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Trialling remote methods of improving patient lives and adapting to systemic autoimmune rheumatic diseases

Submission date
22/03/2023

Recruitment status
No longer recruiting

Registration date
29/03/2023

Overall study status
Ongoing

Last Edited
28/03/2023

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Systemic autoimmune rheumatic diseases (SARDs) are chronic illnesses that can have negative effects on both physical and mental health, as well as overall quality of life. People with lupus (SLE) are at a higher risk of experiencing mental health symptoms that can impact their quality of life, such as depression. Many people with SARDs also have psychosocial problems related to their disease, but these are often not discussed with their doctor due to time constraints.

Although some rheumatology patients report good support from their doctors, there are still gaps in care. Patients need more support to cope with their chronic illness and address their psychosocial needs. With Covid-19 reducing the frequency of appointments, there is an urgent need for remote interventions to provide psychosocial support and patient education.

Our current INSPIRE study (unpublished) results suggests that loneliness has a major negative impact on rheumatology patient QoL yet this has not been know it has not been studied in lupus. Resilience is an important aspect of adapting to living with chronic diseases, yet few studies have assessed resilience in lupus, or the wider rheumatology population. Therefore, we will be trialling measures of loneliness and resilience in addition to the more commonly assessed QoL, depression and anxiety.

The ADAPT study will trial different remote interventions to improve mental health and quality of life measures, such as loneliness, depression, and resilience. The study will also identify which measures are most important to patients.

Who can participate?
For phase 1, participants will be selected from those requesting to take part in ADAPT in our recent INSPIRE study survey, with lupus and aged 18 or over and resident in the UK or Ireland. For phase 2, we will open up participation more widely, and advertise through social media and online disease support groups. Disease groups will include all systemic rheumatic diseases (i.e. including rheumatoid arthritis, Sjogrens, vasculitis etc).

What does the study involve?
The study involves trialling three interventions (in addition to a control group who do not receive an intervention):
1. An online exercise course,
2. The Wren Project listening support, and
3. A text messaging support programme. The interventions have been selected based on patient surveys eliciting their priorities for methods of support, and to attempt to fill some of the multiple gaps in the literature identified.

What are the possible benefits and risks of participating?
We do not foresee any direct risks to your physical health from participating in this study. The following risks, although unlikely, need to be considered:
• It is hoped that texts, courses and listening therapy will be helpful to you, but some people may find some information and discussions about health difficulties and medical experiences distressing. You will be given the contact details of rheumatology charities, mental health charities and the research team who can provide information about how to obtain further support.
• Although the support group contact will be by texts and the courses will be online, some relationships may be formed where you wish to meet face to face too. Please note this will be outside of the study, at your own risk and usual precautions should be followed for meeting online contacts.
• The only rule of the courses and WhatsApp support groups is that everyone be kind and supportive. It is most likely that this will be the case and anyone not following this rule will be asked to leave the group.
• There is a very small risk of unwanted further contact from group members if you decide to withdraw or anyone has been withdrawn due to not following the rules of being kind and supportive.
• Please remember that information shared and/or exchanged in these support groups is no substitute for medical advice. The information given in the texts will always be from – or checked by – qualified clinicians, but will be general advice and not always taking into account your own disease manifestations. Always seek the advice of a qualified medical professional.
• The physical activity course will be gentle and adapted to people with chronic diseases, but any activity may cause problems or injury in anyone, and participation will be at your own risk.

You will be able to receive support that may help improve your quality of life and adapting to the challenges of living with a chronic disease, all from the comfort and safety of your own home. Forming relationships with other patients through the courses and WhatsApp groups may be of benefit in reducing loneliness and providing a deeper level of understanding and support than can easily happen with friends and family without the disease.

We anticipate the information from the questionnaires will help inform doctors and researchers about the impacts of your disease and positive and negative medical experiences leading to greater understanding and support.

Where is the study run from?
Department of Public Health at Cambridge University (UK)

When is the study starting and how long is it expected to run for
November 2022 to December 2025

Who is funding the study?
The Lupus Trust at Guys and St Thomas' hospital and LUPUS UK are funding the study

Who is the main contact
Melanie Sloan, mas229@medschl.cam.ac.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
version 1. PRE.2023.026.

Study information

Scientific Title
The ADAPT randomised controlled trial: Adapting, Disease self-management and Acknowledgement by Psychosocial Targeted interventions for rheumatology patients

Acronym
ADAPT

Study objectives
Aim
To assess the acceptability, feasibility and effectiveness of methods of remote psychosocial support for SARDs patients.

Objectives
1. To trial multiple quality of life and mental health measures to determine the most appropriate primary and secondary outcomes for phase 2.
2. To test processes to inform phase 2 effectiveness trial.
3. To develop and trial our own ADAPT instrument to more accurately reflect, measure and monitor SARD patient personal, social and medical satisfaction.
4. To assess the acceptability (phase 1) and effectiveness (phase 2) of remote psychosocial interventions on the mental health, wellbeing, self-esteem, resilience, loneliness and disease acceptance of patients with systemic autoimmune rheumatic diseases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2023, Cambridge Psychology research ethics committee (Ethics Committees School Office of the School of the Biological Sciences, Cambridge University, 17 Mill Lane, Cambridge, CB2 1RX, UK; +44 1223 76689; SBSadmin@cam.ac.uk), ref: PRE.2023.026

Study design
Interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Systemic autoimmune rheumatic diseases (SARDs), Systemic lupus erythematosus (SLE) (lupus)

Interventions
Participants will be allocated randomly (by block randomisation to ensure equal numbers per group) into one of four groups:
1. Control - no additional intervention
2. Text messaging support - to receive an automated programme of informative and supportive texts and links to videos from 4 experts over an 8 week period at a rate of approximately two texts per day
3. Listening group - to receive listening support from The Wren Project, one a fortnight over Zoom for 12 weeks
4. Exercise group - to receive Pilates/fitness classes over Zoom from Flexifit Pilates twice a week for 8 weeks

Intervention Type
Behavioural

Primary outcome measure
Primary outcomes will be measured at Baseline and Follow-up 2 (6 months post baseline). Phase 1 will include testing multiple outcome measures for acceptability for Phase 2. Primary outcome measures for phase 1 are:
1. Loneliness measured using the UCLA 6 item loneliness scale (RULS-6)
2. Resilience using the Connor Davidson resilience scale

Phase 2: Primary outcome to be selected from Phase 1 trial measures (listed below in secondary outcome measures) and pre-published prior to recruitment for phase 2.

Secondary outcome measures
All measures at baseline, Follow-up 1 (Baseline+12 weeks) and Follow-up 2 (Baseline +6 months)
1. Loneliness measured using the UCLA 6 item loneliness scale (RULS-6)
2. Resilience using the Connor Davidson resilience scale
3. Anxiety measured using the GAD-7 scale
4. Depression measured using PHQ-8
5. Adapting to a chronic disease measured using our own new ADAPT instrument
6. Fatigue measured using the FACIT-F
7. Quality of life measured using EQ-5D-5L

Overall study start date
01/11/2022

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Resident in the UK or Ireland
3.1. Phase 1: Have SLE (lupus) as a diagnosis on clinic letters
3.2. Phase 2: Have any Systemic autoimmune rheumatic diseases (SARD) as a diagnosis on clinic letters

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Phase 1= 120 participants, Phase 2= approximately 800 participants (to be decided following phase 1)

Key exclusion criteria
1. Aged under 18 years
2. Not resident in the UK or Ireland.
3. Not having SLE (lupus) for phase 1 or any systemic rheumatic disease for phase 2.

Date of first enrolment
18/04/2023

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
England

Ireland

United Kingdom

Study participating centre
Department of Public Health, Cambridge university
Forvie Site
Addenbrookes campus
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Sponsor information

Organisation
University of Cambridge

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Sponsor type
University/education

Website
http://www.cam.ac.uk/

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Charity

Funder Name
LUPUS UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
The Lupus Trust

Results and Publications

Publication and dissemination plan
Planned publications in high-impact journal after each phase is completed

Intention to publish date
01/05/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication.
Data will be anonymised.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	17/02/2023	28/03/2023	No	No