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Exploring the impact on patients with lupus and related autoimmune diseases of peer support, relationships with clinicians and COVID-19 changes to care

Submission date
25/02/2020

Recruitment status
No longer recruiting

Registration date
27/02/2020

Overall study status
Completed

Last Edited
28/03/2023

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Research shows that peer support is very important to many patients with lupus and similar autoimmune diseases. Researchers are therefore looking to see if being in small email support groups with other people with the same diseases is an acceptable and helpful form of peer support.
They are also looking for patients to help in deciding what they would like researched in more detail, including helping design questionnaires for patients and doctors; the responses to which should help to identify common patient experiences and develop proposals for improving care and support.
Previous studies and current work with lupus and related autoimmune diseases patients found a need for more support with quality of life, mental health and coping with a long-term difficult condition. There is also more research needed on the impact on patient mental health from the often-lengthy diagnostic delays, misdiagnoses and feelings of a lack of support.
The perception of poor care on the diagnostic journey, especially for the many who report feeling their symptoms were disbelieved, can have a continued influence on a patient's mental health and behaviour. It can therefore damage both mental and physical health, long after the correct diagnosis. Insecurity, fear of rejection and physician's disbelief were widely reported by these patients in earlier studies to be always present even in later positive medical relationships.
Despite the WHO action plan for chronic disease management encouraging governments to provide education, incentives and tools for patients to manage their own diseases, many patients with lupus report there is limited help with self-management education from doctors, thus often relying on peers in online forums and Facebook groups for knowledge transfer and emotional support. Peer support from those who experience the same challenges of living with the same chronic health condition is increasingly being researched in terms of measuring health outcomes, empowerment, mental health and improved quality of life.
The WHO also recognises the importance of mental wellbeing as an important part of health. Studies have shown varied success from peer support initiatives across different disease types. This study will measure the impact of small group peer support on mental wellbeing. The large-

scale questionnaire will determine the current state of mental wellbeing and perceptions of support, in a significant proportion of patients with systemic autoimmune rheumatic diseases in the UK.
The main aims of the study are:
1. To explore whether patients find it acceptable and helpful to receive and give peer support by small group email.
2. To measure the impact of peer support and research involvement on the mental health, wellbeing, self-esteem and disease acceptance of patients with lupus and systemic autoimmune rheumatic diseases.
3. To empower patients and improve research quality and by involving them in research into their own disease; generating research questions and research materials that are relevant to their priorities, needs and experiences.
4. To investigate key factors in effects of the disease and patient-physician interactions before and after diagnosis on patient behaviour, mental health/ wellbeing and disease acceptance.
5. To compare lupus and related disease patients' wellbeing, mental health and perception of medical care with patients with RA, fibromyalgia and healthy controls.
Added 30/03/2021 due to impact of pandemic during data collection:
6. To investigate key factors in effects of the disease and patient-physician interactions pre and post diagnosis on patient behaviour, mental health/wellbeing and disease acceptance
7. To examine the impact of COVID-19 on medical care, relationships, behaviour and wellbeing
8. To examine the impact of COVID-19 on medical care, relationships, behaviour and wellbeing

Who can participate?
Patients aged 18 or over, resident in the UK, with SLE (lupus), UCTD (undifferentiated connective tissue disease), Sjögren's syndrome, discoid/cutaneous lupus or MCTD (mixed connective tissue disease)/ overlap disease. Additional participants for the questionnaire study include those with RA (rheumatoid arthritis) or fibromyalgia, resident in UK and aged 18 or over. Healthy controls must be resident in UK, aged 18 or over, and have no significant illness.

What does the study involve?
The study will involve completing a questionnaire about the patient's disease, wellbeing and feelings. A computer programme will then randomly allocate everyone into three equal groups, which will be labelled A, B and C. Each main group will contain approximately 60 people and be divided into smaller support groups for groups A and B, with Group C being the control group. Group A and B will be divided into small email support groups of 6 people with group A also given research questions (e.g. please discuss in your group what you think are the most important things for rheumatologists to ask in clinic appointments) to discuss and feedback to the researchers every 1-2 weeks. Group C will not be put into support groups initially as it will be the control group (for comparison). However, in order to ensure everyone has the chance of joining an email support group, everyone in Group C will be given the opportunity to be put in an email support group after the first four months of the study if they wish. People in all three groups will receive another questionnaire about their health, feelings and experiences at the end of the study (four months) and after 12 months. The questionnaires designed with help from group A will be sent to LUPUS UK members and clinic patients and physicians.

What are the possible benefits and risks of participating?
Forming a small group with other patients may be of benefit in providing a deeper level of understanding and support than can easily happen with friends and family without the disease. A small group communicating privately may be more personal and comfortable for many people in addition to the support offered by larger public online forums. Being involved in helping with research into their own disease may be empowering and help to improve communication and medical support in the future.

The researchers do not foresee any direct risks to physical health from participating in this study. For those who are randomly allocated to groups A or B, there are small possible risks to consider. It is hoped that discussing experiences will be helpful, but some people may find some discussions about health difficulties and medical experiences distressing. The only rule of the 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 they decide to withdraw or anyone has been withdrawn due to not following the rules of being kind and supportive.

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

When is the study starting and how long is it expected to run for?
March 2020 to April 2021

Who is funding the study?
LUPUS UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

PRE.2019.099

Study information

Scientific Title
Investigating the impacts of peer support, patient-physician interactions and changes in care due to COVID-19, on the healthcare behaviour, satisfaction with care and mental health/ wellbeing in patients with SLE and other systemic rheumatic diseases

Acronym
LISTEN

Study objectives
Current study hypothesis as of 30/03/2021:
1. Peer support improves SLE/SARD patient mental health and wellbeing
2. Active involvement in research into their own disease improves SLE/SARD patient mental health and wellbeing
3. Past and current medical relationships influence satisfaction with care and adherence to medication/advice
4. COVID-19 has adversely affected the medical care of these patients

Previous study hypothesis:
1. Peer support by small group email improves SLE/SARD patient mental health and wellbeing
2. Active involvement in research into their own disease improves SLE/SARD patient mental health and wellbeing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/01/2020, Cambridge Psychology Research Ethics Committee (School of the Biological Sciences, 17 Mill Lane, Cambridge, UK; no tel. provided; cheryltorbett@admin.cam.ac.uk), ref: PRE.2019.099

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Lupus and other related SARDs/CTDs (systemic autoimmune rheumatic diseases/connective tissue diseases)

Interventions

The Phase 1 questionnaire will be made available through the online platform Qualtrics on LUPUS UK forum, lupus UK sufferers Facebook page and other online health forums if recruitment insufficient. This questionnaire contains questions on the impact of the disease and support on their wellbeing and mental health. Questionnaire respondents will be randomly (block) allocated into Groups A, B and C (statistician blinded to groups):
Group A - Small group email peer support and involvement in research questions (designing questionnaires for other patients, physicians, formulating research ideas etc)
Group B - Small group email peer support
Group C - Control group

Groups A and B will be divided into email support groups of 5-6 participants with the aim to provide peer support. In addition, Group A will be given research tasks to discuss, including the pilot questionnaire to redesign in order to distribute to all LUPUS UK members. The email support groups will communicate for 4 months, after which time all three groups will receive another questionnaire to ascertain any changes to their mental health, wellbeing, support perceptions and acceptance. They will also be asked to evaluate the positive and negative aspects of the group support. Another questionnaire will be sent 12 months after the baseline questionnaire. The patient-adapted questionnaire will be made available online and by post to LUPUS UK members and online groups, including the RA and fibromyalgia forums and an adapted questionnaire link given to healthy friends by forum members. The physician questionnaire will be sent to a random sample of consultants and GPs. These questionnaires will contain questions on perceptions of support, wellbeing, mental health, medical relationships and patient behaviour. In-depth interviews will be carried out with purposively selected participants from questionnaire responses.

For phase 1, the primary outcome to be tested is mental wellbeing as measured by the validated Warwick Edinburgh Mental Wellbeing scale, between groups B to C, using the within-person change from baseline to month 4 and the primary endpoint (difference of differences), with illness outcome as a secondary outcome. Similarly, the comparison between groups A to C, and A to B will be examined, with a significance threshold of 5%/2 due to the reuse of groups.

Added 30/03/2021:
The primary outcome for phase 2 will be mental wellbeing using the WEMWS at baseline and 6 months. These will be correlated with multiple measures of satisfaction with care, including how medically supported patients have felt, availability/responsiveness of their doctors and level of abandonment/security during Covid (all obtained through survey responses). Comparison of means (using t-tests) and correlations will be used to test differences between two variables (including satisfaction with care, wellbeing, behaviours and opinions of telemedicine) from different disease groups and between the clinician/patient groups. Correlations will be measured by Pearson correlation coefficient (if linearly related) or Spearman’s rank correlation for ordinal variables. Chi Squared testing will be used where appropriate. Comparison of means (t-tests) will be used.

Intervention Type
Behavioural

Primary outcome measure
Mental wellbeing is measured using the 14-item Warwick-Edinburgh mental wellbeing scale at baseline, 4 months and 12 months

Secondary outcome measures
Illness impact is measured using the PROMIS v1.0-Psychosocial Illness Impact-Negative – Short Form 8a at baseline, 4 and 12 months

Added 30/03/2021:
The primary outcome measure for phase 2 will be mental wellbeing measured using the WEMWS at baseline and 6 months.

Secondary outcome measures for phase 2 include:
1. Medical security measured using survey items of 'scale of abandonment/security' from 0-100 pre-and during COVID and accessibility ratings of medical support at baseline and 6 months
2. 'Adverse Medical Experiences' impact measured using the length of diagnostic journeys > 1 year and presence of previous psychosomatic misdiagnoses at baseline and 6 months. Impact on behaviour and satisfaction with care will be measured using survey responses from those sections at baseline. These will be compared to other participants, with a subdivision of those who report enduring impacts on trust and wellbeing. Those who perceive they received a fibromyalgia misdiagnosis will be compared with all other participants for satisfaction with care and healthcare-reporting behaviour.
3. Impact of COVID and medical support on healthcare: behaviours will be measured using the survey questions on behaviours (reporting of all symptoms, managing symptoms without seeking medical help, reporting non-adherence etc) at baseline and 6 months and satisfaction with care (includes survey sections on listening, trust, availability and security) pre and during COVID.
4. Telemedicine acceptability views measured using multiple survey questions giving agreement /disagreement of various measures of satisfaction with telemedicine for both patients and physicians at baseline and 6 months
5. Patient-physician concordance/discordance outcome measures calculated from a comparison of means of survey items (from both physician and patient surveys) including telemedicine, satisfaction with care and patient behaviours at baseline and 6 months

Overall study start date
01/03/2020

Completion date
01/04/2021

Eligibility

Key inclusion criteria
1. Participants with a self-verified diagnosis of SLE, UCTD, Sjögren's syndrome, discoid /cutaneous lupus or MCTD/overlap disease
2. Resident in the UK
3. Participants aged 18 or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180 (60 in each group)

Total final enrolment
139

Key exclusion criteria
Patients with significant cognitive impairment and unable to undertake informed consent

Date of first enrolment
02/03/2020

Date of final enrolment
06/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Online recuiting
IPH, Forvie Site
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Sponsor information

Organisation

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Sponsor type
University/education

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ROR
https://ror.org/013meh722

Funder(s)

Funder type
Charity

Funder Name
LUPUS UK

Results and Publications

Publication and dissemination plan
This research should generate three publications in rheumatology journals. The first phase will lead to a paper on the impact/acceptability/feasibility of small group peer support. The second phase will report physician views and the large scale questionnaire results will be reported in a paper on the diagnostic journey, patient trust in physicians and mental health/wellbeing.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of consent.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1	02/11/2019	28/02/2020	No	No
Results article		06/01/2022	10/01/2022	Yes	No
Results article		14/12/2020	28/03/2023	Yes	No
Results article		30/05/2020	28/03/2023	Yes	No
Results article		21/01/2021	28/03/2023	Yes	No