there was a tendency for them to perceive the picture demonstrations as absolute methods. For example, one participant explained that she was incapable of performing an exercise ('Arm Extension' or 'Back Scrub') given her inability to replicate the starting position depicted in the picture, due to insufficient shoulder movement.

Therapist's Programme Delivery Notes

The physiotherapist explained that the therapist's notes were difficult to use as they were not in a single document and reflected that it would have been helpful to have a copy of the participant handbook for reference.

4.3.7 Phase 7: Final Modifications to the Programme

The research team and clinical physiotherapist reviewed the pilot programme, including the focus group transcript and researchers' field notes, and following discussion agreed the intervention amendments.

Exercises

The pilot intervention incorporated two exercises for the wrist: the 'Wrist Curl' and 'Wrist Lift'. As participants found the distinction between the two exercises unclear, these were removed from the programme and replaced with a single, simple exercise designed to recruit the wrist extensors, adductors, and abductors: the 'Wrist Alphabet' (as suggested by one of the participants). Whilst this exercise omits concentric recruitment of the wrist flexors, these muscles are recruited eccentrically and isometrically when performing other upper limb exercises (such as the 'Arm Curl'). Therefore, this was considered an appropriate adaptation to the programme.

As participants expressed difficulty in translating some exercise names ('Upright Row and 'Side Raise') into the actions required, and associating exercises with functional outcomes, exercise names were modified (Table 4.12).

Table 4.12 Upper limb exercise list following pilot study

1	Putty Ball Squeeze
2	Finger Tip Pinch
3	Finger Hook and Squeeze
4	Knife and Fork Putty Cutting
5	Paper Clip and Envelope Challenge
6	**Wrist Alphabet**
7	Back Scrub
8	Up and Out of Chair
9	Arm Curl
10	**Lift to Chin**
11	Reach Back
12	**Side Lift**
13	Wall Wash Squares
14	Door Push
15	Shoulder Rotation
16	Reach to Shelf

N.B. Revised exercises are indicated by bold script

As participants expressed difficulty in concisely reporting and reflecting on exercise difficulty and experience at home, the Rating of Perceived Exertion (RPE) scale [343] was introduced to monitor exercise intensity [119]. The RPE scale (range 6-20) provides an index of resistance training intensity [344-345], where a rating of 13 to 17 represents an appropriate submaximal training target for increased muscular strength (approximately 50-80% 1RM) [119, 343], and has been used previously as a measure of resistance training intensity among patients with rheumatic diseases [346-347]. To facilitate participants' use and understanding of the RPE scale, the physiotherapist would support the evaluation and modification of exercise intensity during the first week of the programme.

Educational Seminars

The educational seminar topics were revised: *seminar one*, originally covering aims and objectives of the programme and exercise tips, was extended to include a discussion on arthritis pathophysiology and the role of exercise, *seminar two*, formerly covering pain and fatigue management, was extended to incorporate an overview of RA flare management, *seminar three*, originally focussing on goal setting, was extended to discuss monitoring exercise intensity, *seminar four*, initially covering arthritis flare management and exercise progression, was revised to discuss exercise regression in addition to progression, as well as strategies for overcoming exercise barriers and maintaining motivation (Table 4.13).

Table 4.13 Educational seminar topics and schedule following pilot study

Session	Topics Covered
1	• Aims and objectives of the programme • **Rheumatoid arthritis and exercise** • Exercise tips
2	• Managing flare-ups • Coping with pain and tiredness
3	• **Monitoring exercise intensity** • Personal objectives and goal setting
4	• **Maintaining motivation** • Progressing and **regressing** exercises

N.B. Revised topics indicated by bold script

Whilst participants also expressed an interest in nutrition, physiotherapy clinical practice guidelines precluded the inclusion of this additional material. Therefore, Arthritis Research UK ‘nutrition’ booklets were

made available at the supervised sessions, and other sources of information were included at the back of the EXTRA programme handbook.

Session Structure and Format

As participants suggested that the programme provide sufficient 'one to one' time with the physiotherapist, as well as the potential for peer interaction and support, a class cohort of four to six participants was maintained. To ensure realism and pragmatism of the programme, the 4 supervised sessions, each 1 hour in duration, were maintained. The session timeline was modified (warm up/cool down time reduced), to allow more time for participants to familiarize themselves with their exercises (Table 4.14).

Table 4.14 Supervised session timeline following pilot study

Time (minutes)	
Arrival	**Class register**
0	Educational seminar
15	Exercise warm up
20	Individually prescribed exercises
55	Exercise cool down
60	**End**

Exercise Handbook and Diary

Additional pictures were included in the handbook, to accompany written exercise descriptions, indicating alternative exercise starting positions. To address participants' concerns about exacerbating arthritis symptoms, a troubleshooting section was included in the programme

handbook to support the home exercise regimen, and contact details of the class physiotherapist and trial chief investigator (LB) were also provided.

The exercise diary was modified to enable participants to record the names, rather than numbers, of their exercise, and the diary 'example day' was converted to an 'example week' on a separate sheet, in order to discourage participants from perceiving this as a target for achievement.

Therapist Handbook

A complete ring bound, comprehensive therapist 'handbook' was developed, containing: 1) the participant handbook, 2) a session timeline, 3) discussion points and key messages for each of the educational seminars (to ensure treatment fidelity), 4) exercise details (warm up, cool down, equipment required, delivery format), and 5) general session format and delivery notes (Appendix H).

4.3.8 The Definitive EXTRA Programme

The definitive EXTRA programme consists of an individually prescribed, upper limb home exercise regimen, supplemented by 4 supervised (hospital-based) group education, self-management, and exercise sessions and a programme handbook, aimed at improving global upper limb function and disability (Table 4.15).

Table 4.15 The definitive Education, self-management, and eXercise Training programme for people with early Rheumatoid Arthritis (the EXTRA programme)

Upper Limb Exercises:

- Warm up: **5 minutes** incorporating low-intensity cardiovascular, mobility, and static stretching exercises
- **16 functional exercises** from which **6 individually prescribed**
- **Functional names**
- Participants provided with exercise therapy putty and bands
- Exercise principles:
  - Frequency: 1 to 3 sets, 8 to 12 repetitions
  - Intensity: 50 to 80% 1RM **(13-17 RPE),** moderate contraction speeds
  - **Time: daily**
  - Type: progressive **(monitored by therapist during first week and by participants thereafter, using Borg's 6-20 RPE Scale [343])**
- Cool down: **5 minutes** incorporating low-intensity cardiovascular, mobility, and static stretching exercises

Self-Management/Education:

- Informed by Social Cognitive Theory
- Educational seminars:
  - **Seminar 1: Aims and objectives of the programme, exercise tips, RA pathophysiology and exercise**
  - **Seminar 2: Pain, fatigue, and flare management**
  - **Seminar 3: Goal setting and monitoring exercise intensity**
  - **Seminar 4: Exercise progression and regression, overcoming barriers, and maintaining motivation**
- Programme handbook (ring bound, aesthetically pleasing, lay language) containing:
  - Information sheets (supplementary to educational seminars)
  - Written and pictorial exercise descriptions
  - Weekly goal and exercise diary
  - **Troubleshooting**
  - **Emergency contacts**
  - **Useful organizations and websites**
- **ARUK 'nutrition' booklets available for interested participants**

Format and Delivery:

- Home-based exercise regimen
- 4 supervised group sessions:
  - Delivered twice weekly for 2 weeks
  - Hospital-based
  - Delivered by physiotherapist (experienced, band 6) provided with **ring bound 'therapist handbook' (the participant handbook, session timeline, educational seminar discussion points and key messages, exercise details, general delivery notes**) and 'equipment box' (containing materials required for delivery)
  - 4 to 6 participants per cohort
  - Incorporating educational seminars (patient led, 15 minutes duration) and exercise (circuit training' format)

N.B. Refined components indicated in bold script
ARUK = Arthritis Research UK

4.3.8.1 Home Exercise Regimen

The home exercise regimen consists of 6 upper limb exercises, individually prescribed from a core set of 16 exercises (Table 4.12) on the basis of upper limb assessment, exercise history, and goals, performed progressively on a daily basis according to exercise principles provided in Table 4.3. Exercise intensity will be monitored by participants using Borg's RPE scale (range, 6-20) [343]. Exercises will be pre-ceded and super-ceded by a standardised warm up and cool down (Table 4.1).

4.3.8.2 Supervised Sessions

Four sessions (1 hour duration) will be delivered twice weekly over the first two weeks by an experienced (band 6) clinical physiotherapist, within the Physiotherapy Unit, Dulwich Community Hospital. To ensure standardization of the supervised sessions, the physiotherapist will be provided with a handbook detailing the specifics of delivery content and format (Appendix H).

Four to six participants will be included in each cohort. Sessions will begin with a 15-minute interactive educational seminar (Table 4.13) followed by 45 minutes of individualized exercise (Table 4.12 and 4.3), including a warm up and cool down (Table 4.1). Exercise intensity will be modified by the class physiotherapist during the first 2 sessions (by provision of a more or less intensive hand therapy putty or resistance band, or revision of the prescribed exercises, where appropriate), after which time the participant will be encouraged to take responsibility for exercise adaptation, supported by the physiotherapist.

4.3.8.3 Exercise Handbook and Diary

Participants will be provided with an exercise handbook, containing information sheets supplementary to the interactive educational seminars, pictorial and written instructions on how to perform the exercises, a weekly goal and exercise diary (including Borg's RPE scale [343]), an exercise troubleshooting section, a list of useful organizations and websites, and contact details of the clinical physiotherapist and research chief investigator (LB) (Appendix H).

4.3.8.4 Behavioural Change Techniques Incorporated into the Definitive EXTRA Programme

In accordance with the recommendations of Abraham and Michie (2008) [348], Table 4.16 provides a summary of the behavioural change strategies incorporated into the definitive EXTRA Programme, and a description of how these will be implemented.

Table 4.16 Behavioural change techniques incorporated into the definitive EXTRA programme

Technique (theoretical framework)	Definition	Method of implementation into programme
1. Provide information on consequences (TRA, TPB, SCT)	Information about the benefits and costs of action or inaction, focusing on what will happen if the person does or does not perform the behaviour	Information on the outcomes of exercise and inactivity in RA provided in educational seminar and programme handbook
2. Prompt intention formation (TRA, TPB, SCT)	Encouraging the person to decide to act or set a general goal	Participants encouraged to consider exercise goals at baseline assessment, and short and long-term goal setting incorporated into educational seminar and exercise diary
3. Prompt barrier identification (SCT)	Identify barriers to perform the behaviour and plan ways of overcoming them	General and individualized barriers identified, and ideas for overcoming them (problem solving), discussed in educational seminars (pain, fatigue, flare management, maintaining motivation) and programme handbook (information sheets, troubleshooting)
4. Provide general encouragement (SCT)	Praising or rewarding the person for effort or performance without this being contingent on specified behaviours or standards or performance	Encouragement provided from physiotherapist during supervised sessions
5. Set graded tasks (SCT)	Set easy tasks and increase difficulty until target behaviour is performed	Encouraged participants to set longer-term goals, and work towards these by setting SMART short-term goals (covered in educational seminar and programme handbook)
6. Provide instruction (SCT)	Telling the person how to perform a behaviour and/or preparatory behaviours	Instruction provided by physiotherapist
7. Model or demonstrate the behaviour (SCT)	An expert shows the person how to correctly perform the behaviour (e.g. in a class or video)	Demonstrated through pictorial exercise descriptions provided in programme handbook
8. Prompt self-monitoring behaviour (SCT)	The person is asked to keep a record of specified behaviour (e.g. in a diary)	Participants asked to keep a self-evaluative daily exercise diary
9. Provide opportunities for social comparison (SCT)	Facilitate observation or non-expert others' performance (e.g. in a group class or using video)	Provided through group (others with RA) exercise and self-management sessions

TRA = theory of reasoned action; TPB = theory of planned behaviour; SCT = social cognitive theory; SMART = specific, measurable, achievable, relevant, time

4.4 DISCUSSION

This study develops a theoretically underpinned global upper limb education, self-management, and exercise programme (the EXTRA programme) based on established exercise principles [119, 336, 338], behavioural change strategies, expert opinion, and a feasibility and acceptability study to improve upper limb disability and function in people with early RA.

Sustaining exercise is challenging and psychosocial variables, such as self-efficacy [256], can influence participation in habitual exercise and disease self-management [318, 349]. To enhance self-efficacy, people must have an understanding of their condition and the effect exercise may have on it, believe in the benefits of exercise and that they can perform the exercise regimen effectively. Thus, successfully experiencing a simple, practical exercise regimen that can be performed conveniently at home and enhanced by information, problem solving, and coping strategies to address barriers to exercise, such as pain or variations in disease activity, may enhance long-term adherence. Exercise and self-management programmes are successfully delivered by HCPs for people with lower limb arthritis with long-term benefits [252, 289].

To facilitate longer term behaviour change, the EXTRA intervention is supplemented with 4 supervised physiotherapist-led education, self-management, and exercise sessions. Based on SCT [224], and similar to other exercise and self-management programmes for people with arthritis

[218, 246-247, 252], knowledge, self-efficacy enhancement strategies, goal setting, relapse prevention, and problem solving skills were incorporated.

Before implementing a management strategy into clinical practice it is important to explore the acceptability and experience of the intervention [291] and this chapter reports a preliminary investigation, in preparation for a larger RCT. Overall, the participants and physiotherapists found the EXTRA intervention acceptable, and a positive experience. Adaptations to the intervention, such as refinement of educational topics (e.g. RA pathophysiology), modification of upper limb exercises (e.g. introduction of wrist alphabet), and alterations to the programme handbook (e.g. additional pictorial descriptions, provision of exercise regression strategies, inclusion of trouble shooting section, etc.) were implemented and the final intervention developed.

The EXTRA programme is designed to be pragmatic, and easily implemented into current clinical practice, and is therefore predominantly home-based, utilizing portable and inexpensive equipment. The clinical effectiveness, experience, and acceptability of the EXTRA programme require evaluation.

4.5 CONCLUSIONS

- The EXTRA programme is an integrated global upper limb education, self-management, and exercise programme for the rehabilitation of upper limb disability and dysfunction in people with early RA.

5 Upper Limb Education, Self-Management, and Exercise Training in People with Early Rheumatoid Arthritis (the EXTRA Programme): A Randomized Controlled Trial

5.1 INTRODUCTION

In people with RA, upper limb disability is associated with global upper limb motor deficits [30-31, 37, 53, 55-56] (Chapter 1). Effective upper limb function requires good proximal muscle control to stabilize the upper limb and place the hand for manual tasks.

Exercise improves motor function [156, 174-175, 177-178, 180, 350], and is a key component in the management of RA [7]. To date, no studies have evaluated the clinical effectiveness of global upper limb exercise on function, and there is a need for evidence-based exercise regimens to address global upper limb dysfunction in people with RA.

Successfully experiencing a simple, practical exercise regimen that can be performed conveniently at home and enhanced by information, problem solving, and coping strategies to address barriers to exercise, such

as pain or variations in disease activity, may facilitate behaviour change and enhance long-term exercise adherence.

Therefore, the aim of this study was to evaluate the clinical effectiveness of a pragmatic, global upper limb education, self-management, and exercise programme (the EXTRA programme) for rehabilitating upper limb disability and dysfunction in people with early RA (Chapter 4).

5.2 AIMS OF RESEARCH

The aims of this research were:

1) To evaluate the clinical effectiveness of an integrated global upper limb education, self-management, and exercise programme (the EXTRA programme), compared to usual care, for the rehabilitation of upper limb disability (primary outcome measure) at 12 weeks in people with early RA.
2) To evaluate the safety and clinical effectiveness of an integrated global upper limb education, self-management, and exercise programme (the EXTRA programme), compared to usual care, on motor function, disease activity, and psychosocial parameters (arthritis self-efficacy and QOL) at 12 weeks in people with early RA.
3) To evaluate the safety and clinical effectiveness of an integrated global upper limb education, self-management, and exercise programme (the EXTRA programme), compared to usual care, on self-reported upper limb disability, motor function, disease activity, and

psychosocial parameters (arthritis self-efficacy and QOL) at 36 weeks in people with early RA.

5.2.1 Hypothesis

An integrated global upper limb education, self-management, and exercise programme (the EXTRA programme) improves self-reported upper limb disability at 12 weeks, compared to usual care, in people with early RA.

5.2.2 Null Hypothesis

There is no difference in self-reported upper limb disability following an integrated global upper limb education, self-management, and exercise programme (the EXTRA programme) compared to those who receive usual medical care in people with early RA.

5.3 METHODS

5.3.1 Study Design

This assessor blind, pragmatic, randomized controlled trial (ISRCTN14268051) received ethical and research governance approval from KCH, GSTH, and University Hospital Lewisham NHS Foundation Trust (UHL) and the London (Dulwich) Research Ethic Committee (08/H0808/118) (Appendix B)

5.3.2 Sample and Recruitment

Potential participants were identified from secondary care clinic lists (by a member of the research team) and through referrals from consulting physicians and clinical nurse specialists at the rheumatology outpatient departments of three UK inner-city (south-east London) NHS hospitals (KCH, GSTT, and UHL) between February 2009 and September 2010. Patients were eligible for inclusion in the trial if they met agreed eligibility criteria (Table 5.1).

Table 5.1 Participant eligibility criteria

Inclusion Criteria	Exclusion Criteria
• Rheumatoid Arthritis diagnosed according to the 1987 American Rheumatism Association revised criteria [19] • Aged ≥18 years • Disease duration ≤5 years	• Started biologic pharmacological therapy within the previous 3 months • Intra-muscular or upper limb intra-articular steroid injection within the previous 4 weeks • Upper limb surgery within the previous 6 months • Upper limb physiotherapy within the previous 6 months • Unable to provide written, informed consent

Initially, people with changes in DMARDs 3 months prior to study enrolment were excluded. However, to facilitate recruitment and to ensure that people with a range of disease durations and severities, more representative of the early RA population, were enrolled into the study, this exclusion criterion was removed for the final 6 months of the recruitment period (Appendix B) and only those commencing biologic therapy 3 months prior to study enrolment were excluded.

Potential participants were approached either in person (by a member of the research team, rheumatology consulting physician, or nurse specialist) whilst attending their clinical appointments, or by letter (Appendix I) and contacted one week later by telephone. They were provided with a study information sheet (Appendix J), full verbal explanation of the trial, and an opportunity to ask questions prior to considering participation. Reasons for declining participation were recorded.

5.3.3 Sample Size

Sample size was calculated *a priori* by a standard power calculation [351] using a 12 week change in the primary outcome measure (DASH). To detect a minimal clinically important difference of 10 DASH points [93], based on 0.9 power to detect a significant difference, a significance level of 0.05, and assuming a standard deviation of 21 [292], 50 patients were required for each study group [351]. To allow for an expected 20% attrition rate, a total of 120 patients were required.

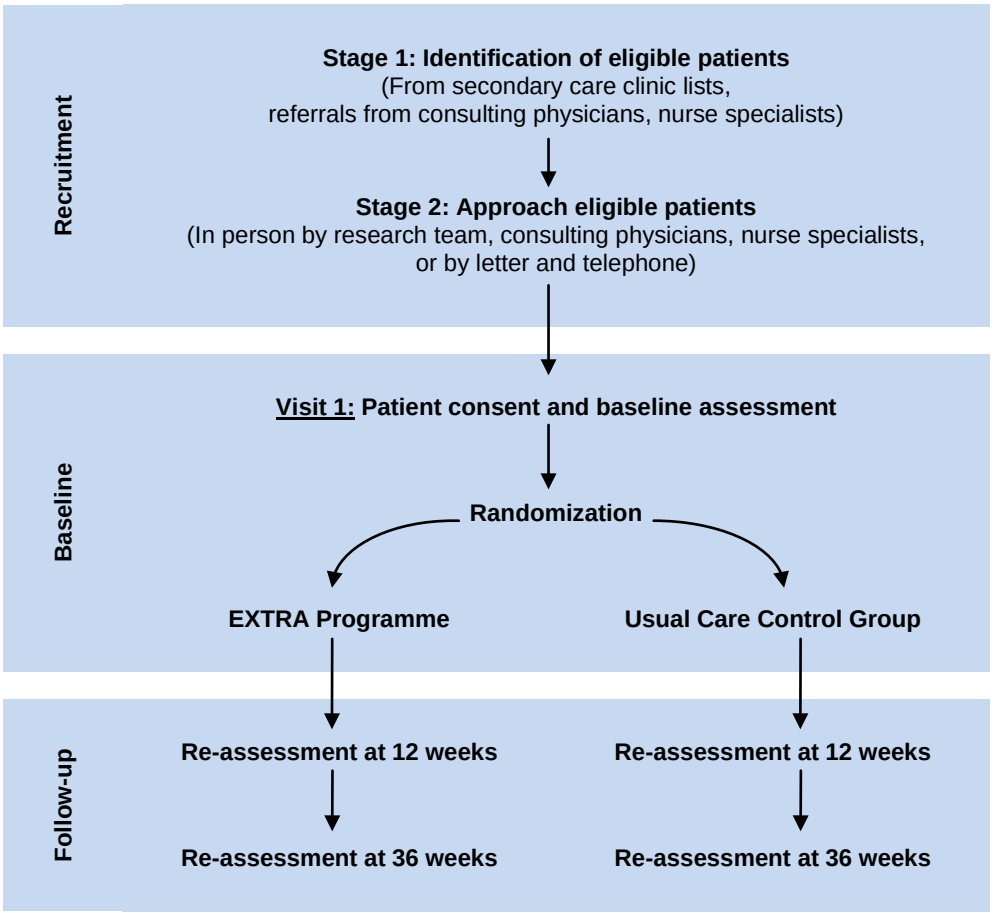
5.3.4 Study Protocol

All participants provided written informed consent (Appendix K) prior to baseline assessment. Follow-up assessments were conducted at 12 weeks (primary end point) and 36 weeks from baseline (Figure 5.1). Assessments were performed at one of two academic research facilities, depending on patient preference: 1) Rehabilitation Research Unit, Dulwich Community Hospital, or 2) Shepherd's House, Guy's Campus, KCL.

5.3.5 Randomization

Following baseline assessment, participants were randomly assigned to receive either usual care or the EXTRA programme in addition to usual care (Figure 5.1). Randomization was conducted via random number generation held by a third party unconnected with the study. Following baseline assessment, a researcher not involved with participant assessment contacted the randomization administrator, and informed the participant of their treatment allocation.

Figure 5.1 'Education, self-management, and eXercise Training in early Rheumatoid Arthritis' (EXTRA) study profile



5.3.6 Assessor Blinding

Treatment allocation was concealed to the outcome assessor. This was explained to participants at their baseline assessment, and they were instructed not to reveal treatment allocation to the assessor at subsequent visits. Participants were reminded of assessor concealment via letter prior to each assessment. Incidences of broken treatment allocation concealment were recorded.

5.3.7 Participant Characteristics

Demographic and general health characteristics were recorded at baseline assessment only. These included: age (years), height (cm), weight (kg), BMI, RA disease duration (months), self-reported smoking status (smoker, non-smoker), number of cigarettes per week (mean), number of comorbidities, ethnicity (white, black, other), and employment status (full-time, part-time, off-sick, other).

5.3.8 Participant Outcome Expectations, History, and Goals

At baseline assessment, participants were interviewed briefly on their potential exercise outcome expectations, history, and goals to inform individualized exercise prescription (Table 5.2).

Table 5.2 Questions incorporated into baseline assessments to explore exercise outcome expectations, history, and goals, and inform individualized exercise prescription

1. **Where do you experience the most problems in your upper limbs; in your shoulders, elbows, wrists, hands?**
2. **With this in mind, do you have any goals you would like to work towards if you were to begin an exercise programme for your upper limbs?**
3. **What activities/exercises, if any, do you do at the moment?**
4. **Tell me about your exercise history, including any previous physiotherapy.**

5.3.9 Outcome Measures

Primary and secondary outcome measures were assessed at baseline, 12, and 36 weeks from baseline. Full details of primary and secondary outcome measures are reported in Chapter 3 (Appendix C and D).

5.3.9.1 Primary Outcome Measure

Upper limb disability was evaluated with the DASH [88-89].

5.3.9.2 Secondary Outcome Measures

Upper limb functional ability was assessed with the GAT [96], and by two timed upper limb ADL (dressing and eating) [37].

Disease activity was evaluated with the DAS28 [299-301], which incorporates the 28 swollen and tender joint counts [299], PADA (VAS, 100-mm) and ESR (mm/hr, recorded during routine clinical practice). In addition, *pain* and *fatigue* (VAS, 100-mm), *morning stiffness* (mean minutes in last week), and *assessor's assessment of disease activity* (1 to 5 Likert scale) were recorded.

DOM and NDOM *upper limb and hand grip strength* was measured using a HHD (Hoggan Health Industries USA, microFET2) and HGD (Lafayette USA Instrument 6, Jamar J00105) [305, 309].

Quality of life was assessed with the self-reported RAQOL [310-311, 340].

Self-efficacy for arthritis self-management was assessed with the self-reported ASES [312, 341].

5.3.10 Intervention

5.3.10.1 Usual Medical Care Control Group ('Usual Care')

Participants randomized to usual care continued to receive usual medical care by their physician and multidisciplinary team (Table 5.3). Any pharmacological, physical, or other therapy interventions prescribed during the study were documented.

Table 5.3 Possible components of usual medical care of patients with early rheumatoid arthritis

- **Pharmacological therapy**
- **Referral to allied health professionals as deemed appropriate by physician**
- **Self-management education by multidisciplinary team**
- **Provision of emergency telephone helpline**
- **Provision of Arthritis Research UK information booklets**

5.3.10.2 Upper Limb Education, Self-Management, and Exercise Training in Rheumatoid Arthritis ('EXTRA Programme')

Patients randomized to the EXTRA programme continued to receive usual care but, in addition, received a short, individually prescribed, upper

limb education, self-management, and exercise programme, consisting of a home regimen supplemented by 4 supervised group sessions delivered twice weekly (in weeks 1 and 2) by a senior clinical physiotherapist (band 6), within the Physiotherapy Department, Dulwich Community Hospital, and an exercise handbook (Figure 5.2, Appendix H). Any pharmacological, physical, or other therapy interventions received during the study period were documented.

The individualized exercise programmes were developed for all participants by the outcome assessor following baseline assessment, on the basis of outcome measure data, and personal exercise outcome expectations, history, and goals. Exercise programmes were given to another researcher and the clinical physiotherapist, who were not blinded to treatment allocation, and only participants randomized to the EXTRA programme received their recommended programme.

Therapist Training and Intervention Fidelity

Therapist Training: The clinical physiotherapist, conducting the EXTRA programme supervised sessions, received 2 hours training and was provided with a 'therapist handbook' detailing the delivery and format of each session (Appendix H).

Intervention Fidelity: A member of the research team attended the supervised sessions regularly to monitor fidelity to the programme.

Adherence to the EXTRA Programme

Attendance of the supervised exercise sessions was recorded by the class physiotherapist in a session attendance log.

Adherence to the home exercise regimen was monitored with a self-completed 12-week daily exercise diary (Appendix H). Participants returned the diary, to a member of the research team not blinded to treatment allocation, at their 12-week assessment. Participants were encouraged to continue exercising throughout the study duration and to contact the researchers or clinical physiotherapist for further advice if required, but no further follow-up appointments were organized.

Figure 5.2 Participants attending the supervised sessions of the upper limb 'Education, Self-Management, and eXercise Training in Rheumatoid Arthritis' (EXTRA) programme. Above *left:* Participant performing the seated 'Door Push' exercise *Above right:* Participant being observed by the physiotherapist whilst performing the 'Putty Ball Squeeze' exercise. *Below:* Participants stretching during the exercise warm up/cool down.

5.3.11 Data Analysis

Statistical analysis followed an *a priori* protocol, based on intention-to-treat. Statistical significance was set at *P* less than or equal to 0.05. Analysis was conducted on SPSS Statistics for Windows version 17.0 (*IBM*).

5.3.11.1 Descriptive Statistics

Values are presented as mean (95% CI) or median (interquartile range (IQR)) of raw and/or change (baseline – follow up) scores.

5.3.11.2 Distribution of Data and Data Transformation

Normal distribution of data was evaluated by calculating Z-scores for skewness (S) and kurtosis (K) (Equations 11 and 12) [352]:

$$Z_{skewness} = \frac{S - 0}{SE_{skewness}}$$

Equation 11 Z Skewness

$$Z_{kurtosis} = \frac{K - 0}{SE_{kurtosis}}$$

Equation 12 Z Kurtosis

Where Z-scores were greater than 2.58 (representing a statistically significant deviation from normal distribution [352]), data was transformed for statistical analysis (Figure 5.3).

Figure 5.3 Transformations applied to data not normally distributed

Data Transformation	Equation
Log transformation	=LN (value + 1*)
Square root transformation	$= \sqrt{\text{value}}$
Reciprocal transformation	$= \frac{1}{\text{value} + 1^*}$

*+ 1 was only applied as a constant where the minimum value in the set of values was 0

Log transformation was applied to BMI and morning stiffness, *square root transformation* was applied to disease duration, number of swollen and tender joints, ESR, and strength values, and *reciprocal transformation* was applied to GAT scores and timed dressing and eating.

5.3.11.3 Baseline Differences

Baseline differences were evaluated with independent samples *t*-tests (age, weight, height, BMI, disease duration, number of cigarettes per week, disability, objective function, disease activity, strength, psychosocial variables), Mann Whitney U tests (number of comorbidities), and Pearson's Chi square test (χ^2) (gender, disease stability, smoking status, ethnicity, employment status).

5.3.11.4 Missing Data

Data missingness was evaluated with 'Little's Missing Completely at Random (MCAR) test' [353]. Missing data was imputed using multiple

imputation (MI) (SPSS v.17.0). Five complete sets of data were generated using a Bayesian fully conditional specification algorithm (Markov Chain Monte Carlo) linear regression model whereby all raw variables (demographic, outcome measures) were used as predictor variables [354]. The imputed data set most closely replicating the mean and standard deviation (SD) of the original primary outcome measure (DASH) data set was used for analysis.

5.3.11.5 Main Analysis

To evaluate the interaction effects between outcome variables and treatment allocation over the 36-week trial period, a full factorial mixed analysis of variance (ANOVA) model was used, with treatment, time, and the treatment by time interaction as fixed effects. Simple, first order contrast effects were used to identify significant between group differences from baseline to 12 and 36 weeks. Where data violated the assumption of sphericity, Greenhouse-Geisser correction was used, and contrast effects were evaluated with independent t-tests using change scores. Post hoc analysis, to determine the significance of within group changes from baseline to 12 and 36 weeks, were conducted using dependent t-tests with Bonferroni adjustment for multiple comparisons.

5.3.11.6 Sensitivity Analysis

A prior sensitivity analyses were conducted to evaluate the effects of:

1) Participant attrition; complete case and imputed results were analysed comparatively (Section 5.3.11).

2) Unstable medication 3 months prior to trial inclusion (initially an exclusion criterion - Section 5.3.2); a comparative analysis was conducted of participants on stable medication versus unstable medication (Section 5.3.11).
3) Baseline disease activity; a comparative analysis was conducted of participants with high disease activity (DAS28 score <5.1) versus moderate and low disease activity (DAS28 score ≥5.1) (Section 5.3.11).

5.3.11.7 Number Needed to Treat

Number needed to treat (NNT) to achieve a MCID in disability (10 DASH points [93]) was calculated (Equation 13 and 14) [355]:

$$NNT = \frac{1}{X}$$

Equation 13 Number needed to treat

Where,

$$X = \frac{\%\ \text{of control non-responders} - \%\ \text{of experimental non-responders}}{100}$$

Equation 14 Value of X when calculating number needed to treat

5.3.11.8 Effect Sizes

Between group effect sizes were calculated using Cohen's *d* (95% CI) (Equations 15, 16, and 17) [356-357].

$$d = \frac{(\mu 1 - \mu 2)}{\sigma}$$

$\mu 1$ = the mean of group 1 change scores
$\mu 2$ = the mean of group 2 change scores
σ = the pooled population standard deviation change scores

Equation 15 Cohen's *d*

95% CI for *d* = ± critical value at 0.05 × SD of *d*

Critical value at 0.05 = 1.96

Equation 16 95% Confidence Interval for Cohen's *d*

Where,

$$\text{SD of } d = \sqrt{\left(\frac{N}{n1 + n2} + \frac{d^2}{2N}\right)}$$

N = total sample size
n1 = sample size of group 1
n2 = sample size of group 2

Equation 17 Standard Deviation of Cohen's *d*

Where appropriate, transformed scores were utilized. Effect sizes were interpreted as 'small, *d* = 0.2', 'medium, *d* = 0.5', and 'large, *d* = 0.8' [358].

5.3.11.9 Correlations

Correlations between outcome measures (upper limb disability, objective hand function, RA disease activity, hand grip strength, and arthritis self-efficacy) were evaluated with Pearson's correlation coefficient (r).

5.4 RESULTS

5.4.1 Participants

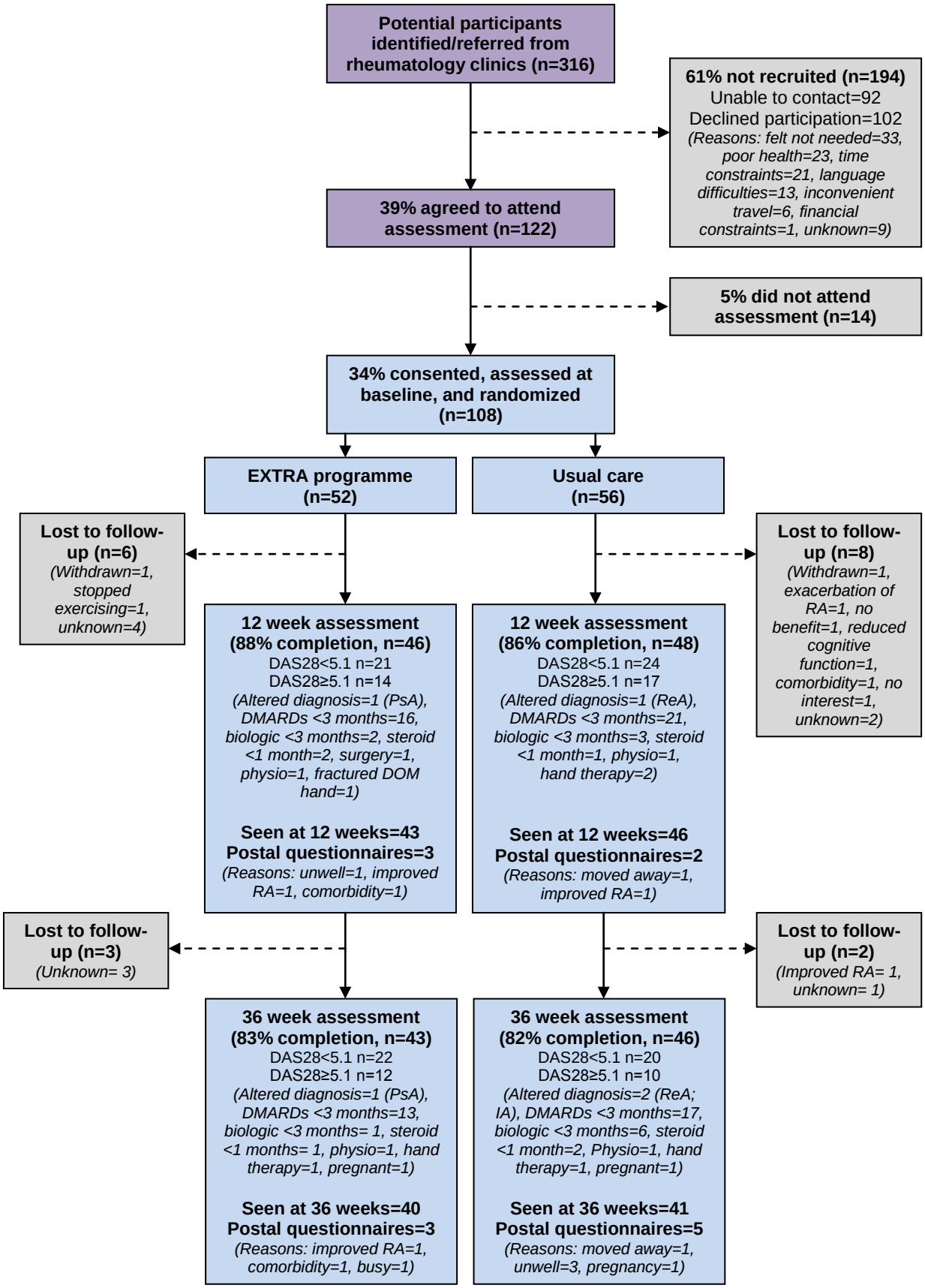
5.4.1.1 Recruitment

Three-hundred and sixteen patients were identified as eligible for the study. One-hundred and twenty-two of the identified patients agreed to participate, however 14 failed to attend baseline assessment. Therefore, 108 patients were assessed at baseline, and randomized (52 intervention group, 56 control group) (Figure 5.4).

5.4.1.2 Attrition

Fourteen patients were lost to follow-up at 12 weeks, and 5 patients were lost to follow-up at 36 weeks. At 12 and 36 weeks, 5 and 8 patients respectively, completed the self-report components of the assessment only (questionnaires) (Figure 5.4).

Figure 5.4 'Education, self-management. and eXercise Training in early Rheumatoid Arthritis' (EXTRA) study participant flow



5.4.1.3 Baseline Characteristics

There were no significant differences in participants' characteristics between those in the EXTRA programme and the usual care group at baseline (all $P>0.05$, Table 5.4), except that there were more males in the usual care group (χ^2 (1) =4.14, $P\leq0.05$) and more participants with highly active disease in the EXTRA programme (χ^2 (1) =5.02, $P\leq0.05$).

Table 5.4 Baseline characteristics of participants completing the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

Variable	All Participants (n=108)	EXTRA Programme (n = 52)	Usual Care (n = 56)
Gender (n) †:			
Male	26	8	18
Female	82	44	38
Age (years)	55 ± 15	53 ± 16	57 ± 15
Weight (kg)*****	79 ± 19	77 ± 19	80 ± 19
Height (cm)*****	164 ± 9	162 ± 8	165 ± 10
BMI*	29 ± 7	29 ± 7	30 ± 7
Disease Duration (months)	20 ± 19	20 ± 18	20 ± 19
Disease Activity (n):			
Moderate/Low (DAS28 < 5.1)	48	17	31
High (DAS28 ≥ 5.1)	50	29	21
Current Smokers (n)	17	6	11
Cigarettes per week (n)******	67 ± 40	66 ± 29	68 ± 48
Comorbidities (n)¥	2 ± 2	2 ± 2	2 ± 2
Ethnicity (n):			
White	60	24	36
Black	36	21	15
Other	12	7	5
Employment Status (n):			
Full Time	20	10	10
Part Time	21	11	10
Off Sick	19	9	10
Other	48	22	26

Values are the mean ± SD, or median ± interquartile range where indicated¥
† Between group difference $P \leq 0.05$
* n=50 intervention, n=50 control; ** n=6 intervention, n=9 control

5.4.2 Missing Value Analysis

Data was not missing at random (χ^2=8146.3, *df*=13199, *P*=1.000) and therefore results from the complete case analysis are presented as the main analysis and the results from imputed data analysis are presented as a sensitivity analysis (Section 5.3.11) [359].

5.4.3 Main Analysis

5.4.3.1 Primary Outcome

Disability

There was a significant between group difference in change in DASH score at 12 weeks (-6.8 points (-12.6 to -1.0), *P*=0.022; *d*=0.50 (0.07 to 0.93)), but not at 36 weeks (-1.3 points (-9.1 to 6.5), NS), favouring the participants in the EXTRA programme (Figure 5.5, Table 5.6).

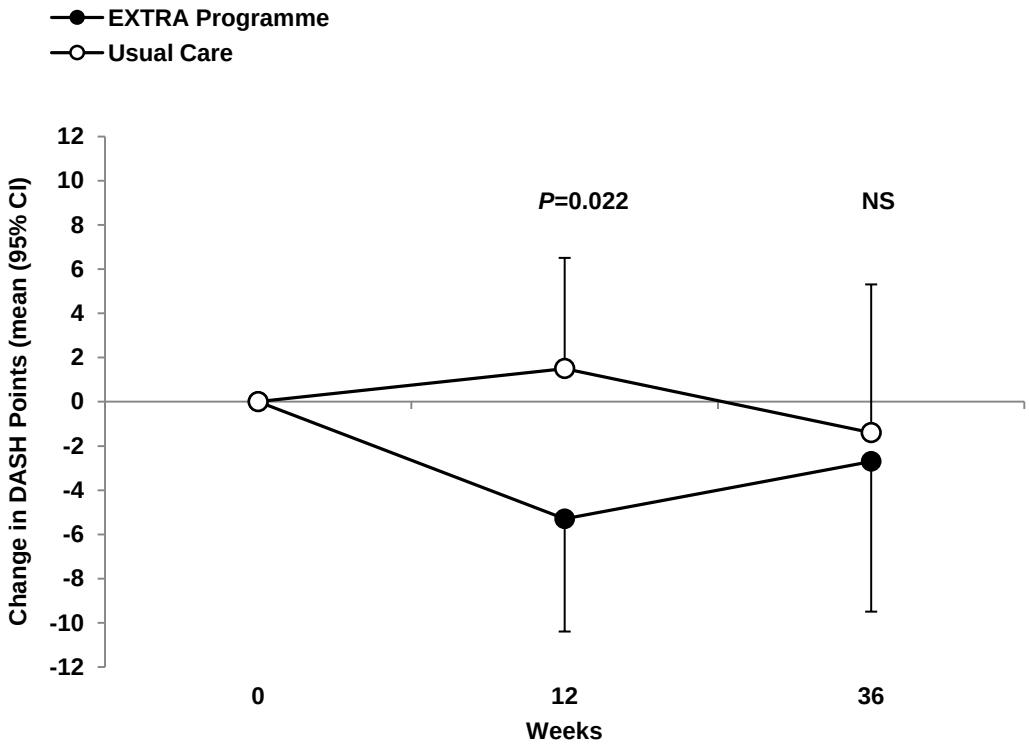
DASH score was reduced by -5.3 ((-10.4 to -0.2), *P*=0.039) points at 12 weeks among participants in the EXTRA programme, indicating an improvement in ability, and this tended to be maintained at 36 weeks (-2.7 points (-9.5 to 4.2), NS).

There were no significant within group changes in DASH score, at any time point, among participants in the usual care group (*P*>0.05).

To achieve a clinically important change in upper limb disability (10 DASH points [93]), the NNT was 9 patients.

DASH Sport (n=8; optional module) and DASH Work (n=23; optional module) scores were excluded from analysis due to small sample sizes.

Figure 5.5 Upper limb disability at 12 and 36 weeks following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care



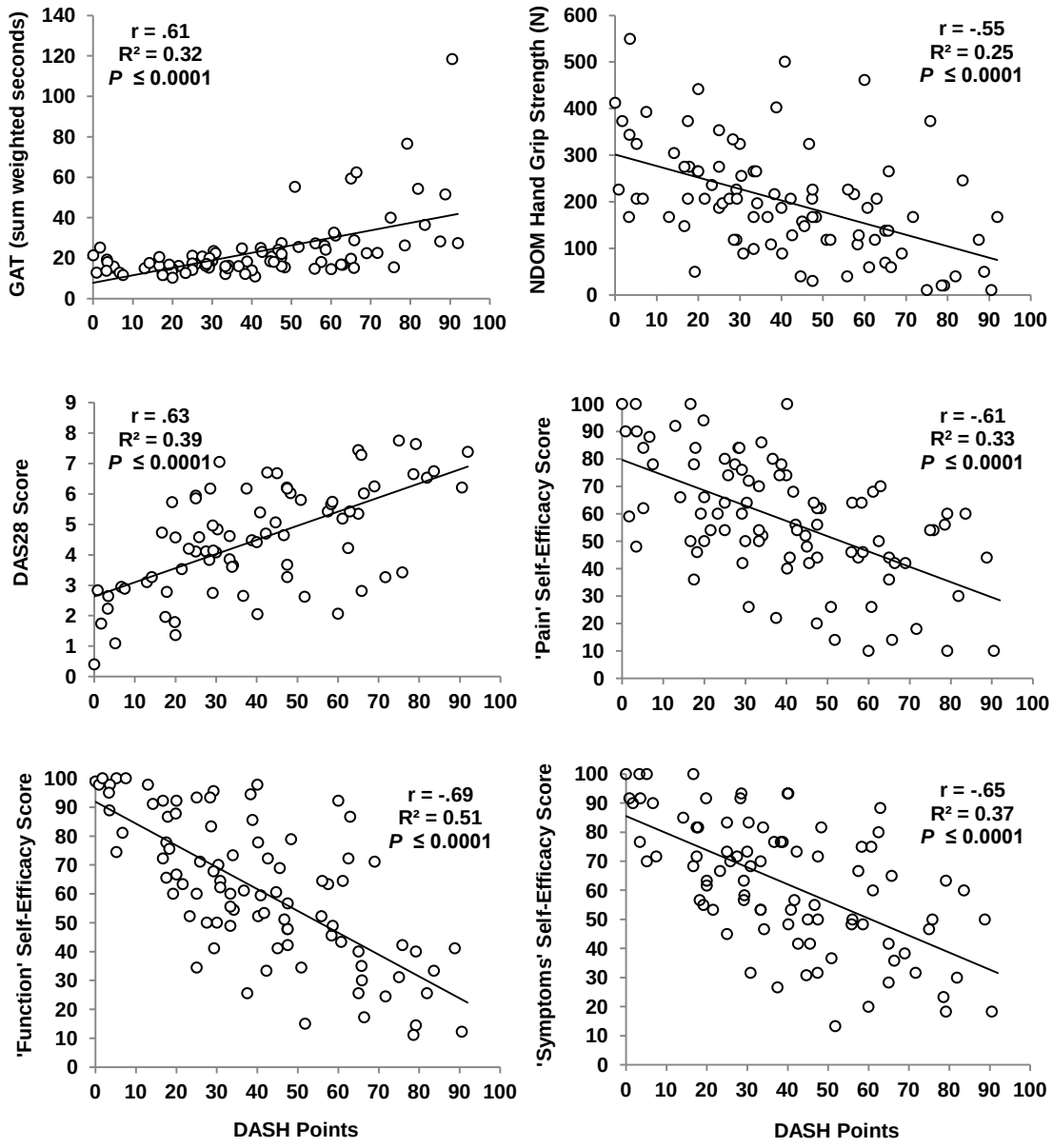
Self-reported upper limb disability was positively correlated with objectively measured upper limb function (GAT score) and RA disease activity, and negatively correlated with NDOM hand grip strength and arthritis self-efficacy ('pain', 'function', 'symptoms'; Arthritis Self-Efficacy Scale) at 12 weeks (Table 5.5, Figure 5.6)

Table 5.5 Association between upper limb disability, function, hand grip strength, disease activity, and arthritis self-efficacy after 12 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

	DASH	GAT	NDOM Hand Grip Strength	DAS28	'Pain' Self-Efficacy	'Function' Self-Efficacy	'Symptoms' Self-Efficacy
DASH	1*						
GAT	.61*	1*					
NDOM Hand Grip Strength	-.55*	-.60*	1*				
DAS28	.63*	.55*	-.59*	1*			
'Pain' Self-Efficacy	-.61*	-.44*	.33‡	-.38§	1*		
'Function' Self-Efficacy	-.69*	-.62*	.57*	-.58*	.67*	1*	
'Symptoms' Self-Efficacy	-.65*	-.51*	.50*	-.45*	.81*	.75*	1*

DASH = Disability of the Arm, Shoulder, and Hand Questionnaire; GAT = Grip Ability Test; NDOM = non-dominant; DAS28 = 28 joint Disease Activity Score
Values are Pearson's correlation coefficient (r); - = negative correlation
‡P ≤ 0.01, §P ≤ 0.001, *P ≤ 0.0001 (one tailed)

Figure 5.6 Association between upper limb disability, objective hand function, non-dominant hand grip strength, disease activity, and self-efficacy after 12 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care



DASH = Disabilities of the Arm, Shoulder, and Hand Questionnaire; GAT = Grip Ability Test; NDOM = non-dominant; DAS28 Score = 28 joint Disease activity Score; r = Pearson's correlation coefficient; R^2 = coefficient of determination

5.4.3.2 Secondary Outcomes

Objective Upper Limb Function

Grip Ability Test

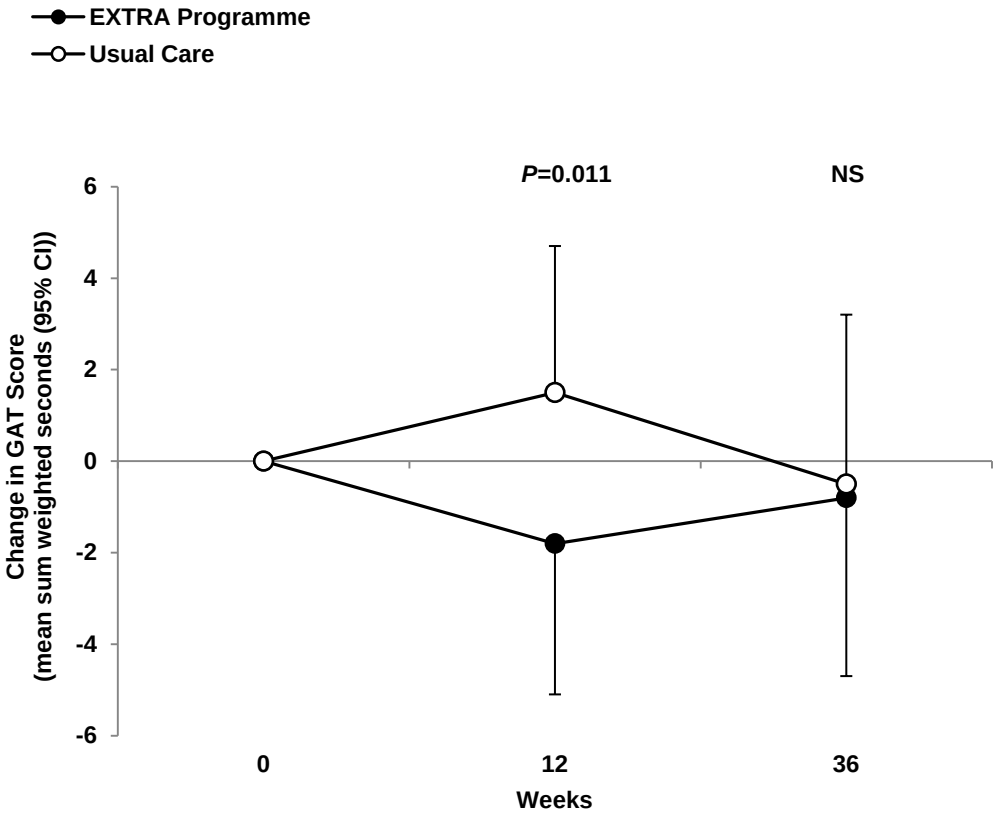
There was a significant main effect between GAT score and treatment group (*P*=0.046) (Table 5.6).

There was a significant between group difference in change in GAT score at 12 weeks (-3.3 weighted seconds (-7.0 to 0.4), *P*=0.011; *d*=0.59 (0.13 to 1.04)), but not at 36 weeks (-0.4 weighted seconds (-4.7 to 4.0), NS), favouring the participants in the EXTRA programme (Figure 5.7).

GAT score was reduced by -1.8 ((-5.1 to 1.5), *P*=0.006) weighted seconds at 12 weeks among participants in the EXTRA programme, indicating an improvement in hand function, and this was somewhat maintained at 36 weeks (-0.8 weighted seconds (-4.7 to 3.0), *P*=0.008).

There were no significant within group changes in GAT score, at any time point, among participants in the usual care group (*P*>0.05).

Figure 5.7 Change in Grip Ability Test Score at 12 and 36 weeks following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care



Global Upper Limb Function (Timed Dressing and Eating)

There were no significant between group differences in changes in the time taken to 'dress' or 'eat', in either treatment group at any point (Table 5.6).

Table 5.6 Upper limb function at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

Parameter	n	Within Group Comparison		Between Group Comparison		*F (df, error df), P*
		EXTRA Programme	Usual Care	Difference Between Groups	Effect Size *(d)*	
DASH Symptoms (0-100 scale)	42/44					
Baseline		44.6 (37.2 to 52.0)	40.8 (33.6 to 48.0)	3.8 (-6.6 to 14.1)		**2.03 (1.8, 150.7), 0.140**
Change after 12 weeks		-5.3 (-10.4 to -0.2)†$^{0.039}$	1.5 (-3.5 to 6.5)	-6.8 (-12.6 to -1.0)†$^{0.022}$	0.50 (0.07 to 0.93)	5.44 (1.0, 84.0), 0.022
Change after 36 weeks		-2.7 (-9.5 to 4.2)	-1.4 (-8.0 to 5.3)	-1.3 (-9.1 to 6.5)	0.07 (-0.35 to 0.49)	0.12 (1.0, 84.0), 0.736
Timed Dressing (seconds)	40/40					
Baseline		25.2 (21.1 to 29.4)	22.5 (18.3 to 26.6)	2.8 (-3.1 to 8.6)		**0.97 (2.0, 156.0), 0.383**
Change after 12 weeks		2.2 (-2.0 to 6.4)	1.9 (-2.3 to 6.1)	0.3 (-4.5 to 5.1)	0.27 (-0.17 to 0.71)	1.47 (1.0, 78.0) 0.229
Change after 36 weeks		0.7 (-4.7 to 6.1)	4.6 (-0.8 to 10.0)	-3.9 (-10.1 to 2.4)	0.28 (-0.16 to 0.72)	1.61 (1.0, 78.0) 0.209
Timed Eating (seconds)	39/40					
Baseline		8.1 (6.7 to 9.6)	7.8 (6.3 to 9.2)	0.4 (-1.7 to 2.4)		**0.66 (2.0, 154.0), 0.517**
Change after 12 weeks		-0.8 (-1.9 to 0.4)	0.2 (-0.9 to 1.3)	-0.9 (-2.2 to 0.3)	0.24 (-0.20 to 0.68)	1.14 (1.0, 77.0), 0.289
Change after 36 weeks		-0.4 (-1.7 to 0.9)	-0.4 (-1.7 to 0.9)	0.0 (-1.4 to 1.5)	0.22 (-0.23 to 0.66)	0.93 (1, 77), 0.339
GAT (sum weighted seconds)	38/41					
Baseline		23.1 (19.3 to 26.8)	21.9 (18.3 to 25.5)	1.1 (-4.0 to 6.3)		**3.13 (2.0, 154.0), 0.046**†
Change after 12 weeks		-1.8 (-5.1 to 1.5)‡$^{0.006}$	1.5 (-1.6 to 4.7)	-3.3 (-7.0 to 0.4)†$^{0.011}$	0.59 (0.13 to 1.04)	6.85 (1.0, 77.0), 0.011
Change after 36 weeks		-0.8 (-4.7 to 3.0)‡$^{0.008}$	-0.5 (-4.2 to 3.2)	-0.4 (-4.7 to 4.0)	0.34 (-0.11 to 0.78)	2.315 (1.0, 77.0), 0.132

DASH = Disability of the Arm, Shoulder, and Hand Questionnaire; GAT = Grip Ability Test; *d* = Cohen's *d*; *F* = F-ratio; *df* = degrees of freedom; Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † $P \leq 0.05$ (superscript = P value); ‡ $P \leq 0.01$ (superscript = P value); Effect sizes interpreted as 'small, $d = 0.2$', 'medium, $d = 0.5$', and 'large, $d = 0.8$'

Disease Activity

Pain

There was a significant main effect between pain and treatment group (*P*=0.033) (Table 5.7).

There was a significant between group difference in change in pain at both 12 weeks (-14.7mm (-26.2 to -3.2), *P*=0.013; *d*=0.57 (0.12 to 1.00)) and 36 weeks (-11.5mm (-23.0 to -0.1), *P*=0.049; *d*=0.45 (0.00, 0.88)) favouring the participants in the EXTRA programme.

Pain was reduced by -13.0mm ((-23.0 to -2.9), *P*=0.007) at 12 weeks among participants in the EXTRA programme, and this tended to be maintained at 36 weeks (-8.0mm (-18.0 to 2.0), NS).

Pain was increased by 1.7mm ((-8.2 to 11.6), NS) and 3.5mm ((-6.4 to 13.4), NS) at 12 and 36 weeks, respectively, among participants in the usual care group.

Tender Joints

There was a significant between group difference in change in the number of tender joints at 12 weeks (-2.5 (-4.9 to -0.1), *P*=0.016; *d*=0.54 (0.10 to 0.98)), but not at 36 weeks (-0.9 (-3.6 to 1.7), NS), favouring the participants in the EXTRA programme (Table 5.7).

The number of tender joints was reduced by -2.4 ((-4.5 to -0.2), *P*=0.007) at 12 weeks among participants in the EXTRA programme, but this was not maintained at 36 weeks (-0.5 (-2.8 to 1.8), NS).

There were no significant within group changes in the number of tender joints, at any time point, among participants in the usual care group.

Disease Activity Score

There was a significant between group difference in change in DAS28 at 12 weeks (-0.7 (-1.4 to 0.0); *P*=0.047; *d*=0.54 (0.00 to 1.07)), but not at 36 weeks (-0.5 (-1.2 to 0.1), NS), favouring the participants in the EXTRA programme (Table 5.7).

The DAS28 was reduced by -0.8 ((-1.4 to -0.2), *P*=0.004) at 12 weeks among participants in the EXTRA programme, and this was maintained at 36 weeks (-0.8 (-1.4 to -0.1), *P*=0.011).

There were no significant within group changes in DAS28, at any time point, among participants in the usual care group.

Other Measures of Disease Activity

There were no significant between group differences in changes in morning stiffness, fatigue, swollen joints, patient's or assessor's assessment of disease activity, or ESR at any point, however small effects (*d*) were observed, favouring the participants in the EXTRA programme (Table 5.7).

Table 5.7 Disease activity at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

		Within Group Comparison		Between Group Comparison		*F (df, error df), P*
Parameter	**n**	**EXTRA Programme**	**Usual Care**	**Difference Between Groups**	**Effect Size *(d)***	
Morning Stiffness (minutes)	40/40					
Baseline		155.9 (55.0 to 256.7)	92.9 (-8.0 to 193.8)	62.9 (-80.2 to 206.1)		**0.57 (2.0, 156.0), 0.568**
Change after 12 weeks		-115.9 (-249.7 to 18.0)	4.1 (-129.7 to 137.9)	-120.0 (-274.0 to 34.0)	0.34 (-0.10 to 0.78)	1.40 (1.0, 78.0), 0.240
Change after 36 weeks		-76.1 (-243.0 to 90.8)	56.9 (-110.0 to 223.8)	-133.0 (-325.0 to 59.1)	0.31 (-0.14 to 0.75)	0.30 (1.0, 78.0), 0.585
Pain (0-100-mm VAS)	40/41					
Baseline		50.6 (42.6 to 58.5)	40.2 (32.3 to 48.0)	10.4 (-0.8 to 21.6)		**3.48 (2.0, 158.0), 0.033†**
Change after 12 weeks		-13.0 (-23.0 to -2.9)‡$^{0.007}$	1.7 (-8.2 to 11.6)	-14.7 (-26.2 to -3.2)†$^{0.013}$	0.57 (0.12 to 1.00)	6.48 (1.0, 79.0), 0.013†
Change after 36 weeks		-8.0 (-18.0 to 2.0)	3.5 (-6.4 to 13.4)	-11.5 (-23.0 to -0.1)†$^{0.049}$	0.45 (0.00 to 0.88)	4.01 (1.0, 79.0), 0.049†
Fatigue (0-100-mm VAS)	40/41					
Baseline		49.6 (40.7 to 58.5)	45.0 (36.2 to 53.8)	4.6 (-7.9 to 17.0)		**1.13 (2.0, 158.0), 0.326**
Change after 12 weeks		-7.9 (-18.3 to 2.6)	1.2 (-9.2 to 11.5)	-9.0 (-21.0 to 2.9)	0.33 (-0.11 to 0.77)	2.27 (1.0, 79.0), 0.136
Change after 36 weeks		-8.6 (-19.6 to 2.5)	-4.5 (-15.4 to 6.4)	-4.0 (-16.7 to 8.6)	0.14 (-0.30 to 0.58)	0.41 (1.0, 79.0), 0.526
Swollen Joints (0-28 scale)	40/41					
Baseline		7.9 (5.6 to 10.2)	8.0 (5.7 to 10.3)	-0.1 (-3.3 to 3.1)		**0.35 (1.8, 143.3), 0.684**
Change after 12 weeks		-1.7 (-4.3 to 0.9)	-2.5 (-5.1 to 0.0)	0.8 (-2.1 to 3.8)	-0.15 (-0.59 to 0.28)	0.44 (1.0, 79.0), 0.494
Change after 36 weeks		-3.5 (-6.4 to -0.5)	-2.9 (-5.8 to 0.0)	-0.6 (-4.0 to 2.8)	0.02 (-0.41 to 0.46)	0.01 (1.0, 79.0), 0.917
Tender Joints (0-28 scale)	40/41					
Baseline		11.7 (9.0 to 14.5)	9.1 (6.4 to 11.9)	2.6 (-1.3 to 6.4)		**2.83 (2.0, 158.0), 0.062**
Change after 12 weeks		-2.4 (-4.5 to -0.2)‡$^{0.007}$	0.1 (-2.0 to 2.2)	-2.5 (-4.9 to -0.1)†$^{0.016}$	0.54 (0.10 to 0.98)	6.01 (1.0, 79.0), 0.016†
Change after 36 weeks		-0.5 (-2.8 to 1.8)	0.4 (-2.8 to 1.8)	-0.9 (-3.6 to 1.7)	0.23 (-0.21 to 0.66)	1.04 (1.0, 79.0), 0.312
Patient ADA (0-100-mm VAS)	40/41					
Baseline		45.6 (37.3 to 53.9)	41.4 (33.3 to 49.6)	4.1 (-7.5 to 15.8)		**1.44 (2.0, 158.0), 0.240**
Change after 12 weeks		-9.7 (-20.3 to 0.9)	0.7 (-9.7 to 11.1)	-10.4 (-22.5 to 1.7)	0.38 (-0.06 to 0.82)	2.93 (1.0, 79.0), 0.091
Change after 36 weeks		-5.5 (-16.0 to 5.0)	0.3 (-10.1 to 10.7)	-5.8 (-17.9 to 6.2)	0.21 (-0.23 to 0.65)	0.92 (1.0, 79.0), 0.339

Parameter	n	Within Group Comparison		Between Group Comparison		*F (df, error df), P*
		EXTRA Programme	**Usual Care**	**Difference Between Groups**	**Effect Size *(d)***	
Assessor ADA (1-5 scale)	40/41					
Baseline		2.7 (2.4 to 3.0)	2.5 (2.2 to 2.9)	0.2 (-0.3 to 0.6)		**0.77 (2.0, 158.0), 0.466**
Change after 12 weeks		-0.2 (-0.5 to 0.2)	-0.2 (-0.5 to 0.1)	0.0 (-0.4 to 0.4)	-0.02 (-0.46 to 0.41)	0.01 (1.0, 79.0), 0.915
Change after 36 weeks		-0.3 (-0.6 to 0.1)	-0.1 (-0.4 to 0.3)	-0.2 (-0.6 to -0.2)	0.22 (-0.22 to 0.66)	1.02 (1.0, 79.0), 0.315
ESR (mm/hour)	27/29					
Baseline		26.3 (19.4 to 33.1)	23.8 (17.2 to 30.4)	2.5 (-7.1 to 12.0)		**2.07 (2.0, 108.0), 0.131**
Change after 12 weeks		-5.3 (-13.2 to 2.7)	2.6 (-5.1 to 10.3)	-7.9 (-16.9 to 1.1)	0.48 (-0.06 to 1.00)	3.22 (1.0, 54.0), 0.078
Change after 36 weeks		-5.1 (-11.4 to 1.2)	-1.1 (-7.2 to 4.9)	-4.0 (-11.1 to 3.1)	0.36 (-0.17 to 0.89)	1.85 (1, 54), 0.179
DAS28 Index (0-10 scale)	27/29					
Baseline		5.3 (4.7 to 5.9)	4.9 (4.4 to 5.5)	0.4 (-0.4 to 1.2)		**2.34 (2.0, 108.0), 0.102**
Change after 12 weeks		-0.8 (-1.4 to -0.2)‡$^{0.004}$	-0.1 (-0.7 to 0.4)	-0.7 (-1.4 to 0.0)†$^{0.047}$	0.54 (0.00 to 1.07)	4.14 (1.0, 54.0), 0.047†
Change after 36 weeks		-0.8 (-1.4 to -0.1)†$^{0.011}$	-0.2 (-0.8 to 0.4)	-0.5 (-1.2 to 0.1)	0.42 (-0.11 to 0.95)	2.51 (1.0, 54.0), 0.119

VAS = visual analogue scale; ADA = assessment of disease activity; ESR = erythrocyte sedimentation rate; DAS28 = 28 joint Disease Activity Score; *d* = Cohen's *d; F* = F-ratio; *df* = degrees of freedom; Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † *P* ≤ 0.05 (superscript = P value); ‡ P ≤ 0.01 (superscript = P value); Effect sizes interpreted as 'small, *d* = 0.2', 'medium, *d* = 0.5', and 'large, *d* = 0.8'

Global Upper Limb Strength

Hand Grip Strength

There was a significant between group difference in change in NDOM hand grip strength at 12 weeks (31.3N (9.8 to 52.8), *P*=0.009; *d*=0.59 (0.14 to 1.03)), but not at 36 weeks (29.6N (-6.9 to 66.1), NS), favouring the participants in the EXTRA programme (Table 5.8).

NDOM hand grip strength increased by 22.4N ((3.7 to 41.2), *P*=0.013) at 12 weeks among participants in the EXTRA programme, (Figure 5.8), and this tended to be maintained at 36 weeks (12.4N (-19.6 to 44.3), NS) (Figure 5.9).

NDOM hand grip strength was reduced at 12 weeks (-8.9N (-27.4 to 9.7), NS) and 36 weeks (-17.2N (-48.8 to 14.3), NS), respectively, among participants in the usual care group.

There were no significant between group differences in changes in DOM hand grip strength at any point, however small effects (*d*) were observed, favouring the participants in the EXTRA programme (Table 5.8).

Upper Limb Strength

There was a significant between group difference in change in NDOM wrist flexion strength at 12 weeks (10.3N (-0.3 to 20.8), *P*=0.021; *d*=0.54 (0.08 to 0.99)), but not at 36 weeks (7.7N (-5.3 to 20.7), NS), favouring the participants in the EXTRA programme (Table 5.8).

NDOM wrist flexion strength was increased by 10.8N ((1.4 to 20.2), *P*=0.008) at 12 weeks among participants in the EXTRA programme (Figure 5.8), and this tended to be maintained at 36 weeks (11.5N (-0.1 to 23.1), NS) (Figure 5.9).

There were no significant within group changes in NDOM wrist flexion strength, at any time point, among participants in the usual care group.

There were no significant between group differences in changes in DOM shoulder extension, NDOM shoulder extension, DOM shoulder flexion, NDOM shoulder flexion, DOM elbow extension, NDOM elbow extension, DOM elbow flexion, NDOM elbow flexion, DOM wrist extension, NDOM wrist extension, or DOM wrist flexion at any point, however small effects (*d*) were observed, favouring the participants in the EXTRA programme (Table 5.8).

Figure 5.8 Change in upper limb strength at 12 weeks following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

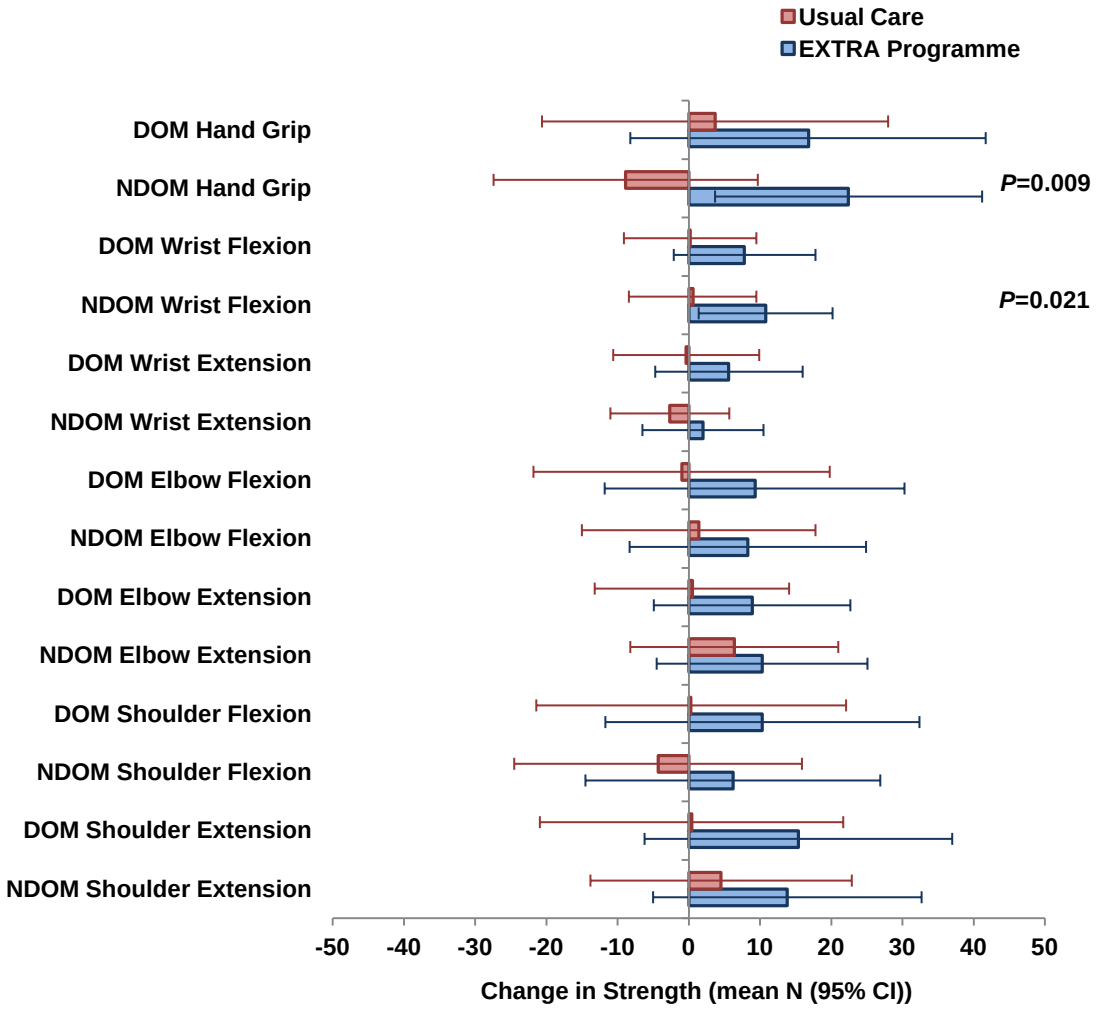


Figure 5.9 Change in upper limb strength at 36 weeks following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

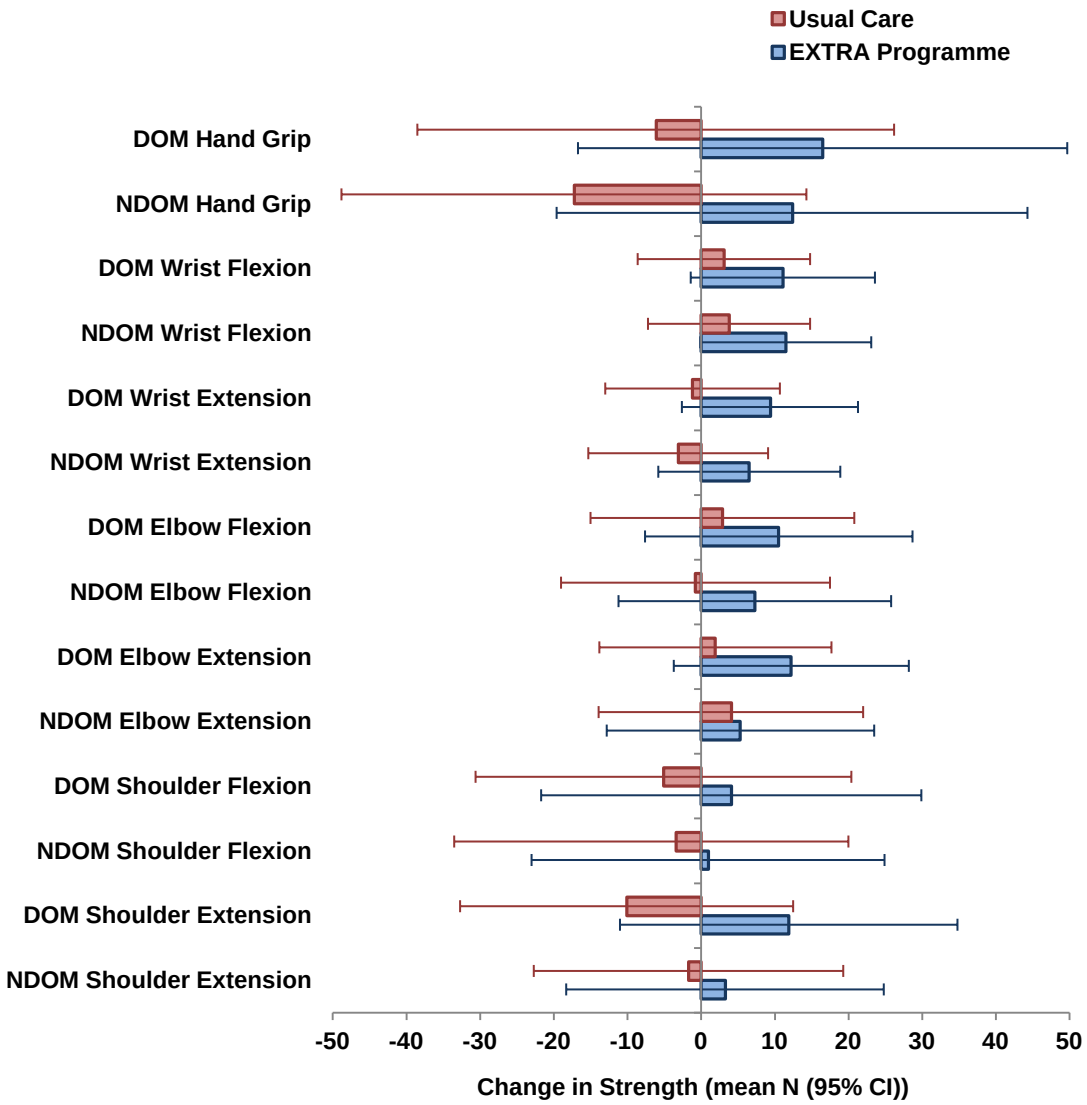


Table 5.8 Upper limb strength at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

		Within Group Comparison		Between Group Comparison		*F (df, error df), P*
Strength (Newtons)	**n**	**EXTRA Programme**	**Usual Care**	**Difference Between Groups**	**Effect Size *(d)***	
DOM Shoulder Extension	38/39					
Baseline		101.3 (78.5 to 124.0)	143.2 (120.7 to 165.6)	-41.9 (-73.9 to -9.9)†[0.015]		**2.36 (1.8, 136.6), 0.103**
Change after 12 weeks		15.4 (-6.2 to 37.0)	0.4 (-20.9 to 21.7)	15.0 (-9.7 to 39.7)	0.38 (-0.08 to 0.83)	2.76 (1.0, 75.0), 0.101
Change after 36 weeks		11.9 (-11.0 to 34.8)	-10.1 (-32.7 to 12.5)	22.0 (-4.2 to 48.2)	0.41 (-0.04 to 0.86)	3.29 (1.0, 75.0), 0.074
NDOM Shoulder Extension	38/40					
Baseline		96.6 (73.4 to 119.8)	134.3 (111.6 to 156.9)	-37.7 (-70.1 to -5.2)†[0.030]		**0.44 (1.8, 136.1), 0.624**
Change after 12 weeks		13.8 (-5.0 to 32.7)	4.5 (-13.8 to 22.9)	9.3 (-12.1 to 30.7)	0.25 (-0.20 to 0.70)	1.24 (1.0, 76.0), 0.268
Change after 36 weeks		3.3 (-18.3 to 24.8)	-1.7 (-22.7 to 19.3)	5.0 (-19.5 to 29.5)	0.10 (-0.35 to 0.54)	0.19 (1.0, 76.0) 0.665
DOM Shoulder Flexion	39/40					
Baseline		90.7 (65.6 to 115.8)	177.0 (92.3 to 141.8)	-26.3 (-61.6 to 8.9)		**0.39 (1.8, 140.9), 0.658**
Change after 12 weeks		10.3 (-11.7 to 32.4)	0.3 (-21.4 to 22.1)	10.0 (-15.2 to 35.2)	0.21 (-0.24 to 0.65)	0.85 (1.0, 77.0), .0360
Change after 36 weeks		4.1 (-21.7 to 29.9)	-5.1 (-30.6 to 20.4)	9.2 (-20.3 to 38.7)	0.11 (-0.34 to 0.55)	0.22 (1.0, 77.0), 0.639
NDOM Shoulder Flexion	39/41					
Baseline		90.9 (66.6 to 115.2)	124.3 (100.6 to 148.0)	-33.4 (-67.1 to 0.2)		**0.33 (1.8, 141.2), 0.700**
Change after 12 weeks		6.2 (-14.5 to 26.9)	-4.3 (-24.5 to 15.9)	10.5 (-13.0 to 34.0)	0.19 (-0.25 to 0.63)	0.74 (1.0, 78.0), 0.391
Change after 36 weeks		1.0 (-23.0 to 24.9)	-3.4 (-26.7 to 20.0)	4.3 (-22.9 to 31.5)	0.05 (-0.39 to 0.49)	0.06 (1.0, 78.0), 0.814
DOM Elbow Extension	39/40					
Baseline		83.5 (66.3 to 100.8)	109.1 (92.0 to 126.1)	-25.5 (-49.8 to -1.2)†[0.049]		**1.07 (1.8, 141.9), 0.341**
Change after 12 weeks		8.9 (-4.9 to 22.7)	0.5 (-13.2 to 14.1)	8.4 (-7.4 to 24.2)	0.29 (-0.16 to 0.73)	1.62 (1.0, 77.0), 0.207
Change after 36 weeks		12.2 (-3.7 to 28.2)	1.9 (-13.8 to 17.7)	10.3 (-8.0 to 28.5)	0.26 (-0.18 to 0.70)	1.341 (1.0, 77.0), 0.250
NDOM Elbow Extension	40/41					
Baseline		76.9 (60.9 to 93.0)	103.7 (87.8 to 119.5)	-26.8 (-49.3 to -4.2)†[0.036]		**0.32 (1.7, 133.7), 0.687**
Change after 12 weeks		10.3 (-4.5 to 25.1)	6.4 (-8.2 to 21.0)	3.9 (-13.0 to 20.8)	0.19 (-0.25 to 0.62)	0.70 (1.0, 79.0), 0.406
Change after 36 weeks		5.3 (-12.8 to 23.5)	4.1 (-13.9 to 22.0)	1.3 (-19.5 to 22.0)	0.01 (-0.42 to 0.45)	0.00 (1.0, 79.0), 0.959

Strength (Newtons)	n	Within Group Comparison		Between Group Comparison		*F (df, error df), P*
		EXTRA Programme	**Usual Care**	**Difference Between Groups**	**Effect Size *(d)***	
DOM Elbow Flexion	39/40					
Baseline		93.6 (74.3 to 112.9)	118.3 (99.2 to 137.3)	-24.7 (-51.8 to 2.5)		**0.71 (2.0, 154.0), 0.494**
Change after 12 weeks		9.3 (-11.8 to 30.3)	-1.0 (-21.8 to 19.8)	10.3 (-13.8 to 34.4)	0.25 (-0.20 to 0.69)	1.23 (1.0, 77.0), 0.271
Change after 36 weeks		10.5 (-7.6 to 28.7)	2.9 (-15.0 to 20.8)	7.7 (-13.2 to 28.5)	0.15 (-0.30 to 0.59)	0.43 (1.0, 77.0), 0.512
NDOM Elbow Flexion	40/41					
Baseline		95.7 (75.9 to 115.5)	121.2 (101.7 to 140.8)	-25.6 (-53.4 to 2.3)		**0.36 (1.8, 141.4), 0.675**
Change after 12 weeks		8.3 (-8.3 to 24.9)	1.4 (-15.0 to 17.8)	6.9 (-12.2 to 25.9)	0.21 (-0.23 to 0.64)	0.86 (1.0, 79.0), 0.357
Change after 36 weeks		7.3 (-11.2 to 25.8)	-0.8 (-19.0 to 17.5)	8.1 (-13.1 to 29.2)	0.10 (-0.34 to 0.53)	0.19 (1.0, 79.0), 0.664
DOM Wrist Extension	39/40					
Baseline		47.5 (35.1 to 59.8)	65.3 (53.1 to 77.6)	-17.9 (-35.2 to -0.5)		**1.22 (2.0, 154.0), 0.298**
Change after 12 weeks		5.6 (-4.7 to 16.0)	-0.4 (-10.6 to 9.9)	6.0 (-5.9 to 17.8)	0.26 (-0.18 to 0.71)	1.39 (1.0, 77.0), 0.243
Change after 36 weeks		9.4 (-2.6 to 21.3)	-1.2 (-13.0 to 10.7)	10.5 (-3.2 to 24.2)	0.31 (-0.14 to 0.75)	1.90 (1.0, 77.0), 0.172
NDOM Wrist Extension	40/41					
Baseline		42.2 (30.6 to 53.8)	59.6 (48.1 to 71.1)	-17.4 (-33.8 to -1.1)†$^{0.049}$		**1.53 (1.8, 144.7), 0.220**
Change after 12 weeks		2.0 (-6.5 to 10.5)	-2.7 (-11.0 to 5.7)	4.7 (-5.0 to 14.4)	0.27 (-0.17 to 0.70)	1.42 (1.0, 79.0), 0.236
Change after 36 weeks		6.5 (-5.8 to 18.9)	-3.1 (-15.3 to 9.1)	9.6 (-4.5 to 23.8)	0.34 (-0.10 to 0.77)	2.33 (1.0, 79.0), 0.131
DOM Wrist Flexion	34/39					
Baseline		47.6 (37.0 to 58.2)	62.9 (53.0 to 72.9)	-15.3 (-29.8 to -0.8)		**1.17 (1.8, 127.7), 0.310**
Change after 12 weeks		7.8 (-2.1 to 17.8)	0.2 (-9.1 to 9.5)	7.7 (-3.4 to 18.7)	0.33 (-0.14 to 0.78)	1.93 (1.0, 71.0), 0.170
Change after 36 weeks		11.1 (-1.4 to 23.6)	3.1 (-8.6 to 14.8)	8.0 (-6.0 to 21.9)	0.27 (-0.20 to 0.73)	1.30 (1.0, 71.0), 0.258
NDOM Wrist Flexion	36/40					
Baseline		39.3 (29.9 to 48.8)	54.4 (45.4 to 63.3)	-15.0 (-28.0 to -2.1)†$^{0.029}$		**2.23 (2.0, 148.0), 0.111**
Change after 12 weeks		10.8 (1.4 to 20.2)‡$^{0.008}$	0.6 (-8.4 to 9.5)	10.3 (-0.3 to 20.8)†$^{0.021}$	0.54 (0.08 to 0.99)	5.56 (1.0, 74.0), 0.021†
Change after 36 weeks		11.5 (-0.1 to 23.1)	3.8 (-7.2 to 14.8)	7.7 (-5.3 to 20.7)	0.29 (-0.17 to 0.74)	1.54 (1.0, 74.0), 0.218

Strength (Newtons)	n	Within Group Comparison		Between Group Comparison		*F (df, error df), P*
		EXTRA Programme	**Usual Care**	**Difference Between Groups**	**Effect Size *(d)***	
DOM Hand Grip	38/40					
Baseline		184.8 (144.1 to 225.5)	223.8 (184.1 to 263.5)	-39.0 (-95.9 to 17.8)		**0.43 (1.8, 136.4), 0.630**
Change after 12 weeks		16.8 (-8.2 to 41.7)	3.7 (-20.6 to 28.0)	13.1 (-15.3 to 41.4)	0.13 (-0.32 to 0.57)	0.32 (1.0, 76.0), 0.573
Change after 36 weeks		16.5 (-16.7 to 49.7)	-6.1 (-38.5 to 26.2)	22.6 (-15.1 to 60.3)	0.19 (-0.26 to 0.63)	0.67 (1.0, 76.0), 0.416
NDOM Hand Grip	40/41					
Baseline		160.5 (122.6 to 198.3)	227.0 (189.6 to 264.4)	-66.5 (-119.7 to -13.3)†$^{0.029}$		**1.87 (1.6, 124.0), 0.167**
Change after 12 weeks		22.4 (3.7 to 41.2)†$^{0.013}$	-8.9 (-27.4 to 9.7)	31.3 (9.8 to 52.8)‡$^{0.009}$	0.59 (0.14 to 1.03)	7.12 (1.0, 79.0), 0.009‡
Change after 36 weeks		12.4 (-19.6 to 44.3)	-17.2 (-48.8 to 14.3)	29.6 (-6.9 to 66.1)	0.24 (-0.20 to 0.68)	1.20 (1.0, 79.0), 0.278

DOM = dominant; NDOM = non-dominant; *d* = Cohen's *d*; *F* = F-ratio; *df* = degrees of freedom; Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † *P* ≤ 0.05 (superscript = *P* value); ‡ P ≤ 0.01 (superscript = *P* value); Effect sizes defined as 'small, *d* = 0.2', 'medium, *d* = 0.5', and 'large, *d* = 0.8'

Psychosocial Measures

Arthritis Self-Efficacy

‘Pain’ Self-Efficacy

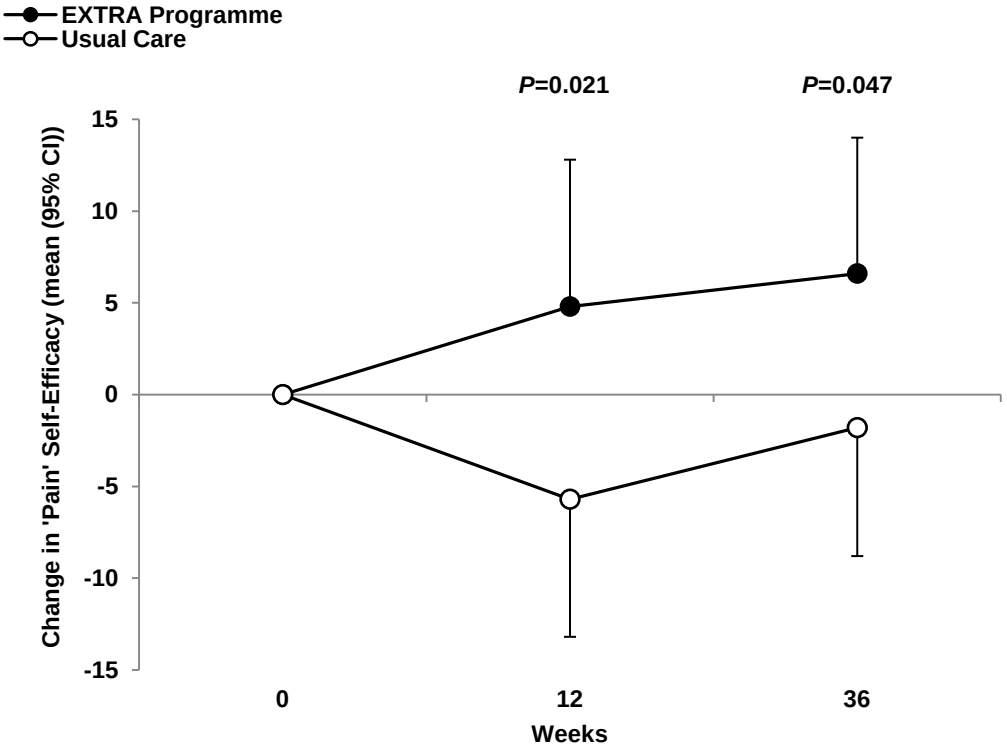
There was a significant main effect between ‘pain’ self-efficacy and treatment group (*P*=0.031) (Table 5.9).

There was a significant between group difference in ‘pain’ self-efficacy at 12 weeks (10.5 (1.6 to 19.5), *P*=0.021; *d*=0.52 (0.08 to 0.96)) and 36 weeks (8.4 (0.1 to 16.7), *P*=0.047; *d*=0.45 (0.00 to 0.89)) favouring the participants in the EXTRA programme (Table 5.9, Figure 5.10).

‘Pain’ self-efficacy tended to increase at 12 weeks (4.8 (-3.1 to 12.8) NS) among participants in the EXTRA programme, and further increased at 36 weeks (6.6 (-0.8 to 14.0), NS), although these changes did not reach significance.

‘Pain’ self-efficacy tended to reduce at 12 weeks (-5.7 (-13.2 to 1.8), NS) and 36 weeks (-1.8 (-8.8 to 5.2), NS) among participants in the usual care group, although these changes did not reach significance.

Figure 5.10 Change in 'pain' self-efficacy at 12 and 36 weeks following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care



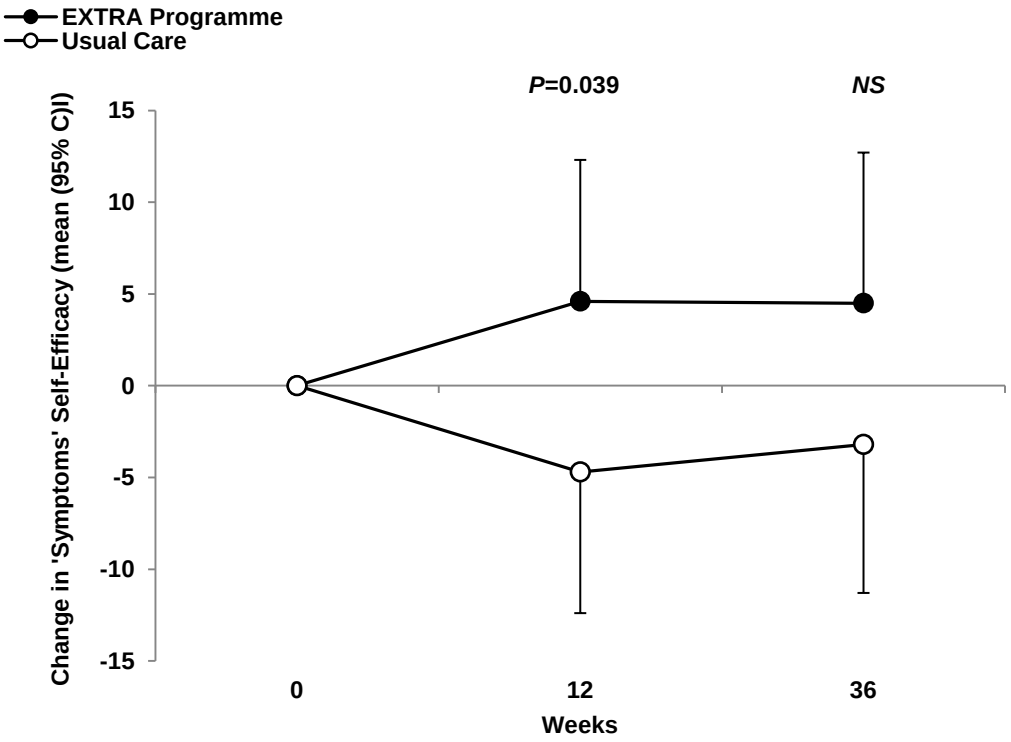
'Symptoms' Self-Efficacy

There was a significant between group difference in 'symptoms' self-efficacy at 12 weeks (9.3 (0.5 to 18.2), *P*=0.039; *d*=0.48 (0.02 to 0.93)), but not at 36 weeks (7.7 (-1.7 to 17.0), NS), favouring the participants in the EXTRA programme (Table 5.9, Figure 5.11).

'Symptoms' self-efficacy tended to increase at 12 weeks (4.6 (-3.1 to 12.3), NS) among participants in the EXTRA programme, and this tendency was maintained at 36 weeks (4.5 (-3.6 to 12.7), NS).

'Symptoms' self-efficacy was reduced at 12 weeks (-4.7 (-12.4 to 3.0), NS) and 36 weeks (-3.2 (-11.3 to 5.0), NS) among participants in the usual care group.

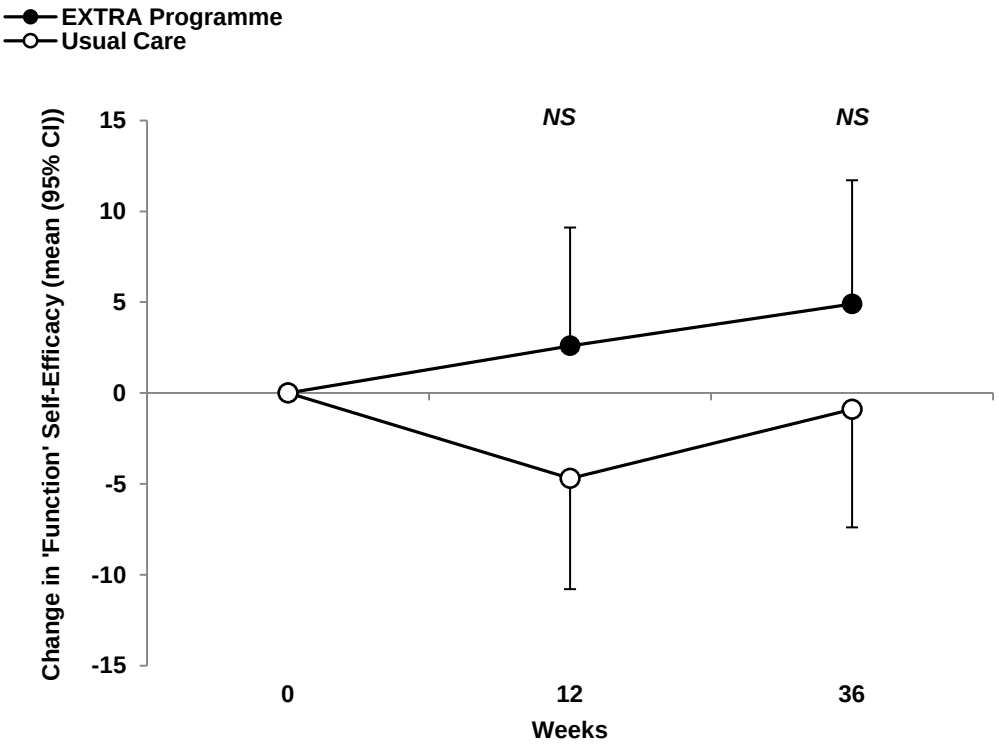
Figure 5.11 Change in 'symptoms' self-efficacy at 12 and 36 weeks following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care



'Function' Self-Efficacy

There were no significant between group differences in changes in 'function' self-efficacy at any point, however small effects (*d*) were observed, favouring the participants in the EXTRA programme (Table 5.9, Figure 5.12).

Figure 5.12 Change in 'function' self-efficacy at 12 and 36 weeks following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care



Quality of Life

There were no significant between group differences in changes in QOL at any time point (Table 5.9).

Table 5.9 Psychosocial parameters at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

Parameter	n	Within Group Comparison		Between Group Comparison		*F (df, error df), P*
		EXTRA Programme	Usual Care	Difference Between Groups	Effect Size *(d)*	
'Pain' Self-Efficacy (10-100 scale)	38/43					
Baseline		57.5 (50.7 to 64.2)	59.2 (52.9 to 65.6)	-1.7 (-11.0 to 7.5)		**3.55 (2.0, 158.0), 0.031**†
Change after 12 weeks		4.8 (-3.1 to 12.8)	-5.7 (-13.2 to 1.8)	10.5 (1.6 to 19.5)†$^{0.021}$	0.52 (0.08 to 0.96)	5.54 (1.0, 79.0), 0.021†
Change after 36 weeks		6.6 (-0.8 to 14.0)	-1.8 (-8.8 to 5.2)	8.4 (0.1 to 16.7)†$^{0.047}$	0.45 (0.00 to 0.89)	4.06 (1.0, 79.0), 0.047†
'Function' Self-Efficacy (10-100 scale)	38/43					
Baseline		62.8 (54.6 to 71.0)	63.6 (55.9 to 71.3)	-0.8 (-12.0 to 10.4)		**2.09 (2.0, 158.0), 0.127**
Change after 12 weeks		2.6 (-3.9 to 9.1)	-4.7 (-10.8 to 1.5)	7.2 (0.0 to 14.5)	0.44 (0.00 to 0.88)	3.92 (1.0, 79.0), 0.051
Change after 36 weeks		4.9 (-2.0 to 11.7)	-0.9 (-7.4 to 5.5)	5.8 (-1.8 to 13.5)	0.33 (-0.11 to 0.77)	2.29 (1.0, 79.0), 0.134
'Symptoms' Self-Efficacy (10-100 scale)	38/38					
Baseline		60.9 (53.6 to 68.2)	62.4 (55.2 to 69.7)	-1.5 (-11.8 to 8.8)		**2.66 (2.0, 148.0), 0.073**
Change after 12 weeks		4.6 (-3.1 to 12.3)	-4.7 (-12.4 to 3.0)	9.3 (0.5 to 18.2)†$^{0.039}$	0.48 (0.02 to 0.93)	4.43 (1.0, 74.0), 0.039†
Change after 36 weeks		4.5 (-3.6 to 12.7)	-3.2 (-11.3 to 5.0)	7.7 (-1.7 to 17.0)	0.38 (-0.08 to 0.83)	2.69 (1.0, 74.0), 0.105
Quality of Life (0-30 scale)	37/44					
Baseline		14.1 (11.2 to 17.0)	14.1 (11.4 to 16.7)	0.0 (-3.9 to 3.9)		**0.63 (2.0, 158.0), 0.535**
Change after 12 weeks		-1.4 (-3.3 to 0.5)	-0.8 (-2.5 to 1.0)	-0.6 (-2.8 to 1.5)	0.13 (-0.30, 0.57)	0.37 (1.0, 79.0), 0.545
Change after 36 weeks		-0.7 (-2.7 to 1.3)	-1.3 (-3.1 to 0.5)	0.6 (-1.5 to 2.8)	-0.12 (-0.56, 0.32)	0.31 (1.0, 79.0), 0.581

d = Cohen's *d*; *F* = F-ratio; *df* = degrees of freedom; Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † $P \leq 0.05$ (superscript = P value); ‡ $P \leq 0.01$ (superscript = P value); Effect sizes interpreted as 'small, $d = 0.2$', 'medium, $d = 0.5$', and 'large, $d = 0.8$'

5.4.4 Sensitivity Analyses

5.4.4.1 Effect of Attrition

Baseline Differences

There were no baseline demographic, disease, strength, functional, and psychosocial differences between participants who completed the study (n=89) and those lost to follow-up (n=19) ($P>0.05$), except that those who completed the study had greater *BMI* (29 (9) vs. 26 (6); $t(98)=2.01$, $P\leq0.05$), *PADA* (43.2 (26.2) vs. 29.1 (18.2); $t(36)=2.82$, $P\leq0.01$), weaker *NDOM shoulder flexor strength* (89.4 (86.0) vs. 137.9 (89.0); $t(105)=-2.54$, $P\leq0.05$), *and* weaker *NDOM elbow extensor* (84.9 (65.0) vs. 117.0 (58.0); $t(106)=-2.24$, $P\leq0.05$) and *flexor* (100.1 (95.0) vs. 146.8 (64.0); $t(106)=-2.08$, $P\leq0.05$) *strength*. Treatment allocation and attrition were not significantly associated (χ^2 (1)=0.006, $P>0.05$).

Effect of Study Attrition on Outcomes

Analysis of the data set with multiple imputation of missing values revealed equivalent results to complete case analysis (Tables 5.10 to 5.13), except that there were no between group differences in changes in *GAT score*, *pain*, *NDOM wrist flexion strength*, or *'symptoms' self-efficacy*, and there was a significant between group difference in change in *ESR* at 12 weeks ($P=0.007$) in the imputed data set only. Effect sizes were comparable between all analyses.

Table 5.10 Upper limb function at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care after multiple imputation of missing values

Parameter	Within Group Comparison		Between Group Comparison		*F (df, error df), P*	% Missing
	EXTRA Programme (n=52)	Usual Care (n=56)	Difference Between Groups	Effect Size *(d)*		
DASH Symptoms (0-100 scale)						
Baseline	44.5 (38.1 to 51.0)	40.6 (34.4 to 46.8)	4.0 (-5.0 to 12.9)		**2.03 (1.8, 192.4), 0.149**	2
Change after 12 weeks	-5.0 (-10.0 to 0.0)†$^{0.049}$	1.4 (-3.4 to 6.2)	-6.4 (-12.1 to -0.8)†$^{0.027}$	0.43 (0.05 to 0.81)	5.06 (1.0, 106.0), 0.027	14
Change after 36 weeks	-3.4 (-10.0 to 3.2)	-1.2 (-7.5 to 5.2)	-2.2 (-9.7 to 5.2)	0.13 (-0.25 to 0.51)	0.35 (1.0, 106.0), 0.556	18
Timed Dressing (seconds)						
Baseline	23.8 (19.6 to 28.0)	23.4 (19.3 to 27.4)	0.4 (-5.4 to 6.2)		**0.41 (1.9, 199.7), 0.650**	2
Change after 12 weeks	3.0 (-1.1 to 7.0)	1.1 (-2.8 to 5.0)	1.9 (-2.7 to 6.4)	-0.17 (-0.55 to 0.21)	0.13 (1.0, 106.0), 0.716	19
Change after 36 weeks	2.4 (-3.4 to 8.2)	4.9 (-0.7 to 10.5)	-2.5 (-9.1 to 4.1)	0.12 (-0.26 to 0.50)	0.66 (1.0, 106.0), 0.418	25
Timed Eating (seconds)						
Baseline	8.2 (6.9 to 9.4)	7.7 (6.5 to 8.9)	0.5 (-1.2 to 2.2)		**1.38 (2.0, 212.0), 0.253**	2
Change after 12 weeks	-0.4 (-1.5 to 0.7)	0.6 (-0.4 to 1.7)	-1.0 (-2.3 to 0.2)	0.11 (-0.27 to 0.49)	2.24 (1.0, 106.0), 0.138	18
Change after 36 weeks	-0.4 (-1.7 to 0.9)	0.1 (-1.1 to 1.3)	-0.5 (-2.0 to 0.9)	0.23 (-0.15 to 0.61)	2.17 (1.0, 106.0), 0.143	27
GAT (sum weighted seconds)						
Baseline	22.5 (19.4 to 25.6)	22.1 (19.1 to 25.1)	0.4 (-3.8 to 4.7)		**1.37 (2.0, 212.0), 0.255**	1
Change after 12 weeks	-0.8 (-3.9 to 2.3)	2.3 (-0.7 to 5.3)	-3.2 (-6.7 to 0.4)	0.57 (0.18 to 0.95)	2.65 (1.0, 106.0), 0.107	19
Change after 36 weeks	0.4 (-3.1 to 3.9)	-0.2 (-3.5 to 3.2)	0.6 (-3.4 to 4.5)	-0.10 (-0.47 to 0.28)	0.79 (1.0, 106.0), 0.377	26

DASH = Disability of the Arm, Shoulder, and Hand Questionnaire; GAT = Grip Ability Test; *d* = Cohen's *d*; *F* = F-ratio; *df* = degrees of freedom; MI = multiple imputation
Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † *P* ≤ 0.05 (superscript = P value); ‡ P ≤ 0.01 (superscript = P value);
Effect sizes interpreted as 'small, *d* = 0.2', 'medium, *d* = 0.5', and 'large, *d* = 0.8'

Table 5.11 Disease activity at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care after multiple imputation of missing values

Parameter	Within Group Comparison		Between Group Comparison		*F (df, error df), P*	% Missing
	EXTRA Programme (n=52)	Usual Care (n=56)	Difference Between Groups	Effect Size *(d)*		
Morning Stiffness (minutes)						
Baseline	132.4 (47.1 to 217.7)	119.3 (37.1 to 201.5)	13.2 (-105.3 to 131.6)		**0.35 (2.0, 212.0), 0.704**	0
Change after 12 weeks	-85.2 (-206.4 to 35.9)	-3.3 (-120.0 to 113.5)	-82.0 (-219.1 to 55.1)	0.12 (-0.26 to 0.50)	0.74 (1.0, 106.0), 0.390	18
Change after 36 weeks	-43.5 (-178.3 to 91.3)	21.3 (-108.6 to 151.1)	-64.8 (-217.3 to 87.7)	0.06 (-0.32 to 0.43)	0.06 (1.0, 106.0) 0.808	26
Pain (0-100-mm VAS)						
Baseline	45.81 (38.7 to 52.9)	41.05 (34.2 to 47.9)	4.8 (-5.1 to 14.7)		**1.60 (2.0, 212.0), 0.204**	0
Change after 12 weeks	-7.7 (-16.7 to 1.4)	1.4 (-7.3 to 10.1)	-9.1 (-19.3 to 1.2)	0.34 (-0.05 to 0.71)	3.07 (1.0, 106.0), 0.083	18
Change after 36 weeks	-2.7 (-11.6 to 6.3)	1.9 (-6.7 to 10.5)	-4.6 (-14.7 to 5.5)	0.17 (-0.21 to 0.55)	0.80 (1.0, 106.0), 0.371	25
Fatigue (0-100-mm VAS)						
Baseline	48.3 (41.0 to 55.7)	45.0 (37.9 to 52.1)	3.3 (-6.9 to 13.5)		**1.92 (2.0, 212.0), 0.149**	0
Change after 12 weeks	-7.9 (-16.7 to 0.8)	1.5 (-6.9 to 10.0)	-9.5 (-19.4 to 0.5)	0.36 (-0.2 to 0.74)	3.58 (1.0, 106.0), 0.061	18
Change after 36 weeks	-7.5 (-16.6 to 1.6)	-4.3 (-13.1 to 4.4)	-3.1 (-13.4 to 7.1)	0.12 (-0.26 to 0.49)	0.37 (1.0, 106.0), 0.545	25
Swollen Joints (0-28 scale)						
Baseline	7.9 (6.0 to 9.8)	7.8 (5.9 to 9.6)	0.1 (-2.5 to 2.8)		**0.07 (1.8, 191.4), 0.920**	0
Change after 12 weeks	-1.7 (-3.8 to 0.3)	-1.6 (-3.6 to 0.4)	-0.2 (-2.5 to 2.2)	0.03 (-0.35 to 0.40)	0.00 (1.0, 106.0), 0.963	18
Change after 36 weeks	-3.4 (-5.8 to -0.9)	-2.8 (-5.1 to -0.4)	-0.6 (-3.4 to 2.2)	0.09 (-0.29 to 0.47)	0.07 (1.0, 106.0), 0.799	25
Tender Joints (0-28 scale)						
Baseline	11.8 (9.5 to 14.2)	9.1 (6.8 to 11.3)	2.8 (-0.5 to 6.1)		**2.24 (2.0, 212.0), 0.016**	0
Change after 12 weeks	-2.6 (-4.6 to -0.6)‡$^{0.003}$	0.3 (-1.7 to 2.2)	-2.9 (-5.2 to -0.6)‡$^{0.003}$	0.66 (0.27 to 1.04)	9.30 (1.0, 106.0), 0.003	18
Change after 36 weeks	-0.9 (-3.1 to 1.3)	0.6 (-1.5 to 2.8)	-1.5 (-4.0 to 1.0)	0.12 (-0.26 to 0.49)	2.32 (1.0, 106.0), 0.131	25

Parameter	Within Group Comparison		Between Group Comparison		*F (df, error df), P*	% Missing
	EXTRA Programme (n=52)	**Usual Care (n=56)**	**Difference Between Groups**	**Effect Size *(d)***		
Patient ADA (0-100-mm VAS)						
Baseline	41.8 (34.7 to 48.8)	39.7 (33.0 to 46.5)	2.0 (-7.7 to 11.8)		**1.27 (2.0, 212.0), 0.284**	0
Change after 12 weeks	-4.9 (-14.0 to 4.2)	3.2 (-5.6 to 12.0)	-8.0 (-18.3 to 2.2)	0.30 (-0.08 to 0.68)	2.40 (1.0, 106.0), 0.124	18
Change after 36 weeks	-0.9 (-9.9 to 8.1)	2.2 (-6.5 to 10.8)	-3.1 (-13.2 to 7.1)	0.11 (-0.26 to 0.49)	0.35 (1.0, 106.0), 0.553	25
Assessor ADA (1-5 scale)						
Baseline	2.7 (2.4 to 3.0)	2.5 (2.2 to 2.8)	0.2 (-0.2 to 0.6)		**0.86 (1.9, 199.6), 0.417**	0
Change after 12 weeks	-0.2 (-0.5 to 0.1)	0.0 (-0.3 to 0.2)	-0.2 (-0.5 to 0.1)	0.22 (-0.16 to 0.59)	1.24 (1.0, 106.0), 0.269	18
Change after 36 weeks	-0.2 (-0.6 to 0.1)	0.0 (-0.3 to 0.4)	-0.2 (-0.7 to 0.2)	0.23 (-0.15 to 0.61)	1.41 (1.0, 106.0), 0.238	25
ESR (mm/hour)						
Baseline	28.0 (22.7 to 33.2)	25.8 (20.7 to 30.9)	2.2 (-5.1 to 9.5)		**4.15 (1.8, 195.0), 0.020**	7
Change after 12 weeks	-8.5 (-14.4 to -2.7)**§**$^{0.001}$	-1.1 (-6.7 to 4.6)	-7.5 (-14.1 to -0.8)‡$^{0.007}$	0.42 (0.03 to 0.80)	7.64 (1.0, 106.0), 0.007	29
Change after 36 weeks	-7.3 (-13.4 to -1.3)†$^{0.014}$	-4.4 (-10.2 to 1.5)	-3.0 (-9.8 to 3.9)	0.13 (-0.25 to 0.51)	2.17 (1.0, 106.0), 0.143	39
DAS28 Index (0-10 scale)						
Baseline	5.2 (4.8 to 5.6)	4.8 (4.4 to 5.2)	0.4 (-0.2 to 1.0)		**2.65 (2.0, 212.0), 0.073**	7
Change after 12 weeks	-0.7 (-1.2 to -0.2)‡$^{0.004}$	-0.2 (-0.6 to 0.3)	-0.5 (-1.1 to 0.1)	0.34 (-0.04 to 0.72)	3.18 (1.0, 106.0), 0.078	29
Change after 36 weeks	-0.9 (-1.4 to -0.4)**§**$^{0.000}$	-0.3 (-0.8 to 0.2)	-0.6 (-1.2 to -0.1)†$^{0.032}$	0.42 (0.03 to 0.80)	4.70 (1.0, 106.0), 0.032	39

VAS = visual analogue scale; ADA = assessment of disease activity; ESR = erythrocyte sedimentation rate; DAS28 = 28 joint Disease Activity Score; *d* = Cohen's *d; F* = F-ratio; *df* = degrees of freedom; MI = multiple imputation; Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † *P* ≤ 0.05 (superscript = P value); ‡ P ≤ 0.01 (superscript = P value); Effect sizes interpreted as 'small, *d* = 0.2', 'medium, *d* = 0.5', and 'large, *d* = 0.8'

Table 5.12 Upper limb strength at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care after multiple imputation of missing values

Strength (Newtons)	Within Group Comparison		Between Group Comparison		*F (df, error df), P*	% Missing
	EXTRA Programme (n=52)	Usual Care (n=56)	Difference Between Groups	Effect Size *(d)*		
DOM Shoulder Extension						
Baseline	104.5 (84.7 to 124.3)	137.1 (118.0 to 156.2)	-32.6 (-60.1 to -5.2)†[0.033]		**1.47 (2.0, 212.0), 0.232**	0
Change after 12 weeks	19.1 (-0.4 to 38.6)	2.2 (-16.6 to 21.0)	16.9 (-5.2 to 38.9)	0.33 (-0.05 to 0.71)	2.80 (1.0, 106.0), 0.098	20
Change after 36 weeks	9.1 (-11.9 to 30.0)	-4.5 (-24.7 to 15.7)	13.6 (-10.1 to 37.3)	0.32 (-0.07 to 0.69)	1.39 (1.0, 106.0), 0.242	26
NDOM Shoulder Extension						
Baseline	101.3 (82.1 to 120.6)	129.4 (110.9 to 148.0)	-28.1 (-54.5 to -1.6)		**0.84 (2.0, 212.0), 0.432**	1
Change after 12 weeks	17.9 (0.8 to 35.0)	4.7 (-11.7 to 21.2)	13.2 (-6.2 to 32.5)	0.28 (-0.10 to 0.66)	1.76 (1.0, 106.0), 0.187	19
Change after 36 weeks	0.7 (-17.9 to 19.3)	-3.6 (-21.6 to 14.3)	4.3 (-16.8 to 25.4)	0.10 (-0.28 to 0.48)	0.09 (1.0, 106.0), 0.761	25
DOM Shoulder Flexion						
Baseline	93.6 (72.9 to 114.2)	115.8 (95.8 to 135.8)	-22.2 (-51.0 to 6.6)		**1.08 (1.8, 191.0), 0.336**	0
Change after 12 weeks	14.0 (-4.6 to 32.6)	-1.5 (-19.5 to 16.4)	15.6 (-5.5 to 36.6)	0.29 (-0.09 to 0.67)	2.48 (1.0, 106.0), 0.118	19
Change after 36 weeks	5.3 (-17.1 to 27.8)	-1.3 (-23.0 to 20.3)	6.7 (-18.7 to 32.1)	0.18 (-0.20 to 0.56)	0.19 (1.0, 106.0), 0.664	26
NDOM Shoulder Flexion						
Baseline	101.2 (80.4 to 121.9)	124.0 (103.9 to 144.0)	-22.8 (-51.7 to 6.0)		**0.80 (1.8, 188.8), 0.437**	1
Change after 12 weeks	5.1 (-13.5 to 23.7)	-7.4 (-25.3 to 10.6)	12.5 (-8.6 to 33.6)	0.23 (-0.15 to 0.60)	1.14 (1.0, 106.0), 0.289	18
Change after 36 weeks	-6.6 (-28.4 to 15.1)	-6.9 (-27.9 to 14.1)	0.3 (-24.4 to 24.9)	0.06 (-0.32 to 0.43)	0.021 (1.0, 106.0), 0.886	25
DOM Elbow Extension						
Baseline	89.5 (74.3 to 104.7)	107.3 (92.6 to 121.9)	-17.8 (-38.9 to 3.3)		**0.55 (1.9, 197.9), 0.566**	0
Change after 12 weeks	8.6 (-4.6 to 21.9)	0.8 (-11.9 to 13.5)	7.8 (-7.1 to 22.8)	0.21 (-0.17 to 0.59)	1.25 (1.0, 106.0), 0.266	19
Change after 36 weeks	9.4 (-5.4 to 24.3)	6.1 (-8.2 to 20.4)	3.3 (-13.4 to 20.1)	0.06 (-0.32 to 0.43)	0.17 (1.0, 106.0), 0.686	26
NDOM Elbow Extension						
Baseline	85.1 (70.9 to 99.3)	101.1 (87.4 to 114.8)	-16.0 (-35.8 to 3.7)		**0.61 (1.7, 183.9), 0.521**	0
Change after 12 weeks	10.1 (-3.1 to 23.4)	6.7 (-6.0 to 19.5)	3.4 (-11.6 to 18.4)	0.11 (-0.26 to 0.49)	0.38 (1.0, 106.0), 0.541	18
Change after 36 weeks	-0.2 (-16.4 to 15.9)	2.7 (-12.9 to 18.2)	-2.9 (-21.2 to 15.4)	-0.14 (-0.51 to 0.24)	0.22 (1.0, 106.0), 0.640	25

Strength (Newtons)	Within Group Comparison		Between Group Comparison		*F (df, error df), P*	% Missing
	EXTRA Programme (n=52)	**Usual Care (n=56)**	**Difference Between Groups**	**Effect Size *(d)***		
DOM Elbow Flexion						
Baseline	96.4 (79.9 to 112.8)	113.8 (97.9 to 129.6)	-17.4 (-40.3 to 5.4)		**0.43 (2.0, 212.0), 0.649**	0
Change after 12 weeks	13.0 (-5.5 to 31.5)	4.8 (-13.0 to 22.7)	8.2 (-12.8 to 29.1)	0.25 (-0.13 to 0.63)	0.78 (1.0, 106.0), 0.380	19
Change after 36 weeks	10.4 (-6.3 to 27.1)	6.5 (-9.6 to 22.6)	3.9 (-15.0 to 22.9)	0.05 (-0.33 to 0.42)	0.08 (1.0, 106.0), 0.774	26
NDOM Elbow Flexion						
Baseline	103.1 (85.8 to 120.5)	121.3 (104.7 to 138.0)	-18.2 (-42.2 to 5.8)		**0.65 (1.8, 190.0), 0.507**	0
Change after 12 weeks	9.7 (-6.4 to 25.9)	-1.0 (-16.5 to 14.6)	10.7 (-7.6 to 29.0)	0.04 (-0.34 to 0.42)	1.27 (1.0, 106.0), 0.263	18
Change after 36 weeks	2.7 (-14.8 to 20.2)	-3.5 (-20.4 to 13.4)	6.2 (-13.6 to 26.0)	0.09 (-0.29 to 0.27)	0.03 (1.0, 106.0), 0.857	25
DOM Wrist Extension						
Baseline	50.6 (40.5 to 60.7)	62.9 (53.2 to 72.6)	-12.3 (-26.1 to 1.5)		**1.25 (2.0, 212.0), 0.288**	0
Change after 12 weeks	6.8 (-2.0 to 15.6)	-0.9 (-9.4 to 7.6)	7.7 (-2.2 to 17.7)	0.17 (-0.21 to 0.54)	2.77 (1.0, 106.0), 0.099	19
Change after 36 weeks	6.2 (-4.2 to 16.7)	2.7 (-7.3 to 12.8)	3.5 (-8.4 to 15.3)	0.20 (-0.18 to 0.58)	0.16 (1.0, 106.0), 0.69	25
NDOM Wrist Extension						
Baseline	45.8 (36.0 to 55.7)	56.3 (46.8 to 65.8)	-10.5 (-24.2 to 3.2)		**0.98 (1.8, 191.7), 0.370**	0
Change after 12 weeks	2.3 (-5.3 to 9.9)	-1.6 (-8.9 to 5.7)	3.9 (-4.8 to 12.7)	0.15 (-0.23 to 0.53)	1.37 (1.0, 106.0), 0.245	18
Change after 36 weeks	4.8 (-5.7 to 15.4)	-0.9 (-11.1 to 9.3)	5.7 (-6.3 to 17.7)	0.02 (-0.36 to 0.40)	1.30 (1.0, 106.0), 0.258	25
DOM Wrist Flexion						
Baseline	50.2 (41.7 to 58.7)	60.9 (52.7 to 69.0)	-10.7 (-22.3 to 0.9)		**0.61 (2.0, 212.0), 0.463**	7
Change after 12 weeks	5.8 (-2.9 to 14.5)	-0.9 (-9.3 to 7.5)	6.7 (-3.1 to 16.6)	0.30 (-0.08 to 0.68)	1.29 (1.0, 106.0), 0.259	19
Change after 36 weeks	9.5 (-0.6 to 19.7)	6.1 (-3.7 to 15.8)	3.5 (-8.0 to 15.0)	0.05 (-0.33 to 0.43)	0.11 (1.0, 106.0), 0.742	26
NDOM Wrist Flexion						
Baseline	43.6 (35.9 to 51.2)	53.7 (46.4 to 61.1)	-10.2 (-20.8 to 0.5)		**1.28 (2.0, 212.0), 0.281**	7
Change after 12 weeks	7.0 (-0.9 to 14.8)	-0.5 (-8.0 to 7.0)	7.4 (-1.4 to 16.3)	0.30 (-0.09 to 0.67)	3.05 (1.0, 106.0), 0.084	18
Change after 36 weeks	6.8 (-2.9 to 16.4)	2.9 (-6.5 to 12.2)	3.9 (-7.0 to 14.9)	0.21 (-0.17 to 0.59)	0.44 (1.0, 106.0), 0.508	25

Strength (Newtons)	Within Group Comparison		Between Group Comparison		*F (df, error df), P*	% Missing
	EXTRA Programme (n=52)	**Usual Care (n=56)**	**Difference Between Groups**	**Effect Size *(d)***		
DOM Hand Grip						
Baseline	183.3 (150.2 to 216.5)	220.5 (188.5 to 252.4)	-37.2 (-83.2 to 8.9)		**0.79 (1.8, 185.5), 0.441**	0
Change after 12 weeks	23.1 (0.8 to 45.4)	0.3 (-21.2 to 21.8)	22.9 (-2.4 to 48.1)	0.32 (-0.06 to 0.70)	2.22 (1.0, 106.0), 0.14	19
Change after 36 weeks	16.0 (-14.3 to 46.2)	-3.0 (-32.1 to 26.2)	18.9 (-15.3 to 53.2)	0.11 (-0.27 to 0.49)	0.50 (1.0, 106.0), 0.48	26
NDOM Hand Grip						
Baseline	171.7 (139.9 to 203.6)	214.2 (183.5 to 244.9)	-42.5 (-86.7 to 1.8)		**1.50 (1.7, 177.2), 0.228**	0
Change after 12 weeks	17.5 (-1.9 to 36.9)†$^{0.040}$	-6.8 (-25.5 to 11.9)	24.3 (2.3 to 46.3)†$^{0.037}$	0.34 (-0.05 to 0.71)	4.46 (1.0, 106.0), 0.037†	18
Change after 36 weeks	6.1 (-22.7 to 34.9)	-8.4 (-36.1 to 19.4)	14.5 (-18.2 to 47.1)	0.01 (-0.36 to 0.39)	0.21 (1.0, 106.0), 0.648	25

DOM = dominant; NDOM = non-dominant; *d* = Cohen's *d*; *F* = F-ratio; *df* = degrees of freedom; MI = multiple imputation; Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † $P \leq 0.05$ (superscript = P value); ‡ $P \leq 0.01$ (superscript = P value); Effect sizes defined as 'small, *d* = 0.2', 'medium, *d* = 0.5', and 'large, *d* = 0.8'

Table 5.13 Psychosocial parameters at baseline, and after 12 and 36 weeks, following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care after multiple imputation of missing values

Parameter	Within Group Comparison		Between Group Comparison		*F (df, error df), P*	% Missing
	EXTRA Programme (n=52)	Usual Care (n=56)	Difference Between Groups	Effect Size *(d)*		
'Pain' Self-Efficacy (10-100 scale)						
Baseline	57.4 (51.5 to 63.4)	57.6 (51.9 to 63.3)	-0.1 (-8.3 to 8.1)		**2.31 (1.9, 199.9), 0.105**	3
Change after 12 weeks	4.5 (-2.5 to 11.5)	-3.7 (-10.4 to 3.0)	8.2 (0.3 to 16.1)†$^{0.042}$	0.40 (0.01 to 0.78)	4.25 (1.0, 106.0), 0.042†	17
Change after 36 weeks	4.6 (-2.6 to 11.8)	0.4 (-6.5 to 7.4)	4.2 (-4.0 to 12.3)	0.20 (-0.18 to 0.57)	1.04 (1.0, 106.0), 0.311	19
'Function' Self-Efficacy (10-100 scale)						
Baseline	63.7 (56.9 to 70.6)	64.1 (57.5 to 70.7)	-0.4 (-9.9 to 9.2)		**0.92 (2.0, 212.0), 0.399**	3
Change after 12 weeks	0.3 (-5.9 to 6.5)	-4.6 (-10.5 to 1.4)	4.9 (-2.2 to 11.9)	0.26 (-0.12 to 0.64)	1.88 (1.0, 106.0), 0.173	16
Change after 36 weeks	0.8 (-6.3 to 7.8)	-2.5 (-9.3 to 4.3)	3.3 (-4.7 to 11.3)	0.16 (-0.22 to 0.53)	0.66 (1.0, 106.0), 0.418	20
'Symptoms' Self-Efficacy (10-100 scale)						
Baseline	61.6 (55.6 to 67.7)	61.9 (56.1 to 67.8)	-0.3 (-8.7 to 8.1)		**1.15 (1.9, 197.2), 0.316**	6
Change after 12 weeks	3.5 (-3.3 to 10.3)	-2.3 (-8.8 to 4.3)	5.7 (-2.0 to 13.5)	0.28 (-0.10 to 0.66)	2.18 (1.0, 106.0), 0.143	19
Change after 36 weeks	1.3 (-6.0 to 8.6)	-1.4 (-8.4 to 5.6)	2.7 (-5.5 to 11.0)	0.13 (-0.25 to 0.50)	0.44 (1.0, 106.0), 0.511	21
Quality of Life (0-30 scale)						
Baseline	14.7 (12.3 to 17.1)	14.2 (11.8 to 16.5)	0.5 (-2.9 to 3.9)		**1.66 (2.0, 212.0), 0.193**	4
Change after 12 weeks	-2.3 (-4.4 to -0.2)	-0.6 (-2.7 to 1.4)	-1.6 (-4.0 to 0.7)	0.26 (-0.12 to 0.64)	1.85 (1.0, 106.0), 0.177	15
Change after 36 weeks	-1.0 (-3.2 to 1.1)	-1.4 (-3.5 to 0.7)	0.4 (-2.1 to 2.8)	-0.06 (-0.43 to 0.32)	0.09 (1.0, 106.0), 0.767	20

d = Cohen's *d*; *F* = F-ratio; *df* = degrees of freedom; MI = multiple imputation; Values: mean (95% CI); *d* (95% CI); **ANOVA: main effects are bold script**; contrast effects are normal script; † *P* ≤ 0.05 (superscript = P value); ‡ P ≤ 0.01 (superscript = P value); Effect sizes interpreted as 'small, *d* = 0.2', 'medium, *d* = 0.5', and 'large, *d* = 0.8'

5.4.4.2 Effect of Medication Stability Prior to Trial Inclusion

Baseline Differences

There were no baseline differences in demographic, disease, motor, functional, and psychosocial variables between participants who had medication (DMARDs) changes 3 months prior to study entry (unstable medication, n=37) and those with stable medication (n=71) (P>0.05) except that those with unstable medication were *older* (57 (15) vs. 51 (16); t(106)=2.18, P≤0.05), had fewer *comorbidities* (2 (2) vs. 3 (2); U=935.0, Z=-2.5, P≤0.05), lower arthritis *self-efficacy* for other symptoms (55.5 (21.6) vs. 65.1 (22.6); t(100)=2.07, P≤0.05), and there were fewer black (African, Caribbean, 'other') (8 vs. 28) and more 'all other' (non-white) (9 vs. 3) participants (χ^2 (2)=11.18, P≤0.05). There was no association between medication stability and treatment allocation (χ^2 (1)=0.542, P>0.05).

Effect of Medication Stability on Outcomes

There were no differences in results between participants with unstable compared to stable medication 3 months prior to study entry except that, among those on stable medication only, there were significant between group differences in change in *GAT score* at 12 weeks (P=0.009) but not at 36 weeks, and *NDOM wrist flexion strength* at 12 weeks (P=0.017) but not at 36 weeks, both favouring participants in the EXTRA programme. Among participants on unstable medication, there were significant between group differences in change in number of *tender joints* at 12 weeks (P=0.034) but not at 36 weeks, *ESR* at 12 weeks (P=0.005) and 36 weeks (P=0.025), and

DAS28 score at 12 weeks *(P*=0.025) but not at 36 weeks, all favouring participants in the EXTRA programme (Table 5.14).

Table 5.14 Sensitivity analysis of outcomes 12 and 36 weeks of participants on unstable compared to stable medication three months prior to study entry following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

		Unstable Medication				Stable Medication		
		Within Group Comparison		Between Group Comparison		Within Group Comparison		Between Group Comparison
Parameter	**n**	**EXTRA Programme**	**Usual Care**	**Difference Between Groups**	**n**	**EXTRA Programme**	**Usual Care**	**Difference Between Groups**
GAT (sum weighted seconds)	12/14				26/27			
Baseline		20.1 (14.1 to 26.2)	22.5 (16.9 to 28.1)	-2.4 (-10.6 to 5.8)		24.4 (19.6 to 29.2)	21.6 (16.9 to 26.3)	2.8 (-3.9 to 9.5)
Change after 12 weeks		0.5 (-3.1 to 4.0)	0.0 (-3.3 to 3.3)	0.4 (-3.5 to 4.3)		-2.8 (-7.4 to 1.8)‡$^{0.005}$	2.3 (-2.2 to 6.8)	-5.1 (-10.4 to 0.1)‡$^{0.009}$
Change after 36 weeks		0.8 (-5.4 to 6.9)	0.5 (-5.2 to 6.2)	0.2 (-6.5 to 6.9)		-1.5 (-6.6 to 3.5)‡$^{0.005}$	-1.0 (-5.9 to 4.0)	-0.6 (-6.3 to 5.2)
Tender Joints (0-28 scale)	12/14				28/27			
Baseline		11.5 (6.1 to 16.9)	11.3 (6.3 to 16.3)	0.2 (-7.1 to 7.5)		11.8 (8.5 to 15.1)	8.0 (4.7 to 11.4)	3.8 (-0.9 to 8.5)
Change after 12 weeks		-4.0 (-7.6 to -0.4)†$^{0.038}$	0.9 (-2.5 to 4.2)	-4.9 (-8.8 to -0.9)†$^{0.034}$		-1.6 (-4.3 to 1.1)	-0.2 (-3.0 to 2.5)	-1.4 (-4.5 to 1.7)
Change after 36 weeks		-0.9 (-5.2 to 3.6)	0.8 (-3.2 to 4.7)	-1.7 (-6.4 to 3.0)		-0.4 (-3.2 to 2.5)	0.2 (-2.7 to 3.1)	-0.6 (-3.9 to 2.7)
ESR (mm/hour)	9/12				18/17			
Baseline		34.3 (22.6 to 46.1)	20.1 (9.9 to 30.2)	14.3 (-1.3 to 29.8)		22.2 (13.6 to 30.8)	26.4 (17.6 to 35.3)	-4.2 (-16.5 to 8.2)
Change after 12 weeks		-16.4 (-32.4 to -0.5)†$^{0.037}$	9.6 (-4.2 to 23.4)	-26.0 (-42.9 to -9.2)‡$^{0.005}$		0.3 (-7.8 to 8.4)	-2.3 (-10.6 to 6.0)	2.6 (-6.8 to 11.9)
Change after 36 weeks		-17.1 (-30.9 to -3.3)†$^{0.013}$	-0.3 (-12.3 to 11.6)	-16.8 (-31.4 to -2.2)†$^{0.025}$		0.9 (-4.5 to 6.2)	-1.6 (-7.2 to 3.9)	2.5 (-3.7 to 8.7)
DAS28 Index (0-10 scale)	9/12				18/17			
Baseline		5.2 (4.2 to 6.3)	5.3 (4.4 to 6.2)	0.0 (-1.4 to 1.4)		5.3 (4.6 to 6.1)	4.7 (3.9 to 5.4)	0.7 (-0.4 to 1.7)
Change after 12 weeks		-1.3 (-2.4 to -0.3)‡$^{0.010}$	-0.1 (-1.0 to 0.8)	-1.3 (-2.4 to -1.8)†$^{0.025}$		-0.6 (-1.3 to 0.2)	-0.2 (-1.0 to 0.6)	-0.4 (-1.3 to 0.5)
Change after 36 weeks		-1.2 (-2.4 to 0.1)	-0.3 (-1.4 to 0.8)	-0.9 (-2.2 to 0.4)		-0.5 (-1.2 to 0.2)	-0.2 (-0.9 to 0.6)	-0.4 (-1.2 to 0.4)
NDOM Wrist Flexion	11/14				25/26			
Baseline		40.3 (23.8 to 56.7)	42.8 (28.3 to 57.4)	-2.6 (-24.5 to 19.4)		38.9 (27.3 to 50.5)	60.6 (49.2 to 72.0)	-21.7 (-37.9 to -5.4)
Change after 12 weeks		10.2 (-5.7 to 26.1)	5.7 (-8.5 to 19.8)	4.5 (-12.5 to 21.6)		11.1 (-1.0 to 23.1)†$^{0.023}$	-2.2 (-14.0 to 9.6)	13.3 (-0.4 to 27.0)†$^{0.017}$
Change after 36 weeks		12.5 (-10.6 to 35.5)	-0.2 (-20.6 to 20.3)	12.6 (-12.0 to 37.3)		11.1 (-2.9 to 25.1)	6.0 (-7.8 to 19.7)	5.1 (-10.8 to 21.0)

GAT = Grip Ability Test, NDOM = non=dominant, ESR = erythrocyte sedimentation rate; DAS28 = 28 Joint Disease Activity Score, NDOM = non dominant; Values: mean (95% CI); † $P \leq 0.05$ (superscript = P value); ‡ $P \leq 0.01$ (superscript = P value)

5.4.4.3 Effect of Disease Activity at Baseline

Baseline Differences

There were no substantial baseline demographic or general health differences between those with high (DAS28 ≥5.1, n=50) and moderate/low (DAS28 <5.1, n=48) disease activity at baseline, although there were more 'white' (31 vs. 22) and less 'all other' (non-white) (1 vs. 11) participants with moderate/low disease activity.

Compared to those with high disease activity, those with moderate/low disease activity had less *upper limb disability* (29.4 (19.2) vs. 57.7 (19.1); $t(94)=7.24$, $P\leq0.001$), better *upper limb function* (timed dressing, timed eating, and GAT; all $P\leq0.01$), less *morning stiffness* (66.4 (210.6) vs. 204.4 (391.4); $t(96)=-4.32$, $P\leq0.001$), *pain* (29.1 (20.7) vs. 57.7 (22.3); $t(96)=-6.55$, $P\leq0.001$), *fatigue* (30.8 (21.7) vs. 61.0 (23.2); $t(96)=-6.66$, $P\leq0.001$), *swollen joints* (5.4 (5.8) vs. 10.9 (6.8); $t(96)=-4.86$, $P\leq0.001$), *tender joints* (4.7 (5.6) vs. 16.8 (7.1); $t(96)=-9.78$, $P\leq0.001$), lower *ESR* (18.4 (16.5) vs. 35.4 (19.2); $t(96)=-5.24$, $P\leq0.001$), reduced *PADA* (25.8 (20.9) vs. 55.0 (20.4); $t(96)=-7.00$, $P\leq0.001$), *assessor assessed disease activity* (2.0 (0.7) vs. 3.3 (0.7); $t(94)=-9.29$, $P\leq0.001$), better *strength* (all $P\leq0.01$), and higher *self-efficacy* (all $P\leq0.001$) and *QOL* (9.5 (7.5) vs. 20.2 (7.3); $t(92)=-6.97$, $P\leq0.001$).

Effect of Disease Activity on Outcomes

Among participants with moderate/low disease activity, there were significant between group differences in change in *pain* ($P=0.011$), *number of tender joints* ($P=0.024$), *DAS28* ($P=0.035$), *DOM shoulder extension strength* ($P=0.012$), *NDOM shoulder extension strength* ($P=0.021$), *DOM elbow*

extension strength (*P*=0.006), *NDOM elbow extension strength* (*P*=0.019), *NDOM elbow flexion strength* (*P*=0.037), and *NDOM wrist flexion strength* (*P*=0.002) at 12 weeks but not 36 weeks, *assessor's assessment of disease activity* (*P*=0.042) at 36 weeks but not at 12 weeks, and *NDOM hand grip strength* at both 12 weeks (*P*=0.001) and 36 weeks (*P*=0.003), all favouring participants in the EXTRA programme (Figure 5.13 and 5.14).

Among those with high disease activity at baseline, there were significant between group differences in change in *dressing time* (*P*=0.012), *'pain' self-efficacy* (*P*=0.038), and *'symptoms' self-efficacy* (*P*=0.047) at 12 weeks but not at 36 weeks, all favouring participants in the EXTRA programme.

In all other outcomes, there were no differences in results (*P*>0.05).

Figure 5.13 Change in upper limb strength at 12 weeks among participants with 'high' and 'moderate or low' disease at baseline following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care

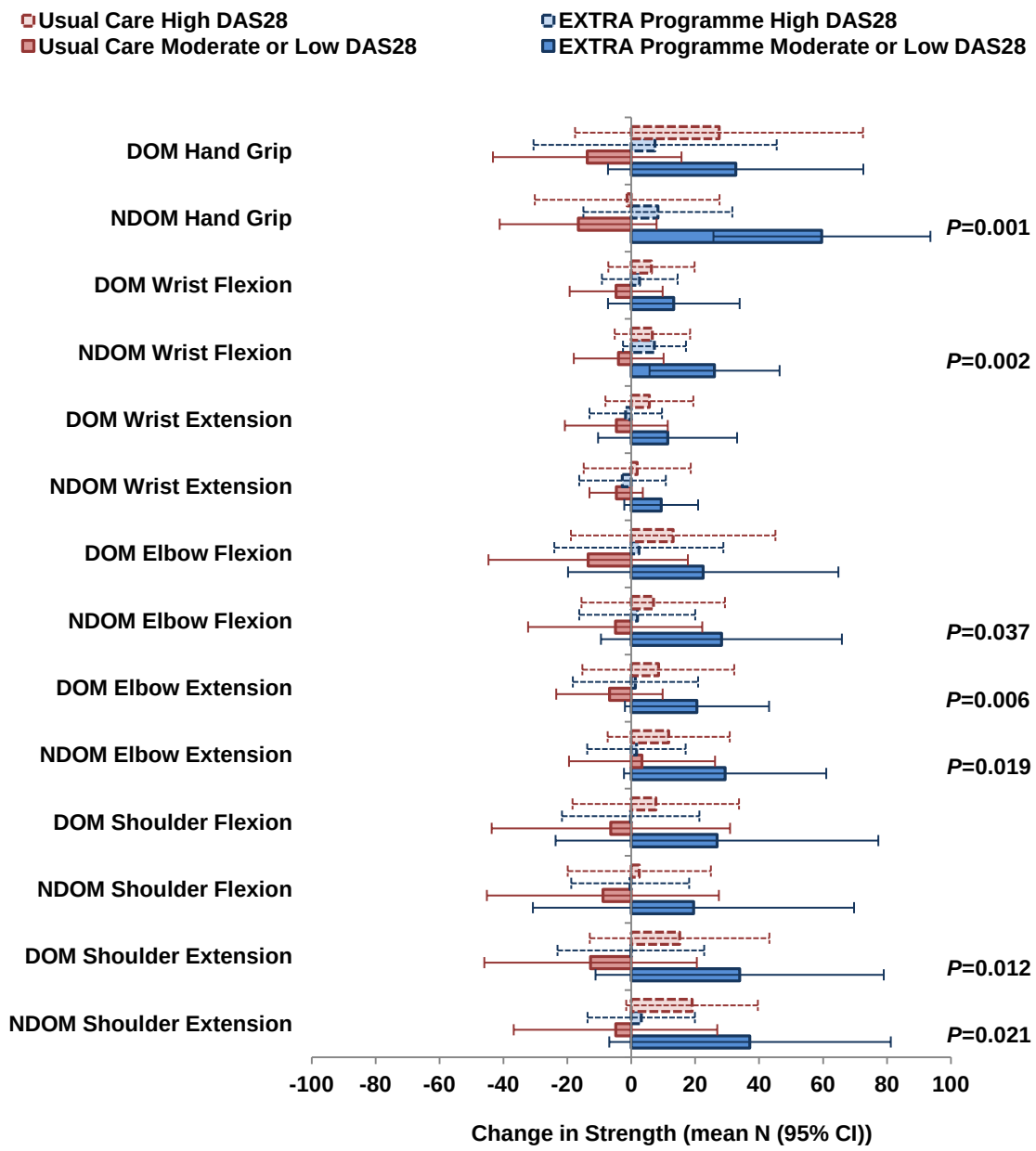
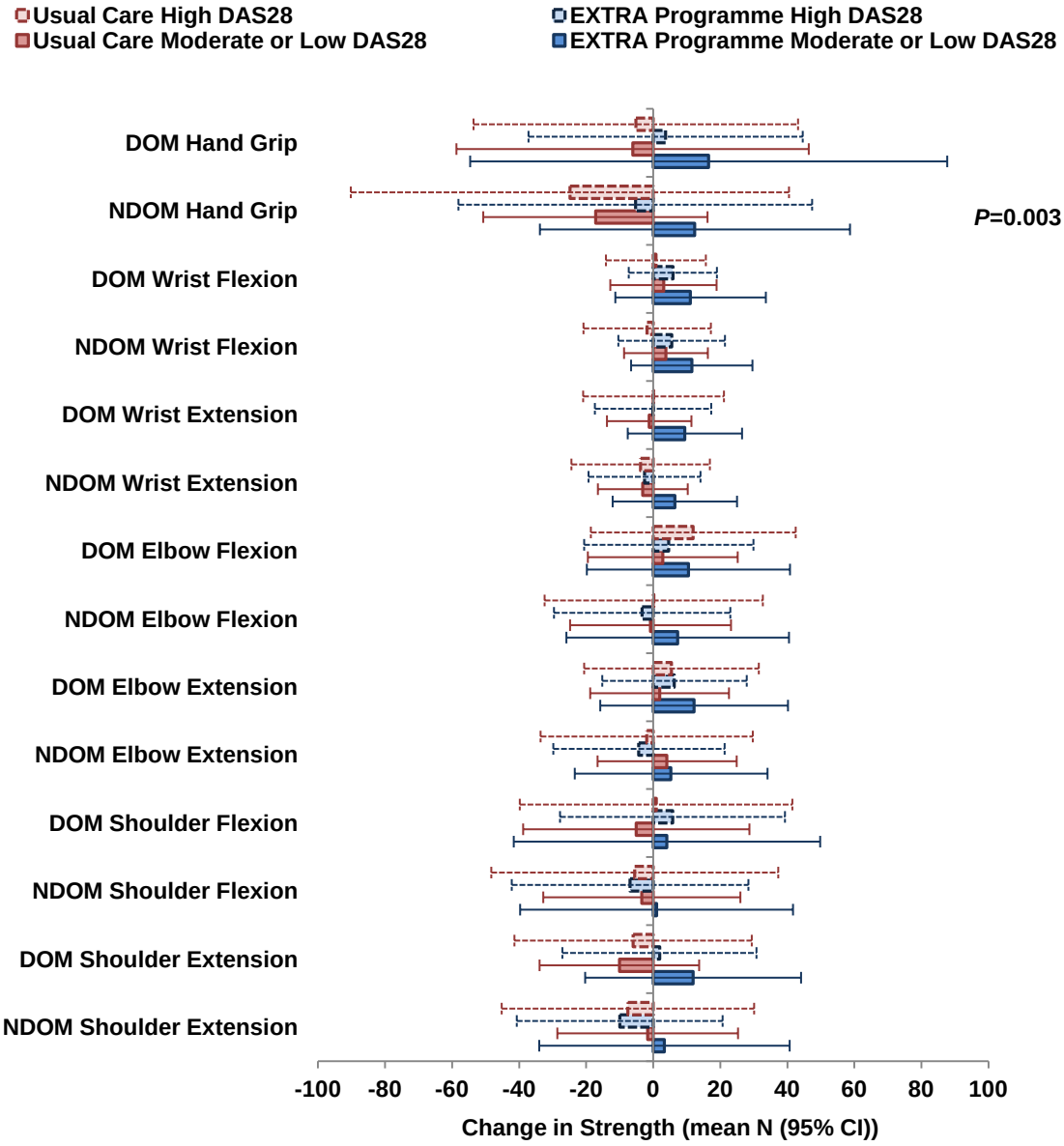


Figure 5.14 Change in upper limb strength at 36 weeks among participants with 'high' and 'moderate or low' disease at baseline following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis) or usual care



5.4.4.4 Adherence

Participants attended a median (IQR) of 3 (2) of the 4 exercise classes, and 71% (n=37/52) attended 3 or more sessions.

Seventy percent (n=30/43) of participants returned the home exercise diary at 12 weeks. They reported completing the home exercise programme a median (IQR) of 6 (3) times per week, performing all 6 (0) prescribed exercises, at an RPE of 13 (2). Seventy-three percent (n=22/30) of participants reported completing the home exercise regimen at least 6 days per week. Adherence reported from weeks 1 to 6 (6 (3) days per week, 6 (0) exercises at an RPE of 13 (2)) was equivalent to that reported from weeks 7 to 12 (6 (4) days per week, 6 (0) exercises at an RPE of 13 (2)).

5.4.4.5 Assessor Blinding

Intervention allocation was revealed to the assessor by 42% (n=45/108) of participants (32 EXTRA programme, 13 usual care).

5.5 DISCUSSION

In people with early RA, an individualized, global upper limb home exercise regimen supplemented by 4 supervised education, self-management, and exercise sessions (the EXTRA programme) improves upper limb disability, function, pain, non-dominant wrist flexion and hand grip strength, and arthritis self-efficacy, for at least 12 weeks, with no adverse effects on disease activity or pain, compared to usual medical care.

This study is the first to evaluate a systematically developed, manualized, global upper limb education, self-management, and exercise programme, where treatment fidelity was monitored during delivery. It was a methodologically robust, pragmatic study which enrolled an ethnically diverse cohort of participants with a range of disease characteristics, and thus may be generalized to a broad range of people with early RA.

Whilst the primary outcome (upper limb disability) did not reach a clinically relevant difference (10 DASH points [93]), MCID is context specific and is not available in an RA population. Moreover, few upper limb exercise studies in RA have utilized the DASH questionnaire rendering comparison difficult. One small study (n=40) of women with RA who completed a 12–week hand exercise programme reported a median increase of 2 DASH points post-intervention, although DASH score also increased by a median of 2 points among healthy age and gender matched control participants, and mean values were not reported, limiting comparison [180]. Another small study (n=40) of women with hand OA who completed a 5-week (twice weekly) educational-behavioural hand exercise and joint protection

programme, supplementing a daily hand strengthening and mobility exercise regimen, reported a mean decrease of 9 DASH points, compared to a mean decrease of 6 DASH points among participants who received the joint protection programme alone, although differences in disease characteristics and response limit the transferability of these findings to people with RA [360]. Whilst the change in DASH score following the EXTRA programme is similar to the MCIDs reported in studies among other chronic musculoskeletal conditions (4 to15 DASH points) [90] which are associated with increases in work capacity [361], and the number needed to treat comparable to rheumatology drug trials [362], future studies are needed to calculate the MCID of the DASH in an RA population. This may be achieved by including a Likert scale to establish the importance of participants' perceived change in upper limb disability following an intervention [93].

The EXTRA programme emphasizes home based exercise and self-management strategies. It requires minimal and inexpensive equipment and the supplementary supervised sessions were delivered in a typical outpatient department by clinical physiotherapists who required minimal additional training. Thus, it could be easily integrated into usual clinical practice [363-364], and may be more cost-effective than inpatient exercise programmes [175] or resource intensive, lengthy, supervised outpatient exercise regimens [168].

Traditionally, early RA was defined as less than 5 years, but more recently (since the early 1990s) this has decreased to 24 months [27] owing to the emphasis on rapid referral and treatment to improve long-term

outcomes. The current study employed the traditional definition of early RA because, whilst disability in RA progresses quickly, at a rate of approximately 1 to 2% (change in HAQ scores) per year [27, 365], disability rates follow a 'J-shaped curve' meaning that ability may improve over the first few years followed by a steady decline thereafter [27]. Thus, typically, people with RA are not referred to physiotherapy until after 2 years when hand disability begins to manifest. Therefore, whilst employing a traditional definition renders comparison with other 'early RA' exercise studies [102, 133, 189] difficult, in order to reflect clinical practice and establish the clinical effectiveness of the EXTRA programme on the primary outcome measure (upper limb disability), it was considered important to target a population within 5 years of RA diagnosis.

People with relatively high disease activity were enrolled into the study, regardless of the stability of their medication 3 months prior to study entry, representing a typical population of people with early RA. Whilst overall differences between participants with recent medication changes compared to those with stable medication were minimal following the EXTRA programme, suggesting that unstable medication did not influence the results, significant strength gains were only observed among participants with moderate or low disease activity at baseline, suggesting that very active disease among some participants may have masked some of the positive effects of the intervention. Pre-planned subgroup analysis revealed that participants with unstable medication had reduced disease activity at 12 weeks compared to baseline measures, and those with highly active RA experienced no exacerbation to disease activity, supporting the overall study

findings that the EXTRA programme had no detrimental effects on disease activity, consistent with other exercise studies [129, 131, 134]. As medication changes and active disease are frequent among people with early RA, the effects of the EXTRA programme may be generalized to all early RA patients, regardless of disease activity status.

Recording reasons for attrition enables the generalizability of trial findings to be assessed [363-364]. In this study, the reasons for attrition were thoroughly documented, and were typical of this population [252, 281-282]. Whilst this study may have been less accessible to those in full time work or with other time consuming responsibilities, such as childcare, the supervised sessions were delivered at a range of times to minimize this potential source of bias.

Sustaining exercise participation is challenging and adherence to treatment frequently poor [366]. Attendance of the supervised exercise sessions and adherence to the home exercise programme was good, consistent with other exercise studies [252]. This may be because the group education, self-management, and exercise sessions contained behavioural change strategies, such as exploring participants' potential barriers to exercise, coping and relapse management strategies, thereby increasing participants' self-efficacy for exercise and self-management, and possibly facilitating adherence to exercise.

Adherence to the EXTRA programme was monitored with an exercise diary for 12 weeks. The majority of participants reported appropriately completing their prescribed exercises, consistent with the improvements

observed to objectively measured strength and function following the EXTRA programme. Nevertheless, it is possible that participants may overestimate exercise participation [367] and exercise diaries may facilitate adherence although this effect is likely to be small [368].

The majority of the effects of the EXTRA programme were not sustained in the longer-term, similar to previous research [168]. Participants maintained higher self-efficacy for self-management and reported lower pain at 36 weeks, which could improve long-term exercise participation [317, 369], but longer-term exercise participation (12 to 36 weeks) was not monitored in this study so participation in the EXTRA programme over the longer term is unknown. It may be that participants need regular 'booster' sessions to facilitate long-term adherence to exercise [370].

This is the first study to evaluate the clinical effectiveness of a pragmatic, individualized upper limb education, self-management, and exercise programme which reduced upper limb disability in early RA. The EXTRA programme improved upper limb function, hand grip strength, and arthritis self-efficacy, with no adverse effects on disease activity or pain, compared to usual care. Despite maintenance of improvements to self-efficacy and pain, other effects were not sustained for 36 weeks.

5.6 CONCLUSIONS

- The EXTRA programme improved self-reported upper limb disability for at least 12 weeks among people with early RA, compared to usual care.
- The EXTRA programme improves objectively measured upper limb function, pain, NDOM wrist flexion and hand grip strength, and arthritis self-efficacy for at least 12 weeks among people with early RA, compared to usual care, with no adverse effects on disease activity.
- The EXTRA programme improves self-reported pain and arthritis self-efficacy for 36 weeks, with no adverse effects on disease activity.

6 *"I think having a programme like that for people who have got rheumatoid arthritis is well worth doing": The Experience of an Upper Limb Education, Self-Management, and Exercise Programme for People with Early Rheumatoid Arthritis (the EXTRA Programme)*

6.1 INTRODUCTION

There is a need for acceptable interventions which are individually tailored and targeted to successfully increase global upper limb function in people with early RA (Chapter 1, [181, 290]). An integrated, global upper limb education, self-management, and exercise programme (the EXTRA programme) improves upper limb disability, function, and strength (Chapter 5).

However, exercise is a complex and burdensome health behaviour [285], and non-adherence to exercise is common [371-372]. Whilst interventions incorporating theoretically underpinned behavioural change

strategies increase adherence to health behaviours (such as exercise) [213-214, 218-223], their success is contextually specific, and varies according to individual beliefs (such as perceived self-efficacy and outcome expectations [204]), and population characteristics (such as disease diagnosis and duration [212-214]). Therefore to be effective, interventions need to be socially, educationally, and culturally appropriate and accommodate the strengths and skills of the target population and HCPs [316].

The MRC recommends that the development and evaluation of complex health interventions requires the interpretation of both qualitative and quantitative data [291]. Within health related qualitative research, an inductive approach, such as Interpretive Phenomenological Analysis (IPA), is commonly applied [373]. IPA aims to apply meaning and insights to aspects of life as experienced and understood by the participants, according to Heidegger's two-stage hermeneutic principles: 1) the participants interpreting their experience, and 2) the researcher interpreting the participants interpreting their experience [374].

Therefore, to explore participants' perceptions and experiences of the EXTRA programme, and to identify factors which affected uptake and maintenance of this programme, a qualitative study utilising IPA was conducted, to complement the existing quantitative research (Chapter 5).

6.2 AIMS OF RESEARCH

The aims of this research were:

1) To evaluate participants' experiences of the EXTRA programme.
2) To explore the factors which affected participants' uptake and maintenance of the EXTRA programme.

6.3 METHODS

6.3.1 Study Design

This qualitative study was underpinned by postmodernist, hermeneutic theory [375]. It received ethical and research governance approval from KCL, GSTH, UHL and the London (Dulwich) REC (08/H0808/118) (Appendix B).

6.3.2 Participants

Participants randomized to the EXTRA programme (Chapter 5) were purposively sampled for age, upper limb disability (DASH) [88-89]), arthritis self-efficacy (ASES), and adherence to the supervised classes [312, 341].

6.3.3 Study Protocol

6.3.3.1 Recruitment

Potential participants were contacted (by telephone), between October 2010 and September 2011, by the PI (VM). Participants were provided with a verbal explanation of the study and an opportunity to ask any questions. If

they were willing to participate, they were invited to attend an interview at a mutually convenient location (e.g. Dulwich Community Hospital) and time.

6.3.3.2 Semi-Structured Interviews

Semi-structured interviews lasting approximately 30 to 45 minutes were conducted by a single moderator (VM). All interviews were audio-recorded, anonymized, and transcribed verbatim (Appendix L).

6.3.4 Semi-Structured Interview Guide

Informed by a review of the literature (Chapter 1), consultation with experienced academics and clinicians, and a pilot study (Chapter 4), a semi-structured interview guide was developed to explore participants' experiences and perceptions of the EXTRA programme (including the supervised sessions, the home exercise programme, and the exercise handbook), and their experiences of the factors which affected their uptake and maintenance of the programme. The guide was amended following three pilot interviews, and iteratively as ongoing analysis revealed additional areas of relevance (Table 6.1).

At the start of each interview, the moderator encouraged participants to recount their own experiences of the programme. Open-ended questions were used to facilitate participants' unbiased opinions. The order in which the questions were presented varied according to the development of each interview. Probe questions were constructed and used where participants answered generally, to enable further exploration of their responses; probe questions were both specific (to remind the interviewer to cover specific

domains) (Table 6.1) and non-specific, such as ‘can you tell me more about that?’ or ‘have I understood you correctly when I hear you say...?’ [374]. Participants were invited to add additional comments or clarifications at the end of the interview.

Table 6.1 Semi-structured interview schedule for evaluation of participants’ experiences of the EXTRA programme (‘Education, self-management, and eXercise programme for people with early Rheumatoid Arthritis’)

1) **What were your expectations of the physiotherapy programme?**
   Probes: Were they met and how, why?

2) **What were your concerns about the physiotherapy programme?**

3) **Tell me about your experiences of the physiotherapy classes.**
   Probes: What about the education seminars, your individual exercises, the physiotherapist, the group, the location?

4) **What did you think about the exercise handbook?**
   Probes: What about the class handouts, the exercise descriptions, the diary?

5) **Tell me about your experiences of doing the exercise programme at home.**
   Probes: What were the positives, negatives? What helped or hindered you?

6) **Tell me about your experiences of maintaining the programme.**
   Probes: What made maintenance difficult, easy? What helped or hindered you?

7) **Is there anything that could have been done to change the programme?**
   Probes: What about the number of classes, the class education seminars, the person delivering the class, the group, the class location, the home exercise?

8) **Have your feelings about exercise changed as a result of taking part in the physiotherapy programme?***
   Probes: What about your confidence to exercises, exercise participation?

9) **Is there anything we have not talked about that you would like to add?**

*Included after interview number 3, following initial data analysis

6.3.5 Reflexive Diary

As the interpretation of qualitative data is subject to the preconceptions and assumptions held by researchers [374], a reflexive diary was recorded during data collection and analyzed to minimize or account for potential bias (Appendix M) [374, 376-377].

6.3.6 Data Analysis

Interview transcripts were analysed by the PI (VM) using NVivo 9 (*QSR International Pty Ltd.*) by IPA [374, 378]. Transcripts were read repeatedly to provide familiarity with the data. Concepts (i.e. words, sentences, complete paragraphs, etc.) within the text were then 'coded' to generate themes. Emergent themes were explored in subsequent interviews according to an iterative process [374]. Themes were then grouped into broader categories (super-ordinate themes). Interviews were conducted until no new themes were identified (data saturation) [379].

Where possible, sub-themes were entitled using illustrative quotations derived from the semi-structured interviews, to enhance pertinence to participants' experiences.

6.3.6.1 Researcher Validation

Data analysis was conducted by two researchers (VM, NG) independently. Following analysis, the researchers discussed and compared their findings until interpretive agreement was reached. A third researcher (LB) validated whether the identified categories were in agreement with the raw data.

6.3.6.2 Respondent Validation

Two participants were contacted by telephone to confirm statements summarising themes derived from their interviews. Both agreed with all statements, and did not wish to offer any amendments.

6.4 RESULTS

6.4.1 Participants

A total of 14 participants were approached (and agreed to be interviewed) however 2 failed to attend (reasons not known). Therefore, 12 participants were interviewed within (mean (SD)) 3 (2) months of completing the EXTRA programme (Table 6.2).

Table 6.2 Characteristics of participants with rheumatoid arthritis interviewed following completion of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis)

Participant	Gender	Age (years)	Ethnicity	Employment Status	Marital Status	Disease Duration (months)	Baseline DASH (0-100)	Baseline Arthritis Self-Efficacy (30-300)	Baseline 'Pain' Self-Efficacy (10-100)	Baseline 'Function' Self-Efficacy (10-100)	Baseline 'Other Symptoms' Self-Efficacy (10-100)	Classes Attended (n)
1	Male	79	Black Caribbean	Retired	Married	25	16	96	18	68	10	1
2	Female	46	White	Full time	Married	20	45	183	50	77	56	3
3	Female	32	Pakistani	Part time	Single	15	14	210	72	76	62	3
4	Female	70	Black Caribbean	Retried	Married	20	24	218	70	71	77	3
5	Female	58	White	Part time	Married	22	12	213	70	73	70	4
6	Female	66	White	Retired	Widowed	57	9	272	88	92	92	4
7	Female	87	White	Retired	Widowed	47	70	101	41	13	47	3
8	Female	65	Black African	Off sick	Divorced	41	63	X	37	X	55	3
9	Male	39	White	Full time	Married	65	8	263	92	99	72	4
10	Female	45	White	Full time	Single	12	11	X	X	88	72	2
11	Female	46	White	Off sick	Divorced	13	48	151	42	41	68	3
12	Female	61	Black Caribbean	Part time	Single	59	16	242	64	90	88	4

Off sick is due to RA; DASH = Disabilities of the Arm, Shoulder, and Hand Questionnaire; Baseline Arthritis Self-Efficacy= sum of 'Pain', 'Function', and 'Other Symptoms' Self-Efficacy; X = missing data

6.4.2 The Experience of a Global Upper Limb Education, Self-Management, and Exercise Programme for People with Early Rheumatoid Arthritis (the EXTRA Programme)

Five superordinate themes reflecting participants' experiences of the EXTRA programme (with 22 subthemes) were identified: 1) The EXTRA programme improves disease status and provides a self-management strategy, 2) Individual needs and lifestyle factors influence acceptability, 3) Others facilitate learning, confidence, and enjoyment, 4) Seminars and written materials increase knowledge and autonomy, and 5) Socio-environmental, self-regulatory, and self-belief factors influence uptake and maintenance (Figure 6.1).

Figure 6.1 The experience of the EXTRA programme ('Education, self-management, and eXercise Training in early Rheumatoid Arthritis') among participants with early rheumatoid arthritis

SUPERORDINATE THEMES	SUB THEMES (LEVEL 1)	SUB THEMES (LEVEL 2)
1. The EXTRA Programme Improves Disease Status and Provides a Self-Management Strategy		"My arthritis has improved tremendously"
		"It does kind of give you hope...you can do something yourself"
2. Individual Needs and Lifestyle Factors Influence Acceptability		"I think the location was okay"
		"It's inconvenient to have it smack bam in the middle of the day"
3. Others Facilitate Learning, Confidence, and Enjoyment	The Support of an 'Expert'	"I think you need some instruction"
		"He seemed quite nice, he was friendly"
	Interaction with Peers	"We're actually learning from each other"
		"Everybody was in the same boat"
		"You feel competitive"
		"It was enjoyable...we had a laugh...we got together...we got to know people"
	The Support of Significant Others	"My son...he used to say to me, "Have you done your exercises today?""

SUPERORDINATE THEMES	SUB THEMES (LEVEL 1)	SUB THEMES (LEVEL 2)
4. Seminars and Written Materials Increase Knowledge and Autonomy		"I think that's useful to know"
		"If I can't remember how to do it I can go back to the handbook"
		"I liked to write it down so that I can look back and see what days I did achieve it"
5. Socio-Environmental, Self-Regulatory, and Self-Belief Factors Influencing Uptake and Maintenance	Socio-Environmental Factors	"If you never turn up...you wasting the peoples' time"
		"At home you have so many distractions"
	Self-Regulatory Factors	"You can do while you're doing other things"
		"I was more disciplined when I had to write a diary than I am today"
	Perception of Self	"I want my health back"
		"Do I need this?"
		"I'm quite self-disciplined"
		"I want to be seen as normal as possible"

6.4.2.1 The Extra Programme Improves Disease Status and Provides A Self-Management Strategy

Overall, participants' perceived that the EXTRA programme improved their disease status, and provided them with an effective self-management strategy.

"My arthritis has improved tremendously" (P4)

Participants were positive about their overall experiences of the EXTRA programme, perceiving that the programme improved their RA symptoms and function:

P1: "...what exercise I did from the instruction I gained from the class, at home, did help my movement to be more smooth, and not so painful."

"It does kind of give you hope...you can do something yourself" (P11)

Participants appreciated the importance of disease self-management:

P4: "I realize that I have an illness, and it doesn't care how much tablets the doctor actually gives me, if I don't try to help myself in some way...i....is not going to help."

They felt that the EXTRA programme provided them with an effective daily self-management strategy:

P12: "Um, sometimes, just thinking about the pain, sometimes when I get [inaudible] [laugh]...or I wake up and feel stiff, I thought, "no, this is no good, I need to get back to those exercises" [laugh]...because they help."

6.4.2.2 Individual Needs and Lifestyle Factors Influence Acceptability

This theme reflects the influence of participants' individual needs and lifestyle factors on the acceptability of structural and organizational aspects of the EXTRA programme (e.g. location, timing, etc.).

"I think the location was okay" (P12)

Participants explained how location impacted on their experience of the supervised sessions. Many indicated that the community hospital location was easy and convenient to attend:

P4:...it is fairly accessible, because you have Lordship Lane which is not very far on various buses. There is one bus that passes outside here..."

However, the impact of travelling and the first floor location of the physiotherapy department distressed less able participants:

P7: "Well, it was a long way up here, to come up here, and for people who are handicapped, that's hard...And I mean, the fact that I ended up having to come up the stairs really annoyed me..."

Some participants suggested that they would prefer attending the supervised sessions elsewhere:

P4: "The hospital is a bit more, gosh, it's a bit depressing"

Conversely, others felt more at ease in a hospital setting:

P5: "...I think with...with going to a gym, i...you know, you [exhale], I always f...I have been to a gym since I've had all of this anyway, and y...you feel that you're...you're not at that that point where other people are. You don't feel, I didn't feel as fit in myself and I didn't know whether I could do as much as I could uh, in a gym."

"It's inconvenient to have it smack bam in the middle of the day" (P3)

Many participants discussed the timing of the supervised sessions (*2 to 3pm*), highlighting the negative impact on their working commitments:

P3: "...I found the...the class timing a bit of an issue...Um, because where I work, I work part time, to come on a, I think it was a Monday and a Thursday, at lunchtime, and I, for me, it poses a bit of a difficulty, coming on those days and especially at lunchtime. Cause had it been at the beginning of the day or at the end of the day, it would have been easier."

However, for others who worked part-time, the class timing was not a problem:

P5: "You know, I mean it it worked well because...the days that they were...were better for me...so for that, for me, that was that was ideal."

6.4.2.3 Others Facilitate Learning, Confidence, and Enjoyment

This theme reflects the ways in which support and guidance received from the physiotherapist, other group members (peers), and significant others, and interaction between peers, influenced participants' learning, confidence (self-efficacy), enjoyment, and overall satisfaction with the EXTRA programme.

The Support of an 'Expert'

"I think you need some instruction" (P7)

Participants identified the physiotherapist as important to their experiences of the EXTRA programme and suggested that the physiotherapist's supervision could not have been substituted by provision of written materials only:

P11: "...if you handed me a booklet and said, "go away and do it", I'd still want to be kind of talked through about what this was doing and why it was important...Rather than just, "here's a book"..."

Participants reported that rehearsing their exercises, supported by the physiotherapist, helped their understanding and personal mastery of the exercises, potentially improving self-efficacy for the exercise regimen:

P10: "the first session you could learn all of your exercises, the second session you could go back, do them and show the physio and she can look at you doing them and say, "yes, that's right"..."

P9: "...I've got more out of actually having one to one, and getting shown how to do it, to, sort of, learn through actually doing...."

However, this was dependent on participants' confidence in the physiotherapist's knowledge and ability:

P3: The "physiotherapist kind of said that, "even if you feel pain, you should still carry on exercising". That was the only concern that I had at the time...I was thinking, "are you sure"?"

P11: "they came and checked what were doing...so if you were doing anything wrong, it was quickly...picked up."

"He seemed quite nice, he was friendly" (P3)

Participants valued the encouragement, support, and empathy they received from the physiotherapist:

P8: "And he talk to you nice way. You know some peoples, if you got pains, he can't bother..."

Developing a good relationship with the physiotherapist enhanced participants' experiences of the programme, and changes in the

physiotherapist delivering the supervised sessions (i.e. due to annual leave, etc.) negatively affected their experiences:

P3: "I...I think it helps to have continuity...So I think that's quite useful to have the same person because you...it's like you become familiar with one person and then there suddenly not there and it's someone else, it seems a bit, kind' a like a little bit disjointed."

Interaction with Peers

"We're actually learning from each other" (P4)

Participants reflected on how interaction with their peers improved their understanding of arthritis self-management and exercise:

P5: "But it...it did help how, to you know, share experience of how...how people are getting on. Whether they found it difficult, whether they found it easy, and, you know, what time of day they did it, or...or whatever. So I think that, I think it is important...to share how other people felt...the sessions...Um, and...and get ideas...I think it's important."

"Everybody was in the same boat" (P5)

Participants valued the experience of meeting other people with RA. They described how this made them feel less isolated, and reminded them that others were experiencing similar difficulties to themselves:

P5: "Um, and...and you feel, you feel isolated, you don't think that anybody's, can understand what you're going through. So when you come to something like the classes, that you realize that other people have got those problems, some have got more severe problems than you have, and some haven't."

Homogeneity between peers (e.g. disease status, functionality, age, gender) was identified by participants as integral to their developing supportive relationships within the group:

P1: "...suppose general we're um, all in the same vain as it were because we all seeking relief from the same kind of thing...So, seems to get on better that way."

Heterogeneity between peers (e.g. disease status, functionality, age, gender) negatively affected participants' experiences:

P9: "...there was only one uh, male that took part...so I was the only male, I was the only male, s'pose that's my main...take on the group."

Dissimilarities in disease status between peers altered participants' perceptions of their condition. Meeting more disabled participants led those who were less severely affected to fear the progression of their RA, or conversely reflect positively on their own condition:

P2: "...if you see people and i...in very bad condition, and y...you feel that, "oh my goodness", you start to worry..."

P10: "Um, um, in terms of the people, the main impression was just, wow, it affects so many different people, different ages, um, yeah I wasn't the youngest um, so that, that was, that was, that was [inaudible] quite nice, it was quite reassuring..."

"You feel competitive" (P4)

Participants explained how observation of their peers successfully performing their exercises (vicarious experience) increased their own self-efficacy for the exercise regimen:

P4: "...and you...you feel competitive, "well, that person can do this...so I'm going to try and do it, she has pain, I have pain, but we are trying to reach that goal...of getting more mobile"."

Comparison with peers also prompted self-doubt; one lady questioned her understanding of her exercises as she was able to perform them more easily than her peers:

P6: "I felt better when I was doing it at home than here...But I think that's because I was, you know, with the other people in the class...I'm seeing them having a lot more difficulty than me, I did feel at times, well perhaps I'm not doing it properly."

"It was enjoyable...we had a laugh...we got together...we got to know people" (P7)

Many participants discussed how peer socialization contributed to their enjoyment of the supervised sessions:

P11: "Um [pause] uh, well it's kind of, it's obviously more nice, it's nicer to do [laugh], do exercise if there's other people, because it's more personable."

P12: "...when you're with people, you know and y...you can talk and laugh and, you find yourself, you continue with your exercises and...it works yeah...I like working in a group."

However, some felt that peer socialization was limited:

P4: "...there was not...not much interaction, you know. Just sort of waiting for the class to start, if you arrive early..."

Non-attendees altered the dynamics of the class, which adversely impacted on the experience of some participants:

P2: "Uh but, we...we were say f..., I can't remember exactly, but definitely four or five. And the next lessons gone to f...to...to four...And the next lesson to three. You know what I mean?...This is um, I wasn't happy of course."

The Support of Significant Others

"My son...he used to say to me, "Have you done your exercises today?"" (P6)

Participants discussed how the support of significant others enhanced their experiences of the EXTRA programme, particularly of the home exercise regimen:

P2: "...you know when you wake up early and doing your exercise they wouldn't mind, they support you, they say, "oh you're doing very well""

P3: "..."uh oh, I have to go down the stairs...I have to do it in the kitchen, and somebody in my family might see", "what what you doing?" you know?"

6.4.2.4 Seminars and Written Materials Increase Knowledge and Autonomy

This theme reflects the ways in which the educational seminars, programme handbook, and exercise diary increased participants' knowledge of exercise and self-management, and facilitated autonomy.

"I think that's useful to know" (P3)

Participants found the educational seminars valuable, and perceived that they covered topics pertinent to them:

P11: "...they were, you know, relevant."

Many participants explained that, prior to starting the programme, their principle concern was that the exercises prescribed would be "too hard" (P2),

cause pain, or exacerbate disease progression. The educational seminars addressed these fears:

P9: "...I'm more, yeah more sort of positive to doing exercise...feel more confident...I know it's not gonna, sort of, cause me, you know, damage or pain, or anything like that..."

P12: "I was thinking that if the exercises were too strenuous or rigorous it, I would, it would hurt more. But, I found out th...it wasn't like that. They were gentle and, you know, you were told how to manage them..."

However, some participants felt that the educational seminars were "quite basic" (P10) and suggested other topics that they would have valued covering (Section 6.4.3):

P10: "...I guess I didn't learn anything in those...little chats that I didn't already know."

"If I can't remember how to do it I can go back to the handbook" (P2)

Participants valued the exercise handbook as a supplementary aid to the EXTRA programme:

P10: "Very good, very comprehensive. Very clear um, very well designed, no, very good."

The handbook provided an aid memoire for the exercise regimen, enabling participant's to refresh their understanding of the exercises:

P12: "I think it was quite good because it's informative, and you can go back, have a look at your pictures if you forget what to do, and it will show you, and tell you how to do them."

It supported adaptation and personalization of the exercises at home:

P6: "I thought it was good...Very good, yes, as to, you know, what to do if we found it too difficult or not difficult enough, yeah."

The handbook also provided advice, and enhanced participant's ability to self-manage their exercises and condition:

P6: "Yes I would look back at the tips and that sort of thing."

Participants found the pictorial illustrations of the exercises particularly useful:

P11: "Um, because it, it's, it can be, it's too subjective with words, you don't, I mean I just think if you're doing things that are very dependent on position, for your muscles, you really know where to start, which angle to move at, and where to end up...I think, otherwise...you know, I don't think it's nearly as good."

The handbook increased participants' confidence in their exercise ability:

P12: "Just to make sure that I'm doing the right thing, you know."

"I liked to write it down so that I can look back and see what days I did achieve it" (P3)

Participants discussed the value of keeping an exercise diary for monitoring their progress:

P10: "It's just I don't, I, you know, otherwise I might forget how many repetitions I've done, or how difficult it felt."

However, a number of participants remarked that the Borg Rating of Perceived Exertion (RPE) scale was difficult to use and understand:

P3: "Um, I remember there was something a little bit like a, bit, you had to put like the level of activity or how difficult the exercise was...Yeah, and that I don't think I fully understood properly."

6.4.2.5 Socio-Environmental, Self-Regulatory, and Self-Belief Factors Influence Uptake and Maintenance

This theme reflects the ways in which socio-environmental (feeling a sense of loyalty toward the physiotherapist, other competing responsibilities), self-regulatory (the adaptability of the home exercise regimen, keeping an exercise diary), and self-belief (perceptions of their own disease status, need, ability, as well as of the way they were perceived by others) factors influenced participants' uptake and maintenance of the EXTRA programme.

Socio-Environmental Factors

"If you never turn up...you wasting the peoples' time" (P8)

Several participants explained that they felt compelled to maintain the regimen out of a sense of loyalty they felt toward the physiotherapist:

P2: "...for example, w...w...if...if I'm physiotherapist, yeah?...And then I...I personally, I try my best to...to...to...to help you, and if you come to my sessions, yeah? And say, "oh, I couldn't do it". Is...is no good."

"At home you have so many distractions" (P12)

Participants reflected that they frequently had competing responsibilities (e.g. housework, childcare, etc.) which made it difficult to prioritise exercise at home:

P12: "Knowing well at home you have so many distractions and you're always doing other things, you know, chores or shopping, and sometimes the time goes, and you, the days finished and you don't get to do anything..."

Participants explained how their exercises were interrupted (e.g. telephone calls, etc.) at home, limiting their ability to focus; thus attending another location at a dedicated time facilitated exercise:

P8: "Like, if you, I'm doing exercise now, maybe I'm home, like if somebody phone, "oh, this and this and this", I stop...And after that I go back. But if you in hospital and you do it in time, you can't stop to listen to phone."

Self-Regulatory Factors

"You can do while you're doing other things" (P6)

Participants reflected on how the adaptability of the home regimen facilitated their maintenance of exercise.

Many valued being able to exercise at a time convenient for them:

P6: "But at home, and plus you can sit down, you haven't got to sort of think, "well thirty seconds between [inaudible], I'll go an' do something and then I'll come back and I'll carry on", it hasn't got to be done in a certain time sort of thing, and at a certain time which I think is good."

The portability of the exercise equipment (therapy putty and bands) enabled participants to incorporate their exercises into everyday activities (e.g. break at work, watching television, etc):

P4: "But I don't do it as much. But um, with the ball, but it's some, if I'm even on the bus, I find myself doing the exercise, and doing the finger ones."

P12: "...because I work nights...I take my booklet with me and [laugh]...my straps to work, and if I have a...free time, if we're not very busy, and I'm sitting down, I try to do them [laugh]."

At home, participants could personalise their programmes, by adding music or altering the order in which exercises were performed:

P12: "Well, I play music...And it makes me, get me a bit more lively...And I thought, "okay, I'll...while I listen to that music I'll do my exercises, whichever one I want to do", or you know um...that gives me, that gets me going."

"I was more disciplined when I had to write a diary than I am today" (P6)

The exercise diaries facilitated participants' adherence to the daily exercise regimen:

P6: "...because as I say, I had to do it because I had to write it in that book. I couldn't be seen to write in that diary...if I hadn't done it...Cause that's just like telling a big big lie."

P11: "Um, but the diary as well was quite good because if you suddenly realise, you know, at seven o'clock you haven't done them you, you go, "oh no" [laugh]...Was quite good...Yeah it's a kind of...it's a kind of aid-memoir I suppose...thinking, "right, yeah... I've got to do it"."

The exercise diaries also enabled participants to monitor their progress, providing an incentive to adhere to the programme:

P12: "The diary, I think it was good because um, it has a section that you have to, like if you want to reach a target...a point, a goal, yes, your goal, and you write that in, and you work towards that...And, it's a reminder, it's there, so you can turn back to the page and look at it...And, yeah, keep going."

Perception of Self

"I want my health back" (P2)

Anticipated improvements to health, functional ability, and disease status encouraged participation in the programme:

P9: "I think that was one of the things I was saying I was looking out, to get out of this, was to get energy to do more...exercise."

P12: "...I was thinking that maybe if I could get to do extra things, you know, extra exercises from the physio, that would probably help...Well like my hands for example because I, I bake and I decorate cakes, and I was finding it difficult to kneed my icing and rolling out because of my shoulders and the stiffness in the joints, it was taking me longer...and sometimes I wasn't pleased with the work I'm producing and then I have to do it over again and get somebody to help me."

Disease symptoms such as pain, fatigue, and poor function, influenced programme maintenance:

P4: "But if I sit, I feel so tired, and pain, having this pain, and I can't do this, I want to do it, I get frustrated."

P6: "...I feel that if I lapse, and I don't do them, you know I I know not to the extent that I I did last year, but if I don't then I could obviously...lapse back to to not doing anything at all and then wondering why this hurt so much and...why I can't move this and....cause I do feel it's done me the power of good."

"Do I need this?" (P5)

Participants would only initiate and maintain the EXTRA programme if they perceived they had a need for it; many participants with well controlled RA felt that exercise was unnecessary:

P10: "So I suppose the...the problem with the, with my rheumatoid arthritis is that I don't, because of the drugs, my joint mobility's quite good. So, it's very difficult for me to see why I need to strengthen the muscles around the joints."

Those participants who were physically active also questioned the need for specific exercise:

P1: "But, don't forget, like I said, I do a lot of physical work at me allotment when I have the time...So that gives me enough time to, well, do body exercise then because I'm using my arms and I've got to use my uh, I use fork, hoe, and...and...do like that. So that gives me enough exercise there..."

"I'm quite self-disciplined" (P6)

Participants reflected on how aspects of their own personalities influenced their uptake and maintenance of the EXTRA programme. If participants considered themselves determined and capable, uptake and maintenance was facilitated:

P6: "I'm sort of quite self-disciplined, there were times when I thought, "oh was, oh better do me exercises, look at the time"."

However, where participants felt unable to persevere with the exercises, exercise participation was impeded:

P3: "No, and to be honest, w...it terms of my exercises, I haven't really done them...since coming to the group. And I...I...I think maybe that's a failing on my part cause I know that I find it hard to establish habits, new habits."

"I want to be seen as normal as possible" (P3)

Uptake and maintenance of the programme were influenced by participants' perceptions of their disease status. One participant described her difficultly in accepting her RA diagnosis. She felt a sense of "denial" (P3) about having RA and explained that by participating in the programme she

was reminding herself of her condition. She identified this as a barrier to her uptake and maintenance of the programme:

P3: "I guess for me it's probably a reminder that I'm, that I have a chronic health problem rather than doing a bit of exercise."

6.4.3 Participants' Recommendations for Development of the EXTRA Programme

Participants made recommendations to improve the acceptability of the EXTRA programme (Table 6.3).

Participants suggested delivering the sessions in an alternative location, such as a community hall or leisure centre:

P11: "...if it's outside um, a hospital, it's, environment it would be um, you know, say if you were in a sports hall or somewhere, it would kinda get you into the, kind of, mind set of thinking, "oh well this isn't about, you know, hospital and drugs, this is about life, and getting on with your life"..."

A number of participants recommended delivering the supervised sessions outside of normal working hours:

P10: "...perhaps a time after the working day would have been good to have the classes...because um, a lot of, well everything seems to be geared up to people who don't work."

Participants suggested ways of tailoring the supervised sessions to meet individual needs, included individualizing the number of supervised sessions:

P2: "The number of classes, it was short for me..."

P10: "I think one would have been enough...Perhaps two sessions..."

Additionally, participants advised creating homogeneous groups of individuals, on the basis of demographic, general health, disease, and psychosocial (self-efficacy) characteristics:

P2: "...find out exactly what's wrong....and uh, in general your health, and...and everything, and then make a group...like a level"

Participants would have valued an individual consultation with the physiotherapist, prior to commencing the group sessions, to address individual needs, targets, and concerns:

P2: "And uh, I think i...instead of having group straight away, just maybe first session to talk...To find out exactly individual problem. How uh your uh difficulties affecting you?"

Alternatively, participants recommended extending the duration of the supervised sessions to enable more opportunity for individual interaction with the physiotherapist.

P4: "I don't think he had enough time to interact with...the people that was actually taking it."

Participants encouraged maintenance of the same physiotherapist throughout the programme:

P2: "...if you have different physiotherapist, you have to start from the beginning again...You know what I mean?...So I prefer to have same physiotherapist..."

They also felt that introducing a 'follow up' session with the physiotherapist would be useful:

P2: "...what about and having the sessions so three months later?...To see what is the improvement...And, have you done your exercise? And, does it help?"

Some participants identified additional topics which they would have valued covering in the educational seminars, including the “physiology of pain” (P11), the functional benefits of exercise, and the “long term effects of inactivity on the joints” (P3); therefore, educational seminars should be tailored to meet the needs of the individual.

Participants found the RPE scale [343] difficult to use, and suggested employing a different method of measuring exercise intensity, or incorporating better instructions on how to use the RPE scale in the programme:

P7: “Um, where it was worked out what did you think of one to ten and that kind of thing...on each question um, was good. But, it left open a lot of comments. It wanted a page to write some kind of comments, in each, on each item.”

Many participants suggested reducing the daily frequency of the home exercise regimen:

P11: “...would have been nice to have a day off really...”

Table 6.3 Summary of participants' suggested recommendations for development of the EXTRA programme

Supervised Sessions		
	Location	• Consider an alternative location
	Timing	• Alter timing to increase accessibility • Individualize number of supervised sessions • Increase class duration
	Staffing	• Include a introductory individual consultation with the physiotherapist • Keep the same physiotherapist • Include a follow up session with the physiotherapist
	Peers	• Compose peer group of similar individuals: ✓ Health and disease status ✓ Exercise ability ✓ Demographic characteristics (i.e. age and gender)
Educational Seminars		• Incorporate additional content into educational seminars and tailor to individual needs • Additional suggested topics include: ✓ Physiology of pain ✓ Functional benefits of exercise ✓ Long term effects of inactivity
Exercise Handbook and Diary		• Use a different measure of exercise intensity or improve explanation of existing method (Borg RPE scale [343])
Home Exercise Regimen		• Reduce exercise frequency from a daily

6.5 DISCUSSION

This study explored participants' experiences of the EXTRA programme and identified five super-ordinate themes: 1) The EXTRA programme improves disease status and provides a self-management strategy, 2) Individual needs and lifestyle factors influence acceptability, 3) Others facilitate learning, confidence, and enjoyment, 4) Seminars and written materials increase knowledge and autonomy, and 5) Socio-environmental, self-regulatory, and self-belief factors influence uptake and maintenance.

Overall, the EXTRA programme was acceptable and a positive experience for people with early RA. Participants perceived that the programme improved their function, health, and disease status, and provided them with an effective self-management strategy. Participants' individual needs and lifestyle factors, such as disability and employment status, influenced the acceptability of structural and organizational aspects of the programme. Support and guidance received from the physiotherapist, other group members, and significant others, and interaction with peers, were integral to participants' learning, self-efficacy, enjoyment, and overall satisfaction with the EXTRA programme. Seminars and the provision of written materials increased participants' knowledge of exercise and self-management, and facilitated autonomy. Socio-environmental factors (including loyalty toward the physiotherapist and competing responsibilities), self-regulatory factors (such as the adaptability of the home regimen and the exercise diary), and self-perceptions (of disease status, need, ability, and of the way they were perceived by others) influenced participants' uptake and

maintenance of the EXTRA programme. Participants offered recommendations to improve programme acceptability.

This study has a number of strengths. Participants were purposively sampled to reflect a range of ages, functional abilities, and arthritis self-efficacy scores; thus a diversity of views are represented. Participants who did not complete the EXTRA programme were also interviewed, allowing a comprehensive exploration of the factors which influenced programme uptake and maintenance. Respondent and independent researcher validation methods were employed to ensure appropriate interpretation of the data, and potential researcher bias was acknowledged with a reflexive diary (Appendix M).

However, all interviews were conducted at the Dulwich Community Hospital by a researcher involved with the EXTRA study assessments, which may have influenced how comfortable participants were in declaring their criticisms of the programme. Nevertheless, as participants who did not complete the programme agreed to be interviewed, and all interviewees made recommendations to improve programme acceptability, this potential bias was probably minimal.

As reported in previous studies, participants valued meeting others with RA [207], and receiving guidance and support from a knowledgeable practitioner [207, 281-283, 380-382]. Exercising in a group, with the support and encouragement of an ‘expert’, provided participants with vicarious experience, verbal persuasion, and the opportunity for personal mastery;

mechanisms identified in Social Cognitive Theory (Chapter 1) which enhance self-efficacy [224, 257].

Participants' primary concern was that exercise would result in pain and exacerbate joint damage, concurring with previous research [199]. These concerns were alleviated by the educational seminars, and participants' experiences of exercising with no ill-effects, concurring with SCT which proposes that knowledge is the precondition for behaviour change, and physiological cues facilitate the development of self-efficacy [224, 257]. Some participants identified additional topics which they would have valued covering in the educational seminars, highlighting the need for further individualization of information provision [383].

Participants considered the exercise handbook a useful supplementary aid to the EXTRA programme. This may be because, initially, they were unable to understand and remember all of the exercise instructions, and the written and pictorial exercise descriptions may have facilitated their learning and recall, thereby enhancing mastery and self-efficacy [252]. The exercise diary provided participants with a means of self-monitoring, prompted goal setting, and provided a source of performance feedback which are all evidence based behaviour change strategies [348], and components of successful interventions facilitating adherence to exercise and self-management [218, 252, 384].

Similar to previous studies, participants encountered distractions and competing responsibilities at home which impeded their adherence to the programme [281]. These may be negated by the adaptability of home

exercise and participants valued being able to modify and control when, where, and how they completed their exercises. The adaptability of home exercise also empowered participants to determine and implement an exercise approach most suitable to their lifestyles and preferences [385], prompting self-management.

Uptake and maintenance of the EXTRA programme were impeded by participants' concerns about being viewed as abnormal by others, consistent with other work [383]. It may be particularly difficult to accept one's condition, find support, and feel 'normal' among a heterogeneous group of peers. The influence of personal beliefs and subjective norms are recognized as important for directing health behaviour in the Theories of Reasoned Action and Planned Behaviour [225-231]. Refinements of the EXTRA programme may include composing exercise groups of homogeneous individuals, as suggested by participants.

Overall, the EXTRA programme was acceptable to the participants interviewed, but developments to the programme were recommended. Offering classes across a range of facilities and times may allow people with conflicting lifestyle demands to attend, and may encourage a more homogeneous group of participants, so facilitating peer support. Individualizing the delivery format (i.e. providing a single personal consultation with a physiotherapist or a short course of supervised sessions) may reduce costs related to non-attendance, and providing follow-up with a physiotherapist may improve long-term adherence to the programme [207, 284-286, 370].

Overall, the EXTRA programme was acceptable and a positive experience for people with early RA. Participants suggested refinements to the programme based on the factors which influenced their uptake and maintenance. These will need to be considered before implementation in clinical practice.

6.6 CONCLUSIONS

- The EXTRA programme was acceptable and a positive experience for people with early RA.
- Participants perceived that the EXTRA programme improved their function, health, and disease status, and provided them with an effective self-management strategy.
- Participants' experiences of the EXTRA programme were influenced by individual needs and lifestyle factors, others, including the physiotherapist, peers, and significant others, and the provision of written and verbal information.
- Uptake and maintenance of the EXTRA programme is challenging, and was influenced by participants' loyalty toward the physiotherapist, competing responsibilities, the adaptability of the home regimen, the exercise diary, and perception of self.
- Participants recommended changes to programme format, composition, location, and timing.

7 *'Are Patients Meeting the Updated Physical Activity Guidelines?' Physical Activity Participation, Recommendation and Preferences Among Inner-City Adults with Rheumatic Diseases*

7.1 INTRODUCTION

Whilst specific exercise programmes improve disease status in people with RA [102, 121, 129, 131, 386-387] (Chapter 5), maintaining exercise participation is challenging [285, 388] (Chapter 6). Regular physical activity (PA) (defined as "any bodily movement produced by skeletal muscles which results in energy expenditure" [112]) also conveys health and disease specific benefits in people with rheumatic diseases, including reduced pain, disability, risk of comorbidities and premature mortality [389-390] and may be more readily integrated into everyday life so improving long-term participation [391-392].

Clinical guidelines recommend that PA should be integral to the management of rheumatic diseases (NICE 2008, 2009 [393-394]) however,

when assessed against previous PA guidelines, people with rheumatic diseases report low levels of PA [117-118].

In recognition that overall PA volume is more fundamental than frequency for achieving health benefits, revised PA guidelines (published: US 2008, UK 2011) recommend that adults participate in ≥150 minutes of moderate-intensity PA or ≥75 minutes of vigorous-intensity PA, or equivalent, (in bouts of ≥10 minutes) per week [113-114]. However, to date, no studies have evaluated the PA levels of inner-city adults with rheumatic diseases against these updated guidelines, or explored what, if any, specific PA preferences they hold. Research is required that will inform the delivery of targeted PA interventions in deprived, inner-city, often difficult to reach populations, which have poor disease outcomes [395].

Receiving tailored PA advice from HCPs increases PA participation [396-397]. However, only 42% of American adults with arthritis report ever being advised by a HCP to increase their PA, and it is not known whether UK HCPs integrate PA recommendation into disease management.

Therefore, this study explores the PA levels of adults with rheumatic diseases from a deprived, inner-city area against the updated PA guidelines [398]. It explores their PA preferences, and assesses the proportion who report ever receiving PA advice from a HCP.

7.2 AIMS OF RESEARCH

The aims of this research were:

1) To evaluate the PA levels of inner-city adults with rheumatic diseases against the updated (US 2008, UK 2011) PA guidelines [113-114].
2) To assess the proportion of inner-city adults with rheumatic diseases who report ever receiving PA advice from a HCP.
3) To evaluate the proportion of inner-city adults with rheumatic diseases who would like help from a HCP to become more physically active.
4) To explore the PA preferences of inner-city adults with rheumatic diseases.

7.3 METHODS

7.3.1 Participant Sampling and Recruitment

Patients aged 18 years and over, attending the general rheumatology clinics of a public hospital (KCH) in a deprived, inner-city area [398] between July and October 2010, were invited to complete a two-page questionnaire (Appendix N) whilst waiting for their routine clinical appointments. Ethical and research governance approval was sought, but not required, from the KCH Research Ethics and Research and Development Committees (Appendix B).

Questionnaires were distributed to patients directly (from a member of the research or rheumatology team) or indirectly (questionnaires were made available in the clinic waiting room) and returned via an anonymous deposit box in the clinic reception area.

7.3.2 Outcome Measures

7.3.2.1 Demographic Characteristics

Demographic characteristics including gender, age (≤25, 26-34, 35-44, 45-54, 55-69 or ≥70 years), all self-reported doctor-diagnosed rheumatic diagnosis(es) (rheumatoid arthritis (RA), osteoarthritis (OA), psoriatic arthritis (PsA), gout, systemic lupus erythematosis (SLE), ankylosing spondylitis (AS), fibromyalgia syndrome (FMS), other and unknown), and self-reported disease duration (years) (very early (≤1.0), early (1.1-5.0), intermediate (5.1-10.0), long-standing (>10.0)) were obtained. Where more than one rheumatic diagnosis was reported, respondents were categorized under all (i.e. more than one) reported diagnoses.

7.3.2.2 Physical Activity Level

Physical activity level was assessed using the valid and reliable short form International Physical Activity Questionnaire (IPAQ) [399], which estimates the frequency (defined as the number of days per week) and duration (defined as the number of minutes per day) of PA performed (in bouts of at least 10 minutes) during the last 7 days, at three intensity levels (walking, moderate, vigorous) and across four domains (home, work, transport, and leisure). Respondents are provided with definitions and examples of moderate-intensity (“moderate physical effort and make you breathe somewhat harder than normal, like carrying light loads or bicycling at a regular pace”) and vigorous-intensity (“hard physical effort and make you breathe much harder than normal, like heavy lifting, digging, aerobics, or fast bicycling”) PA, and instructed to report any walking undertaken at work,

home, to travel from place to place, or solely for recreation, sport, exercise or leisure. In addition, average sitting time on weekdays was recorded.

7.3.2.3 Physical Activity Advice

Physical activity advice received from HCPs was explored using the closed questions: “Has a doctor or other healthcare professional ever suggested (an increase in) physical activity or exercise to help your arthritis or joint symptoms?” (2009 Behavioural Risk Factor Surveillance System Questionnaire [400]), and “Would you like help from your doctor or health service to become more physically active?” Response options were ‘yes’, ‘no’, ‘don’t know/refused’.

7.3.2.4 Physical Activity Preferences

Physical activity preferences were assessed using the open question: “Which physical activities do you enjoy?” Response options were ‘walking’, ‘swimming’, ‘cycling’, ‘jogging’, ‘lifting weights’, ‘aerobics’, ‘other sports’, ‘Pilates/Yoga/Tai Chi’, ‘gardening’ and ‘don’t know’. Participants were informed that the questionnaire aimed to explore the “kinds of physical activities that people do as part of their everyday lives at the moment”, and instructed to select as many options as applicable and to provide any additional answers in a free text box.

7.3.3 Data Analysis

To determine compliance with updated (2008, 2011) PA guidelines [113-114], IPAQ data was converted to metabolic equivalent (MET) minutes per week (METs x weekly minutes x weekly days), as per IPAQ ‘continuous’

scoring guidelines [401]. METs describe the rate of energy expenditure, or intensity of PA, relative to resting values (1 MET). Therefore, 2 METs refers to a metabolic rate twice that at rest. The IPAQ defines vigorous-intensity PA as 8 METs, moderate-intensity PA as 4 METs, and walking as 3.3 METs [399].

PA level was categorised as: High (meeting and exceeding the PA guidelines; defined as >1000 MET minutes per week), Medium (meeting the PA guidelines; defined as 500 to 1000 MET minutes per week), Low (not meeting the PA guidelines; defined as <500 MET minutes per week), and Inactive (not meeting the PA guidelines and no PA beyond basal activities of daily living, defined as less than 10 minutes of PA (per activity bout) per week), as per updated PA guidelines [113-114].

Descriptive statistics were completed, and data presented as % (n) (PA level, PA advice, PA preferences) or median (IQR) (MET minutes, daily sitting time). Associations between variables were evaluated using Pearson's chi square test (χ^2 (*df*)). 'Unknown', 'don't know/refused', and free text responses were omitted from analysis. Statistical analysis was performed on SPSS for Windows 17. Significance was accepted at $P \leq 0.05$.

7.4 RESULTS

7.4.1 Participants

One thousand and ninety three patients (60% inflammatory arthritis, 4% OA, 1% Fibromyalgia syndrome (FMS), 36% other), attending inner-city rheumatology clinics at a public hospital between July and October 2010, had the opportunity to complete the questionnaire whilst waiting for their routine clinical appointments. Five hundred and eight questionnaires were returned (46% response rate). 477 responses about PA level (IPAQ), 470 responses about PA advice received, and 461 responses about wanting PA advice and PA preferences were analysed due to incomplete or illegible responses.

7.4.2 Physical Activity Level

Overall, 61% (291) of respondents met the updated PA guidelines and 39% (186) did not meet guidelines.

48% (230) of respondents were categorized as performing high PA levels, 13% (61) of respondents were categorised performing medium PA levels, 12% (57) of respondents were categorised as performing low PA levels, and 27% (129) of respondents were inactive (Table 7.1).

PA level was associated with *age* (χ^2 (15) = 31.39, P<0.01), with inactivity increasing with age, but not with *gender* (χ^2 (3) = 1.63, P>0.05), *rheumatic diagnosis* (χ^2 (5) = 3.94, P>0.05) or *disease duration* (χ^2 (9) = 11.91, P>0.05) (Table 7.1).

Table 7.1 Demographic characteristics and physical activity levels of adults with rheumatic diseases attending an inner-city UK hospital

Characteristic	Physical Activity Level									
	All		Inactive*		Low *		Medium†		High†	
	n	%	n	%	n	%	n	%	n	%
Total	508	**100**	129	**27**	57	**12**	61	**13**	230	**48**
Gender										
Male	119	**24**	31	**28**	12	**11**	18	**16**	51	**46**
Female	386	**76**	98	**27**	45	**12**	43	**12**	178	**49**
Age (years)										
≤25	18	**4**	3	**18**	1	**6**	0	**0**	13	**77**
26 - 34	53	**10**	9	**18**	5	**10**	9	**18**	28	**55**
35 - 44	92	**18**	18	**21**	18	**21**	15	**18**	33	**39**
45 - 54	115	**23**	30	**27**	13	**12**	14	**13**	54	**49**
55 - 69	146	**29**	37	**27**	16	**12**	15	**11**	70	**51**
≥70	82	**16**	32	**43**	4	**5**	7	**10**	31	**42**
Rheumatic Diagnosis¥										
RA	271	**53**	72	**29**	27	**11**	33	**13**	120	**48**
OA	68	**13**	17	**26**	9	**14**	9	**14**	31	**47**
PsA	33	**7**	7	**21**	4	**12**	5	**15**	17	**52**
SLE	29	**6**	9	**35**	3	**12**	0	**0**	14	**54**
Gout	25	**5**	5	**23**	5	**23**	2	**9**	10	**46**
FMS	25	**5**	9	**38**	5	**21**	2	**8**	8	**33**
AS	14	**3**	3	**21**	1	**7**	1	**7**	9	**64**
Other	52	**10**	9	**18**	7	**14**	6	**12**	27	**55**
Disease Duration (years)										
≤1.0	85	**27**	15	**20**	10	**14**	9	**12**	40	**54**
1.1 - 5.0	95	**30**	18	**19**	10	**11**	11	**12**	54	**58**
5.1 - 10.0	47	**15**	15	**33**	9	**20**	2	**4**	19	**42**
>10.0	88	**28**	27	**31**	10	**12**	12	**14**	37	**43**

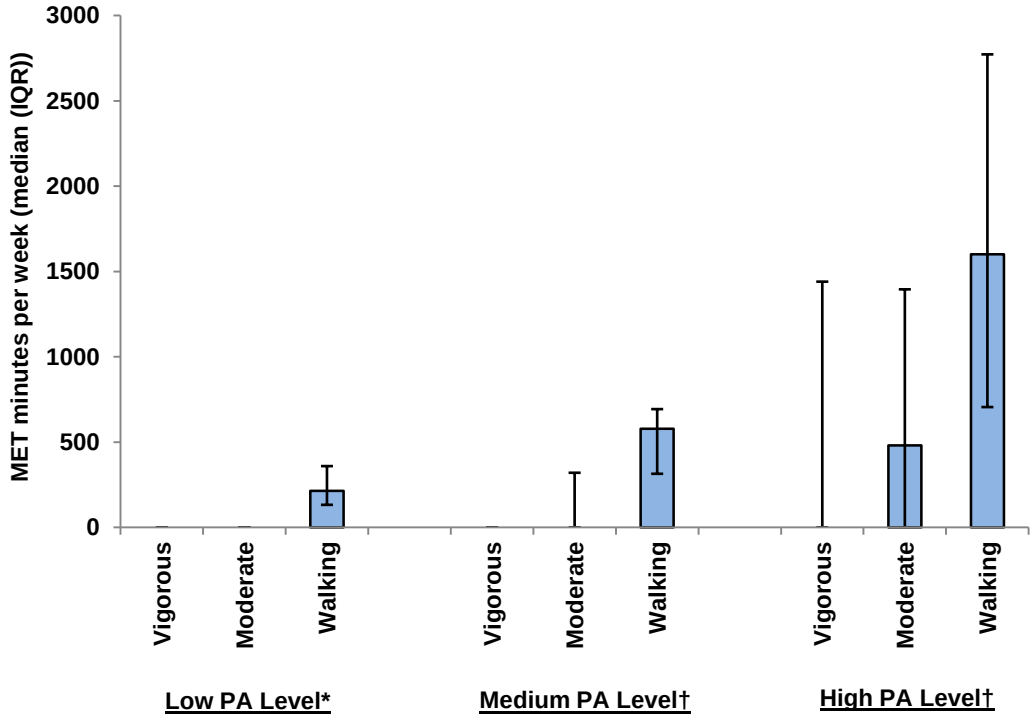
RA = rheumatoid arthritis; OA = osteoarthritis; PsA = psoriatic arthritis; SLE = systemic lupus erythematosis; FMS = fibromyalgia syndrome; AS = ankylosing spondylitis

¥13 (2.6%) missing responses, 85 (17%) respondents reported >1 rheumatic diagnosis

†Meeting physical activity guidelines: High activity = >1000 MET minutes of physical activity per week; Medium activity = 500 to 1000 MET minutes of physical activity per week
*Not meeting guidelines: Low activity = <500 MET minutes per week; Inactive = 0 MET minutes of physical activity per week in bouts ≥10 minutes

Walking accounted for the majority of respondents' weekly energy expenditure, irrespective of PA level (Figure 7.1).

Figure 7.1 Weekly energy expenditure of adults with rheumatic diseases attending an inner-city hospital performing low, medium, and high levels of physical activity, showing the proportion accounted for by vigorous-intensity physical activity, moderate-intensity physical activity, and walking



PA = physical activity; MET = metabolic equivalent (walking = 3.3 METs, other moderate intensity physical activity = 4.0 METs, vigorous intensity physical activity = 8 METs); MET minutes per week = METs x weekly minutes x weekly days

†Meeting physical activity guidelines: High activity = >1000 MET minutes of physical activity per week; Medium activity = 500 to 1000 MET minutes of physical activity per week
*Not meeting guidelines: Low activity = <500 MET minutes per week; Inactive (not shown) = 0 MET minutes of physical activity per week in bouts ≥10 minutes

Respondents performing high levels of PA spent 7 (4) hours sitting per day, those performing medium levels of PA spent 8 (5) hours sitting per day, those performing low levels of PA sat for 10 (8) hours per day, and inactive respondents spent 10 (7) hours sitting per day.

7.4.3 Physical Activity Advice

43% (204) of respondents reported ever receiving PA advice from a HCP, 48% (227) reported never discussing PA with a HCP, and 8% (39) didn't know/refused. Receiving PA advice from a HCP was associated with *disease duration* (χ^2 (3) = 10.39, *P*<0.05) and *PA level* (χ^2 (3) = 8.08, *P*<0.05), with those diagnosed within the last year and those performing low levels of PA least likely to report ever receiving PA advice. Receiving PA advice was not associated with *gender* (χ^2 (1) = 0.99, *P*>0.05), *age* (χ^2 (5) = 5.09, *P*>0.05) or *rheumatic diagnosis* (χ^2 (5) = 5.11, *P*>0.05) (Table 7.2).

50% (230) of respondents reported that they would "like help" from a HCP to become more physically active. However, 35% (160) would not "like help" and 15% (71) didn't know. Wanting help was associated with *rheumatic diagnosis* (χ^2 (5) = 17.25, *P*<0.01) and *receiving PA advice* (χ^2 (1) = 12.35, *P*<0.001); those with OA, SLE, and gout and those who had already discussed PA with a HCP were most likely to report that they would "like help" to become more physically active. Wanting help was not associated with *gender* (χ^2 (1) = 3.17, *P*>0.05), *age* (χ^2 (5) = 3.91, *P*>0.05), *disease duration* (χ^2 (3) = 5.91, *P*>0.05), or *PA level* (χ^2 (3) = 6.54, *P*>0.05) (Table 7.2).

7.4.4 Physical Activity Preferences

Walking (65% (328)), swimming (32% (162)), and gardening (28% (140)) were the most frequently reported PA preferences. Preference for walking was associated with *gender* (χ^2 (1) = 4.53, *P*<0.05) and *PA level* (χ^2

(3) = 40.64, *P*<0.001); with women and those meeting the PA guidelines most likely to favour walking. Preference for swimming was associated with *age* (χ^2 (5) = 18.00, *P*<0.01), with younger respondents most likely to favour swimming. Preference for gardening was associated with *age* (χ^2 (5) = 25.72, *P*<0.001) and *PA level* (χ^2 (3) = 12.02, *P*<0.01); with older respondents and those meeting the PA guidelines most likely to favour gardening. *Rheumatic diagnosis* and *disease duration* were not associated with PA preference (all *P*>0.05) (Table 7.2). Other PA preferences were reported by less than 15% of participants (unreported data).

Table 7.2 Reported physical activity preferences, receiving, and wanting physical activity advice among adults with rheumatic diseases attending an inner-city hospital

Characteristics	Physical Activity Advice				Physical Activity Preferences					
	Received		Want		Walking		Swimming		Gardening	
	n	%	n	%	n	%	n	%	n	%
Total	204	**43**	230	**50**	328	**65**	162	**32**	140	**28**
Gender										
Male	44	**43**	42	**51**	68	**63**	40	**37**	29	**27**
Female	160	**49**	188	**61**	259	**74**	122	**35**	111	**32**
Age (years)										
≤25	7	**41**	11	**69**	11	**65**	9	**53**	0	**0**
26 - 34	20	**44**	26	**59**	37	**73**	23	**45**	9	**18**
35 - 44	36	**47**	42	**60**	58	**68**	38	**45**	17	**20**
45 - 54	57	**56**	62	**65**	80	**76**	40	**38**	33	**31**
55 - 69	55	**43**	60	**56**	98	**73**	36	**27**	57	**43**
≥70	27	**44**	28	**1**	43	**65**	14	**21**	23	**35**
Rheumatic Diagnosis										
RA	102	**45**	115	**55**	166	**69**	87	**36**	76	**32**
OA	25	**44**	38	**79**	40	**69**	19	**33**	15	**26**
PsA	11	**9**	17	**63**	24	**80**	11	**37**	13	**43**
SLE	15	**58**	21	**78**	20	**71**	6	**21**	6	**21**
Gout	10	**48**	12	**71**	18	**75**	6	**25**	8	**33**
FMS	12	**50**	15	**65**	20	**83**	11	**46**	5	**21**
AS	8	**57**	7	**58**	11	**85**	4	**31**	3	**23**
Other	17	**36**	19	**46**	38	**76**	19	**38**	19	**38**
Disease Duration (years)										
≤1.0	23	**31**	35	**52**	59	**76**	25	**32**	24	**31**
1.1 - 5.0	47	**53**	57	**70**	68	**76**	33	**37**	30	**33**
5.1 - 10.0	23	**55**	22	**31**	31	**72**	16	**37**	13	**30**
>10.0	38	**49**	39	**57**	49	**64**	28	**36**	26	**34**
Physical Activity Level										
Inactive*	54	**50**	67	**66**	53	**49**	33	**31**	25	**23**
Low*	18	**37**	29	**66**	34	**62**	23	**42**	12	**22**
Medium†	33	**62**	29	**57**	43	**75**	22	**39**	15	**26**
High†	91	**44**	92	**52**	182	**82**	80	**36**	86	**39**
Physical Activity Advice										
Received	\	****	116	**67**	137	**47**	69	**47**	56	**43**
Welcome	116	**57**	\	****	161	**59**	75	**57**	53	**49**

RA = rheumatoid arthritis; OA = osteoarthritis; PsA = psoriatic arthritis; SLE = systemic lupus erythematosis; FMS = fibromyalgia syndrome; AS = ankylosing spondylitis

†Meeting physical activity guidelines: High activity = >1000 MET minutes of physical activity per week; Medium activity = 500 to 1000 MET minutes of physical activity per week

*Not meeting guidelines: Low activity = <500 MET minutes per week; Inactive = 0 MET minutes of physical activity per week in bouts ≥10 minutes

7.5 DISCUSSION

This study reports that nearly two thirds of people with rheumatic diseases attending an inner-city hospital meet the updated (US 2008, UK 2011) PA guidelines, but many of those who do not meet the guidelines are entirely inactive. Approximately half our respondents reported never discussing PA with a HCP, and half reported that they would like help from a HCP to become more physically active. Walking was the most frequently preferred PA.

This is the first study to investigate PA participation against the updated (2008, 2011) PA recommendations [113-114] in a relatively large number of people with a range of rheumatic diseases. Strengths of the study include the use of an internationally validated and reliable standardised questionnaire (IPAQ), and calculation of weekly energy expenditure to enable PA level categorization and assessment of guideline achievement. The sample is drawn from a deprived, inner-city population, so elucidating the PA levels and preferences in this traditionally hard to reach group of people will inform the delivery of PA interventions.

Whilst these findings are likely to reflect other inner-city populations, the results cannot be generalised to a wide population of people with rheumatic disease because the respondents were recruited from a single hospital. Moreover, deprived, inner-city populations are typically more physically active than rural populations or those of higher socioeconomic status [402-404]. Our sample may also be biased toward more active respondents, who may be more comfortable declaring their PA participation.

Furthermore, self-report measures may overestimate PA, particularly vigorous-intensity PA, when compared to objective measures (e.g. accelerometry) [367], although only a small proportion of our highly active respondents reported vigorous-intensity PA. Moreover, accelerometry does not capture all PA (thus underestimating energy expenditure) [405], potentially explaining some of the discrepancy between objective and self-report measures.

A surprisingly high proportion of our respondents met the updated PA guidelines, consistent with other European [115], but not American, populations with rheumatic diseases [117-118]. This may be because the updated PA guidelines are more flexible and therefore potentially easier to achieve than previous guidelines [406-407]. Our results are comparable to PA participation in the general US population where 62% of American adults comply with revised PA guidelines [408]. Whilst the proportion of UK adults meeting the current guidelines (2008, 2011 [113-114]) is not known, 36% of men and 25% of women [391] met the previous PA guidelines [406-407]. However, this is likely to be an underestimation, as respondents only reported activities performed for “at least 30 minutes at a time”, rather than in bouts of ≥10 minutes.

Our study confirms that physical inactivity increases with age, [118] but is independent of diagnosis and disease duration. Disease severity, disease activity, and symptoms may also influence PA participation in some rheumatic conditions [409], although were not recorded in this study due to

challenges in assessing disease severity and activity accurately in the diverse range of rheumatic diseases included.

Concurring with previous work, less than half of our respondents reported ever discussing PA with a HCP [410], particularly those diagnosed within the last year. Receiving tailored PA advice from HCPs increases PA participation among people with rheumatic diseases [281-282], and many of our respondents reported that they would like PA advice. As work-related disability, and cardiovascular morbidity and mortality occur early in some rheumatic diseases [365, 411], and as even modest increases in PA among inactive adults produce health benefits [113-114], PA recommendation should be included in early disease management. Consequently, investigation into physician and therapist PA recommendation is warranted.

Walking accounted for the majority of our respondents' weekly energy expenditure, and was the most preferred PA, particularly among women. This may reflect walking undertaken for transportation which is particularly pertinent to deprived, inner-city populations where car usage may be less frequent. However, gardening was favoured by older respondents, and swimming was preferred by younger respondents, so the assessment of individual preferences for exercise is crucial prior to providing PA advice.

Encouragingly, this study suggests that nearly two thirds of inner-city adults with rheumatic disease meet the updated (US 2008, UK 2011 [113-114]) PA guidelines using self reported data. Physical activity advice would be welcomed by many inner-city adults with rheumatic disease, and should be routinely included in disease management, as minimal PA, even

insufficient to meet PA guidelines, confers disease and health benefits to those who are entirely inactive. Walking may provide an accessible, inexpensive, and acceptable form of PA among inner-city populations.

7.6 CONCLUSIONS

- Nearly two thirds of inner-city adults with rheumatic diseases met the updated (US 2008, UK 2011) physical activity guidelines. However, most of those who did not meet the guidelines were entirely inactive.
- Less than half of inner-city adults with rheumatic diseases reported ever receiving physical activity advice from a healthcare professional.
- Half of inner-city adults with rheumatic disease would like help from a healthcare professional to become more physically active.
- Walking was the most preferred physical activity among inner-city adults with rheumatic diseases, followed by swimming and gardening.

8 General Discussion

8.1 SUMMARY OF FINDINGS

On the basis of established exercise principles [119, 336, 338] and informed by the MRC framework [291] and NICE guidance for developing behaviour change interventions [316], a novel and pragmatic global upper limb home exercise programme, supplemented by a short course of supervised group education, self-management, and exercise sessions, for the rehabilitation of upper limb disability and dysfunction in people with RA (the EXTRA programme) was developed (Chapter 4).

The EXTRA programme improved global upper limb disability, measured by the valid and reliable DASH [74, 93], in the short-term (12 weeks from baseline) among people with early RA. Upper limb function, pain, strength, and arthritis self-efficacy also improved as a result of the EXTRA programme, consistent with previous research [172, 174-175]. The EXTRA programme had no adverse effects on disease activity, even among those with unstable medication or active disease, concurring with previous work [102, 131-133]. Improvements in arthritis self-efficacy and pain were sustained in the longer-term (36 weeks from baseline) [136, 168, 188], and there was a tendency toward long-term maintenance of all other outcomes.

This is the first time a global upper limb exercise-based rehabilitation programme incorporating behavioural change strategies has been developed and rigorously tested in people with RA (Chapter 5).

It is vital that efficacious health interventions are appropriate, acceptable, and feasible for the participants and HCPs [291, 316]. Qualitative evaluation of participants' experiences revealed that they perceived the EXTRA programme improved their RA disease status, and provided them with an effective self-management strategy. They identified aspects which contributed toward their positive experiences, including meeting, learning, and socializing with other individuals with RA, receiving feedback and encouragement from a physiotherapist knowledgeable about RA and exercise, the provision of a programme handbook and exercise diary, the portability of the exercise equipment, and the adaptability of the home exercise regimen. Participants made recommendations to increase the acceptability of the EXTRA programme, such as reducing the frequency of the daily home exercise regimen, altering the location, time, duration, and frequency of the supervised sessions, individualizing the educational content of the interactive seminars, and introducing a 'follow up' session with the physiotherapist (Chapter 6).

Consistent with previous research, participants identified factors which facilitated or impeded their uptake and maintenance of the EXTRA programme, including socio-environmental (loyalty toward the physiotherapist, competing responsibilities), self-regulatory (the adaptability of the home exercise regimen, keeping an exercise diary), and self-belief

(perceptions of their disease status, need, ability, as well as of the way they were perceived by others) factors [210, 281-282, 381] (Chapter 6).

Sustained exercise is challenging and often poor [372, 388], and integrating exercise and PA into everyday life may be more achievable in the long-term. A survey of PA participation among inner-city adults with a range of rheumatic diseases revealed that, encouragingly, more than two thirds of respondents met the updated UK PA guidelines [114]. However, despite national PA incentives (e.g. ‘Go London!’ [412], ‘Change4Life’ [413]), most of the remaining respondents were entirely inactive, and many, particularly those diagnosed within the last year or performing low levels of PA, reported never discussing PA with a HCP. Inactivity increased with age, consistent with previous research [117], but was unrelated to gender or disease characteristics, such as rheumatic diagnoses or disease duration. Walking accounted for the majority of respondents’ weekly energy expenditure, and was the most preferred PA. Interestingly, many respondents reported that they would like more help, from HCPs, to become more physically active (Chapter 7).

8.2 IMPLICATIONS OF THE RESEARCH

Rheumatoid arthritis is a chronic systemic disabling disease which reduces the independence [29, 414-416], QOL [36, 417-418], and life expectancy [3, 15] of people affected.

The upper limbs are involved in over 80% of people with RA [315], often early in the disease [50-51], contributing to work incapacity rates [60] and the individual and societal burden of RA [4, 39-47]. However, whilst global upper limb motor deficits are associated with upper limb disability [31, 37], and the clinical effectiveness of exercise therapy for safely [131-134, 136, 419] rehabilitating lower limb and hand motor dysfunction is well established [102, 133, 165, 172, 174-175, 360], prior to the studies in this thesis, a global upper limb exercise-based rehabilitation programme for people with RA had not been systematically developed and rigorously evaluated.

If implemented, the findings of this thesis could inform and improve patient care by providing a novel physiotherapist-led intervention for improving upper limb dysfunction in people with RA. They address a key healthcare agenda identified in the Chartered Society of Physiotherapy Research Priorities Project (2010) [420], and are concordant with clinical guidelines for the management of adults with RA [7].

The EXTRA programme concurs with other exercise-based hand or shoulder rehabilitation interventions which report strength and functional improvements in people with RA [148-149, 170-175, 177-180]. However, many of these studies lack methodological robustness (e.g. due to small

sample sizes [148-149, 170-171, 173, 177-178]) limiting the conclusions which can be drawn, and few integrate exercise prescription with theoretically underpinned behavioural change strategies. It is essential that physical therapies are rigorously evaluated prior to implementation into clinical practice. Therefore, this research, developed in accordance with the MRC framework for the design and evaluation of complex healthcare interventions [291], provides a foundation for, and enhances the evidence underpinning, the clinical management of RA.

The EXTRA programme is one of the first to integrate exercise and behavioural change strategies in RA [169, 222]. Whilst previous integrated interventions have reported reductions in disability, pain [222], and improvements in aerobic capacity [169], but not strength or self-efficacy [169], conclusions are limited by small sample sizes [169], inadequate description of the behavioural change strategies included [222], and lack of longer-term follow-up [169]. The mechanisms by which behavioural change strategies were incorporated into the EXTRA programme were clearly described (Chapter 4) [348], and both the longer and short-term effects on self-efficacy and health outcomes were rigorously evaluated.

Healthcare professionals, particularly occupational and physical therapists, are ideally placed to provide advice on exercise and PA, and this research builds on previous work evaluating PA and exercise interventions, increasing the evidence-base for PA promotion by HCPs. Moreover, this efficacious intervention could easily be introduced into clinical practice,

equipping HCPs with evidence-based health psychology behavioural change strategies which could be applied to other rheumatic disease populations.

Thus, the EXTRA programme provides the first evidence-based, comprehensively described, rigorously tested with longer-term follow-up, pragmatic and realistic global upper limb exercise programme incorporating behavioural change strategies, which is efficacious for improving upper limb disability, sensorimotor deficits, and self-efficacy, in the short-term at least among people with RA. It is acceptable to both participants and clinicians and may be readily implemented and integrated into current clinical practice.

To sustain and improve health status, exercise needs to be maintained long-term, and this is challenging for HCPs and people with chronic disease [372, 388]. Physical activity conveys health and disease specific benefits for people with rheumatic diseases [389-390], and may be easily integrated into everyday life so improving long-term participation [391-392]. Public health campaigns promote PA [412-413], and PA recommendations were updated in 2011 in the UK in light of new evidence on effective dosage [114]. The PA survey in this thesis is the first to evaluate whether people with RA and other rheumatic diseases meet these updated PA guidelines [114], and to what extent UK HCPs integrate PA recommendation into rheumatic disease management (Chapter 7).

Encouragingly two thirds of respondents in this PA survey achieved recommended levels of PA [114], but many of those who did not meet the guidelines were entirely inactive, concurring with previous work [116]. As work-related disability and cardiovascular morbidity and mortality occur early

in some rheumatic diseases [365, 411], it is concerning that those diagnosed within the last year were among those least likely to have received PA advice. Whilst there is no minimum dosage of PA to produce health benefits, modest increases in PA among inactive adults, even if insufficient to meet the guidelines, reduce mortality and morbidity, including the risk of developing comorbid conditions such as coronary heart disease, hypertension, and diabetes [113-114].

As PA advice received from HCPs facilitates PA participation [281-282], and national and clinical guidelines recommend regular PA for people with rheumatic diseases [7, 114, 393-394], it is imperative that PA and exercise should be routinely integrated into disease management. However, many of our respondents reported never discussing PA with a HCP (Chapter 7). There may be several reasons why HCPs do not provide PA advice, despite believing that PA counselling is important [421]. A recent systematic review [422] reported that barriers to HCPs providing PA advice to their patients include their uncertainty as to the effectiveness of PA counselling, feeling uncomfortable about providing detailed advice, lack of knowledge about PA, lack of training, and insufficient time and reimbursement. Moreover, HPCs are more likely to provide PA advice if they are active themselves, or if they feel that their patients' medical condition would benefit from a lifestyle change [422]. Therefore, educating HCPs about appropriate PA levels, behavioural change strategies, and the value of PA in rheumatic conditions may be warranted to facilitate effective and appropriate PA advice for people with rheumatic diseases.

8.3 METHODOLOGICAL CONSIDERATIONS

The studies in this thesis have a number of strengths.

Development of the EXTRA programme was informed by the MRC framework [291], existing evidence and service requirements, and guidance from experienced clinicians and academics, and tested with an acceptability and feasibility pilot study exploring both participants' and clinicians' experiences. The developmental process was clearly described (Chapter 4).

Whilst the pilot study sample was small, it included a range of participants who were encouraged to reflect freely on the EXTRA programme to inform the subsequent RCT.

The EXTRA study was a large, rigorously conducted RCT which recruited participants from a number of inner-city (south-east London) hospitals. Assessments were conducted by a single moderator, who was blinded to treatment allocation. Characteristics of the intervention, including exercise frequency, intensity, duration, type, means of progression, and incorporated behavioural change strategies were clearly described, as were details of the sample, such as disease characteristics, method of randomization, and reasons for attrition [290]. Validated and reliable self-report outcome measures were utilized [31, 93, 292, 301, 310, 312], and the validity and reliability of all other outcome measures were assessed and reported (Chapter 3). Robust statistical analyses were conducted, and potential sources of bias, including attrition, medication instability and disease activity, were accounted for by multiple imputation of missing data and sensitivity analyses.

Whilst the EXTRA programme did not exacerbate disease activity or pain, other aspects of disease progression, such as articular damage, were not assessed in this study, similar to other work [166]. However, the safety of exercise is well recognised, and studies evaluating radiographic disease progression following exercise have reported no alteration of joint erosion rates in the long term [136].

The qualitative evaluation of participants' experiences of the EXTRA study (Chapter 6) included a purposive sample of participants with a wide range of ages, disability levels, and arthritis self-efficacy scores. Participants who completed the EXTRA programme, as well as those who did not, were interviewed, so a diversity of views and experiences were explored which will inform further development of the EXTRA programme. Respondent and independent researcher validation methods were employed to ensure validity and reliability of conclusions, and a reflexive diary was used to acknowledge researcher bias.

However, the interviews were conducted at the Dulwich Community Hospital (the location of the EXTRA programme) by a researcher involved with the EXTRA study, thus potentially biasing results by inhibiting participants' account of their negative experiences. Despite this, a large number of recommendations were made for improving the EXTRA programme, suggesting that this potential disadvantage was minimal.

The PA survey (Chapter 7) included a large sample of adults reporting a range of rheumatic diseases derived from a socioeconomically deprived inner-city area [423], and is one of the first surveys of PA in rheumatic

diseases in the UK. It used an internationally validated and reliable PA questionnaire (IPAQ) [399], facilitating comparison with international data, and enabling translation of PA participation into MET minutes per week and thus assessment against updated PA guidelines [114].

Nevertheless, the sample was derived from a single inner-city hospital, and therefore the results may not be generalized to rural populations, which typically report lower levels of PA [194]. Moreover, participation was voluntary, and thus the sample may be biased toward more active respondents comfortable in declaring their PA participation. Furthermore, self-report measures may overestimate PA compared to objective measures, such as accelerometry [367], although accelerometry does not capture all PA (thus underestimating energy expenditure) [405], potentially explaining some of the discrepancy between objective and self-report measures.

8.4 FUTURE RESEARCH

Whilst this thesis reports the development and testing of the efficacious EXTRA programme for people with RA, a cost utility analysis from a healthcare perspective is required to establish the cost-effectiveness of the EXTRA programme compared to usual care, to inform integration of the programme into current clinical practice.

Further development of the EXTRA programme, incorporating participants' recommendations for increasing its acceptability, and a health economic analysis are required to confirm the findings of this thesis. A

definitive multi-centred RCT is warranted to establish the clinical effectiveness of the EXTRA programme among people with established, as well as early disease, in the long term. Future research should incorporate monitoring of upper limb articular erosive damage.

Future studies should seek to understand physical inactivity among people with rheumatic diseases. A larger scale, national survey is required to establish the PA levels of rural as well as inner-city UK adults with rheumatic diseases using self-reported and objective measures of PA. A qualitative evaluation is required to identify, from the patients' perspective, how the health service and HCPs might provide further help to patients to increase their PA levels and, from the clinicians' perspective, what training/help is required to facilitate the provision of PA advice to patients.

9 Conclusions of the Thesis

- An integrated ‘Education, self-management, and eXercise Training programme for people with early Rheumatoid Arthritis’ (the EXTRA programme) improved upper limb disability, function, pain, strength, and self-efficacy, but not quality of life, and had no adverse effects on disease activity, among people with early RA compared to a usual care control group.
- An integrated ‘Education, self-management, and eXercise Training programme in early Rheumatoid Arthritis (the EXTRA programme) improved self-efficacy and pain, but not disability, function, strength, or quality of life, in the longer-term, compared to a usual care control group.
- Overall, the EXTRA programme was acceptable to participants. They perceived that the EXTRA programme improved their disease status and provided an effective RA self-management strategy.
- Nearly two thirds of inner-city adults with rheumatic diseases met the updated physical activity guidelines, but most of those who did not meet the guidelines were entirely inactive.
- Less than half of respondents reported ever receiving physical activity advice from a healthcare professional, and many would like help to become more physically active.

10 Dissemination of Research and Research Awards

10.1 PEER REVIEWED MANUSCRIPTS

- Manning, V.L., Hurley, M., Scott, D. & Bearne, L. **Are our patients meeting the current physical activity guidelines? Physical activity participation, recommendation, and preferences among inner-city adults with rheumatic diseases**. (Accepted for publication: *Journal of Clinical Rheumatology*, August 2012)

10.2 CONFERENCE PRESENTATIONS

- Manning, V.L., Hurley, M., Scott, D.L. & Bearne, L. **Are patients meeting the updated physical activity guidelines? Physical activity participation, recommendation, and preferences among adults with rheumatic diseases.** *American College of Rheumatology* (Conference Proceedings), *Washington D.C., U.S.A* (2012) (Poster Presentation)

- Bearne, L. Manning, V.L., Scott, D.L. & Hurley, M. **A Brief exercise and self-management programme Improves upper limb disability in people with early rheumatoid arthritis.** *American College of Rheumatology (Conference Proceedings), Washington D.C., U.S.A* (2012) (Oral Presentation)

- Manning, V.L., Frith, J. & Bearne, L. **Understanding physical inactivity in the rheumatic diseases: The patients' perspective**. *Rheumatology, Glasgow, U.K.* (2012) 51:3-3 (Oral presentation)

- Bearne, L., Manning, V.L., Scott, D.L. & Hurley, M. **Exercise therapy in the management of upper limb dysfunction in rheumatoid arthritis**. *Rheumatology, Glasgow, U.K.* (2012) 51:16-17 (Oral presentation)

- Manning, V.L., Hurley, M., Scott, D.L. & Bearne, L. **Physical activity levels in adults with rheumatic conditions**. *World Confederation of Physical Therapists* (Conference Proceedings), *Amsterdam, Holland* (2011) (Oral presentation)

- Manning, V.L., Hurley, M., Scott, D. & Bearne, L. **Physical activity levels in adults with rheumatic conditions**. *King's College London, London, U.K.* (2011) (Oral presentation)

- Manning, V.L., Hurley, M., Scott, D. & Bearne, L. **Physical inactivity in adults with rheumatic conditions**. *Rheumatology, Brighton, U.K.* (2011) 50:34-34 (Oral presentation)

10.3 RESEARCH AWARDS

- **BHPR/Arthritis Research UK Silver Medal Research Prize 2012**
  Victoria L. Manning. Awarded for 'Physical inactivity among adults with rheumatic diseases: An evaluation of physical activity participation, recommendation, and preferences'.
  Rheumatology, Glasgow, U.K (May 2012)

- **World Confederation for Physical Therapy Outstanding Abstract and Presentation Award 2011**
  Victoria L. Manning. Awarded for 'Physical activity levels in adults with rheumatic conditions'.
  16th International Congress of the World Confederation of Physical Therapists
  Amsterdam, Holland (June 2011)

- **King's College London Graduate School Conference Fund Award 2011**
  Victoria L. Manning. Awarded to attend 16th International Congress of the World Confederation of Physical Therapists
  Amsterdam, Holland (June 2011)

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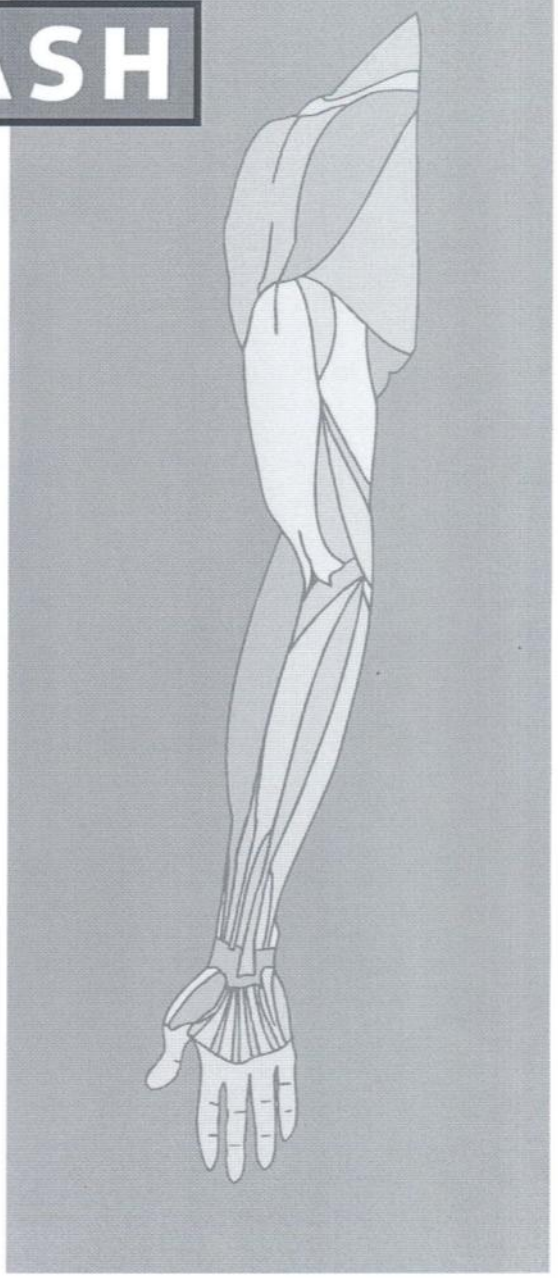
Appendices

Appendix A Disabilities of the Arm, Shoulder, and Hand Questionnaire

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE DASH



INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

DISABILITIES OF THE ARM, SHOULDER AND HAND

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\left[\frac{(\text{sum of n responses})}{n} - 1\right] \times 25$, where n is equal to the number of completed responses.

A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is:_____

p I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*.
If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_

O I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may not be calculated if there are any missing items.

Appendix B Ethical and Research and Development Approval

NHS
National Research Ethics Service
King's College Hospital Research Ethics Committee
Camberwell Building
King's College Hospital
94 Denmark Hill
London
SE5 9RS

27th of August 2008.

Dr Lindsay Bearne,
Lecturer in Physiotherapy,
King's College London,
Department of Physiotherapy,
3.25c Sheppard's House,
Guy's Campus,
London,
SE1 1UL.

Dear Dr Bearne,

Full title of study: **Rehabilitation of upper limb sensorimotor dysfunction and disability in patients with early rheumatoid arthritis; an assessor blind, pragmatic, randomised, controlled trial.**
Education and eXercise Training in early Rheumatoid Arthritis (EXTRA study)

REC reference number: **08/H0808/118**

Thank you for your letter of 08 August 2008, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). The favourable opinion for the study applies to all sites involved in the research. There is no requirement for other Local Research Ethics Committees to be informed or SSA to be carried out at each site.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	dated 13/06/2008	
Investigator CV	Lindsay Bearne	
Protocol		
Questionnaire: Euro-QoL		
Questionnaire: Arthritis Self-Efficacy Scale		
Questionnaire: DASH		
Questionnaire: RAQoL		
Questionnaire: Client Services Recipt Inventory	2	01 August 2008
Participant Information Sheet	2	01 August 2008
Participant Consent Form	2	01 August 2008
Response to Request for Further Information		08 August 2008
Client Services Receipt Inventory		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/H0808/118 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely,

Doctor Jewitt,
Chair.

Email: chris.ward@kch.nhs.uk

Enclosures: "After ethical review – guidance for researchers": *SL- AR2*

Copy to: *Dr Keith Brennan, King's College London*
R&D office for NHS care organisation at lead site

King's College Hospital NHS
NHS Foundation Trust

Directorate of
RESEARCH & DEVELOPMENT

King's College Hospital
Denmark Hill
London SE5 9RS

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Fax: 020 3299 3445
www.kch.nhs.uk

Dr Lindsay M Bearne
Lecturer in Physiotherapy
King's College London
3.25c Shepherd's House
Guy's Campus
London, SE1 1UL

Date: 3rd October 20008

Full Research & Development Approval

R&D 08RH04
Title: The rehabilitation of upper limb sensorimotor dysfunction and disability in patients with early rheumatoid arthritis – an assessor blind, randomised controlled trial
REC Number: 08/H0808/118

Dear Dr Bearne

Thank you for submitting your research project to the R&D Department. The project has now been approved by the Trust. Please quote the R&D registration number noted above in any communications with the R&D Department regarding your project.

Conditions of Approval:

- The Principal Investigator must notify R&D of the actual start and end date of the project.
- The Principal Investigator is responsible for ensuring that Data Protection Principles are observed throughout the course of the project.
- The agreed protocol must be followed. R&D must be notified of any changes to the protocol prior to implementation.
- The Principal Investigator and research team must have appropriate substantive or honorary contracts with the Trust. The Principal Investigator is responsible for ensuring that the team is covered, including new staff recruited to the study.
- If your study is a medicinal clinical trial all members of the research team must have completed GCP, Pharmacovigilance and Trial Master File training - please contact scott.vezina@kcl.ac.uk if training or annual updates are required.
- Please submit a copy of the progress report on the anniversary of the Ethics favourable opinion (sent via the CI)
- Please submit a copy of copy of confirmation of the extension of your honorary contract to cover the duration of the project as soon as this is available.

Trust approval for the research is subject to the research being undertaken in line with the Department of Health's Research Governance Framework, and Trust policies relating to Research Governance.

The Research Governance Framework and details of you and your researchers responsibilities within this framework can be found on the Department of Health's website at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

If appropriate it is recommended that you register with the Current Controlled Trials website; http://isrctn.org/

In line with the Research Governance Framework, your project may be randomly selected for monitoring for compliance against the standards set out in the Framework. For information, the Trust's process for the monitoring of projects and the associated guidance is available from the Trust's intranet or on request from the R&D Department. You will be notified by the R&D Department if and when your project has been selected as part of the monitoring process. No action is needed until that time.

Many thanks for registering your research project

Yours sincerely

Wendy Fisher
Research and Development Manager (non-commercial)
Research and Development Department
Kings College Hospital NHS Trust
First Floor Jennie Lee House, 34 Love Walk
London SE5 8AD

R&DRegistration@kch.nhs.uk

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28 July 2009

Dr Lindsay Bearne
Lecturer in Physiotherapy
King's College London
Lecturer in Physiotherapy
Department of Physiotherapy
3.25c Sheppard's House
Guy's Cmapus, London
SE1 1UL

Dear Dr Bearne

Study title:	**Rehabilitation of upper limb sensorimotor dysfunction and disability in patients with early rheumatoid arthritis - an assessor blind, pragmatic, randomised, controlled trial Education and eXercise Training in early Rheumatoid Arthritis study (EXTRA study)**
REC reference:	**08/H0808/118**
Amendment number:	**1**
Amendment date:	**13 July 2009**

The above amendment was reviewed on 27 July 2009 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	2	
Notice of Substantial Amendment (non-CTIMPs)	1	13 July 2009

Membership of the Committee

The members of the Committee who took part in the review were Dr David Jewitt and David Rushton.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H0808/118:	Please quote this number on all correspondence

Yours sincerely

Chris Ward
Committee Co-ordinator

E-mail: Chris.Ward@kch.nhs.uk

10 Nov 2009

King's College Hospital NHS
NHS Foundation Trust

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:

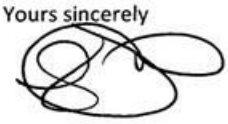
Acknowledgement of Amendment

R&D: 08RH04
Title: Rehabilitation of upper limb sensorimotor dysfunction and disability in patients with early rheumatoid arthritis – an assessor blind, pragmatic, randomised, controlled trial of Education and Exercise Training gin Early Rheumatoid Arthritis (EXTRA Study)
REC Number

Dear Dr Bearne

Thank you for submitting your recent amendments. I can confirm that these do not change the terms of your R&D Approval here at Kings. You may implement the new protocol, which changes your inclusion/exclusion criteria with immediate effect.

Yours sincerely



Jamie Peterson
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Prof. Andrew Cope
Professor of Rheumatology and Consultant Rheumatologist
New Hunt's House
Guy's Hospital Campus
King's College London
London
SE1 1UL

26 September 2012

Dear Prof. Cope,

Title: Education and eXercise Training in early Rheumatoid Arthritis (EXTRA)

In accordance with the Department of Health's Research Governance Framework for Health and Social Care, all research projects taking place within the Trust must receive a favourable opinion from an ethics committee and approval from the Department of Research and Development (R&D) prior to commencement.

- **Ethics number:** 08/H0808/118
- **Sponsor:** KCL
- **Funder:** Physiotherapy Research Foundation
- **Anticipated End date:** 01/09/2012
- **Protocol:** Version 2 01/07/2009
- **Incorporating Amendment:** 1 01/07/2009
- **Site:** GSTFT
- **R&D approval Date:** 01/12/2009

R&D have reviewed the documentation submitted for this project and I am pleased to inform you that we are approving the work to proceed within Guy's and St Thomas' NHS Foundation Trust and has been allocated the Trust R&D registration number **RJ109/N230**. Please quote the R&D registration number in any communications with the R&D Department regarding your project.

Conditions of Approval:

- The principal investigator must notify R&D of the actual end date of the project.
- The Principal Investigator is responsible for ensuring that Data Protection procedures are observed throughout the course of the project.
- The project must follow the agreed protocol and be conducted in accordance with all Trust Policies and Procedures especially those relating to research and data management.
- R&D must be notified of any changes to the protocol prior to implementation.
- Please submit a copy of the progress report on the anniversary of the Ethics favourable opinion (**Anniversary of the Ethics approval 27th August**)

If appropriate it is recommended that you register with the Current Controlled Trials website; http://isrctn.org/

Please ensure that you are aware of your responsibilities in relation to The Data Protection Act 1998, NHS Confidentiality Code of Practice, NHS Caldicott Report and Caldicott Guardians, the Human Tissue Act 2004, Good Clinical Practice, the NHS Research Governance Framework for Health and Social Care, Second Edition April 2005 and any further legislation released during the time of this study.

Members of the research team must have appropriate substantive or honorary contracts with the Trust prior to the study commencing. Any additional researchers who join the study at a later stage must also hold a suitable contract.

If the project is a clinical trial under the European Union Clinical Trials Directive the following must also be complied with:

1. The EU Directive on Clinical Trials (Directive 2001/20/EC) and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Regulations 2004;
2. The EU Directive on Principles and Guidelines for Good Clinical Practice (EU Commission Directive 2005/28/EC); and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006;

Amendments
Please ensure that you submit a copy of any amendments made to this study to the R&D Department.

Annual Report
It is obligatory that an annual report is submitted by the Chief Investigator to the research ethics committee, and we ask that a copy is sent to the R&D Department. The yearly period commences from the date of receiving a favourable opinion from the ethics committee.

Should you require any further information please do not hesitate to contact us.

In line with the Research Governance Framework, your project may be randomly selected for monitoring for compliance against the standards set out in the Framework. For information, the Trust's process for the monitoring of projects and the associated guidance is available from the Trust's intranet or on request from the R&D Department. You will be notified by the R&D Department if and when your project has been selected as part of the monitoring process. No action is needed until that time.

Many thanks for registering your research project

Yours faithfully

Harpreet Grewal
R&D Governance Coordinator

cc. Chief Investigator
cc. Sponsor

King's College Hospital Research Ethics Committee
Camberwell Building
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94 Denmark Hill
London
SE5 9RS

Tel: 0203 299 3923
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5th May 2009

Miss Victoria Manning
Division of Applied Biomedical Research
3.11 Shepherd's House
Guy Campus
King's College London
London SE1 1UL

Dear Miss Manning

Full title of project: **Are patients with rheumatoid arthritis fulfilling the exercise recommendations in the NICE guidelines?**

Thank you for seeking the Committee's advice about the above project.

You provided the following documents for consideration:

Correspondence of 21st April 2009

This document has been considered by the Chairman who has advised that the project is not one that is required to be ethically reviewed under the terms of the Governance Arrangements for Research Ethics Committees in the UK.

Although review by a Research Ethics Committee is not required, you should check with the R&D Department whether management approval is required before the project starts.

Yours sincerely,

Will Bowen
Committee Co-ordinator

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Appendix C EXTRA Study Baseline Assessment Form

EXTRA PROGRAMME –

PATIENT BASELINE ASSESSMENT FORM

Date: **Assessment Period: 0** (Week)

Patient Code: **Assessor's Initials:** / /

SECTION 1: **PATIENT DETAILS**		
Name:		
Hospital Number:		
Address:		
Post Code:		
Telephone:	**Home:**	
	Mobile:	
	Work:	
	E-mail:	
Date of Birth:	/ /	
If Working, Current Occupation:		

SECTION 2: **GENERAL HEALTH AND MEDICAL**	
Hospital:	*KCH / Guy's / St. Thomas' / Lewisham*
Consultant:	
Name of GP:	
Address of GP:	
Postcode of GP:	
Telephone of GP:	
Date of RA Diagnosis:	
RA Medication:	

Medical History:	**Please Circle:**	**Notes/Medication:**
Other Arthritis (Osteoarthritis, Psoriatic, etc.)	Yes / No	
Osteoporosis	Yes / No	
Chronic Obstructive Pulmonary Disease (COPD), Acquired Respiratory Distress Syndrome (ARDS), Asthma or Emphysema	Yes / No	
Angina	Yes / No	
Connective Heart Failure	Yes / No	
Peripheral Vascular Disease	Yes / No	

Stroke, TIA	Yes / No	
Diabetes	Yes / No	*type I / II*
Upper Gastrointestinal Disease (Ulcer, Hernia, Reflux)	Yes / No	
Neurological Disease (MS, Parkinson's, Epilepsy)	Yes / No	
Depression	Yes / No	
Anxiety or Panic Attacks	Yes / No	
Visual Impairment (Cataracts, Glaucoma, Macular Degeneration)	Yes / No	
Hearing Impairment (Very Hard Of Hearing)	Yes / No	
Degenerative Disc Disease (Back Disease, Spinal Stenosis, Severe Chronic Back Pain)	Yes / No	
Obesity (BMI > 30)	Yes / No	
Allergies:	Yes / No	
Smoker:	Yes / No	*How many per week?*
Pregnant or given birth in the last 3 months:	Yes / No	*How many weeks ago?*
Weight (kg):		
Height (cm):		
BMI (kg/m²):		
Any other information that the patient believes might be relevant before starting an exercise programme:	Yes / No	

SECTION 2 ASSESSOR'S NOTES:	

SECTION 3: **OUTCOME ASSESSMENT**

DISEASE ACTIVITY:	
Hand Dominance:	*Right / Left*
Length of Morning Stiffness (mean/min/week):	
Fatigue Today:	

No Fatigue **Fatigue As Bad As It Could Be**

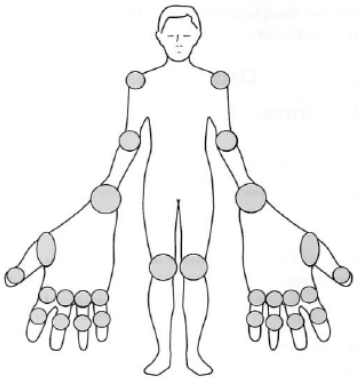
Score (mm):

DISEASE ACTIVITY – EULAR CORE DATA:

PAIN

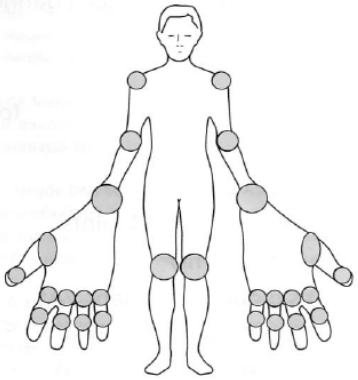
No pain _____ Pain as bad as it could be

Swollen Joints



Number ☐☐

Tender joints



Number ☐☐

ESR ☐☐☐ mm/hr

C-reactive protein ☐☐☐ g/l

PATIENT'S GLOBAL ASSESSMENT OF DISEASE ACTIVITY

Not active at all _____ Extremely active

ASSESSOR'S GLOBAL ASSESSMENT OF DISEASE ACTIVITY

(1-5): ☐ 1 = asymptomatic; 2 = mild; 3 = moderate; 4 = severe; 5 = very severe.

(Reference: Scott, D.L., van Reil, P.L., ven der Heijde, D. & Benke, A.S. (1995) Assessing Disease Activity in Rheumatoid Arthritis: The EULAR Handbook of Standard Methods, 2nd edn, Pharmacia AB, Uppsala, Sweden).

MAXIMUM ISOMETRIC VOLUNTARY STRENGTH (LYING SUPINE):				
	FLEXION		EXTENSION	
	RIGHT	LEFT	RIGHT	LEFT
WRIST				
1				
2				
3				
Max Score (N)				
ELBOW				
1				
2				
3				
Max Score (N)				
SHOULDER				
1				
2				
3				
Max Score (N)				

MAXIMUM ISOMETRIC VOLUNTARY STRENGTH CONTINUED (USING HAND TABLE):
(Patient's other hand should be rested on their lap)

RIGHT		LEFT	
HAND GRIP STRENGTH			
1		1	
2		2	
3		3	
Max Score (kg)		Max Score (kg)	

GLOBAL UPPER LIMB FUNCTION:		
ACTIVITY		TIME (SECONDS)
1. Dressing	1	
	2	
	3	
2. Eating	1	
	2	
	3	

GRIP ABILITY TEST:		
ACTIVITY		TIME (SECONDS)
1. Pour Water From Jug to Cup	1.	
	2.	
	3.	
2. Place Paper Clip on Envelope	1.	
	2.	
	3.	
3. Place Tube-Grip Over Non-Dominant Hand	1.	
	2.	
	3.	

SECTION 3 ASSESSOR'S NOTES:	

SECTION 4: EXERCISE OUTCOME EXPECTATIONS, HISTORY, AND GOALS

QUESTIONS TO BE DIRECTED TOWARD PATIENT:

1	**Where do you experience the most problems in your upper limbs; in your shoulders, elbows, wrists, hands?**
2	**With this in mind, do you have any goals you would like to work towards if you were to begin an exercise programme for your upper limbs?**
3	**What activities/exercises, if any, do you do at the moment?**
4	**Tell me about your exercise history, including any previous physiotherapy.**

COMPLETE QUESTIONNAIRES

SECTION 5:	**EXERCISE LIST**
PATIENT NAME:	**DATE:**
PATIENT CODE:	**ASSESSOR'S INITIALS:**

EXERCISE NUMBER	EXERCISE	SELECTED
1	PUTTY BALL SQUEEZE	
2	FINGER TIP PINCH	
3	FINGER HOOK AND SQUEEZE	
4	KNIFE AND FORK PUTTY CUTTING	
5	PAPER-CLIPS AND ENVELOPE CHALLENGE	
6	WRIST-ALPHABET	
7	BACK-SCRUB	
8	UP-AND-OUT OF CHAIR	
9	ARM CURL	
10	LIFT TO CHIN	
11	REACH BACK	
12	SIDE LIFT	
13	WALL-WASH SQUARES	
14	DOOR-PUSH	
15	SHOULDER ROTATION	
16	REACH TO SHELF	

SUGGESTED EQUIPMENT STRENGTH AND NOTES:		
EQUIPMENT	**STRENGTH**	**NOTES (PHYSIOTHERAPIST'S PROGRESSIONS/REGRESSIONS):**
THERA-BAND		
HAND PUTTY		

GENERAL NOTES FOR PHYSIOTHERAPIST'S ATTENTION:

Appendix D EXTRA Study Follow-Up Assessment Form

EXTRA PROGRAMME –

PATIENT 12W / 36W ASSESSMENT FORM

Date: **Assessment Period:** (Week 12 / 36)

Patient Code: **Assessor's Initials:** / /

SECTION 1: GENERAL HEALTH AND MEDICAL

	Please Circle:	**Notes/Medication:**
Any change in health since baseline assessment?	Yes / No	
Weight (kg):		
Height (cm):		
BMI (kg/m²):		

SECTION 1 ASSESSOR'S NOTES:	

SECTION 2: **OUTCOME ASSESSMENT**

DISEASE ACTIVITY:	
Hand Dominance:	*Right / Left*
Length of Morning Stiffness (average/mins):	
Fatigue Today:	

No Fatigue — **Fatigue As Bad As It Could Be**

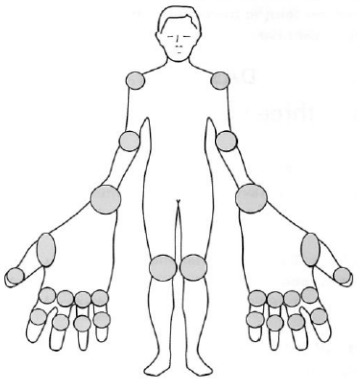
Score (mm):

DISEASE ACTIVITY – EULAR CORE DATA:

PAIN

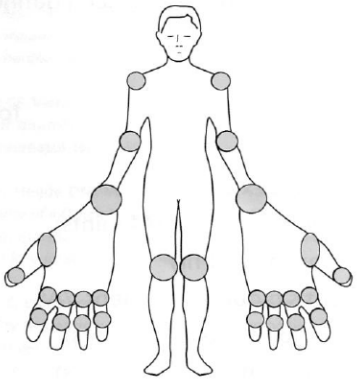
No pain _____ Pain as bad as it could be

Swollen Joints



Number ☐☐

Tender joints



Number ☐☐

ESR ☐☐☐ mm/hr

C-reactive protein ☐☐☐ g/l

PATIENT'S GLOBAL ASSESSMENT OF DISEASE ACTIVITY

Not active at all _____ Extremely active

ASSESSOR'S GLOBAL ASSESSMENT OF DISEASE ACTIVITY

(1-5): ☐ 1 = asymptomatic; 2 = mild; 3 = moderate; 4 = severe; 5 = very severe.

(Reference: Scott, D.L., van Reil, P.L., ven der Heijde, D. & Benke, A.S. (1995) Assessing Disease Activity in Rheumatoid Arthritis: The EULAR Handbook of Standard Methods, 2nd edn, Pharmacia AB, Uppsala, Sweden).

MAXIMUM ISOMETRIC VOLUNTARY STRENGTH (LYING SUPINE):				
	FLEXION		**EXTENSION**	
	RIGHT	**LEFT**	**RIGHT**	**LEFT**
WRIST				
1				
2				
3				
Max Score (N)				
ELBOW				
1				
2				
3				
Max Score (N)				
SHOULDER				
1				
2				
3				
Max Score (N)				

MAXIMUM ISOMETRIC VOLUNTARY STRENGTH CONTINUED (USING HAND TABLE):
(Patient's other hand should be rested on their lap)

RIGHT		**LEFT**	
HAND GRIP STRENGTH			
1		1	
2		2	
3		3	
Max Score (kg)		Max Score (kg)	

GLOBAL UPPER LIMB FUNCTION:		
ACTIVITY		TIME (SECONDS)
1. Dressing	1	
	2	
	3	
2. Food Handling	1	
	2	
	3	

GRIP ABILITY TEST:		
ACTIVITY		TIME (SECONDS)
1. Pour Water From Jug to Cup	1.	
	2.	
	3.	
2. Place Paper Clip on Envelope	1.	
	2.	
	3.	
3. Place Tube-Grip Over Non-Dominant Hand	1.	
	2.	
	3.	

SECTION 2 ASSESSOR'S NOTES:	

COMPLETE QUESTIONNAIRES

Appendix E Rheumatoid Arthritis Quality of Life Questionnaire

RAQoL

PLEASE READ THIS CAREFULLY

On the following pages you will find some statements
which have been made by people who have Rheumatoid Arthritis

We would like you to tick 'Yes' if the statement applies to you
and tick 'No' if it does not

Please choose the response that applies best to you
AT THE MOMENT

Please read each item carefully and tick the ***one*** response that applies best to you ***at the moment***

1. I have to go to bed earlier than I would like to

Yes ❒
No ❒

2. I'm afraid of people touching me

Yes ❒
No ❒

3. It's difficult to find comfortable shoes that I like

Yes ❒
No ❒

4. I avoid crowds because of my condition

Yes ❒
No ❒

5. I have difficulty dressing

Yes ❒
No ❒

6. I find it difficult to walk to the shops

Yes ❒
No ❒

7. Jobs about the house take me a long time

Yes ❒
No ❒

8. I sometimes have problems using the toilet

Yes ❒
No ❒

9. I often get frustrated

Yes ❒
No ❒

Please read each item carefully and tick the ***one*** response that applies best to you ***at the moment***

10. I have to keep stopping what I am doing to rest

Yes ❒
No ❒

11. I have difficulty using a knife and fork

Yes ❒
No ❒

12. I find it hard to concentrate

Yes ❒
No ❒

Please read each item carefully and tick the ***one*** response that applies best to you ***at the moment***

13. Sometimes I just want to be left alone — Yes ❒ No ❒

14. I find it difficult to walk very far — Yes ❒ No ❒

15. I try to avoid shaking hands with people — Yes ❒ No ❒

16. I often get depressed — Yes ❒ No ❒

17. I'm unable to join in activities with my family or friends — Yes ❒ No ❒

18. I have problems taking a bath/shower (Please answer for the one you usually use) — Yes ❒ No ❒

19. I sometimes have a good cry because of my condition

Yes ❒
No ❒

20. My condition limits the places I can go

Yes ❒
No ❒

21. I feel tired whatever I do

Yes ❒
No ❒

Please read each item carefully and tick the ***one*** response that applies best to you ***at the moment***

22. I feel dependent on others

Yes ❒
No ❒

23. My condition is always on my mind

Yes ❒
No ❒

24. I often get angry with myself

Yes ❒
No ❒

25. It's too much effort to go out and see people

Yes ❒
No ❒

26. I sleep badly at night

Yes ❒
No ❒

27. I find it difficult to take care of the people I am close to

Yes ❒
No ❒

28. I feel that I'm unable to control my condition

Yes ❒
No ❒

29. I avoid physical contact

Yes ❒
No ❒

30. I'm limited in the clothes I can wear

Yes ❒
No ❒

Thank you for taking the trouble to fill in this questionnaire.

Please go back to the beginning and make sure that you have ticked one response for each question

Appendix F Arthritis Self-Efficacy Scale

ARTHRITIS SELF-EFFICACY SCALE

Assessment Date: **Participant ID:**

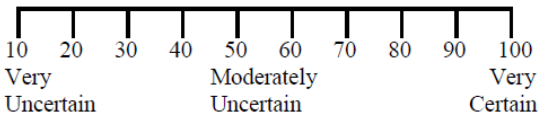
Assessment: *(circle one)* **Baseline/12W/9M** **Assessor's Initials:**

A. Pain Subscale

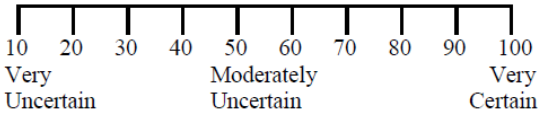
In the following questions, we would like to know how your arthritis pain affects you.

For each of the following questions, please **circle the number** which corresponds to your certainty that you can **now** perform the following tasks.

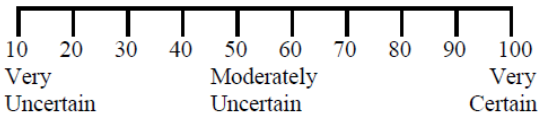
1a. How certain are you that you can decrease your pain quite a bit?



2a. How certain are you that you can continue most of your daily activities?



3a. How certain are you that you can keep arthritis pain from interfering with your sleep?

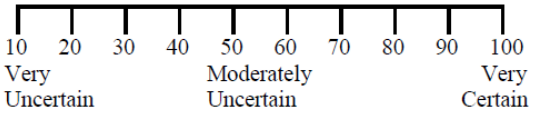


Arthritis Self-Efficacy Scale (Lorig et al., 1989)

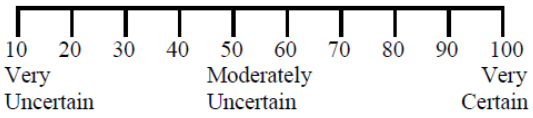
Reference: Lorig, K., Chastain, R.L., Ung, E., Shoor, S. & Holman, H.R. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis and Rheumatism. 1989. 32 (1): 37-44.

Page 1 of 6

4a. How certain are you that you can make a small-to-moderate reduction in your arthritis pain by using methods other than taking extra medication?



5a. How certain are you that you can make a large reduction in your arthritis pain by using methods other that taking extra medication?



B. Function Subscale

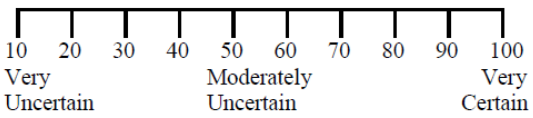
We would like to know how confident you are in performing certain daily activities.

For each of the following questions, please **circle the number** which corresponds to your certainty that you can perform the tasks **as of now**, **without** assistive devices or help from another person.

Please consider what you **routinely** can do, not what would require a single extraordinary effort.

AS OF NOW, HOW CERTAIN ARE YOU THAT YOU CAN:

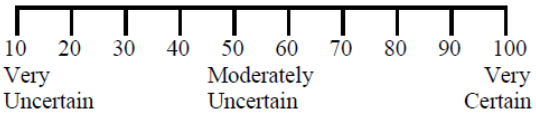
1b. Walk 100 feet on flat ground in 20 seconds?



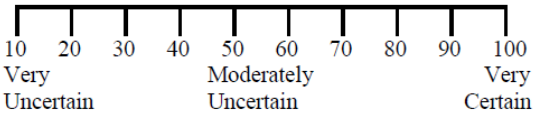
Arthritis Self-Efficacy Scale (Lorig et al., 1989)

Reference: Lorig, K., Chastain, R.L., Ung, E., Shoor, S. & Holman, H.R. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis and Rheumatism. 1989. 32 (1): 37-44.

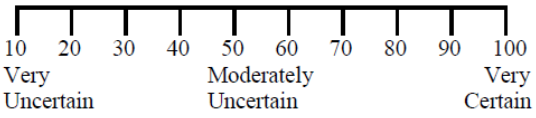
2b. Walk 10 steps downstairs in 7 seconds?



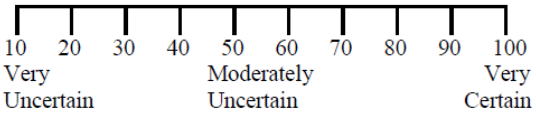
3b. Get out of an armless chair quickly, without using your hands for support?



4b. Button and unbutton 3 medium-size buttons in a row in 12 seconds?



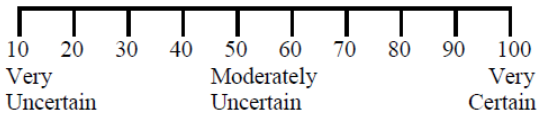
5b. Cut 2 bite-size pieces of meat with a knife and fork in 8 seconds?



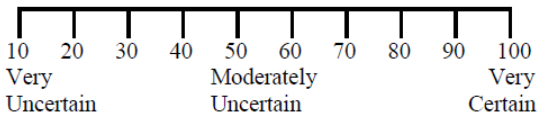
Arthritis Self-Efficacy Scale (Lorig et al., 1989)

Reference: Lorig, K., Chastain, R.L., Ung, E., Shoor, S. & Holman, H.R. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis and Rheumatism. 1989. 32 (1): 37-44.

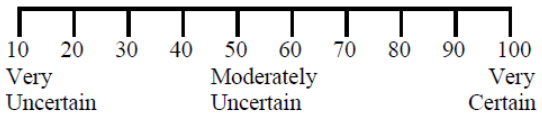
6b. Turn an outdoor tap all the way on and all the way off?



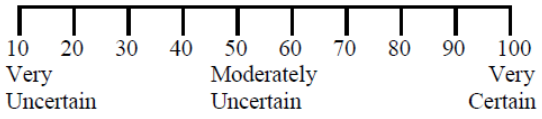
7b. Scratch your upper back with both your right and left hands?



8b. Get in and out of the passenger side of a car without assistance from another person and without physical aids?



9b. Put on a long-sleeve front-opening shirt or blouse (without buttoning) in 8 seconds?



Arthritis Self-Efficacy Scale (Lorig et al., 1989)

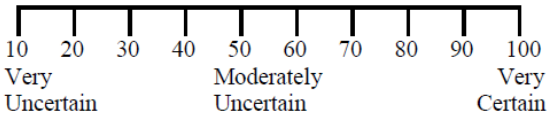
Reference: Lorig, K., Chastain, R.L., Ung, E., Shoor, S. & Holman, H.R. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis and Rheumatism. 1989. 32 (1): 37-44.

C. Symptoms Subscale

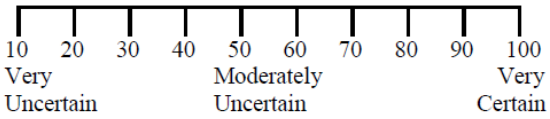
In the following questions, we would like to know how you feel about your ability to control your arthritis.

For each of the following questions, please **circle the number** which corresponds to the certainty that you can **now** perform the following activities or tasks.

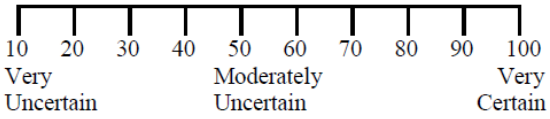
1c. How certain are you that you can control your fatigue?



2c. How certain are you that you can regulate your activity so as to be active without aggravating your arthritis?



3c. How certain are you that you can do something to help yourself feel better if you are "feeling blue"?



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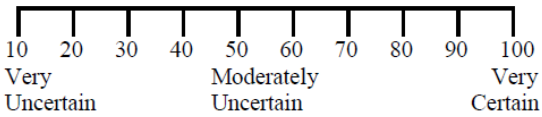
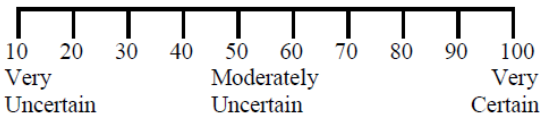
Reference: Lorig, K., Chastain, R.L., Ung, E., Shoor, S. & Holman, H.R. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis and Rheumatism. 1989. 32 (1): 37-44.

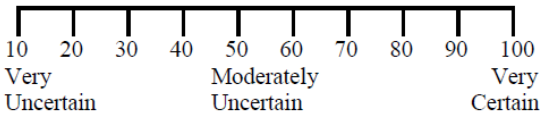
4c. Compared with other people with arthritis like yourself, how certain are you that you can manage arthritis pain during your daily activities?



5c. How certain are you that you can manage your arthritis symptoms so that you can do the things you enjoy doing?



6c. How certain are you that you can deal with the frustration of arthritis?



You have answered all of the questions. Thank you for taking the time to complete this questionnaire.

For Office Use Only:

Subscale	*Mean Score*
A. Pain	
B. Function	
C. Symptoms	
Total	

Arthritis Self-Efficacy Scale (Lorig et al., 1989)

Reference: Lorig, K., Chastain, R.L., Ung, E., Shoor, S. & Holman, H.R. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis and Rheumatism. 1989. 32 (1): 37-44.

Appendix G EXTRA Pilot Study Focus Group Transcript

Date: January 2009; Duration: 45.46 minutes
Interviewees: Patients (P1, P2, P3), all patients (GRP), physiotherapist (PT)
Interviewers: PI (VM), researcher (MH)

VM: Um...so first of all I just wanted to, you know, find out, you know when you were in, you were in the classes...
GRP: Yes
VM: ...and doing the exercises...
GRP: Yes
VM: ...and then, what, how did you feel about it? It was an enjoy...an enjoyable experience?
P2: It was a very enjoyable. I had a great [inaudible].
VM: Yeah?
P3: I must admit though, the first class for me was a trauma, it really was.
VM: Yeah.
P3: Because...
VM: Because you had the pain in the shoulder?
P3: The pain in the shoulder was so bad for the next forty-eight hours really.
VM: Yeah.
P3: Even a day.
VM: Yeah.
P3: But then I think I kind of went overboard.
VM: Yeah.
P3: Trying to keep up and doing things I shouldn't have.
VM: But you felt better after session two, once...
P3: Yeah.
VM: ...once...
P3: And today I feel quite good after.
VM: You felt quite good after doing it.
P3: Yes.
VM: Because today was the first day doing it sort of...
P3: Yup.
VM: ...the the ch...the modified way you know.
P3: That's right yeah. Because I couldn't cope with the um, the wall one, you know, that was...
VM: Um the wall wash squares.
P3: Yeah yeah. With the um band and that it was just...
VM: Too much.
P3: ...horrendous. I think that's where the damage was done to my shoulder. Not damage. Aggravation.
VM: Yeah the aggravation. Yeah.
P3: Because the damage was already there.
VM: Yeah.
P3: But um, that with the band pushing up there, really was...
VM: Was tough.
P3: It was tough.
VM: Yeah. So um, just to home in, so now, just focusing on the the, sort of, you know the, at the start of every session we always did a little talk, a sort of education thing...
P3: Mm.

VM: ...on different topics, and I just wanted to find out, sort of, how much of what we discussed you already knew about uh, and what um, and what things were were new to you. You know um, whether there were things that we touched on that you'd already sort of heard from other, kind of, groups that you've been to or anything like that, and...
P2: [cough]
VM: ...how beneficial you found those talks at the beginning, and what you thought about them. So what's everyone's views?
GRP: [pause]
P2: Well I think they were um, very beneficial...
P3: Yeah.
P2: [Cough]...beneficial.
VM: Did you? Did you find them quite sort of helpful or?
P2: Very helpful and uh, I I think I uh, [inaudible] improved.
VM: Good.
P2: [inaudible]
VM: Good.
P2: [inaudible]
P1: And also I felt that although you hear things and you've got them in the back of your mind...
VM: Mm.
P1: ...just to bring that awareness to the forefront I thought was very good.
VM: Yeah.
P1: [You know,] "Oh yes I've heard that before", you know, but you don't actually observe it that much...
VM: Yeah.
P1: ...[inaudible] very very different thing this time, it keeps going, and I feel better.
VM: Yeah, yeah.
P1: [inaudible]
VM: D...did you find it made you feel more confident as well in in...
P1: Yeah.
VM: ...in that uh, you know reassuring I suppose.
P1: Yes.
VM: Yeah.
P1: Well I haven't actually um, triggered off a rheumatoid disadvantage.
VM: No.
P1: [inuadible]
VM: Yeah.
P1: ...but that is quite different isn't it?
VM: Yeah.
P1: But that is quite a good tool to follow if you can.
P2: [cough]
VM: Yup.
PT: Um, did you find um, the level of detail, you know, too scant or too shallow or too deep or was it kind of right or was there...
P1: Uh...
PT: ...any area where...
P1: ...how to tell us what to do [inaudible].
VM: Yeah?
GRP: Mm.
PT: Was there any areas, in any of the education sessions, where you would have liked maybe more detail so, for example, when we were talking a little bit about today flare ups, would you have liked more detail about some of

the, kind of, physiology and anatomy side of things or did you think it kind of...

P3: That would have been useful I think, because if you know what's happening...

PT: Mmhm.

P3: ...you know, and not being, I mean, it's in your field, you know what's happening when we do these exercises. I think being told when these flare ups [inaudible] coming there and what part of you is not functioning.

VM: So a little bit more, kind of, biology [next] to it all?

P3: Yeah, I think that's always useful.

VM: Right.

P3: And I also learnt from this, too, I didn't know I had weaknesses in my two little fingers. It wasn't until the exercise you gave me...

VM: Mm.

P3: ...with that, that I realized that those were weak as well. Up until then, I thought it was just my index finger and my thumb.

VM: Yeah.

P3: So that has helped. That's why I felt those first two exercises were really for me personally, because...

VM: Yeah. You felt those really suited you.

P3: Yeah, really suited me.

VM: Mm.

P3: I think it's sorting out what suits you...

VM: Mm.

P3: ...and that can't be easy for you giving out different exercises.

VM: No well I...

GRP: [inaudible]

VM: ...I think that, you know, sometimes, d...different, you know, in your case, the exercises that you did that y...caused pain in the shoulder...

P2: [cough]

VM: ...um, in some ways they were very suited to you...

P3: Mm.

VM: ...because because if you, you know, you you were working, sort of, to, you know, to such, too much of an advanced degree...

P3: Mm.

VM: ...when you started, but by modifying them, they were right...

P3: Right.

VM: ...and think that's what we need to do...

P3: Yup.

VM: ...to strengthen through the shoulders.

P3: I think, when you modified them, which was on the second day...

VM: Then it, then they...yeah

P3: Then it started to, I feel uh, do a bit of good.

VM: Yeah. And and how did everyone feel about the actual, sort of, exercises themselves? Any comments on any particular exercises that you did? Because, really, everyone tried different exercises.

GRP: Mm.

P3: Yeah, we did.

VM: So any, sort of, comments? For example, Pat, you were doing the, you were doing some wrist, the wrist circles.

P1: Yeah.

VM: I mean, was, is there anything that you thought of that was a bit sort of complicated or a bit difficult to be able to do, or...

P1: No.

VM: ...um, or did you feel quite happy with all of them?

P1: The push ups from the chair were quite challenging, but then, on the other hand, I needed that challenge.
VM: Yeah.
P1: [inaudible]
P3: I agree with *[patient name [P1]]* there because I have done more push ups today...
P1: Yeah.
P3: ...than doing them at home. I think the, the business of rising from a chair, that would have been, perhaps, one of the things that was most beneficial for me.
VM: Mm.
P1: Mm.
PT: What about the um, the general set-up of the class? How, how we, kind of, structured the class? So uh, having the education at the start, and then the exercises...
P3: [inaudible]
PT: ...and [inaudible] um...
P3: Mm.
PT: ...how'd you find that structure?
P3: Yes, I felt that, I was a little confused today [laugh].
VM: [inaudible]
P3: The time I needed um...
PT: Yeah, yeah.
P3: ...I really needed Vicky to take me through...
P2: [cough]
P3: ...because I got confused, what I'd done and what I hadn't done. I think it's an age thing, you know.
GRP: [laugh]
PT: Do you think that was the diary? It wasn't easy for you to see what you had and hadn't done or...?
P3: [inaudible] I [inaudible] thinking, "now what did I do before that? I don't know". You get a, well I did anyway, I get a little confused of what I'd done, and whether...
VM: I know what you mean because...
P3: [laugh]
VM: ...if you were working through it in a, sort of, circuit...
P3: Mm, yup.
VM: ...rather than doing one exercise, finishing that, and then moving onto the next one.
P3: But that was good because it gave a rest for the uh, the muscles before you go back.
VM: Go back...
P3: So it was beneficial, it's just confusing to begin with.
VM: So, if I, if I just ask you, which which way did you prefer? So, i...i...the first two sessions, we did it more, we just...
P3: Yeah.
VM: ...let everyone get on work through your repetitions. The last two sessions, we did more of a timed approach.
P1: Mm.
VM: Which one do you think you preferred doing, and and...
P3: It's hard...
VM: ...or did you like both?
P3: ...or would I get used to this session?
P1: Mm.
P3: It's because we've done it the other way.

VM: Yeah.
P3: I don't know really, but what do you think *[patient name [P2]]*?
P2: Well, well, I I quite enjoyed the...
P3: The the timing?
P2: ...the timing....
P3: Yes, perhaps, did you feel that *[patient name [P1]]*?
P2: ...because I was...
P1: I...I don't mind either way.
VM: Either way, you didn't mind?
P1: No.
P3: Yeah.
P2: ...because I felt I was achieving more each time.
VM: [inaudible]
P3: Right, because you're working under a time?
P2: Yeah [inaudible].
GRP: [laugh]
P1: But then I...I...I do my hand exercises separately.
VM: Mm.
P1: I do my [difficult] before...
VM: Yeah.
P1: [inaudible]
VM: So you've got a, sort of, set order that you like to do them in? So it's quite nice to, sort of, get them out...
P1: Yes, yes.
VM: So everyone really, so perhaps it's quite good to include both in the class...
GRP: Mm.
VM: ...because everyone can learn which one they prefer...
P1: Yes.
P2: Mm.
VM: ...and then perhaps do that, do it that way at home if they want to.
GRP: Yeah, yeah.
PT: H...hopefully, at least with that timed clock, it allows for tuning the um, toward which you do the exercises.
P1: Yes.
PT: Which means that, you know, *[patient name [P2]]* might have liked to do wrist-wrist...
GRP: Mm.
PT: ...shoulder-shoulder exercises, and you might have liked to go through one at a time...
P2: [cough]
PT: ...and and and then you have a particular order as well, which makes you remember them, for example. So you might always think, "I do my two finger ones, and then I wrist ones, and then I do shoulder one, and then I do", you know, and that might be an easy way for you to remember it. So, hopefully, the class structure we did today, facilitates being able to do them...
P3: Mm.
PT: ...how you might do them at home.
P3: Mm. But I think it's also how you're feeling. Some days you'll think, "right, I can cope with that today"...
VM: Yeah.
P3: ...but you couldn't the day before. And I think if you can be given that choice of doing, like you did today...
VM: Yeah.
P3: ...which do you want to do first?
VM: So you can do it in whichever order.

P3: That's right.
PT: Yeah.
VM: Um...
P3: I found it easier today by doing the difficult ones, because I was getting very tired, and I knew, ahead of me, I had my more, my more simple ones.
VM: Yeah, yeah, so you you...
P3: Mm.
VM: ...knew that. Um, how did everyone feel about the actual handbook? But, I mean, that's going to be changed to something [inaudible]...
P3: Mm.
VM: ...because it was a very rough version.
P3: Mm.
VM: Um, it's going to be a lot more, it's going to be chapters, and page numbers, and the, a...a...and...
P3: [inaudible]
VM: ...and the handouts are changing...
P3: Yeah.
P2: Right.
VM: ...so they're a little bit more interesting looking and...
P3: Right.
VM: ...uh...
P3: [inaudible]
VM: ...and adding bits in.
P3: Will you still be keeping the diary at the, the back?
VM: The diary will be, will be um, the same.
P3: Yeah.
VM: But we might modify that based on some of the comments...
P3: Yeah.
P2: [cough]
VM: [inaudible]
P3: Yeah, could have a little more room...
VM: More room?
P3: ...to put the comments down.
VM: Yeah.
P3: Or put uh, perhaps numbers, "exercise eight was good today or bad today". Something like that.
VM: Yeah, yeah.
PT: Mm.
VM: So, that's all going to change. What about...
P2: [cough]
VM: ...did you find the pictures quite useful?
P2: Oh yeah, definitely.
P3: Yeah.
VM: Yeah? So, they were useful in helping...
P1: When I take my blank sheet home, I actually think to write in more [inaudible]...
VM: The exercise names. Yeah.
P3: That's what I want too *[patient name [P1]].*
P1: Cause I forgot the numbers.
PT: Just the numbers, which, wasn't enough to get you to remember which was which.
P1: No, no.
P3: I found that.
P1: [inaudible]
VM: Yeah.

GRP: [inaudible]
P1: [laugh]
PT: The other question I noted down, that you mentioned *[patient name [P1]]* was there was a bar across the top which had an example of sort of sets and repetitions and...
P1: [inaudible]
PT: No, no [inaudible]...
VM: No, no, that's a valued comment.
PT: ...in getting everyone's sort of, personal experiences with it is important so um, yeah, y...you just kind of mentioned that you felt it was, perhaps a suggestion of what you sh...how many reps...
P3: Yeah, I agree with *[patient name [P1]]* there, yeah.
VM: Yup, so that's something to, that's im...im...
PT: Maybe a b...bit misleading, maybe.
VM: Yeah.
PT: Okay.
P1: [inaudible]
VM: Yeah, as as if you should be doing, sort of, you know...
P1: That's my aim.
VM: Yeah. Okay, right.
P1: Did anybody else?
P3: Mm, I found that.
P1: Did you [patient name [P2]]?
VM: Yeah, so that's definitely worth something taking out.
GRP: Mm.
VM: Um, so, and and the actual handouts for the classes, were were they quite helpful, or do you think they could be, sort of, changed...
P3: What are we talking about here?
VM: You know for each class you were given a sort of handout? So, for today it was, flare up handout, you know...?
P3: Oh yes.
P2: [inaudible]
P3: I'm trying to think of something...
P2: [cough] Sure.
P3: No [inaudible]...
VM: [inaudible] sort of goal setting...
GRP: [inaudible]
VM: Did you find them fairly, sort of...
P3: Yeah.
VM: ...useful and clear or...?
P2: Oh yes.
PT: Because they're there for you to refer back to also, as well.
VM: Yeah.
P2: That's right.
VM: And there, sort of, there for you if you want to go back on something.
PT: Is there any other information um, that we talked about in the education sessions um, for example, you know um, that you like in the handbook? I don't know, you know, some of the things that you mentioned...
P3: What do you mean, other treatments, you saying or...
PT: Um, not other treatments but just, sort of, you know, sort of, information that would be useful for you to, kind of, be able to have with you, to read back over in the booklet? You know how we had the management of a flare up?
P3: Yes.
PT: And that will also be quite handy to refer back to at anytime.
P3: It would, yes.

PT: To remind you.
P3: Yeah.
PT: Was there anything else that we talked about, that might be also handy to have in there?
P3: I can't think of anything at the moment.
GRP: [pause]
PT: So, you mentioned that um, some more detail on the actual, on on rheumatoid arthritis itself um...
P3: [inaudible]
PT: ...so, would something like that in the handbook as well...
P3: Yes.
PT: ...be...
P3: That would be useful.
PT: So if there was some more information, just bullet points even it would be [inaudible].
P3: I know you can't differentiate between the two really, but having both rheumatoid and osteo um, it's difficult to line up one pain against another.
PT: Mm.
P3: I'm getting used to the idea now, I'm coping and I think, "well that's the osteo, not the rheumatoid". It's when you've got both, it's very difficult...
GRP: [cough]
P3: ...to differentiate the two.
PT: The difficulty is they affect the same structures?
P3: I know.
PT: The joints...
P3: But they're both in pain.
PT: Yeah, mm [inaudible].
P3: But I mean I, how you would do that, I've got no idea [inaudible] [laugh].
VM: Um.
P2: [clear throat]
VM: So thinking back, you know when you all first came in for your initial assessment?
P3: Yes.
VM: I just wanted to, sort of, get a bit of feedback as to what you thought about that first assessment. You know when you came in here and we did the, sort of...
P3: Mm.
VM: ...tests? You know, the the cutting of the putty and all, and all...and and testing the range of movement and all, how did you find that, sort of, process? It was quite time cons...it was quite time consuming.
P3: It was wasn't it? Yeah.
VM: I just wanted to see what everyone, sort of, felt about that.
P3: Mm.
P1: Well, I didn't know what set of exercises you were going to uh, prescribe.
VM: No, not at that point, no.
P1: So, I thought you interpreted that for me very very well.
VM: Oh, good.
P1: Mm.
VM: Good. So um, and you didn't find the assessment too sort of uh, long?
P1: Not really, no, no.
VM: No.
P1: If I'd been out in ten minutes, I'd wonder why [inaudible] really.
VM: Yeah, yeah.
P3: [inaudible] [laugh]

VM: No, well. I mean, you know, it is quite, there are a lot of quite, you know, everything's sort of, weren't there and a lot of things to go through so...
P1: So, unless you know [inaudible]...
VM: ...it's difficult to...
P1: ...you've got to answer all the questions...
VM: Yeah.
P1: ...and go through all the exercises...
VM: Yeah.
P1: ...[inaudible].
P3: We did say, didn't we? Why did finance come in to our assessment? Didn't we?
P2: [inaudible]
VM: Oh yes, yes the finance questionnaire.
GRP: [inaudible]
P3: And I couldn't see why, unless of course the national health are gonna give us grants for the [inaudible].
GRP: [inaudible]
VM: [inaudible] the context, because rather than just do a class for the sake of doing them, we want to see how it would fit in on a financial level as well, which is obviously important.
GRP: [inaudible]
VM: You know we were doing the CRSI, which is the the the um, financial...
GRP: Income.
VM: Yeah, income. When we were talking about your income...
P3: I couldn't see what it had to do with it really.
VM: And and uh, all those things it's just to, as I say, put the whole programme into into sort of context. So that we can see how it would actually work um, practically, rather than just being a, kind of, so this programme's...
GRP: [cough]
VM: ...not just a pie in the sky idea, but you can actually fit it in in a real life, sort of, context. So that's why we go through all of that.
P3: Mm, so really, you're seeing how we are dealing with it if we were in constrained circumstances, aren't you really?
VM: Yeah, I mean in a, in in any...
P3: What you're saying, how economically you're coping with your problems.
VM: Mm, yeah.
P3: So you needed to know our income because of that.
VM: And all that sort of thing, yeah.
P3: Mm.
MH: I think it's also the fact that what we what we've found, among other things, is that uh, people think arthritis is, people just carry on with it. What you actually find is that they're doing all sorts of things to adapt their lives...
P3: Mm.
MH: ...and cope with it...
P3: Right.
MH: ...and very often, people are having to spend quite a lot of money...
P3: Right, that, yeah.
MH: ...uh, in all sorts of ways. So, we're trying to get a hands on that, and adapt that particular, kind of, questionnaire a bit to try and explain...
P3: Right, which is why you asked what we had paid out for...
MH: Yeah.
P3: Like a rail on the stairs, a bath rail, because that's why, for a minute, I thought somebody was going to offer me a [budget] income there.
GRP: [laugh]
MH: [laugh] No, you won't be having [inaudible].

P3: That's why I thought, "well, why does this come into it?" and you wanted to know the cost, didn't you...
VM: Mm.
P3: ...of a handrail that we had put up [inaudible], etcetera.
VM: Yeah. It's all, it's all as as as Mike said, it's all, you know, trying to, sort of, find out...
P3: [inaudible]
VM: ...what implications arthritis has in in in everyone's, sort of, everyday lives, as well as...
GRP: Mm.
VM: ...as well as everything else. Um...
P1: I think people who've got a better income...
P3: Mm.
P1: ...generally might fair better...
P3: Mm.
P1: ...because if they need stuff, they can pay for it.
GRP: [inaudible]
P1: They can't actually pay [inaudible].
P3: That would be useful question, excuse me [inaudible]...
VM: [laugh]
P3: Um, that would be useful for somebody who is very, in very dire straits. Would they get any help because of that?
P1: I think they would.
P3: They would?
P1: Mm.
P3: Oh right, good [inaudible].
MH: I think one of the things is we need to document that. Otherwise, the government's never gonna listen and help at all.
GRP: Mm.
P3: Mm.
MH: So that's just a ways of doing that, in in in a, kind of, structured way if you like.
P3: Yeah.
MH: And also uh, we ask you about, not just how much you've paid out but how much healthcare you've used so how many time you've been to the doctor...
P3: Yeah. Oh yes.
MH: ...[inaudible] bits and all the rest of it.
P3: Cause you did ask me how many visits to the doctor had been made in that year.
MH: But it is very rough estimate, you know.
P3: [inaudible]
P1: [inaudible]
P3: No no, it didn't worry me. It just...
P1: Yes.
P3: ...all it, we did say was, "how does that come into the survey and treatment?"
P1: But people who are ill, generally, spend more money, on that sort of area...
P3: Yeah.
P1: ...because it's important to them.
P3: Yeah.
VM: So, obviously when when we're running this this programme, and it'll start at at some point in February um, what we'll do, like all you have done uh, the patients will come in for four exercise sessions, and then, hopefully, carry on with their exercise programme...
P3: [inaudible]
VM: ...at home for the following...

P3: Mm.
VM: ...sort of um, two and half months, and then we'd ask them to come in again...
P3: Mm.
VM: ...and we'd reassess them to see, you know, how their strength has changed, range of movement, all these things that we measured in the initial assessment. How how how the programme had benefited them. So obviously we, we can't ask you to come in in, sort of, three months time, cause by then, the main study will be up and running.
P3: That's it.
VM: But, what what we would like to do is, hopefully, ask you to come in in, sort of, in a couple of weeks, and I've got a date down on the forth of February, I don't know if anyone's got their diaries with them or they know [inaudible].
GRP: [inaudible]
P3: What day of the week that is?
VM: Uh, it's a Wednesday.
GRP: Wednesday.
P3: No, Wednesday's out. We baby sit on Wednesdays.
VM: So Wednesday's a no, Wednesday's a no.
P2: [inaudible]
P3: [inaudible]
VM: Right, how about you *[patient name [P1]]*, is a Wednesday sort of...
P1: I think I could come on a Wednesday.
VM: Cause what I'd like to do is, hopefully, you'll all feel really, sort of, inspired after doing the exercise programme, and you'll, sort of, go home and carry on doing the exercises, and then you'll come in, and then we can, sort of, see see see how things have changed.
P2: Mm.
VM: So that's the, that's the plan. Would you all be happy to do that, to come back in again...
GRP: Mm.
VM: ...and, to be reassessed?
P2: Yup.
VM: Yeah?
P3: So be reassessment?
VM: Reassessment, so doing the same, essentially the same assessment we did when you came in the first time, but doing it again to see how the, how all the values have changed and how things...
P3: So you think there should be a big change...?
VM: ...the improvement.
P3: Right.
VM: I mean obviously, you know, you're coming in, it'll be, in, sort of, three weeks. So it won't be as large an improvement as if you came in in three months, if you see what I mean, but it still, hopefully, we'll see an improvement. So uh, I'll have to sort that out, we'll get a diary and hopefully we can, kind of, book book everybody in to come in again. Um, well I think those are, can you think of any questions Mike that you w...
MH: I...I'd like to a...ask just sort of a few general points. Has...has anybody talked to you about exercise before?
P3: Yup.
MH: You...you....you seem...
P3: [inaudible]
P2: Well we go to a seated exercise class every Monday.
P3: But we haven't been since we've been going here because I couldn't go to both of them [laugh].

P2: [We can't do both of them].
MH: Are you going there because someone said it, or because [inaudible]?
P3: It's a local um uh, association, 'JOY', I don't know if you've heard it. It's, they get a grant from the government.
MH: Mmhm.
P3: It's seated exercise for the over sixty-fives.
MH: Mmhm.
P3: And we felt that we were getting very sluggish...
MH: Mmh.
P3: So that's why we joined, and it's not just the exercise, it's the social side...
MH: Yeah.
P2: There's about twenty in the class.
P3: ...side. Yes. And they have other classes, Tai-Chi, and things like, all for people. I think it was very good for our age group, because sometimes people don't know about these things.
P2: I think it's mainly they're for anyone over fifty in there.
P3: Well uh, Tai-Chi is but I think the, is seated exercise?
P2: Seated exercise is [inaudible] mainly for over fifties.
P3: [inaudible]. And it's a very modest kind of price. We pay a pound per session.
MH: Right.
P3: And we've got a lot of benefit from that.
MH: Right.
P3: And uh, so that is how we get, it was advertised locally, it was the [inaudible] association [inaudible]. They're just like, well they're, they get grants, government grants to run these projects and and it continued, didn't it?
P2: Mm.
P3: It was so successful. We've been in it over two years now.
MH: Right, okay.
P3: [cough] But...
MH: You *[patient name [P1]]*, do you do anything like that or do you...?
P1: Uh, only when um, I have a problem, like my back problem.
MH: Yeah.
P1: I go to King's physio, and and I get exercise sheets, which are helpful as well.
MH: Right.
P1: So.
MH: And do you think you carry on with the exercises? Because, what we tend to find is that people are...
P1: Drop off.
P3: Mm.
MH: ...keen on the exercise, and they drop off...
P3: Mm.
MH: ...their motivation drops off, they haven't got much to shout about.
P1: Well...
MH: Is is is that a [motivator] or?
P1: This this um, exercise, as I say, because it's not pain related, I think it's human nature, if you don't have the pain, you don't...
P3: That's true *[patient name [P1]]*, [inaudible] yup.
P1: [inaudible] but, I find because this isn't pain related...
VM: No.
P1: ...it's just, generally, to feel better and keep everything...
P3: Mm.
P1: ...moving, I'm actually, I feel more motivated to do it.
MH: Mmhm. Mmhm.

P1: Um, I have got lazy with my back exercises, but if I even a twinge, which I do, several times in the a night...
VM: [inaudible]
P1: ...for a week, I'm definitely doing those exercises every day, warding off the problem really.
VM: Mm. Mm.
P1: And they do that.
VM: You do, you do a lot of walking, you're quite active...
P1: Yes.
VM: ...but not so much with your upper body.
P1: No, no.
VM: So really, this fits quite well into your...
P1: Mm.
VM: Mm.
MH: Can I ask another one um, why else would you come on this? I mean, lots of people will say no, I mean [inaudible] like people to come on these things. And I mean, I'm sure you've got other things that you want to do, so what what what made you decide, actually, "that sounds quite interesting, I think I'll..."?
P1: [inaudible] it can help me...
MH: Mmhm.
P1: ...as well as helping someone do a research programme.
MH: Mmhm.
P1: If you don't do research, you don't find out...
P3: That's it. You don't get anywhere. [cough]
P1: [inaudible] thought it would be generally um, beneficial [inaudible]...
P3: [inaudible]
P1: Yeah.
MH: Mmhm.
P3: And I did a research programme on a new drug uh, for the rheumatoid uh, rheumatoid, for Professor Scott, was on it, and it didn't work for me. But I did it for three months. It was no good to me, but at least it may help somebody else.
MH: Mmhm.
P3: And, you think, if you don't do anything, it's no good moaning all the [time], you've got to make some effort to uh, do something.
MH: Mmhm.
P3: And, I did one for [inaudible] as well didn't I?
P2: Uh, very [stressful] to because uh, this injection, I had to give her the injection.
P3: Terrible injection.
VM: Uh, I had [inaudible].
VM: Yeah.
P3: Everyday at ten o'clock.
P2: *[patient name [P2]]* doesn't mind the injection [inaudible]...
P3: Injec...I'm not frightened of them.
VM: No.
P2: [inaudible] syringe.
P3: Oh, it was horrendous. I was crying every time...
VM: Mm.
P3: ...and I was screaming abuse at him but he had to do it you see.
P2: [inaudible] painful injected into us.
P3: Yeah, so I did, I managed to get through ten weeks on that?
P2: Yeah.

P3: And I couldn't cope anymore, so I told them they could [inaudible] I just couldn't, and they accepted that. But then I was, an awful guilt thing where, if you was to have proceeded with it a little bit further, and put up with it a bit more, you would have got somewhere. Well I felt, after ten weeks, if I'd got relief, and I wasn't, I was still taking other medicines.

MH: Mm.

P3: So, but I would never say not to um, researching, because I think we're not going to move forwards otherwise.

P1: No.

P3: And, you can't turn round and go, I can't go then back to Professor Scott and say, "look you've got to do something, I can't go on", cause he would turn round and say, "well, you didn't try this and I asked you to". Which is fair enough, it's a fair comment. But um, I think that, a [inaudible] of do it just for your benefit, if it doesn't help you. That injection never hurt me. It never helped me, but it might help another person down the line.

MH: Mm.

P3: I think there were a hundred of us on that, about the um, the different hospitals in London.

MH: D...did you ever get any feedback from that [inaudible]...

P3: Not a lot, no. I think I would have had more. I was um, I think he was a bit cross when I didn't finish.

GRP: [laugh]

MH: He wasn't giving you the injection in your bum everyday was he?

P3: That's right.

P3: [inaudible] because he put me on Methotrexate...

P2: [inaudible] I'm used to it all.

P3: ...which is what I'm on now, and the last time I saw him, I think it was when I met Vicky...

VM: Yeah.

P3: ...I said to him, "can I reduce my pill here Professor?" "Why?" I said, "Because my hair's falling out" "Oh [inaudible]" because he is a little like that.

VM: Mm.

P3: I'm not asking you to comment...

VM: No, no, I think...

P3: I know you're in a difficult position.

P2: [inaudible]

P3: You can do, cause I've only said to you...

GRP: [laugh]

P3: ...what I've said to him, so I certainly wouldn't worry over that. But um, you know, that was, because it didn't put me off when you asked me, I think you were there weren't...

VM: Mm, yeah, I was.

P3: ...and you asked me and I said, "yes, I'm quite happy". We both agreed to that.

VM: Mm.

P3: And this one wasn't quite as painful as...

GRP: [laugh] [inaudible]

PT: Just one.

P3: That's it, just one.

PT: Um, I've got to head off um...

P3: Yes my love, thank you very much.

PT: ...so I just to say um, when I was, liked to go a bit earlier but um, if you [inaudible]...

P3: [inaudible] and thank you for helping me.

PT: And thank you [inaudible] as well.

P3: And giving me encouragement when I was feeling [inaudible].
GRP: [laugh]
PT: Now now that I'm leaving, you can give any other feedback on me.
P3: Alright then, will I be asked?
GRP: [laugh] [inaudible]
P3: Will I be asked [inaudible] [laugh]? Oh dear, thank you very much dear.
GRP: Thank you.
PT: Bye.
P3: Bye bye.
MH: If there was something that you would drop out, what would it be?
P3: What, in the exercise? Oh, I think the shoul...that one that really tortured me, because I have a problem, I've got uh, swelling here because the bone's come out of alignment. And um, that's...
MH: [inaudible] exercise?
P3: Yup. And that one is very tr...anything where I'm raising that right arm...
MH: Mmhm.
P3: I can raise it up to about that height but now, not that I can on this one, but I can put my arm up easily without pain. So, it would be the shoulder exercise if anything, but uh...
MH: [inaudible]
P3: Yeah.
MH: Is there any sort of topic that was covered that you think, "oh I know that, it's a waste of time, that's not, not much use to me"?
P3: Can you think?
P1: Not really, no.
MH: [inaudible]
P3: Yeah, I can't say I felt it was a waste of time...
P1: No.
P3: ...about anything really. But I think...
MH: What about things you'd want to add in? What would you think?
P1: More se...
P3: What to the exercise?
P1: More sessions.
MH: More sessions?
VM: [laugh]
P3: Or, I would have liked, p...perhaps, I know it's not your field, but any other, just, are there any massage, heat treatments, that could be recommended for people like us, so, you know [inaudible]...
VM: So so perhaps, it may have been...
P3: [cough]
VM: ...do you think, I mean, because one of the things that just, sort of, comes to mind is, you know, is perhaps, one of the education sessions could have been talking about something else like nutrition or something, something that...
P3: [inaudible]
VM: ...like another sort of thing that can help.
P3: Yes, now that'd be useful.
VM: Would that be, would that have been something...
P3: Yup.
VM: ...that you might have quite liked to have heard about?
P1: Well yes, actually that would have been quite good.
VM: Sort of like nutrition...
P3: Yes.
VM: ...nutrition and the benefits of different...?
P1: Well especially with rheumatoid, there are so many things you...

P3: Can't have, yeah.
P1: Well apparently, but then if you re...read different research papers...
P3: Yeah.
P1: ...they contradict.
P3: Yes, like tomatoes, grapes, anything with [inaudible].
P1: Mm.
P3: But then you read something else and they tell you to go ahead.
P1: Mm.
P3: So that would be useful, nutrition, yeah.
P1: Surely...surely if you've been on a very good, mixed diet [inaudible]...
P3: Yeah.
P1: ...but if you could have been specific [inaudible] gone into it more say...
VM: Yeah [inaudible]...
P1: ...that would be.
GRP: [inaudible]
P1: But even at our next session, you know when we come back?
VM: Mm.
P1: If you have something lined up then just to...
VM: [inaudible], yeah.
P1: ...just to explain [inaudible]...
VM: That would be quite interesting. Yeah. And the other thing I wanted to ask was, obviously we've had four sessions, and they've been twice a week. So you've come in four times, and it's been in quite a short space of time. Do you think that that worked quite well, or would you have perhaps preferred to have come in say, twice in one week, and then come in, sort of, once the next week, and then once, so stagger it a little bit more, so it lasted a bit longer or...
P3: It is a bit difficult because we've got quite a bit on.
P2: Yeah.
P3: And let's face it, I had to cancel [inaudible].
P2: Cause we've got so many hospital commitments too.
P3: Yeah.
P2: [inaudible]
P3: Plus family commitments, it is difficult to get out.
VM: To come in for four...
P3: Yeah.
VM: ...tw...twice.
P3: For you to say...
P2: [inaudible] probably just once a week.
P3: Yeah, once. But other than that, we've got too many other things going on.
P2: I know, I know.
VM: Mm. So perhaps you would have preferred it if it had been, you could have managed say, twice for the first week, and then coming once the following week...
P3: Or I think we we perfectly managed this alright but if it was...
P2: Yeah.
P3: ... go....ongoing.
VM: Longer?
P3: Any longer then...
P2: [inaudible]
P3: ...it would have been more difficult.
P2: Mm.
P3: And then we'd be saying, "well I can do that session, but I can't do that", and then you're messing people around.
P2: Mm.

VM: Yeah.
P3: [inaudible]
VM: What about you *[patient name [P1]]*, do, how do y...how do you feel? Do you think you would have preferred it if it was more staggered or [inaudible]?
P1: I actually quite like it being quite intensive.
VM: Yeah.
P1: Yeah.
VM: For the first...
P1: Yes.
VM: Yeah, and then, sort of, being on your own after that?
P1: Yes, yes.
P2: Yeah.
VM: It's just a pity we can't have more session after that really.
P1: Mm.
VM: Okay.
MH: Did you like um, what did you like about the environment? Dulwich? Brian? He's back now so we can't say too much [inaudible].
GRP: [laugh]
P3: Oh, I thought it was friendly...
P2: Very friendly.
P3: ...I thought it was all a very friendly atmosphere when we came in.
P2: Mm.
P1: And it was fun.
P3: It was.
P2: And uh uh, we enjoyed the tea here too.
GRP: [laugh]
P3: No I I think the atmosphere is good. I think they need a new lift, but never mind that.
GRP: [laugh]
P3: And I mean that is over a hundred years old so uh, not quite as old, well [inaudible].
MH: If, if it was done at a local hall or centre, would you be more or less inclined to go there?
P3: Well that's why we go locally...
MH: Right.
P3: ...you see because it's within walking distance...
MH: Yup.
P3: ...we don't need the car to get down there. It's a short walk, which is also good for us.
MH: Mmhm.
P3: No stairs, cause stairs for me are a [nightmare]. And uh, that's why we attend this class you see. So, but I mean here, it doesn't hurt, I come, find difficulty in getting up the stairs, but I can walk down the stairs quite easily.
MH: Mm. How about you *[patient name [P1]]*, how do you feel?
P1: Well, I s'pose I'm local so, it would be nice if there was a group, in a local hall...
P3: Mm.
P1: ...um, that was geared for people that had any form of arthritis.
P3: Of arthritis, yeah.
P1: Well I have been to several sessions where they have a [inaudible], but getting down on the floor and off up from the floor and all this sort of thing, [inaudible] can't manage it was actually quite embarrassing...
GRP: Mm.
P2: [inaudible]
P1: ...if you're in a group of people who with problems...

P3: [inaudible]
P1: ...and similar...
VM: Similar to your own.
P1: ...and the instructor emphasises we're all doing as much as we can and we're not...
P3: Mm.
P1: ...in competition etcetera, [inaudible].
P3: Yeah.
P2: [inaudible]
P3: Well they're very good cause um...
P1: [laugh]
P3: ...they do different exercises to suit us. Don't they?
P2: That's right, yeah.
P3: And they know we can't do it.
P1: Mm.
P3: And then, while the instructors taking through, "*[patient name [P3]]* you can't do this one, do that".
P2: Mm.
P3: And I get on and do that.
P1: Mm.
P2: It's all very similar exercise to the ones we've been doing here.
P3: Yeah, and Harry, "if you can't do this one, then try that".
VM: Yeah, yeah, similar, yeah.
P3: Which I find useful because then you are not standing like a lemon, when everybody else is doing the exercise.
VM: Mm.
P1: Mm.
P3: So you are being given instructions, and still told to do something else. Very...
MH: [inaudible]
P3: ...sorry.
MH: S...no, no, no, it's fine. *[Patient name [P1]]*, because you don't go to an exercise class, do you it makes a difference being run by a physiotherapist, and if it was run by an exercise professional or someone like that, would that've of made any difference, or [inaudible]?
P1: It um, it depends actually what their um, training I think included. I think anybody that's been trained um, physically to deal, even if you've got an injury, for instance...
MH: Mm.
VM: ...they're not going to want to...
MH: Mmhm.
P1: ...exacerbate anything. Um, they're just wanting you to move...
P3: Mm.
P1: ...to the best of your abilities. But I think [inaudible]...
MH: Right.
P1: ...um, I don't know what um, you know, a general exercise teacher's...
P3: Well, I think...
P1: ...profile would be like.
MH: Is that because there more of less like [inaudible]...
P3: ...[inaudible] because we know physios have been trained [inaudible].
P1: I'd be less likely to go to a general exercise class, sharing my, what I, you know, [inaudible].
P3: [inaudible]

VM: If, if it was a sort of, if it was a group, class, say delivered by a fitness instructor, who'd got, sort of um, a qualification in sort of refer...you know, referrals, so...
P1: Oh yes.
VM: ...you know um, how would you feel about that? If it was a sort of class run say every week, and you went once a week, and you paid like *[patient name [P3]]* said...
GRP: Mmhm.
VM: ...so...something like a pound to go, and it was geared up for people with arthritis...
P1: I'd definitely go.
VM: You'd be quite keen to...
P1: Oh yes.
VM: And it was in the local area...
P1: Yes.
VM: ...you'd be quite keen to go to it?
P3: But you've raised the question you see, with Hugh, our trainer, or instructor...
P2: Is qualified.
P3: ...is qualified. This is something we don't know. We know possibly that he would not be employed in his position when it's council based as well, I would think...
P1: I would think [inaudible].
P3: They must do. I mean we know here that you're all trained.
VM: Mm.
P3: So perhaps, you don't know. You see, we've got the advantage in this that we've had qualified physios seeing us.
PT: Mm.
P3: And that is a question that I think perhaps we ought to...
P1: I think you'd have to justify government funding, wouldn't you [inaudible]?
P3: I would hope so. But they get grants from the council. I would hope the council...
P1: Well, I would think the council [inaudible].
P3: ...and I certainly wouldn't [inaudible].
GRP: [inaudible]
MH: Well, you've been very happy with them, so...
P3: [inaudible]
MH: ...and and I'm almost sure that they are.
P3: Yeah, I'm sure they are.
MH: They're probably not physios as such...
P3: No, that's what...
MH: ...[inaudible] as long as they're qualified in exercise and and and they're aware of...
P2: The exercises, they're quite intensive.
P3: They are and...
P2: [inaudible] relax.
P3: [inaudible] already haven't you.
P2: ...[inaudible] one exercise after the other, so like here, you know, we do that for a rest.
VM: Yeah.
P3: And they're very keen you don't take too long to [inaudible]. We have a cooling off point at the end, relaxation....
VM: Yup.
P3: ...which we do need. We have a [inaudible], she winds us down gradually.
P2: Yeah.
P3: But um, I would hope her and Felix are fully trained, I mean...

MH: I'm sure she [inaudible]...
P3: I'm sure they will, cause...
MH: Can I just push you on another bit...
P3: Mm.
MH: ...that's uh, really important, the socialization.
P3: [inaudible]
MH: Have you enjoyed that, has it helped you facilitate exercises?
P3: It does. There's a lot of com...and um, laughing going on. It's very relaxed atmosphere really, and um, Tracy particularly has got a good personality.
P2: Oh she does, yeah.
P3: And she gets us all moving. And I think in between, th...there are twenty people there, and we never meet anywhere else, but I wouldn't say you can't count them as friends.
MH: Mm.
P3: But, you know, you know them and I think it's a social, it's a bit of intermingling, and all races and creeds, which is good.
P2: And they arrange uh, different outings too, you know [inaudible].
P3: Yeah, yeah.
MH: [inaudible] social [inaudible]...
P3: Well it is really...
MH: ...[inaudible] [do] other things.
P3: That's right.
MH: Would that interest you *[patient name [P1]]* or, I mean, some people don't like that [inaudible].
P1: I'm not entirely sure because I don't got a partner who has got arthritis or...
P3: Ah, right.
P1: ...any health problem.
P3: No, yes.
P1: So, it's difficult really, potential to do things together.
P3: Mm.
P1: But, I mean, I was going to [come to] a class once a week, on my own obviously...
P3: Yup.
P1: ...um, that I would do. Yes.
VM: Because also, if you got to know the people within the group...
P1: Mmhm.
VM: ...that you went to. So say you were going to a class and there were always, like here...
P1: Mmhm.
VM: ...it's always the same people...
P1: Mm.
VM: ...is that quite...
GRP: [inaudible]
VM: [inaudible] factor as well.
P1: Yes.
VM: It helps to, "right, well I better go or..." you know.
P1: Mm.
VM: Yeah?
P1: Mm.
P3: We've had a phone call sometimes from other members, "you weren't there last week, are you alright?"
P2: [inaudible]
P3: And I thought that was rather nice.
GRP: Mm.

P3: You know, that's a thing that we didn't expect, isn't it? And uh, vice versa. If someone's gone into hospital there, [inaudible] make arrangements to go to see. You know, that's the sort of, that's a side effect I know really, but that still helps with your exercise, you know. You feel more inclined to go there.
P1: Mm.
MH: Have you ever been to a leisure centre, or swimming pool or...?
P3: Uh, not really. Um...
MH: Right.
P3: Have we, leisure centre?
P2: No.
P3: We haven't have we?
P2: No.
P3: No.
MH: Why, why do you think?
P3: I don't know uh, I don't know what they charge even. Because obviously, if you're paying quite a bit to belong to a leisure centre, like to do the gym...
MH: Mm.
P3: ...that would be difficult for us, wouldn't it? On a, on a pension you tend to think, "oh, that's a lot of outlay per month" [inaudible].
MH: [inaudible]
P1: [inaudible] the name, but I was explaining to you, wasn't I...
VM: Mm.
P1: ...that um...
VM: Got a bit stressful.
P1: Yes, because they're trying to make as much money as they can.
MH: Right.
P1: So they've got two lots of kiddies in two lanes being [fought to extend].
MH: Right.
P1: Then they've got the [inaudible].
P3: [inaudible] yeah.
P1: Yeah. I wear contact lenses, so I'm sort of, like this if someone's...
P3: Coming at you, sort of...
P1: Yeah. So um, it's only occasionally where you actually go in and think, "oh, I've chosen the right time"...
P3: Mm, yeah.
P1: ...and you've got a range to swim in and you're not under pressure.
MH: Mmhm.
P1: So...
P3: I would find that a bit depressing as well.
P1: And also [sometime] your very restricted...
P3: Mm.
P1: ...as to when...
MH: Mmhm.
P1: ...you can go.
MH: Mmhm.
P1: And then, in the holiday times, they're running clubs and things [inaudible]...
MH: [inaudible]
P1: ...in the village, so...
MH: Okay.
P1: ...and I don't like the Pulse, I don't know if I [inaudible].
MH: Peckham Pulse?
P1: Mm.
P2: Oh no, we went there...
P3: We went, no.
P1: No.

P2: There's no supervision.
P3: No supervision. Not sufficient I guess for that, cause we went there...
P2: Uh [inaudible] for the children.
P3: Can I say that after I had the two knee operations, I went to Lewisham for the hydro pool, which was very beneficial for me...
MH: Mmhm.
P3: ...because then you can do exercises then without...
MH: [cough]
P3: ...especially my size being a large person, without pressure on the joints. So then I couldn't get another session cause you have to have [inaudible], so they suggested we went to the Pulse, didn't they?
P2: Mm.
P3: Well, I rang up and I said um, "do you have sessions for people", "oh yes, yes, you can use the pool". I said, "because", just what you said, I thought there would have been people with like problems in that pool. There were children, oh it was horrendous.
MH: Mm.
P3: And there were adults, I mean, alright I know people go there for leisure. I felt that the leisure and the medical side should be totally separate, that that pool, if not all of it, some of it should be cornered off, or an area...
P1: Or an hour a week even.
P3: Yes, something to allow...
P1: Even an hour a week.
P3: ...but no it was horrendous, I can't tell you, I wouldn't go ever again.
GRP: No.
P3: And I voiced my um, and they said, "but we have too many people wanting to come here".
P1: Mm.
P3: I said, "well I did ring up and ask, and explained it was post operative", and things like that, and they said, "well sorry, we can't offer you a [inaudible], not just for me but surely they could have a session for people...
GRP: [cough]
P3: ...to use the pool.
MH: Mmhm.
P3: But there again...
P2: I think you're right [inaudible].
P3: I've not tried them *[patient name [P2]]*.
P2: No, no.
P3: You haven't been there though.
P2: No, I've been meaning to go [inaudible]...
P3: Why haven't...?
P2: ...[inaudible] time to go there.
P3: They do.
P2: Mm.
P3: Yes but that's swimming, that's not hydro pool, is it?
P2: It's not hydro pool?
P3: No, but it is [inaudible]...
P2: But you do exercises in the pool?
P3: Yeah, yeah. Oh it might be worth trying there again.
MH: You, you didn't like the Pulse [inaudible] *[patient name [P1]].*
P3: No, I didn't like it.
P1: I think it was too too busy.
P3: Mm.
P1: It was.
P3: It's horrendous, wasn't it?

P1: Mm.
P3: I mean people bashing here, there, and everywhere.
P1: Mm.
P3: I s'pose that's my age.
P1: Mm.
GRP: [laugh]
MH: One more and then I'll shut up and let you go home, but, who who should be [breaking in] the next class to you?
P1: GPs, or I think cause um...
MH: Does your GP ever talk to you about exercise?
P1: No.
MH: Never?
P1: Nope.
MH: And they know you've got arthritis and...
P1: Yup.
P3: Mm.
P1: But, because I go to the RA clinic, they think that that will [inaudible] because they're not necessarily geared to rheumatoid...
MH: Mmhm. Mmhm.
P1: ...perhaps they wouldn't feel...
MH: Mmhm. Mmhm.
P1: ...quite as [inaudible].
PT: Has your GP ever asked you, not necessarily tell you about exercise, but has he, has he ever asked you about general exercises that you do or don't do?
P1: No, not at all.
MH: Would it make a difference if he did?
P3: Yeah, it might do.
P1: Yes, and I will sort of respond upon [inaudible] to anyway that I, you know, that local GPs could have a much needed Dulwich swimming pool, just to get two hours a week...
P3: A session...
P1: ...a daily time.
P3: Mm.
P1: ...and then an hour, and hour on an evening basically, for people who work...
MH: Mmhm.
P1: ...um, you know, just to give some sort of incentive, so that you wouldn't go along and you're competing with all these...
PT: But GPs should be doing that, because they do have [GP] referral forms, where it's in Southwark and Lambath um, because we used to fill them out here, physios used to fill them out, because GPs will often send their patients here, whether it's kind of exercise based or you know, for a physio opinion...
P3: Mm.
PT: Um and and quite often it was exercise that was, you know, the best thing to do. And we'd fill out these community referrals, and we'd send them to, whether it was uh, the Dulwich Fusion, or the Peckham Pulse, or whatever, when we sent it, and they'd have um, the qualified instructor set up the exercise programme in the community, so they were do it, you know...
GRP: Yeah.
PT: ...near to them, and we'd arrange them. But now GPs actually do that. You should be able to ask your GP, although in some cases, I don't know if your GP would prompt or suggest, you could ask your GP um, about exercise, and they should suggest, "well I could fill out a community exercise referral form and and have you reviewed at the gym".
P3: Mm.
PT: Did, what about [patient name [P2]] and [patient name [P3]]...

P3: Well.
PT: ...did your GP suggest anything to you...?
P3: Well ours is very, we've got an excellent GP, and I don't know if one of us...
P1: [inaudible] I don't think it actually occurred [inaudible].
P3: [inaudible]
P1: I mean, when I had um, back problems um, I was immediately referred to physio at Kings um, because they were part of the private scheme. It would have been about a year ago, and I was seen in like two days, I couldn't believe it.
PT: [inaudible]
P1: Yeah.
P3: Mm.
P1: Yeah. So...
VM: So, this is interesting, because there is, there is this exercise referral scheme that no one's sort of, no one's um...
P1: No, I haven't had that...
VM: No [inaudible].
MH: I think that, I think the exercise referral scheme, one of the problems with it, you can only get one referral and then...
VM: No, you can, you can get r...you can get repeated referrals.
MH: Can you?
VM: If necessary, yeah.
MH: Oh.
P3: I I, our class, we had to get a signature from our GP for our our exercises.
P2: [inaudible]
P3: We were, we were not allowed to join there until we had a a letter from our GP.
PT: That's the point of the referral, the the form, yeah [inaudible].
P3: Shall I tell you I was amazed that the GP wanted a, how much was the price, twelve pounds?
P2: [inaudible] they wanted fourteen pounds.
P3: I mean, we're going there to...
P2: [inaudible] then they decided no, they don't.
P3: Oh well I was [inaudible] about that, because I thought, he's telling us, she, both of them, are telling us to go...
VM: Mm.
P3: ..."you must get", and then they said, "well that is the standard fee", paying twelve pounds for a signature on a form to say that you can go and do exercise, which I thought was outrageous. But they did, and they they, when I put it to them, they say said, "no, you're right, we shouldn't do that".
P2: Mm.
P3: But that is the standard form. I said, "well I'm not asking you to sign a passport or anything like that...
VM: Yeah.
P3: ...it's just so that we can exercise".
VM: Mm.
P3: And they didn't, in the end they wavered it, didn't they for us *[patient name [P2]]*? But, they, our class will not have you in their exercise, exercise class without your GP knowing what you will be doing and everything. Which I...
VM: Mm.
P3: ...thought was a good thing.
VM: Yeah, no. That's standard practice to...
P3: Mm, yeah.
VM: ...to do that.
P3: But uh, no I mean...

P2: [cough]
P3: ...you said the clinic you go to, are you talking about the clinic at King's?
P1: [inaudible]
P3: Right, but...
P1: [inaudible] specific.
P3: Oh, right.
P1: Oh, the clinic? The RA clinic?
P3: Yeah, at King's. Is that like under Professor Scott?
P1: Yes, yes.
P3: Oh right, it's just that I hadn't seen you there, and I just thought...
P1: [inaudible]
P3: So, we are actually talking about the same clinic?
MH: Does David, does David...
P3: [cough]
MH: ...ever talk to you about exercise?
GRP: Mm?
MH: Professor Scott from the...
P1: N...no.
P3: No.
P1: No.
P3: You're asking what...
MH: Are you aware of any exercise posters up, or leaflets or?
P1: Well, there, there was um, there was one that I, had a stack of them, and it was um, walking in Dulwich park.
MH: Yeah.
P1: I thought, "well that's just up the". But um, whenever I went [laugh] there was nobody there.
P3: Nobody there.
PT: No.
P1: So, [I thought], "oh" you know.
MH: Yeah.
P3: Well our clubs done [inaudible]...
P1: But also, I have been...
GRP: [inaudible]
P1: ...my physio sessions at um um, King's was quite an eye opener to me because, there were ten people supposed to attend the exercise classes, and the [inaudible]...
PT: [inaudible]
P1: Yes.
PT: Yeah.
P1: Yes. And the maximum that ever arrived was four.
P3: Really? Oh.
P1: And I thought that was dreadful. That these places were given out to people that had no intention...
PT: Yeah.
P1: ...for [inaudible].
PT: [inaudible]...
P1: Were they?
PT: ...[inaudible] rolling programme.
GRP: Really?
PT: As soon as we know people aren't turning up, we can...
P1: [inaudible]
PT: ...add more people, cause otherwise the waiting list spirals out of control...
GRP: Yeah.
PT: ...while classes are half empty. Now, most of them are rolling programmes...

GRP: Oh.
PT: ...so that we can eliminate that problem. And [inaudible]...
GRP: Sure.
PT: ...a lot of better service really because...
P1: Yeah.
PT: ...you don't, I ran the back class here for six weeks and I had eleven people referred, and I had between two and five show up for it.
GRP: That's terrible.
P1: Yeah.
PT: And I think that [inaudible]...
P1: [inaudible] why they say yes. If they say yes, [inaudible].
P3: If they're not going to do it, you know.
P1: [inaudible]
P3: Well it's like at the GP, when I'm there, last week, there were eighty two people who did not turn up for their appointments.
P1: No.
P3: They've got that on the board. And I think to try and bring it home to people...
P1: Yes.
P3: ...why make the appointment and not...
VM: And then not do it?
P3: No. But um, [inaudible], anything else you want to ask?
MH: All I wanted to ask is if any of you want to ask anything or?
GRP: [inaudible] [laugh]
P3: I think I've done enough speaking.
MH: Mm.
P3: Anyway, thank you very much anyway.
VM: Right, well thank you.

END

Appendix H EXTRA Programme Physiotherapist and Patient Handbooks

Please see enclosed CD ROM

Appendix I EXTRA Study Patient Cover Letter

School of Medicine
Division of Health Care Research
King's College London

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Dulwich Community Hospital
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London, SE22 8PT
United Kingdom

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Email victoria.v.manning@kcl.ac.uk

Date

Dear

Your details were given to me by the rheumatology team at King's College Hospital/Lewisham Hospital/Guy's Hospital (*delete as applicable*). I am writing to you because I would like to invite you to participate in an upper limb education and exercise programme which has been specifically developed for people with early rheumatoid arthritis (those who have been diagnosed within the last 5 years). Please note that this is being delivered as part of a research study.

The aims of the programme are to increase function, strength, and movement in your shoulders, elbows, wrists and hands. It is predominantly home-based, however it will also involve attending 4 physiotherapist-led group classes which are intended to familiarize you with your exercises. These will be held at the Dulwich Community Hospital. Participants who find getting to this hospital difficult or inconvenient are welcome to ask for free transportation.

Before you decide whether you would like to take part, please read the enclosed information sheet which provides further details, and explains the pluses and minuses of participating in a research study. If you think you might be interested in finding out more, please do get it touch on the number provided above.

Best wishes,

Victoria Manning

Appendix J EXTRA Study Patient Information Sheet

KING'S College LONDON

King's College Hospital NHS
NHS Foundation Trust

Education and eXercise Training in Rheumatoid Arthritis (the EXTRA study)

Patient Information Sheet

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Rheumatoid Arthritis (RA) frequently causes joint pain, muscle weakness and difficulty doing everyday activities. Whilst supervised exercises improve leg function, it is unclear if they improve arm function and disability. Home exercises also improve function and, if individually tailored and completed in the long term, they could increase an individual's management of their arthritis and independence. However, it is often difficult to maintain the motivation and commitment to exercise long term.

Therefore this study investigates, if a home exercise programme combined with 4 sessions of supervised group exercise and advice, makes it easier to continue exercising at home and also improves upper limb function in people with RA.

Why have I been chosen?

You have been chosen because you have had RA for less than 5 years and are under the care of the Rheumatologists at Kings College Hospital. One hundred and thirty people with RA will be asked to participate in the study.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. If you decide to take part you are still free to withdraw from the study at any time without giving a reason. This will not affect the standard of care you receive. All answers you give will be anonymous and confidential and you will not be identified in any way by your responses.

What will happen to me if I take part?

You will be invited to attend the Rehabilitation Research Unit, at Dulwich Community Hospital for an assessment which will take about 2 hours. During this assessment you will be asked to complete a series of easy tests. These include completing every day tasks such as doing up buttons and tying shoes laces, strength tests for the arm and an upper limb re-positioning test to assess limb awareness. You will also be asked to complete some questionnaires about your ability to do activities at home and how your arthritis affects work.

As we don't know whether arm home exercises improves function and disability. We will ask half of the study participants to complete a home exercise programme and attend 4 one hour supervised exercise and education sessions (2 sessions per week for 2 weeks). You will also be asked to complete a small number of easy arm and hand exercises daily at home for a further 10 weeks and keep a record of how much you exercise.

Additionally, a small number of people (approximately 10- 15) who have completed the home exercises will be invited to attend a 30 minute interview to discuss their experience of doing home exercises to try to help us understand what may encourage or stop people with RA exercising at home. These interviews will be audio-taped and then transcribed verbatim, after that the recording will be destroyed.

If you are not assigned to the exercise group you will continue to be cared for by your Rheumatologist as usual. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly).

You will be invited to return for further assessments (the same as the first assessment) 3 months and 9 months later – regardless of which group you have been randomly assigned to.

What will happen to the information collected?

All information collected about you during the course of the research will be kept strictly confidential e.g. in a locked filing cabinet and stored on a dedicated computer. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. Records of any interviews will be transcribed and the tapes destroyed immediately. The results of the study will be published in medical journals and presented at medical conferences. Copies of the results can be obtained from the study organiser (Dr Lindsay Bearne) when the study is completed.

What are the other possible disadvantages and risks of taking part?

Occasionally testing arm strength causes discomfort. If you feel pain on testing, we will stop the test immediately.

If you have concerns about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions and address your concerns (Dr Lindsay Bearne: 0207 848 6332). If you are not satisfied with the outcome of these discussions, you can contact the Patient Advice and Liaison Service (PALS), at the Hambledon Wing at Kings College Hospital, who may be able to offer help in resolving problems or provide information that may be of help (0203 299 3625). If the PALS team are unable to resolve your concerns or you wish to make a formal complaint, standard National Health Service mechanisms are available to you.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Kings College London but you may have to pay your legal costs. The normal complaints NHS mechanisms will still be available to you.

What are the possible benefits of taking part?

All people in the research will have their arm function monitored regularly over the duration of the study (9 months). We cannot promise the study will help you but the information we get might help improve the treatment of people with Rheumatoid Arthritis.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving us a reason and we will destroy all your identifiable samples, but we would like to use the data (which will not be identifiable) collected up to your withdrawal in the final study analysis, if you do not object.

If you have any questions please contact
Dr Lindsay Bearne or Ms Victoria Manning Tel: 0203 299 6358
The Rehabilitation Research Unit
Dulwich Community Hospital
East Dulwich Grove, London SE22 8PT

Appendix K EXTRA Study Patient Consent Form

King's College Hospital NHS
NHS Trust

CONSENT FORM

Centre number: .....
Study number: .....
Patient Identifier number
For this trial: .....

NB Three copies should be made, for (1) patient, (2) researcher, (3) hospital notes

Education and eXercise Training in Rheumatoid Arthritis (EXTRA study)

Name of Researchers: Ms Victoria Manning, Dr Lindsay Bearne

Please initial box

1. I confirm that I have read and understand the information sheet dated May 2008 (*version* 2)[1] for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from King's College or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I give permission for my General Practitioner to be informed of my participation in this study. ☐
5. I agree to take part in the above study.

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature
Researcher	Date	Signature

[1] Education and eXercise Training in Rheumatoid Arthritis information Sheet August 2008 version 2
Consent form August 2008 version 2

Appendix L EXTRA Qualitative Study Sample Interview Transcript

Date: 04/07/2011; Duration: 41.30 minutes
Interviewee: M-099 (INT)
Interviewer: PI (VM)

VM: Right, so we're recording. Hopefully, fingers crossed.
INT: [laugh]
VM: Right, so, I've already sort of run through the purpose of, you know, all of this. So first of all thank you very much...
INT: [inaudible]
VM: ...for uh, coming and giving me your views.
INT: Your welcome [laugh].
VM: Um, so um, really um, I mean I...like I said to you, I just want you try to be as open as possible.
INT: Mmhm.
VM: Don't sort of uh, worry about offending me with, you know...
INT: Okay.
VM: ...because I'm not directly related to it anyway, so you can give me your overall opinion without without worrying. Don't censor your views...
INT: Okay...
VM: ...in other words.
INT: Alright, I won't [laugh].
VM: So first of all I just want you to sort of, let's go back to the very beginning.
INT: Mmhm.
VM: So uh, cast your mind back to um [tutt], you know when I sort of first approached you and told you about the physiotherapy programme. And and you decided, "okay, I'll, I...I'm going to take part in the study"...
INT: Yeah.
VM: ...and um, and then, you know, before you started the classes, you know, you probably had some ideas of what you might get out of it...
INT: Mm.
VM: ...and what your expectations were. Um, so I just want you to tell me a bit more about that. What what you hoped to, sort of, get out of the programme.
INT: Um, well I guess I...I...I, well I suppose I was a bit clueless really about [laugh] what the programme would be. Um, so actually, I didn't really have any idea, and I didn't really, cause I never had any physio before, so I didn't, couldn't really guess what was going to be involved.
VM: Okay.
INT: Uh so, um, and I, also I was so ill to be honest [laugh]...
VM: Yeah, mm.
INT: ...that I thought, "oh, just just come", but I...w...I just wanted to improve my function, so I was very grateful...
VM: Mm.
INT: ...actually to, to want to be, to be in it. And I actually wanted to be in the exercise group [laugh].
VM: Yeah.
INT: I really wanted to be.
VM: Yeah.
INT: So, no I was glad that I was picked for that.
VM: Di...w...w...did you hope that it would sort of help you in some way, or did that um?

INT: Um, no I definitely, I...I mean, I thought it would, I suppose I don't know, I...because I hadn't really had physio before, I didn't really know whether it would help me at all actually.
VM: Right.
INT: Um, and probably I was quite negative at the time generally about my condition, so I wasn't really expecting too much to be honest.
VM: No.
INT: But I thought, "well, you know, give it a go", particularly as my upper body, um, and arms were very bad, and that's, in a way, the thing that has most impact on your life, because you can't open jars, or cook,...
VM: Mm.
INT: ...or type, or do your job...
VM: Mm.
INT: ...because I have a sedentary job, then that's a huge impact on me...
VM: Mm.
INT: ...and, you know, how I, how I can do everyday tasks, so...
VM: Yeah.
INT: ...so actually I wasn't really expecting too much to be honest because I was so bad [laugh].
VM: Yeah, you just sort of thought, "right, I'll give it a go".
INT: Yeah.
VM: And, so let's sort of turn it around. What about concerns? Did you have anything that you were worried about?
INT: Um...
VM: You know, in taking part in a physiotherapy programme?
INT: I s'pose just um, I mean I had, I guess I had some concerns about the exercises but not not really to be honest. I just thought [exhale].
VM: What sort of concerns did you have about the exercises?
INT: Well whether they'd work [laugh].
VM: Okay. Yup.
INT: And um, yeah obviously, I didn't have any concerns about the pain, because I was in so much pain anyway.
VM: Yeah.
INT: That it wasn't...I...I didn't for instance think I'd get worse, it would make me worse actually, or anything, I just, I just wanted it to be successful.
VM: Yeah.
INT: That was just my primary...
VM: Sort of...
INT: ...motivator, my overriding thought. I didn't really have any...
VM: Okay.
INT: ...concerns.
VM: Okay, so you went into it sort of fairly, you know, "let's see how, what happens".
INT: Yes, open-minded.
VM: And, then, okay so you, then the then the classes started...
INT: Mm.
VM: ...and what was your overall impression of them? What did you think?
INT: Of the two classes that I came to?
VM: Yeah.
INT: Um, yeah I thought they were, they were well organised, I thought the people were very helpful, who facilitated...
VM: Yup.
INT: ...um, and um, I did think, "oh, I'm never going to be able to do these" [laugh].
VM: The exercises?

INT: Yes [laugh]. I thought, “oh no, this is too much” [laugh]. Um, uh, but they were, it was um, yeah they were, they were, I missed one unfortunately because I had a doctor’s appointment, so I would have liked to have, probably have the other one. Cause that, I missed the one about uh, managing relapsing so...

VM: Right. So there was one of them that you...

INT: Yeah.

VM: ...kind of, didn’t get to do.

INT: Yeah, so I wish I could have done that one.

VM: Okay, well...

INT: [inaudible]

VM: ...there are a few things that you brought up there which I’m gonna ask you about. My stomach’s rumbling.

INT: [laugh].

VM: Um, the first one was, you mentioned uh, you thought it was quite well organised and...

INT: Mm.

VM: ...the people. So first of all, uh, what did you think of the physiotherapist?

INT: Um, yeah they were, yeah she was good um, she was good, she was kind of knowledgeable about people with arthritis, I think knew ...

VM: Yeah.

INT: ...about the problems, and it was well demonstrated, and then before we went off and did the individual bit, the individual exercises uh, they came and checked what were doing and it was quite, so if you were doing anything wrong, it was quickly...

VM: Yeah.

INT: ...picked up.

VM: Yeah.

INT: So...

VM: Okay, and what about...

INT: [inaudible].

VM: ...what about the um, the other people in the group?

INT: [tutt] Um, it was interesting to see other people in the group because everyone was so different, with their own kind of problems.

VM: Yeah.

INT: So um, it was kind of interesting to, well for me [laugh] to see that people had a lot bigger problems with their hands, whereas I had big problems with my shoulders.

VM: Yeah.

INT: So...

VM: So um,...

INT: But I guess in a way sometimes I think it would be nice to go to, kind to talk, to have a kind of support group, but that’s a separate issue, but it would have been nice to talk to people.

VM: Yeah. To have a sort of forum where you can...

INT: Mm, yeah.

VM: ...chat to other people in the same situation?

INT: Mm.

VM: Because, had you ever been to anything like that b...before?

INT: No I mean, there is, I did look, and there is one, but it’s in Bromley, so I mean that’s not much use to me.

VM: Right. It’s a bit too far way.

INT: Yeah.

VM: Yeah. Um, so that that sort of side of it, because obviously there were two sort of uh, components to the classes.

INT: Mm.
VM: There was, you know, you did your exercises...
INT: Yeah.
VM: ...but then there was also the time when you sort of sat down...
INT: Yeah.
VM: ...and everyone um, discussed a certain topic or whatever.
INT: Yeah.
VM: I mean, what what did you think about those discussions?
INT: Um, they could have been longer really.
VM: Yeah.
INT: Yeah.
VM: So you felt that they maybe were a bit too short?
INT: Yes, yeah.
VM: Yeah. And what about the actual topics?
INT: Um, yeah I mean th...the one I really wanted to go to I missed [laugh]...
VM: Yeah.
INT: ...so um, so I didn't, as I said, the other...but they were, they were, you know, relevant.
VM: Yeah.
INT: Yeah.
VM: Was, were there any topics that weren't brought up that you would have liked to have um, discussed? I mean apart from obviously, you missed the one...
INT: Mm.
VM: ...but...
INT: I suppose the one thing is a bit more about the managing of pain.
VM: Right.
INT: And that would have been a bit, I guess it could have gone into a bit more about the kind of physiology of pain, or because you're doing the exercises and they were painful, and it's very hard to gauge you know, when you're filling out your form...
VM: Yeah.
INT: ...and then you're trying to decide for yourself whether you should do a few more or not. It's quite hard to gauge that. If you're in a lot of pain, it's hard to gauge, "oh how much...
VM: Yeah.
INT: ...should you push yourself?". Um, and I know it's very subjective but I suppose more information on kind of pain and exercise would have helped...
VM: Yeah.
INT: ...when you're actually doing the twelve week programme.
VM: Yeah.
INT: Uh, I mean I understa...I mean they did, you know, emphasise that you, there was some pai...you would have pain, and pain doesn't make your arthritis worse um, but I think that's very difficult to...to judge for people with arthritis because, actually, you know, if I, if I think about my knee for example, if I go out and walk for the afternoon, I'm I'm in a lot of pain.
VM: Yeah.
INT: Um, so obviously I've overdone it, but it's about trying to...
VM: Sort of...
INT: ...so...
VM: ....find a balance?
INT: Yeah, so um...
VM: Yeah.
INT: I guess a bit more information about that, and what actually, what pain means for the joints, cause you don't actually really know, because obviously pain's a physiological signal that you shouldn't be doing something...

VM: Yeah.
INT: ...um, so it's quite hard.
VM: Yeah.
INT: Obviously everyone with arthritis pushes through the pain, cause you have pain all day.
VM: Yeah, you're sort of coping with it.
INT: Then you have pain killers and...
VM: Yeah.
INT: ...deals with it, so. So yeah, I guess...
VM: So that would have been uh, one of, a key sort of...
INT: Mm.
VM: ...feature which would have, you know. Um, okay, and what about um, the actual, I mean obviously we've talked about the members of the group, the other group members, I mean, y...and you said that everyone had um, you know everyone was a bit different...
INT: Mm.
VM: ...and it was interesting seeing...
INT: Yeah.
VM: What did you think about the mix of people in the group? You know, would it, would, was there anything that could, we could, could that have been improved in any way to have made the class better?
INT: Uh, well the mix was interesting because it was young people going up to elderly people, although not that elderly sorry, forgive me [laugh], that sounds a bit rude [laugh].
VM: [laugh]
INT: Well people obviously older than I was.
VM: [laugh]
INT: Um [tutt], uh yeah, I guess piss....some people missed the class as well...
VM: Yeah.
INT: ...some people only went to one and that was uh, shame. And it was predominantly women but that's arthritis...
VM: Mm.
INT: ...for you, so.
VM: So what did it, did it, what effect did it have on the group, you know when s...if if people missed the class?
INT: I thought the last class there weren't that many actually. Or as I seem to remember. I felt a bit flat I guess...
VM: Yeah.
INT: ...when there are less people.
VM: Yeah. So, do you think, I mean obviously some people missed the classes, but do you think, what did you think of the group size? The planned group size?
INT: Yeah I thought it was fine...
VM: Yeah.
INT: ...actually.
VM: Not sort of uh, you wouldn't have made it bigger or smaller?
INT: No it wasn't too big or small, no.
VM: And what about uh, the location? You know, the classes were sort of set...
INT: Mm.
VM: ...in a hospital environment. What did you think of that?
INT: Um, I think um, I mean it doesn't make much difference to me. It's, Dulwich is a nice hospital, it's not like King's, you know, where everything's so frenetically...
VM: Yeah.
INT: ...crazy so...

VM: Yeah.
INT: Um, so here's l..., kind of, not quite typical I don't think.
VM: Yeah.
INT: Um, but uh, yeah, this is, that's that's a, interesting one.
VM: Because I mean uh, because you know, there are loads of places...
INT: Mm.
VM: ...where you could have these sort of classes...
INT: Mm.
VM: ...um.
INT: I don't think it make that much diff...I mean I'd happily go to class in a sports place or any...anywhere really.
VM: Do you think it makes a...a difference to the sort of, you know, to the feeling that you get from the class, or the benefit of the class in terms of where it's held?
INT: Mm, where it's held. Um, I guess um, out of hospital environment it would be more pleasant, it's just cause you, there's a patient [inaudible], I've been trotting up to the hospital night and day now...
VM: Mm.
INT: ..for some time cause I was having to keep having emergency appointments and everything. Well not night and day but you know...
VM: [laugh]
INT: ...three times a week...
VM: Yeah, regularly.
INT: ...for awhile which was a bit [inhale], bit much, um [tutt], um, so yeah I I think it would be nice to have a change, to go somewhere different. Um, and also it's about rehabilitation so it's all about management as such, it's about people and so...
VM: Yeah. So, you mean um, you mean uh, so tell me a bit more about that, you know, your last comment about the rehabilitation.
INT: Well, if it's outside um, a hospital, it's, environment it would be um, you know, say if you were in a sports hall or somewhere, it would kinda get you into the, kind of, mind set of thinking, " oh well this isn't about, you know, hospital and drugs, this is about life, and getting on with your life",...
VM: Mm.
INT: ...rather than just treating your symptoms, and trying to stop the progression, it's it's kind of different type of um, uh, yeah kind of different attitude I guess...
VM: Mm.
INT: ...it it can make you have a different attitude I think...
VM: Yeah.
INT: ...to it, because it's, you can be more positive I think. And also, if you're having to go to a sports hall, it would make you look around to see what else you could probably be doing [laugh].
VM: Yeah.
INT: Cause i...people with arthritis get very stuck.
VM: Mm.
INT: Y...you get very stuck in the house and going somewhere different can be quite pleasant [laugh]...
VM: [laugh]
INT: ...which sounds a bit [inaudible].
VM: I mean, if if um, if I'd sort of, you know, say um, y...you know, when you, when we'd, when uh, Lindsay had contacted you and said, "right, you're in the exercise group", and she'd said, "right, you're going to be doing an exercise group in a, you know, fitness centre somewhere",...
INT: Mm.

VM: ...what do you, how do you think you would have, what would've your feeling been at that stage?
INT: Yeah, I'd have been happy to do that actually.
VM: Yeah.
INT: Yeah.
VM: Okay.
INT: Probably actually thinking about it, more than coming to the hospital. Actually.
VM: Yeah.
INT: Mmhm.
VM: Okay. Um, right, the other thing that I wanted to ask you about was um, in the classes you were given a sort of handbook...
INT: Mm.
VM: ...and it contained pictures of the exercises a...
INT: Yeah.
VM: ...and you know uh, handouts.
INT: Mm.
VM: What was your feeling about the handbook?
INT: It was good. The handouts, yeah, the [pause], I mean the exercises were all well designed, an [shown] so it was very easy to just go back and up, you know, particularly some of them like, when you were doing some of them y...you could start your initial hand position could be wrong, and it's quite easy to forget...
VM: Mm.
INT: ...actually, you know, especially if you kind of go onto auto-pilot, so it's quite good to check, cause it does clearly shows where you're supposed to be starting...
VM: Yeah.
INT: ...in your hand movement from...
VM: Yeah.
INT: ....cause that's the thing I'm most likely to get sloppy about [laugh].
VM: Sort of do it any old how? [laugh]
INT: Well n...no I'd start, I...if you don't start in the right position I realised, you're d...not doing it right.
VM: Mmhm.
INT: So I started doing the shoulder um, flex, you know [inaudible] [laugh]...
VM: Uh, the the shoulder rotation?
INT: Yeah the shoulder rotation [laugh]. You know, it says do it like this, and I'd be d...going like this [laugh].
VM: Yeah.
INT: Well not, that's exaggerated [laugh].
VM: [laugh] [inaudible]
INT: Or the back rub thing...y...
VM: Yeah.
INT: You c....
VM: Yeah.
INT: You c...
VM: The back scrub?
INT: Yeah, back, yeah. Back scrub thing. Um, you can start that in the wrong. So I mean it was quite good to kind of...
VM: Yeah.
INT: ...remind yourself.
VM: So did you find it sort of useful in the class, or useful at home,...
INT: No it's useful...
VM: ...or both or?

INT: ...both, yeah, it's useful at home.
VM: Okay.
INT: Yeah, I think you really need that cause I think, I mean I, I...I think, I did go for leg physio once and they hand you a sheet and it wasn't, there wasn't a picture, it's just like...
VM: Just a...
INT: ...just instructions, and I don't think that works as well as actually being f...having a picture or [somebody] showing you...
VM: Yeah.
INT: ...the position you're supposed to be in.
VM: What did you find most useful? Was it the photograph or the description of the exercises?
INT: No the photograph definitely.
VM: Okay.
INT: Yeah.
VM: And why do you think, why why do you think that is? As opposed to having the, just the words?
INT: Um, because it, it's, it can be, it's too subjective with words, you don't, I mean I just think if you're doing things that are very dependent on position, for your muscles, you really know where to start, which angle to move at, and where to end up.
VM: Yup.
INT: I think, otherwise...
VM: Yeah.
INT: ...you know, I don't think it's nearly as good.
VM: Yeah.
INT: Just to be given a set of instructions, and and memories funny, you can go along and think you've been shown it, and think you know what you're doing, but um, you know ten ten minute or half an hour session of doing an exercise, I think it's very hard to move away from doing it correctly.
VM: Yeah, yeah.
INT: That's what, that's me anyway. That's what I find.
VM: Yeah, um, so what about, you know in the handouts, there was one uh, which was all to do with um, well, a few of them included changing your exercises or modifying them in ways to make them harder or easier. How did you get on with that?
INT: Um [tutt], yeah and, I mean, for me it was easy to increase the number whereas [pause] you could kind of tighten the band. I found that quite difficult to measure. You know, as the kind of, from day to weeks went on, cause I didn't know, you know, actually how tight I'd done it, so...
VM: Yeah.
INT: ...that's that's the one thing I'd say about the exercises. If you want, wanted to progress, it is quite hard in that sense to know, say uh, yeah, I...I'd tighten it a bit, but then I'd think, "well, how much did I tighten in, hold on" [laugh]...
VM: Yeah.
INT: ...[you'd think] "[contemplative noise] okay", uh, but maybe that doesn't matter so much as maybe just tightening it...
VM: Yeah.
INT: ...you know, making it shorter's the...
VM: Yeah.
INT: ...most important thing.
VM: Yeah.
INT: Um, and you can slip back as well so it's kind of, you know, you can think, "oh, hold on a minute". I...It's just harder to gauge I think...
VM: Mm.

INT: ...the progression.
VM: Mm.
INT: Um, so I found it easier to increase the number actually...
VM: Yeah.
INT: ...[to see].
VM: And what about um [tutt], you know th...there was a sort of scale, it was from zero to ten I think...
INT: Yeah.
VM: ...and it was, or or zero to twenty.
INT: Mm.
VM: I can't remember exactly and...and it's um, it's sort of, you know, uh, according to numbers, it gauged how difficult it is...
INT: Yeah.
VM: ...and you had to sort of, decide how difficult you thought it was and...
INT: Mm.
VM: ...then record it down.
INT: Yeah.
VM: What did you think of that?
INT: Um, yeah I...I...it was okay. Yeah yeah, I mean once you get into the rhythm of it, it's hard at first cause your numbers are kind of all over the place. But, once you sort of r...get to know the exercises more, know what you're doing, know your body more...
VM: Yeah.
INT: ...um, then it's easier...
VM: Yeah.
INT: ...to kind of give a subjective view. Um, so.
VM: Okay. Did you feel that your um [tutt], you know you said you sort of get to know the exercises etcetera...
INT: Mm.
VM: ...[tutt] um, how do you think that progressed from the start of the programme to, you know, after you, you know when you came to see me...
INT: Mm.
VM: ...the second time after twelve weeks?
INT: Mm.
VM: How did, how did your sort of, feeling about doing the exercises um, how did you feel about it, how did that change over the t...over the period of time from the beginning?
INT: Um, well obviously they got easier um, to do, um, I think. I mean I think well, they did get easier to do. Um, yeah I g...I enjoyed it more the more I did it actually.
VM: Yeah.
INT: To begin with it's um, [pause] I guess that, I guess that my experience was that it was definitely more, the longer I did them the less pain I got, so obviously it was more [laugh]...
VM: Yeah yeah.
INT: [laugh]
VM: So, it becomes a bit more pleasant [laugh].
INT: Yes it wasn't um, it wasn't as comfortable but uh, yeah and I could, I could see why I was doing them so I was very happy to be doing them, I guess.
VM: Yeah.
INT: Yeah, because obviously I wanted to improve my shoulder...
VM: So...
INT: ...strength and...
VM: ...what were the benefits that you started noticing?
INT: [tutt] Um, better rotat...better movement basically.

VM: Okay.
INT: And less stiffness as well so I wasn't, yeah, it kind of seemed to free up my joints a lot.
VM: Right.
INT: Um, make them much more, un-tighten them I guess. Yeah.
VM: Yup.
INT: If that's a word, un-tighten?
VM: I know what you mean.
INT: [laugh]
VM: So, you feel they're more sort of moveable?
INT: Yeah, yeah. And, I mean my pain kind of varies a lot from day to day. I would s...but nevertheless they were definitely less painful by the end, than than the beginning. Um, yeah. Some were, some were um, some...some were much, got much less pain, there's much less pain in some of them than others.
VM: Yeah.
INT: Some were still really...
VM: Yeah.
INT: ...were still quite painful to do...
VM: Yeah.
INT: ...whereas others were easier.
VM: And, the the next thing I wanted to ask you about was obviously after, I mean you did the classes, but there were only, you know, you had two or three...
INT: Two, yeah.
VM: ...and then um, you obviously carried on at home.
INT: Mm.
VM: How did those two, sort of, ways of exercising compare? You know, being in the class...
INT: Mm.
VM: ...versus being at home? How how, tell me a bit about that.
INT: Um [pause] uh, well it's kind of, it's obviously more nice, it's nicer to do [laugh], do exercise if there's other people, because it's more personable. But um [pause], yeah I mean it's its' fine though to do it at home.
VM: Yeah? [pause] What uh, what do you think the benefits or difficulties of exercising at home were? What would be the things that really stuck out for you?
INT: Um, I guess you know, I guess it's kind of the motivation to do them first of all, um, and I mean the record keeping's a bit of a bind as well but...
VM: You mean the diary?
INT: Yeah, the diary.
VM: Yeah.
INT: Um, but in a way that's good because it, overall you know, you realise, "yeah, that's good because you can see progress", so that's fine but it's, it's just getting started that, you know that the difficulty I suppose. Um, but the diary as well was quite good because if you suddenly realise, you know, at seven o'clock you haven't done them you, you go, "oh no" [laugh].
VM: Yeah.
INT: [laugh] Was quite good.
VM: It's sort of...
INT: Yeah it's a kind of...
VM: ...acts as a reminder.
INT: ...it's a kind of aid-memoir I suppose...
VM: Yeah.
INT: ...thinking, "right, yeah...
VM: Yeah.

INT: ...I've got to do it".
VM: Okay. So it sort of has it's downsides but...
INT: Yeah.
VM: ...it also has it's plus-sides.
INT: Yeah.
VM: Um, and so, you know you said when you're at home it's sort of, you know, one of the things is lack of motivation?
INT: Mm.
VM: Um, what what are the um, things that you found got in the way of you doing your exercises when you were at home?
INT: Um, well mainly just feeling unwell.
VM: Yeah.
INT: Basically [inaudible]. If I was having a bad day, um um, yeah if I was feeling unwell, I just thought, "oh, this is one more thing I've got to [laugh] overcome or get over".
VM: Yeah, do.
INT: Yeah [laugh]. Um, but you know, but having said that, if I was, you know, watching TV or, then it's not, it's fine, I just did it.
VM: Yeah.
INT: [Intended to...]
VM: Yeah.
INT: ...[occupy me].
VM: So that helps? Having...
INT: Yeah, I listen to the radio or do something. I did find that...
VM: Yeah.
INT: You know.
VM: Sort of gave you...
INT: Mm.
VM: ...a bit of a boost.
INT: Yeah.
VM: And did you find, when you were in the class, you know when you were in the class, if you felt unwell, how was, how did that affect you in the class?
INT: [tutt] Um, th...on...I, the one I struggled with so much they changed, so um [tutt] uh, yeah.
VM: So one of the...
INT: Mm.
VM: ...exercises was swapped for a different one?
INT: Mm, yeah, and um [tutt] yeah, I mean it was, it's good to have someone there.
VM: Mm.
INT: Um, kind of shame you had to do it and um, yeah.
VM: Yeah, and how did you think the other people in the class got on with their exercises?
INT: Um, well I'm I'm sure that they weren't too comfortable either looking at people [laugh], didn't look too happy.
VM: No.
INT: [laugh] I'm sure everyone had the same [laugh]...
VM: Yeah.
INT: Yeah. Um, yeah I mean obviously some people had much bigger problems with their hands so I was feeling sorry for them.
VM: Yeah.
INT: [laugh] [inaudible]
VM: Do you, I mean, when you were doing your exercises...
INT: Mm.

VM: ...do you think that you found yours sort of easier, more difficult, or about the same as other people?
INT: Uh, probably about the same.
VM: Yeah.
INT: Yeah.
VM: Yeah.
INT: As I'm sure it was all, um, we were assessed beforehand so I'm sure everyone's level...
VM: Yeah.
INT: ...of difficulty was assessed and their exercises...
VM: Yeah, yeah.
INT: So yeah, I didn't think mine were any more difficult than anyone else [laugh].
VM: Um, and, did you think, I know that y...obviously you couldn't go to one of the classes but um, do you think that there should have been more classes, or less?
INT: Um, as I said before, I would have liked to have done that class, um, I mean it was about an ex... it was about an exercise kind of programme rather than a kind of general kind of rehab lifestyle problem solving. I mean, it would be great if we could have a, I mean it would be fantastic if for arthritis there was like a reha..., you know, a full rehabilitation programme like there is for cardiac rehab.
VM: Mm.
INT: You know where you had concentrated on problem solving and, you know, dealing with um, you know like an occupational therapist kind of approach was incorporated into that.
VM: Mm.
INT: Because the thing is, the services are quite disjointed. Um,...
VM: Mm.
INT: ...in that sense, so it pe...it would have been interesting to hear other people's difficulties, and then kind of solving those problems, um, you know in terms of hearing about other, how other people manage cooking, and cleaning, and what they do as well...
VM: Yeah.
INT: ...so.
VM: But so that w...that was one of the things that wasn't really touched on either...
INT: No, no.
VM: And, so wha...what would your sort of ideal..?
INT: [Oh and] diet and things like that, you know, would have been interesting to hear [inaudible].
VM: Diet?
INT: Yeah.
VM: Yeah.
INT: For example. So diet [had helped them]. I know that's very personal as well, but you know, that type of...
VM: Yeah.
INT: ...just to hear what, how other people would, what other people had found had helped them.
VM: Yeah. So how many classes do you think would have been ideal? Or what what, how would you, what would your views be?
INT: Um, I guess six classes would have been good.
VM: Okay.
INT: Yeah. But incorporating that into other things, obviously you can't have six classes doing this [laugh].
VM: Yeah. But sort of...

INT: Yeah.
VM: ...incorporating the topics that you just mentioned...
INT: Yeah.
VM: ...like diet and...
INT: Pai...
VM: ...pain management.
INT: Pain management and, you know, general kind of occupational problem solving, and things like that.
VM: Yeah. And then wha...and then when the six, and then after the six classes...
INT: Mm.
VM: ...um, [tutt] would it, would there be, would people sort of be encouraged to carry on exercising at home and then, or would...what what would sort of, what do you think would be the ideal mode after that?
INT: Um, yeah...
VM: [inaudible]
INT: ...I think people should be encouraged but you, unfo...you know it's things like, obviously there's always kind of a motivation problem so, it's good to have follow-up as well.
VM: Right.
INT: I think.
VM: Okay. Um [tutt], so are you still doing your exercises now?
INT: No [laugh].
VM: [laugh] So uh, um how l...how long um, did you sort of carry on with them, you know after the classes finished?
INT: Yeah, um.
VM: How long would you say you kept them going?
INT: I didn't really [laugh].
VM: So it was a bit iffy?
INT: No I di...I mean I di...I did do, no I didn't really, it was a bit...
VM: Yeah.
INT: ...no I can't really say that I carried on...
VM: No.
INT: ...doing them.
VM: So would you say, sort of, after the classes, then after that it was sort of a bit, you know?
INT: Mm.
VM: Um, or did you do them a bit here and there or?
INT: [tutt] I did a few, I thought oh well I...I'll, I should really...
VM: [laugh]
INT: ...carry on with this but then I didn't really. So I thought,...
VM: Yeah.
INT: ..."oh", you know, "oh" you know an odd day I'd do a few.
VM: Yeah, yeah. A bit here and there.
INT: Yeah.
VM: Yeah [tutt]. Okay and, ah, is there anything that we could have done do you think, that you know, as in the physiotherapist...
INT: Mm.
VM: ...to have helped you uh, continue your exercises more regularly?
INT: Um [tutt], well I s'pose, I suppose in a way i...it's quite a, the exercises are quite um [tutt], I suppose it, it would have been good to be kind of, to have been reassessed kind of for those exercises, and then sort'a said, "well, yes, this is still good, and maybe you should try this now", because, so a kind of, second kind of planned programme...
VM: Right.

INT: ...I guess would have been good. And I think i...they were quite intense and I, I suppose if they'd been stepped down, I think I might have, if they'd have said, "well, yes well to ma...if it was a kind of maintenance kind of programme, rather than, I mean maybe that should be a maintenance programme [laugh].

VM: [laugh]

INT: [laugh] [inaudible]

VM: [laugh]

INT: But maybe say say, "well this is, you know, this would be beneficial to do this three times a week", or something, I'm not saying, I'm not quite sure, I'm not a physiotherapist [laugh]...

VM: No, but you know, you still have ideas.

INT: ...I'm not quite sure how, but kind of think, I think it's yeah, I thi...I...I think if, if I, if I'd been reassessed and they, and then they said, "right well this has obviously clearly helped you, and then you need to really do, focus on this, but step it down a bit, and do this for, you know, say three days a week and just keep going with that...

VM: Yeah.

INT: ...and that'll keep you [inaudible].

VM: Cause the original one was five days a week, I mean not five days a week, everyday.

INT: Yeah, everyday.

VM: So did you, how did you find that.

INT: Um, would have been nice to have a day off really [laugh].

VM: So, you know in the days in between the classes, cause obviously we know, after the classes it sort of...

INT: Mm.

VM: ...you know, but you know obviously you had uh, two classes a week, or whatever is was, or it might have been one class one week and, but you know you had...

INT: Mm.

VM: ...sort of days in between each class. Did you do your exercises then? You know...

INT: From when when you started?

VM: Uh yeah, so you know...

INT: Yeah.

VM: ...you had the first class and then you had maybe a day or two's gap...

INT: Mm.

VM: ...before the next one...

INT: Yeah.

VM: ...did you...

INT: Yeah.

VM: ...did you keep them going whilst...

INT: Mm.

VM: ...you will still attending the cla...

INT: Yeah.

VM: ...the physiotherapy classes? Okay, and then it was just after the last class that...

INT: Mm.

VM: ...you sort of, you know, it fizzled off a bit? You mean?

INT: At the twelve week assessment?

VM: Yeah, after that?

INT: I didn't have any...

VM: No I mean, you know like [tutt], so up until the twelve week assessment...

INT: Yeah.

VM: ...uh you, did you manage to keep, you...you...did you keep them going everyday or was...would you [inaudible]...
INT: No, yeah yeah.
VM: So up until that point...
INT: Yeah.
VM: ...you were doing them every day?
INT: Yeah.
VM: So you kept going...
INT: Mm.
VM: ...on the sort of daily basis regime?
INT: Yeah.
VM: And then after that, that's when it...
INT: Yeah, kind of [inaudible].
VM: ...fizzled off?
INT: Yeah.
VM: Okay, right.
INT: Yeah.
VM: Okay, so really it was up until that point?
INT: Mm.
VM: So, for for those twelve weeks [you were okay]?
INT: Yeah, so I was dedicated to doing it...
VM: Yeah.
INT: ...for the trial, and then...
VM: Yeah yeah. And then after that it sort of...
INT: Mm.
VM: ...cooled off a bit.
INT: Yeah.
VM: Um [tutt] right, and there was one other thing that I had in my mind, ah! Yes, I remember. Um, do you feel, uh, you know I asked you at the very beginning...
INT: Mm.
VM: ...I said, "did you have any sort of um, expectations?"...
INT: Mm.
VM: And you said, "well I wasn't really sure what to expect...
INT: Mm.
VM: ...cause I...I'd never really done any physiotherapy before".
INT: Mm.
VM: And you weren't quite sure what t...to think about the, you know, what sort of benefits...
INT: Mm.
VM: ...the exercises would have. And so, how do you feel, how has your feeling, how has...how, do you still feel the same way, or has that changed having done the the classes?
INT: No, it's definitely changed. I definitely, yeah. Well, of my expectation I'd say I definitely would kind of recommend it, especially when you're acutely ill, to get going, and doing something. Cause, it does, it does kind of give you hope as well. In the sense that, you know, you can do something yourself. To...to make...
VM: Yeah.
INT: ...yourself more comfortable. Um, so no I think, I think it's, I think it's been quite amazing really...
VM: Yeah.
INT: ...to see that change and progress...
VM: Yeah.

INT: ...um, in my mobility and function in my shoulders and, yeah, it's quite amazing.
VM: Okay. Um [tutt], and in terms of your, this is my last question.
INT: Mmhm.
VM: In terms of your, when you started, if I'd, if I'd, I...say I'd just given you a handbook...
INT: Yes.
VM: ...you know the handbook, and I'd said, "right, here's the handbook and the band"...
INT: Mm.
VM: ...um, and I hadn't, there'd been no classes...
INT: Mm.
VM: ...with other people or with the physio. How would you have felt?
INT: Um, I think you need to be shown how to do them. I don't think I'd, I felt a bit [pause] kind of lost I suppose...
VM: Yeah.
INT: ...really, especially as I hadn't really done any physio before...
VM: Yeah.
INT: ...so if you don't, you know, if it's, s...I don't think it's very easy just to be given just a booklet and told to go away and do it.
VM: Yeah. Um, but now, you know obviously, after having done the group classes, if I gave you a booklet...
INT: Mm.
VM: ...with some exercises, how would you feel?
INT: Well...
VM: The same or...?
INT: No, I...I think I'd f...I've done it before so I'd be, I'd be fine, especially as I've kind of seen the benefit. But I've kind of, now I'm kind of sitting here thinking I've gone on, reflect back and think, "oh, well it's been a huge benefit", and I'm thinking, "well why did I stop?" [laugh].
VM: [laugh] Well...
INT: [laugh] [inaudible] Than I'm thinking, "oh, that's not so good is it?" I suppose it's because I'm so much better and I...
VM: Mm.
INT: Yeah.
VM: Yeah [pause]. So...
INT: I s'pose yeah, and I s'pose no one's really explained to me as well [laugh]. No one's specifically explained to me the benefit of keeping doing this for the next five years...
VM: Mm.
INT: ...actually. I think, we need to be told, well I need to be told why I need to do something.
VM: Yeah.
INT: Really, and i...it needs to be laid down [laugh].
VM: [laugh] Yeah.
INT: [laugh] Um, yeah so I...I actually to be, yeah, I guess going back to what I said then, if you handed me a booklet and said, "go away and do it", I'd still want to be kind of talked through about what this was doing and why it was important.
VM: Yeah.
INT: Rather than just, "here's a book"...
VM: Yeah, yeah.
INT: ...and I'm not s...unless, I wouldn't need to, you know, I don't think um, I'd have to go to a class and do the exercises unless they were radically different.

VM: Yeah.
INT: Just to check I was doing it, but...
VM: Yeah.
INT: ...otherwise um, think, yeah, I need to know, so, yeah, I guess that's my kind of, kind of clinical evidence head on.
VM: Yeah, you want to sort of know what the...
INT: Mm.
VM: So, with all of that sort of in mind...
INT: Mm.
VM: ...uh, this is my, I said that was my last question...
INT: [laugh]
VM: ... I lied, this is my last question now, definitely. I'm telling the truth. Is there anything that we haven't mentioned, or anything that I haven't brought up, that you think might be worth adding, or something that we could, that is important?
INT: Um [pause]. Um, no, just what, just what I've said really.
VM: Okay.
INT: Yeah. I guess, I guess now having sitting here and reflecting on it all, I guess it is, yeah, it is um, it will be helpful to kind of think about where do I go from here, I guess...
VM: Right.
INT: ...in terms of those exercises, because I don't, I mean, hand on my heart, I'm not going to be doing them every day...
VM: [laugh]
INT: ...for the rest of my life, and that, or you know, and I think [pause], because it's such a high bar, if I don't do it, if I don't, the type of person I am it's kind of, if I, it's easier for me to do something three days a week say, or less, than or, you know, or less exercise but longer than it is for me to have to, if I think I'm failing massively on a seven day a week programme [laugh] then I, I don't, I just lose motivation to do...
VM: Yeah.
INT: ...any of it if you see what I mean.
VM: Because it makes you feel as though you're not, sort of...
INT: Yeah.
VM: ...doing the full...
INT: Yeah.
VM: ...thing that you should be doing.
INT: Mm.
VM: Yeah.
INT: So...
VM: Okay, so that's something to think about.
INT: Mmhm.
VM: Right, well that's it then so I'm going to turn this off.
INT: [laugh]
VM: So signing out.

Appendix M EXTRA Qualitative Study Researcher Reflexive Diary

21st October 2010
Interviewed M-038
I felt that this interview was a bit repetitive. I seemed to keep asking the subject the same questions. I think the subject started the interview feeling a bit concerned about giving her true opinion of the programme. Later in the interview, she was more frank about her feelings. The subject was interested in discussing diet and the benefits of her holiday, as well as the exercise classes she attends at her local gym. It was sometimes difficult to steer her answers back to the EXTRA programme.

29th October 2010
Interviewed M-034
The subject was very talkative and did not require a great deal of probing. On occasion, the subject's answers strayed away from the scope of the questions asked. She made considerable effort to answer each question as fully and openly as possible.

3rd November 2010
Interviewed M-022
The subject required quite a bit of prompting to elaborate further in answering questions. I am concerned that he sometimes answered according to how he thought he should feel, as opposed to always conveying his true opinion. It was interesting to explore his reason for not attending three of the classes.

November to December 2010
Transcribing M-034
I may have influenced the subject's response when I said, "in other words, you build a relationship with the physiotherapist..." I deduced my own meaning from the subject's account of the education component of the classes when I said, "so it was useful". I answered my own question, rather than allowing the subject to respond, when I asked what factors made class attendance difficult. I also added my own answer, "or if your arthritis..." Arthritis was not mentioned by the subject in the context of this question. I asked a leading question; "are your family quite good at supporting you?" I asked a leading question; "do you think exercises are a way of managing your arthritis?" I asked a leading question; "did you find the handbook useful?"

December 2010 to January 2011
Transcribing M-022
I asked a leading question; "Did you find the diary and the handbook in general useful when exercising at home?" I used the term physical activity, yet it may not have been clear to the subject what I meant by this. I asked a leading question; "do you think it's good...to keep really active?" I asked a leading question, and may have made assumptions about the subject's meaning in a previous statement; "you mentioned the same person, so it's quite important to have the same person".

January 2011
Transcribing M-038
I asked, "what do you think the plus sides are of doing things in a group?" This is a biased question, focusing on the plus sides only. I asked a leading question; "do you find exercise beneficial in making you feel well?"

25th January 2011
Interviewed M-070
This subject was very cheerful to interview. She was unique in that she had a very positive outlook from the beginning of the programme. She was very confident in her ability to exercise, she managed to adhere to the daily exercise regimen, and she still performs the exercises several times weekly.

25th January 2011
Interviewed M-075
The subject began the interview by giving a large amount of feedback on the programme. Overall, it seemed that her opinions of the classes and home regimen were positive. She experienced a great deal of stress following completion of the classes, when she was forced to move house. This has lead to difficulties in her adherence to the exercise regimen.

25th January 2011
Interviewed M-060
The subject seemed to answer openly and honestly. The interview ended slightly abruptly as the subject had informed me that she needed to leave promptly to be on time for another commitment.

25th January 2011
General Comments
Many subjects have described the importance of the group in maintaining motivation, for support from those in the same position, and for learning. This arose again today. Today I sought to explore subjects' confidence at the start of the programme and how this evolved over time, as well as how this was affected by the handbook and exercising at home. This was sometimes difficult to do, and I felt perhaps rather superficially covered, because I did not want to make the subjects aware of my own expectations.

14th February 2011
Transcribing M-070
I asked a leading question; "Did you feel um, quite sort of happy about exercising, quite confident about it..."

25th March 2011
Interviewed M-035
This was a very interesting interview. This subject is a clinical psychologist herself, and therefore I found her answers particularly thoughtful and enlightening, sometimes grounded in psychological theory. However, I have to take care not to give more weight to her responses than those of other subjects. Furthermore, I have to be aware that her responses may be somewhat biased by her own background. She has learnt to evaluate her own and others behaviour in a given way. The interview itself went very well. I feel that I have come a long way since my initial pilot interviews. I now allow the subjects to answer my questions in their own time, and take the time myself to think about wording my questions in a way which will not, or is least likely to, bias the subject's responses.

11th May 2011
Transcribed M-035
Unfortunately, this interview was inadvertently deleted after the first draft of transcription, prior to proof reading, and therefore may contain minor errors.

4th July 2011
Interviewed M-099
Overall, the subject seemed to have had a positive experience of the programme. She was much more cheerful than when she attended her baseline assessment, and said that she was feeling much better. As an academic, she expressed an interest in reading the study results once available. I believe she was happy to have been chosen to share her experience. At times, my questions were not as clear as they could have been. There was some misunderstanding when I asked about the subject's adherence to the exercise regimen. Initially, I was under the impression that she had adhered to the regimen only up until completing the physiotherapy classes. However, it later became clear that she had meant that she had adhered to the exercise regimen up until her 12-week assessment. This created some confusion, and should be taken into account when interpreting the interview at a later date.

4th July 2011
Interviewed M-076
Due to language difficulties, it took time to gain a deeper understanding of this subject's views. However, ultimately, the subject rose some interesting points, which reiterated some of those expressed by other subjects.

13th July 2011
Interviewed M-103
This lady was very positive about the programme. She had particularly favourable views about the physiotherapist. She expressed confidence in the knowledge and ability of the physiotherapist by contrast to a fitness professional, for example. However, she herself is a nurse, and therefore, her views may be somewhat biased. She explained that her main incentive to participating in the programme was to improve her ability to carry out her hobby: baking and decorating cakes. She was well supported at work and by her family, and therefore her adherence to the programme was facilitated by being able to perform her exercise at work and receiving transportation from her daughter. She was open and honest in her views, and I got the impression that she genuinely valued the experience of participating in the programme.

15th to 17th August 2011
Transcribing M-099
I asked a leading question about the physiotherapy intervention, "did you hope that it would sort of help you in some way, or did that um?" Fortunately, this did not seem to influence the subject's response. The subject gave a lot of thought in answering the questions.

17th August 2011
Transcribing M-076
This subject was very positive about the physiotherapy programme.

19th August 2011
Transcribing M-060
This subject mentioned that the nurse specialist at UHL spoke positively about the exercise programme at the time of recruitment. I failed to ask how this made her feel. This might be a worthwhile question in the future – to explore the effect of healthcare professional in influencing patient opinion to exercise. Early in the interview I say, "So, a bit worried about the um, the exercises causing you, sort of, more harm than..." and the subject replies, "Than good, yes". I am not sure that this is exactly what the subject meant, or at least she referred to the affects of pain. Some care should be taken in interpreting this part of the interview.

25th August 2011

Analysing M-060

The subject mentions that when she doesn't go to the gym because of the weather, she does other things. It would have been interesting to question her as to what other exercise or forms of activity she does in these circumstances. There is limited data on goals. It would be interesting to explore subjects' goals further, including goal achievement, the effect of setting goals on exercise participation and adherence, the effect of goal achievement, etc.

29th August 2011

General Comments

It seems that some of the subjects are confused about the frequency and duration of the exercise classes they attended.

8th September 2011

Interviewed M-098

This subject was unusual in that she is very active; cycling 22 miles to and from work, at least three times a week. Prior to diagnosis with RA, she ran regularly; up to half marathon distances. Therefore, she is highly self-motivated to exercise. She comes from an academic background, and works 6 days per week. Her arthritis is well controlled with medication. She clearly regarded the exercises as an investment for her future with RA, as opposed to necessary therapy for arthritis related limitations at this point in time. She was adherent to the programme, despite not enjoying it. She withdrew from the trial due to medical reasons unrelated to her arthritis. My impression was that she found the programme geared up for people who do not work, and whose arthritis was more active. She also felt that the information covered in the educational seminars uninformative, given that she had read independently about the condition when diagnosed. She may have been more suited to an individual consultation with a physiotherapist, followed by home exercise. She often remarked on the intensity of the home exercise programme, referring to the daily frequency. She would have found it more acceptable if it were three days per week.

20th September 2011

Interviewed M-089

This subject required a lot of probing to encourage his responses. I was concerned that this directed his responses to some extent, and limited his original thought. He seemed as though he was a very easy going character, whose approach to exercise was just that; some expectations and concerns but quite happy with the programme, the physiotherapist, the locations, etc. He felt that he benefited from the class experience, i.e. attending the classes motivated him to continue independently, and from one to one time with the physiotherapist. He could not remember the education sessions in any great detail, and found the diary, rather than the exercise instructions, useful for his progression.

Appendix N Physical Activity Questionnaire

PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. Your answers are important, so please answer each question even if you do not consider yourself to be an active person.

1. Gender (Please tick the appropriate box): ☐ male or ☐ female

2. Age (Please tick the appropriate box):

☐ Under 25 ☐ 35 – 44 ☐ 55 – 69

☐ 26 – 34 ☐ 45 – 54 ☐ 70+

3. What is your reason for attending the rheumatology clinic? (Please tick **all** of the appropriate boxes)

☐ Rheumatoid Arthritis ☐ Gout ☐ Fibromyalgia

☐ Osteoarthritis ☐ Lupus ☐ Don't know / Not sure

☐ Psoriatic Arthritis ☐ Ankylosing Spondylitis ☐ **Other:** _____

4. Time since date of diagnosis (Please write in the spaces provided):

_____ Years _____ Months ☐ Don't know / Not sure

5. During the last **7 days**, on how many days did you do **vigorous** physical activities?
Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal, like heavy lifting, digging, aerobics, or fast bicycling. **Do not include walking**.

Think about only those physical activities that you did for **at least 10 minutes** at a time.

_____ **days per week** ⇒ How much time in total did you usually spend on *one of those days* doing **vigorous** physical activities?

OR ☐ **None** _____ **Hours:** _____ **Minutes**

6. During the last **7 days**, on how many days did you do **moderate** physical activities?
Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal, like carrying light loads or bicycling at a regular pace. **Do not include walking**.

Again, think only about those physical activities that you did for **at least 10 minutes** at a time.

_____ **days per week** ⇒ How much time in total did you usually spend on *one of those days* doing **moderate** physical activities?

OR ☐ **None** _____ **Hours:** _____ **Minutes**

7. During the last **7 days**, on how many days did you **walk** for **at least 10 minutes** at a time?
(*This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure*).

_____ **days per week** ⇒ How much time in total did you usually spend walking on *one of those days*?

OR ☐ **None** _____ **Hours:** _____ **Minutes**

8. During the last **7 days**, how much time in total did you usually spend **sitting** on a **week day**?
(This includes time spent sitting at a desk, visiting friends, reading travelling on a bus or sitting or lying down to watch television).

_____ **Hours :** _____ **Minutes**

9. Which physical activities do you enjoy? (Please tick **all** of the appropriate boxes, and write any additional ideas in the space provided):

- ☐ Walking
- ☐ Swimming
- ☐ Cycling
- ☐ Jogging
- ☐ Lifting weights
- ☐ Aerobics
- ☐ Sports (*e.g. tennis, cricket, golf, football*)
- ☐ Pilates / Yoga / Tai Chi
- ☐ Gardening
- ☐ Don't know / Not sure
- ☐ **Other:** _____

10. How do you prefer to exercise? (Please tick **all** of the appropriate boxes, and write any additional ideas in the space provided):

- ☐ On my own
- ☐ With friends / family
- ☐ Outside
- ☐ In a gym
- ☐ At a community centre
- ☐ At home
- ☐ In water (*i.e. swimming pool or hydro-pool*)
- ☐ With workout video or game (*e.g. Wii Fit*)
- ☐ In an exercise group with a mixed group of people
- ☐ In an exercise group with people who have the same condition as me
- ☐ In an exercise group with people who are the same age as me
- ☐ Don't know / Not sure
- ☐ **Other:** _____

11. Has a doctor or other health professional **ever** suggested an increase in physical activity or exercise to help your arthritis or joint symptoms? (Please tick the appropriate box):

☐ Yes ☐ No ☐ Don't know / Not sure ☐ Refused

12. Would you like help from your doctor or health service to become more physically active? (Please tick the appropriate box):

☐ Yes ☐ No ☐ Don't know / Not sure

If you would be happy for us to contact you about your responses, please print your name and address below. Otherwise, your answers will be anonymous.

Name: .....

Address: .....

.....

.....

Please post your completed questionnaire into the collection box on the reception desk.
Thank you for participating.

Appendix O WEB OF SCIENCE Search Strategy

1 “rheumatoid arthritis” [ti]
2 arthritis [ti/topic]
3 rheumatic [ti]
4 finger [ti]
5 thumb [ti]
6 hand [ti]
7 wrist [ti]
8 elbow [ti]
9 shoulder [ti]
10 “upper limb” [ti]
11 arm [ti]
12 exercise [topic]
13 “physical activity” [topic]
14 training [topic]
15 strength [topic]
16 resistance [topic]
17 flexibility [topic]
18 balance [topic]
19 aerobic [topic]
20 dynamic [topic]
21 isometric [topic]
22 isotonic[topic]
23 static [topic]
24 adherence [ti]
25 uptake [ti]
26 maintenance [ti]

1 or 2 or 3 **AND** 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 **AND** 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
FOUND REFERENCES UP TO DECEMBER 2008: 259

2 **AND** 12 or 13 **AND** 26 or 27 or 28
FOUND REFERENCES UP TO DECEMBER 2008: 39

Appendix P MEDLINE AND COCHRANE Search Strategy

1 “rheumatoid arthritis” [ti]
2 arthritis [ti/tiab]
3 rheumatic [ti]
4 finger [ti]
5 thumb [ti]
6 hand [ti]
7 wrist [ti]
8 elbow [ti]
9 shoulder [ti]
10 “upper limb” [ti]
11 arm [ti]
12 exercise [ti]
13 “physical activity” [ti]
14 training [ti]
15 strength [ti]
16 resistance [ti]
17 flexibility [ti]
18 balance [ti]
19 aerobic [ti]
20 dynamic [ti]
21 isometric [ti]
22 isotonic [ti]
23 static [ti]
24 weight [ti]
25 intensity [ti]
26 adherence [ti]
27 uptake [ti]
28 maintenance [ti]

1 or 2 or 3 **AND** 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 **AND** 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
Filter: Humans
FOUND REFERENCES UP TO DECEMBER 2008: 1800

2 **AND** 12 or 13 **AND** 26 or 27 or 28
FOUND REFERENCES UP TO DECEMBER 2008: 63