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Can Pilates and Tai Chi group online classes improve fatigue and mental health symptoms in patients with rheumatological diseases?

Submission date
19/08/2025

Recruitment status
Recruiting

Registration date
19/08/2025

Overall study status
Ongoing

Last Edited
01/09/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people with rheumatological diseases experience severe fatigue (extreme tiredness) and other symptoms, which can make participating in everyday life very difficult. Previous research found that doctors cared about fatigue among people with rheumatological diseases, but said that the NHS didn't have the time or money to provide much support for dealing with it. There is some evidence to suggest that group exercise classes may help with fatigue in people with rheumatological diseases. This study is looking at whether Pilates or Tai Chi online group classes can reduce fatigue and improve quality of life.

Who can participate?
Patients aged 18 years and over who are resident in the UK and diagnosed with a systemic autoimmune rheumatic disease (SARD). These include, but are not limited to, inflammatory arthritis, systemic lupus erythematosus, systemic sclerosis, Sjögren's, myositis, vasculitis, and undifferentiated (UCTD) or mixed (MCTD) connective tissue disease. They should be currently experiencing fatigue that impacts their daily life and not currently attending a regular exercise class, either in person or online, once a week or more regularly.

What does the study involve?
Participants are randomly divided into three groups. One group will receive usual care (i.e. the control group), one will be offered Pilates classes, and the other group will be offered Tai Chi classes. Classes will be delivered by qualified instructors online via Zoom, twice a week for 8 weeks. Participants will have the option to continue classes once a week for an additional 8 weeks. The researchers will follow the participants for 6 months to measure the impact on fatigue and other mental health symptoms. Participants will complete online questionnaires at four separate timepoints: baseline, 10 weeks, 18 weeks and 6 months.

What are the possible benefits and risks of participating?
The physical activity course will be gentle and adapted to people with chronic diseases, but any activity may cause problems or injury in anyone. In the case of minor injuries, you will be allowed to continue with the class but should avoid movements which cause pain. In the unlikely event of

a significant injury during the class, you will be advised to stop the activities and directed to seek medical advice from your usual care provider, i.e. your GP. You may be able to rejoin the classes later if deemed appropriate by your care provider.
If you are randomly selected for the Pilates or Tai Chi classes you may experience improvements in your fatigue and quality of life over the 8-week course. You may also benefit from the social aspect of attending regular group classes and interacting online with others during the class.
We anticipate the information gained from this trial will help inform doctors and researchers about the impacts of social online exercise classes on people with systemic autoimmune rheumatic diseases. You will be contributing to research that aims to improve the lives of people with systemic autoimmune rheumatic diseases.

Where is the study run from?
The trial is being organised by the University of East Anglia in collaboration with the University of Cambridge and King's College Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
April 2025 to March 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Miranda Van Emmenis (Trial Coordinator), ADAPT@medschl.cam.ac.uk

Study website
https://www.phpc.cam.ac.uk/primary-care-unit/long-term-conditions-group/adapt-trial

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
341357

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61364; NIHR207162

Study information

Scientific Title
Randomised controlled trial to investigate the effectiveness of online exercise interventions in improving fatigue and reducing the high burden of mental health symptoms in rheumatology patients

Acronym
ADAPT (Exercise)

Study objectives
Primary objective:
1. To measure the effectiveness of online exercise classes for reducing fatigue among rheumatology patients compared with usual care.

Secondary objectives:
1. To measure the effect of online exercise classes on quality of life, depression, anxiety, resilience, cognitive dysfunction, physical activity, disease adaptation, and opioid and daily steroid use among rheumatology patients compared with usual care.
2. To evaluate the cost and cost-effectiveness of online classes versus usual care, from the perspective of the NHS, patients and families.
3. To ascertain participant views and experiences of the two types of online exercise classes (Pilates and Tai Chi).
4. To assess the sustainability of continuation of increased physical activity following the initial 8-week main intervention period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/07/2025, Faculty of Medicine and Health Sciences Research Ethics Subcommittee (FMH S-REC, Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, NR4 7TQ, UK; Tel: not provided; fmh.ethics@uea.ac.uk), ref: ETH2425-1992

Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatological diseases

Interventions
Participants are randomly divided into three groups. One group will receive usual care (i.e. the control group), one will be offered Pilates classes, and the other group will be offered Tai Chi classes.

Exercise classes will be delivered by a qualified instructor via Zoom twice per week, in 1-hour sessions, over 8 weeks. Participants will receive the intervention in group sizes of 18-20. Exercises will be tailored to participants with chronic diseases with an emphasis on participation and enjoyment. Although the nature of the exercise will differ between the Pilates and Tai Chi arms, the key elements will remain consistent: a set time for warm up, balance and strength components, a seated chair-based section, a cooldown stretch and 10 minutes at the end of each class allocated to facilitate communication between participants. There will be regular intervals for rest and water throughout the sessions. Patients are free to ask questions regarding the exercises during the sessions if they are unclear on technique or where they should be feeling each exercise.

There will be adaptations provided for every exercise for every level of ability. The classes will be carefully tailored to provide a combination of similar exercises each week to improve confidence and ability, with some variations to maintain interest. Those who are able (and want to) will be given the opportunity to increase the difficulty of exercises, but there will be no expectation or pressure other than to enjoy themselves and carry out whichever of the movements each individual can manage.

Intervention Type
Behavioural

Primary outcome measure
Fatigue measured by Functional Assessment of Chronic Illness Therapy (FACIT-Fatigue) at baseline and 6 months post-randomisation

Secondary outcome measures
1. Fatigue measured by FACIT-Fatigue at baseline, 10 weeks and 18 weeks post-randomisation
2. Quality of life measured by the EQ-5D-5L at baseline, 10 weeks and 6 months
3. Depression measured by the Patient Health Questionnaire –8 (PHQ-8) at baseline, 10 weeks and 6 months
4. Anxiety measured by the Generalised Anxiety Disorder Questionnaire (GAD-7) at baseline, 10 weeks and 6 months
5. Cognitive dysfunction measured by the Cognitive Failures Questionnaire (CFQ) 2.0 at baseline, 10 weeks and 6 months
6. Resilience measured by the Connor-Davidson resilience scale (CD-RISC 10) at baseline, 10 weeks and 6 months
7. Physical activity measured by the International Physical Activity Questionnaire (IPAQ-SF) at

baseline, 10 weeks and 6 months
8. Coping, control, participation in life, and satisfaction with life, measured using the ADAPT instrument, our patient-designed disease adapting tool, at baseline, 10 weeks, 18 weeks and 6 months
9. Proportion of participants achieving oral steroid reduction, measured using a non-validated four-item questionnaire at baseline and 6 months post-intervention
10. Proportion of participants achieving opioid reduction, measured using a non-validated single-item question at 6 months post-intervention

In addition, the following will be measured:
1. Views and experiences of the exercise classes, collected via in-depth qualitative interviews at 6 months
2. Health and social care use, and costs borne by patients, measured using a retrospective resource use questionnaire at baseline and 6 months

Overall study start date
01/04/2025

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Resident in the UK
3. Report a diagnosis of a systemic autoimmune rheumatic disease (SARD). These include, but are not limited to, inflammatory arthritis, systemic lupus erythematosus, systemic sclerosis, Sjögren's, myositis, vasculitis, and undifferentiated (UCTD) or mixed (MCTD) connective tissue disease
4. Report a score of 3 or more on question 1 of the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scale (BRAF-NRS) for fatigue severity
5. Able to attend a minimum of two exercise classes per week, from the choice of timeslots offered in the expression of interest form
6. Understand spoken English language
7. Able to read/write English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 420; UK Sample Size: 420

Key exclusion criteria
1. Are unable to provide informed consent
2. Currently attend regular exercise classes, either in person or online, once a week or more regularly.
3. Have medical (physical and/or mental health) instability or comorbidities preventing safe participation in physical activity
4. Are participating in another fatigue-related intervention study

Date of first enrolment
01/09/2025

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Participants are recruited via social media and advertisement posters
United Kingdom
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Sponsor information

Organisation
University of East Anglia

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Norwich Research Park
Earlham Road
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NR4 7TJ

Sponsor type
University/education

Website

https://www.uea.ac.uk/

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the study team at ADAPT@medschl.cam.ac.uk. Following publication of the main trial outcome, a pseudonymised version of the trial dataset will be shared following any reasonable request and subject to a data sharing agreement in accordance with the consent provided by participants. This will be deidentified in a manner to reduce the risk of reidentification, with a data sharing agreement overseen by the sponsor.

IPD sharing plan summary
Available on request