Title

SCOUT: Sarcoidosis Clinical OUTcomes task force: protocol for the development of a core outcome set in pulmonary sarcoidosis

Version

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Introduction

Background

Sarcoidosis is a systemic granulomatous disease of unknown causality that most commonly affects the lungs but can involve any organ.[1] It has been postulated that the granulomatous inflammation of sarcoidosis is the results of an environmental exposure in genetically susceptible individuals.[2] Potential environmental exposures that may induce sarcoidosis include infectious agents and occupational; however, no clear triggers or causes have been identified. Implicated genetic factors include human leukocyte antigen (HLA) polymorphisms [3]

The lung is involved in more than 90% of sarcoidosis patients,[4] and is responsible for the majority of deaths from sarcoidosis.[5] Pulmonary sarcoidosis may cause significant pulmonary symptoms, pulmonary dysfunction, and life threatening complications such as pulmonary hypertension and end-stage pulmonary disease. The management of pulmonary sarcoidosis is aimed at preventing/controlling organ damage, relieving symptoms, and improving the patient's quality of life. Presently, numerous outcomes have been used in various clinical trials to measure sarcoidosis symptoms, pulmonary dysfunction, quality of life and functional impairment. These disparate outcome measures have made it problematic to assess the absolute and comparative outcomes of various therapeutic interventions.

Inconsistencies in outcome measurement could be reduced with the development and application of core outcome sets (COS). A COS represents an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical research studies in a specific area of health care.[6] COS allow comparison of research findings, thus ensuring research evidence is of maximum benefit to patients. In addition, a COS can increase the relevance of research by ensuring that the outcomes most important to all stakeholders are measured. There is no agreed gold standard method for COS development. However, the COMET Initiative, an organisation who collate and stimulate the development, reporting, and application of COS, have produced guidance to encourage evidence-based methods for COS development. This protocol has been written in accordance with the COS-STAP Statement (Core Outcome Set-STAndardised Protocol Items), which lists the minimum items needed for inclusion in a published protocol applicable to COS development studies.[7] This project, which will adhere to the Core Outcome Set-STAndards for Development (COS-STAD),[8] will determine what outcomes to measure, but further work will be necessary to agree and recommend a measurement instrument for each of the outcomes in the COS.

Aims and objectives

The aim of the Sarcoidosis Clinical Outcomes Task force (SCOUT) project is to develop a COS for use in future pulmonary sarcoidosis clinical research. Kampstra and colleagues have previously developed a set of patient-centred outcomes for pulmonary sarcoidosis amongst a group of clinical experts.[9] The SCOUT project, in line with the COS-STAD recommendations,[8] will build upon this work by including input from clinicians, patients, researchers and industry representatives. Stakeholders will input into all stages of the current project to ensure that the outcomes included in the final COS are relevant to all stakeholders. In addition, the development of this COS will also be informed by other recent sarcoidosis research, which has involved a survey of the treatment outcomes that matter most to patients[10] and a systematic review of the key patient-reported outcome concepts used in sarcoidosis assessments.[11]

The specific objectives are to:

1. Identify a list of outcomes measured in randomised clinical trials for pulmonary sarcoidosis
2. Identify what outcomes patients regard as important following treatment for pulmonary sarcoidosis
3. Prioritise which outcomes patients, healthcare professionals, researchers and industry representatives think should be included in a COS for pulmonary sarcoidosis
4. Integrate the outcomes important to all stakeholder groups through a consensus process to agree a COS for clinical trials of treatment for pulmonary sarcoidosis

Identifying existing knowledge

Prior to completing this project, a search of the Core Outcome Measures in Effectiveness Trials (COMET) Initiative database (on 28th November 2018) revealed that there were no published or ongoing COS for sarcoidosis research.

Scope of the core outcome set

Health condition

Pulmonary sarcoidosis

Population

Adults aged > 18 years who self-identify as having impactful pulmonary sarcoidosis defined as having sarcoidosis that affects their lungs.

Healthcare intervention

Any

Context of use

Clinical research

Registration

The SCOUT Study has been registered with the Core Outcome Measures for Effectiveness Trials (COMET) database, reference www.comet-initiative.org/studies/details/1156

Project oversight

A Steering Committee comprised of five sarcoidosis experts and healthcare professionals, a psychometrician, a patient, two pharmaceutical representatives with sarcoidosis research experience, 2 regulatory experts with FDA experience, a representative from the Foundation for Sarcoidosis Research and three members from the COMET Initiative will oversee the project. The committee will advise on all stages of the project, providing feedback on the study protocol and list

of outcomes to be considered in the consensus process and contributing to the dissemination of the online Delphi survey, the final consensus meeting and the dissemination of the COS.

Methods

Figure 1 provides an overview of each of each phase of the project.

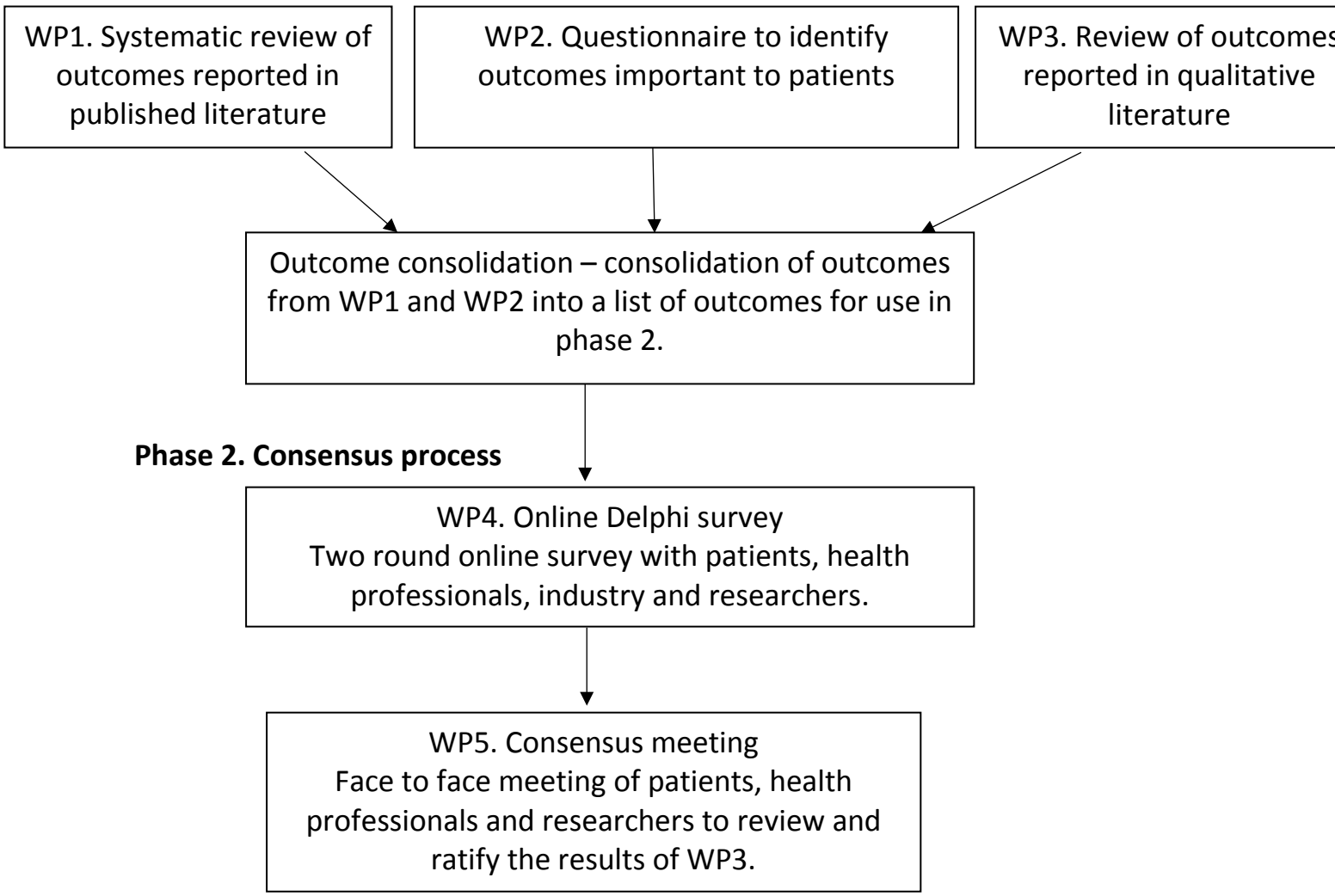

Figure 1. Flow chart of project phases

Phase 1 – Identification of outcomes

A comprehensive list of individual outcomes that have been assessed in pulmonary sarcoidosis clinical trials will be generated. This list will be comprised of outcomes extracted from clinical trial registries (WP1). The published literature will be assumed to represent the views of healthcare professionals and clinical trialists. The primary list will be supplemented with any additional outcomes that are identified through qualitative work with individuals who have pulmonary sarcoidosis (WP2).

WP1. Systematic review

A systematic review of trials registered with clinicaltrials.gov, ISRCTN and ICTRP (International Clinical Trials Registry Platform) will be performed to identify phase 2, 3 and 4 trials of pulmonary sarcoidosis. The search will be completed using the terms:

Condition: Sarcoidosis, **Study type:** Interventional: Clinical Trial, **Study phase:** Phase 2, 3 & 4, **Recruitment stage:** Recruiting/Completed; Not yet recruiting; Unknown.
Each registry entry will be screened for eligibility and outcomes extracted from the primary and secondary outcomes data fields and free text study information. All outcomes will be recorded verbatim.

Where a reported outcome is a composite outcome, the individual outcomes used in the composite will be recorded. Likewise, if a patient reported outcome measure (PROM) is used, then the domains measured by the PROM will be extracted.

All outcomes extracted from clinical trial registries will be categorised according to the 38 core domains of the COMET taxonomy.[12]

WP2. Qualitative work with patients

Method

Qualitative data collection will provide the opportunity to hear directly from patients about their experiences with sarcoidosis and their clinical care. Questions will focus on three topics to find out what matters most to patients: 1) symptoms that matter most 2) daily impacts that matter most 3) outcomes that matter most.

Three patients with self-reporting pulmonary sarcoidosis will be identified. Patients will be provided with a full explanation of the SCOUT project and how data from their worksheets will be used. Although the identified patient participants may not fully represent the sarcoidosis patient population, attempts will be made to ensure that the input received reflects a range of experiences with sarcoidosis.

Data collection

Due to limitations on available staff and the resources needed to conduct real-time interviews with a group of 10 or more patients, patient input will be collected through worksheets. The questions will be provided to patients in a word format document (see Appendix A), where they will be given two-weeks to answer each question and return their comments for consolidation.

Participant answers will be de-identified and data from the transcriptions will be indexed to produce a list of outcomes as well as the correlating definition, as described by the patient. Only members of the project management group will have access to the de-identified transcripts.

WP3. Review of qualitative literature

A rapid review of the qualitative studies of patients' views and experiences of pulmonary sarcoidosis will be undertaken. A search of the literature in MEDLINE, with no restrictions on date, will be

performed. The search terms, described in Table 1, comprise empirically tested qualitative methodological filters designed to identify qualitative research from the MEDLINE electronic database with the best balance of sensitivity and specificity (Wong, 2004).

Table 1. MEDLINE search strategy	
Multi-Field Search	
	sarcoidosis.ab
AND	patient*.ab
AND	((interview: OR experience:).mp OR qualitative.tw.)
AND	(symptom OR treatment OR living with).ab

Abstracts will be screened and the full text will be reviewed for articles meeting the following inclusion criteria: participants are patients with sarcoidosis, the focus is pulmonary sarcoidosis and not an associated co-morbidity, and qualitative methods (interviews and/or focus groups) have been used.

A recent study by van Helmondt and colleagues has explored recently published literature concerning the sarcoidosis patient perspective. The articles identified from this review will also be screened for eligibility.

A narrative synthesis of the eligible qualitative studies will identify text relevant to pulmonary sarcoidosis outcomes, which will be interpreted and categorised into the COMET taxonomy domains.[12]

Outcome consolidation

The lists of outcomes identified from the systematic review and qualitative work will be supplemented by the outcomes identified in other relevant sarcoidosis research.[9-11] All outcomes will be reviewed by SG and NH to group and categorise each outcome according to the COMET taxonomy.[12] The COMET taxonomy, an outcome classification system designed to provide high-level differentiation between outcome domains to facilitate uniformity of outcome classification in electronic databases.[12] The taxonomy comprises 38 core domains structured within five top level core areas: death, physiological/clinical, life impact, resource use, and adverse events. Following outcome categorisation, the co-chairs (MJ and JG) will perform a batch check to verify that the outcomes have been appropriately categorised.

The consolidated list of outcomes will be presented to the SSC for review and confirmation of appropriate grouping and that there are no duplications within the outcomes. The SSC will also be asked to review and comment on the wording of each outcome and descriptive help text. This wording will then be presented to a small group of patients to confirm understanding of the outcome. The number of outcomes on the list for the Delphi will also be considered and, where the list is extensive, the SSC may decide to remove outcomes that were measured in a single study or where the SSC consider the outcome to be of low clinical relevance. The final list of outcomes agreed during this meeting will be used to create the online Delphi survey (WP3).

Phase 2 – Consensus process

WP4. Delphi

Stakeholder Involvement

Participants will be recruited from the following stakeholder groups: people with pulmonary sarcoidosis, healthcare professionals (pulmonologists/sarcoidologists), researchers in the field and industry representatives.

At registration patients with pulmonary sarcoidosis will be asked to report whether they experience factors that define clinically impactful sarcoidosis. Patients will be asked to report if they have sarcoidosis that affects their lungs.

The Delphi survey will be distributed to international patient and healthcare professional organisations, specifically: WASOG (World Association of Sarcoidosis and other Granulomatous Disorders), AASOG (Americas Association of Sarcoidosis and Other Granulomatous Disorders), and St. Antonius international network of expertise sarcoidosis centres. In addition, FSR will use social media platforms to publicise the Delphi survey.

Regulatory representatives (FDA/EMA or individuals who have previously worked in or worked closely with these agencies) will not take part in the Delphi survey but instead will be invited to the consensus meeting (WP4).

The participant information sheet will be provided online, on the study homepage, prior to the registration page. Consent for participation in the online survey will be sought online prior to accessing the survey. Registration for the online Delphi survey will also include questions relating to eligibility.

There will be no restriction on the number of eligible participants in each stakeholder group completing the Delphi survey.

Online Delphi survey

The list of outcomes identified during Phase 1 will be prioritised in a two round online Delphi survey delivered using DelphiManager software designed, hosted and delivered by the University of Liverpool. The Delphi approach involves iterative surveys being administered to participants, with anonymised feedback of the results provided to participants after each round. This approach is designed to minimise the potential for bias by giving equal influence to all who participate.

The outcomes list will be presented grouped into the core areas of mortality, physiological/clinical, life impact, resource use and adverse events. The list will then be ordered within these domains according to the 38 categories within the COMET taxonomy as described above. Domains will be presented in the online Delphi survey in a random order for each participant.

In the online Delphi survey, participants will be asked to score each outcome using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) nine point Likert scale.[13] In the Delphi process the scale will be presented in the format 1 to 9, with 1 to 3 labelled 'not that important', 4 to 6 labelled 'important but not critical' and 7 to 9 labelled 'critical'. An option of "unable to score" will also be included together with an option to add a comment on each outcome about the reasons for their score. All outcomes will be written in plain language and the same description used for all stakeholders with further help text provided when participants hover their cursor over each outcome. Participants will be able to suggest additional outcomes they think are important but not already included on the list at the end of round one. Any additional outcomes suggested will be summarised and presented to the SSC for confirmation of new outcomes or if

clarification of existing outcomes is required. Any new outcomes identified and agreed by the SSC will be added to round 2 of the Delphi survey.

In the second round of the online Delphi survey responses for each stakeholder group will be summarised for each outcome and displayed graphically as the percentage of each stakeholder group who have given each score. All outcomes scored in round 1 will be retained for round 2. Participants will be able to view the grouped responses together with their own score in round 1 and will be asked to re-score the outcome based on this information using the same 1-9 scale. Participants may choose to change their score or to keep it the same. New outcomes identified from free text responses in round 1 will be presented in round 2 alongside the verbatim text that led to the outcome. Participants will be asked to score these new outcomes.

Round 2 responses will be summarised using descriptive statistics and a predefined definition of consensus (Table 2). Participants will be encouraged to provide a response (a score or 'unable to score') for each outcome. Responses will be included in the analysis if a participant assesses more than 80% of the outcomes. However, this approach will be reviewed with the SSC based on the response rate to round 1.

Table 2. Definition of consensus

Consensus Classification	**Description**	**Definition**
Consensus in	Consensus that outcome should be included in the core outcome set	70% or more participants, in each stakeholder group, scoring as 7-9 AND <15% participants, in each stakeholder group, scoring as 1-3
Consensus out	Consensus that outcome should not be included in the core outcomes set	50% or fewer participants scoring 7-9 in each stakeholder group.
No consensus	Uncertainty about importance of outcome	Anything else

Attrition

To minimise attrition within and between rounds automated reminder emails will be sent to registered participants who have yet to complete the current round of the Delphi survey. At least two reminder emails will be scheduled for each round with additional reminders determined by the response rate and any extensions to the duration of the round. Regular social media updates will also be used to promote registration and completion of the study.

Attrition bias will be assessed by comparing the distribution of mean R1 scores for participants completing R1 only and participants completing both R1 and R2 for each stakeholder group.

Delphi helpdesk intervention sub-study

Research has shown that some patient participants are likely to require assistance when completing a Delphi survey.[14] But to date there has been little evaluation of what this support should look like with only retrospective assessment of participant satisfaction evaluated.[15] There are resource considerations when developing a supporting video and we will seek to systematically evaluate the impact of providing additional support to Delphi participants on recruitment and attrition. A Helpdesk intervention will be offered as part of the SCOUT study, which will involve patients being

randomized to two different groups. Pulmonary sarcoidosis patients who are registered in the FSR internal database will be pseudo-randomised to receive two different emails. One group will receive the link to the Delphi survey and one group will received the Delphi survey link plus Helpdesk details. As the Helpdesk is a new intervention it will only be offered to the FSR patients who have been pseudo-randomised to the intervention group. Evidence is required to demonstrate the effectiveness of the Helpdesk intervention before scaling up to include all Delphi participants. All other participants in the SCOUT study (e.g. international patients, healthcare professionals, researchers in the field and industry representatives) will receive the non-Helpdesk link to the Delphi survey.

The Helpdesk intervention will involve participants being provided with an email address where they can send any queries they have about completing the Delphi survey. Participants will receive prompt responses, where advice will be given in relation to their queries. Participants will also be directed to relevant resources (including the 'What are Core Outcome Sets? Video', Delphi plain language summary and a Delphi survey demonstration video), which may be able to assist them when completing the Delphi survey. Links to the resources will be provided at multiple stages of the study and unique links will be used to allow assessment of the way in which the materials are accessed.

The sub-study analyses will involve a comparison of the two groups (those who receive the Helpdesk link and those who receive the standard non-Helpdesk link) in terms of the percentage registering to take part in the survey, R1 completion rates, percentage starting R2 and R2 completion rates. A descriptive summary of the nature of emails received via the Helpdesk will also be reported.

An overview of the helpdesk sub study is provided in figure 2 .

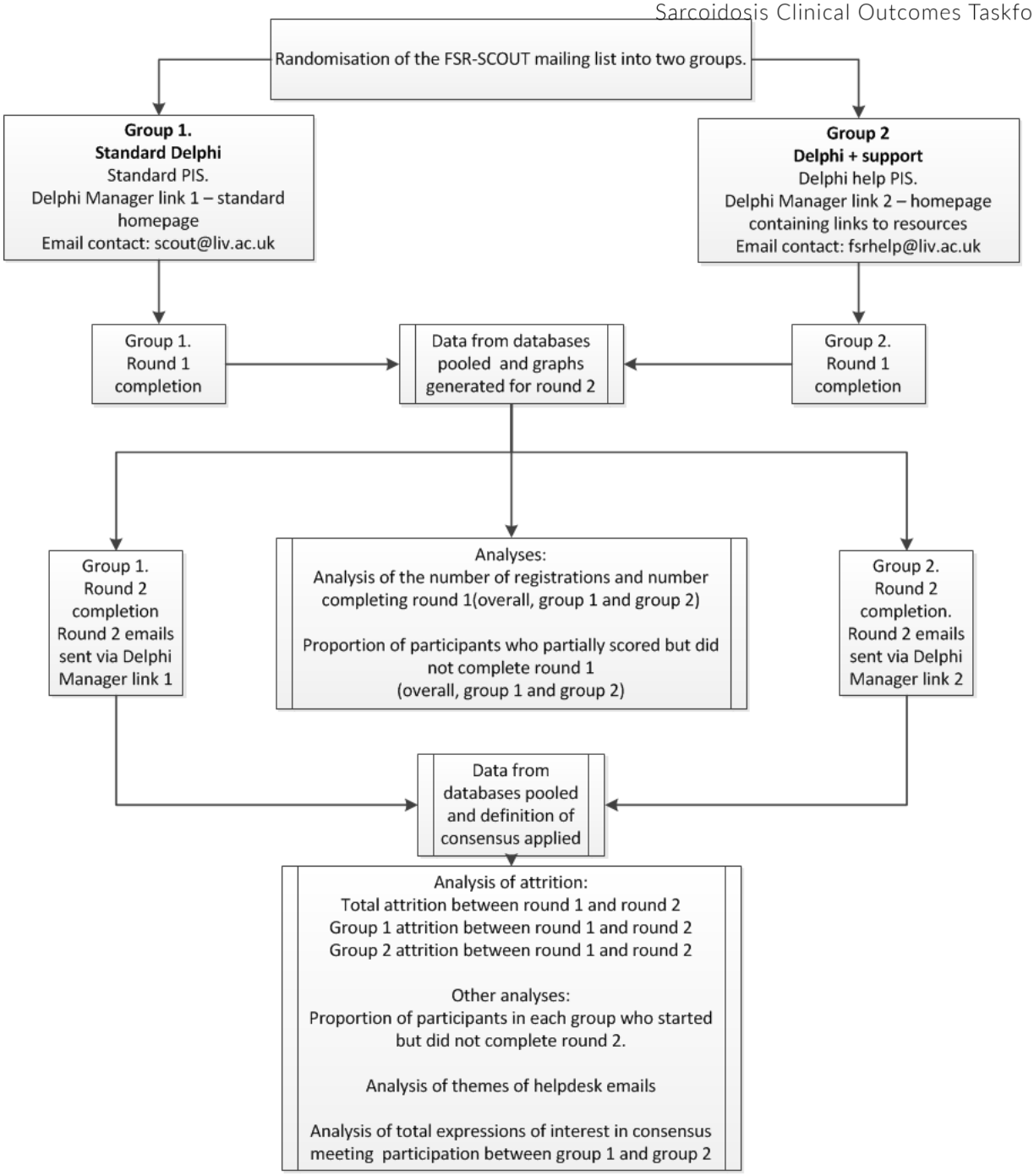

Figure 2. Helpdesk sub study overview.

WP5. Consensus meeting

The results of the Delphi survey will be discussed in a face-to-face consensus meeting chaired by an independent facilitator. A sample of participants who completed both rounds of the Delphi survey and expressed an interest in attending the consensus meeting will be invited to attend, ensuring similar numbers from each stakeholder group. It is anticipated that a maximum of 30 participants will attend the consensus meeting, distributed equally across stakeholder groups completing the online Delphi survey. In addition, representatives of regulatory agencies (FDA/EMA) will be invited to the consensus meeting as non-voting participants. Prior to the consensus meeting participants will receive written information about what to expect from the day, attendance at the meeting will be considered as consent to participate.

The consensus meeting will ratify the results of the Delphi survey to confirm the outcomes that have met the definition of inclusion or exclusion from the COS after R2.

Outcomes that have no consensus at the end of R2 will be discussed and voted on, for inclusion in the COS, using electronic voting software.

All other outcomes that have not reached consensus during the Delphi will then be discussed and participants of the consensus meeting invited to re-score the outcome.

Ethical approval

Ethical approval for the online Delphi survey and the consensus meeting has been sought from the University of Liverpool Research Ethics Committee (approval reference 5211) Participant information will be provided online on the Delphi home page as the homepage text.

Consent for participation in the online Delphi will be recorded online and will be mandatory prior to accessing the outcome scoring section of the survey. Participant information will be provided online prior to the registration/consent page. Participants are free to withdraw from the survey at any time without giving reason, partial responses will not be considered as withdrawal and data will be used unless participants specifically ask for their data to be withdrawn from the analysis. For the face to face consensus meeting, participants of the Delphi, interested in attending, will consent to being contacted with further information at the end of round 2. A PDF information sheet will be emailed to participants and attendance at the consensus meeting considered to be consent to participate.

Ethical approval for the patient questionnaires is not required as the purpose of the questions is to collect information from patients in order to assess currently utilized outcomes related to their sarcoidosis. The data collected is not intended to create new knowledge. Instead, it is intended to help improve the quality of the healthcare sarcoidosis patients receive.

The data collection will involve patient-recollection of past and current clinical practices. The sarcoidosis patients will not be subjected to any risk or burdens during the collection of this data. Patients would have no change to their routine standard of care as no information will be shared with their healthcare providers. While there is no formal consent, it will be stressed that the individual is free to decline involvement at any time of the data collection process without penalty

Dissemination

Following completion of the project, a lay summary of the findings will be fed back to all participants. Additionally, the findings will be publicised on the Foundation for Sarcoidosis Research website and submitted for publication in a peer reviewed journal, where findings will be presented following the COS-STAR reporting guideline.[16]

Administrative Information

Funding

This project has been funded by the Foundation for Sarcoidosis Research. The Foundation of Sarcoidosis research has two representatives in the SSC and will undertake WP2 of the project. Any decisions around publication or dissemination of the results will be made in conjunction with the SSC and will not be the sole decision of the funder.

Conflicts of interest

SLG, NLH, JG, RB, HJ, NK, NS, MKW, DC and PRW have no conflicts of interest with this work. MJ and DV developed Sarcoidosis Assessment Tool (SAT). EB is a Janssen R&D employee involved in developing new agents for Sarcoidosis treatment. ES is an Insmed Inc. employee and serves as a consultant to numerous pharmaceutical firms.

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APPENDIX A

WRITTEN QUESTIONNAIRE CAPTURING PATIENT VOICE

FSR Endpoints Initiative

The members of the Endpoints Steering Committee for the Endpoints Initiative are committed to ensure that both the physicians and the patients have a voice in determining which Core Outcomes are important based on life experience alongside data. The purpose of this questionnaire is to hear from you, as a pulmonary sarcoidosis patient, and learn how the disease impacts your life. This will help to identify Core Outcomes that are important to pulmonary sarcoidosis patients.

What is a Core Outcome? A Core Outcome is something that physicians and researchers use to measure how well a treatment or an assessment is working. Research studies testing treatments often measure different outcomes. For example, one pulmonary sarcoidosis trial might use a CT scan to track improvements, while another might use a 6-minute walk test. For patients, outcomes related to pain and fatigue might be of great importance, but can be hard to measure. If researchers measure different things, it makes it difficult to compare and combine the results. But if all future research studies measure the same important outcomes, then the results will be combined and new treatments that work will be available for people with pulmonary sarcoidosis more quickly. The information you provide in this questionnaire will help to decide what outcomes are the most important and should be measured in all future pulmonary sarcoidosis research. Your opinion is very important.

Written Questionnaire

Topic 1: Symptoms That Matter Most to Patients

Of all the symptoms you have experienced with pulmonary sarcoidosis, which do you consider to have the most significant impact on your daily life?
How often do these symptoms affect you, using scale - never, sometimes, often, always?

Rank the top three aspects/symptoms of the disease that impact your daily life.

How has your condition and its symptoms changed over time?

How much of your day is spent thinking and planning activities because of shortness of breath? (0-25%, 25 – 50%, 50 – 75%, or >75%) Please explain.
Things to consider when answering: Planning steps and routes in order to get form one place to the next. Avoiding stairs or inclines, and looking for elevators or escalators. Planning meals around times you know you have to walk.

Topic 2: Daily Impacts That Matter Most to Patients

Are there specific activities that are important to you, but you can't do at all or as fully as you would like because of your condition?

How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
Things to consider when answering: How do your symptoms impact you at work? How do they impact you at home? How do they impact you with your relationships or social activities?

How has your condition and its symptoms impacted you emotionally?

How often do you avoid interactions with people or feel embarrassed due to the breathlessness brought on by sarcoidosis? Use the scale - never, sometimes, often, always. Please explain.
Things to consider when answering: Trouble walking at a "normal" pace with others, trouble walking and talking at the same time, and inability to participate in activities.

How fearful has sarcoidosis caused you to become? Use the scale – not at all fearful, somewhat fearful, often fearful, very fearful. Please explain.
Things to consider when answering: Fear of contracting infections, impact on your financial future, declining health, and dying.

How often has sarcoidosis made you feel guilty? Use the scale – never, sometimes, often, always. Please explain.
Things to consider when answering: Not being able to fulfill responsibilities at work or home, and the perception of being a burden to family and friends.

In addition to the care you receive from your doctors, what else or who else has helped you manage the disease? How important are they to you?
Things to consider when answering: support groups, family, friends, spirituality, and faith.

Topic 3: Outcomes That Matter Most to Patients

In your own words, describe a core outcome?

What outcomes do you think are the most critical to measure during a pulmonary sarcoidosis clinical trial?