Symptoms, classifications, and themes related to harms in rheumatology: Qualitative semi-structured interviews with patients with inflammatory arthritis

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ABSTRACT

Introduction: From randomized controlled trials (RCTs), benefit over harm of an intervention is more likely to be published. However, the majority of harm information collected in clinical trials comes from clinician rather than patient perspective on harms, and clinicians tend to underestimate the severity of patients' symptoms.

Objectives: First, we will explore what patients consider important to measure in RCTs in relation to side effects. Second, we will seek to understand which, if any, of the candidate self-reported symptomatic side effects are relevant to patients. We will further explore patients' comprehension of the candidate self-reported symptomatic side effects, and how patients classify these.

Methods and analysis: International focus groups (phase A) and individual interviews (phase B) will be conducted with patients with a diagnosis of inflammatory arthritis (i.e., rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis) who have had one or more prescribed drug for their inflammatory arthritis for at least 12 months. We will conduct the interviews using an interview guide. All interviews will be recorded, transcribed verbatim, and anonymized. The data will be analyzed using reflexive thematic analysis.

Dissemination: The results of this study will be disseminated through presentations at rheumatology meetings, including OMERACT meetings, and through a publication in an international peer-reviewed journal.

INTRODUCTION

Patients and healthcare professionals have different perspectives on benefit and harms of pharmacological interventions. However, while benefit over harm of an intervention is more likely to be published from randomized controlled trials (RCTs), both patients and healthcare professionals express much concern regarding harms in commonly used medical treatments within rheumatic and musculoskeletal diseases (RMDs) (1). Clinicians tend to underestimate the severity of patients' symptoms (2,3), and patients value different aspects of harms compared to clinicians (4,5). Nevertheless, most information on harms collected in clinical trials comes from clinicians' impressions of patients' symptoms, while less attention has been paid to patients' perspective on harms (6).

Outcome Measures in Rheumatology (OMERACT) is an international collaboration of health care professionals, patient research partners (PRPs) and others aimed at improving outcome measurement and instrument methodology across RMDs (7). The organization has successfully developed Core Outcome Sets (COS) for many RMDs (8,9) and encourages equally measuring benefits *and* harms when developing COS (9). A COS is a minimum consensus-based set of outcomes that should be measured and reported in all clinical trials of a specific health condition and/or intervention. We consider harms to be the totality of possible adverse consequences of an intervention or therapy; they are the direct opposite of benefits (20). However, in this study we will use the term "side effect" instead of "harm", as this term is more widely used in lay-populations, and avoids the possibility of leading patients to focus only on the worst side effects.

To assess side effects in RMDs, the OMERACT Safety Working Group (SWG) has previously developed Rheumatology Common Toxicity Criteria 2.0 (RCTC 2.0) (10), revised (RCTC 2.1) based on use in practice (11), which provides guidance on harm collection and reporting in rheumatology RCTs from the clinician perspective. However, a suitable measurement instrument for assessing the patient perspective on side effects is lacking (12). To fill this gap, the SWG conducted international focus group interviews identifying four themes of concerns over side effects on DMARD therapy important to rheumatoid arthritis (RA)-patients (13). One example of themes identified was that patients and clinicians have different perspectives of side effects, as the cumulative effect of "nuisance side effects" can have a substantial impact on patients' lives (13), which can lead to discontinuation of treatment over time (14). However, the best way to address the cumulative effect in RCTs from patients' point of view is unclear. The themes further reflect that concerns are influenced by disease. As rheumatology covers a wide range of RMDs, this present study will address inflammatory arthritis (IA), which includes rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (AxSpA). These diseases are all characterized by

autoimmune inflammation that affects the joints, and usually present joint swelling, pain, tenderness, stiffness, warmth in the joints, and can lead to joint damage and disability, while symptoms such as fatigue are also well-known (15).

Further, the SWG conducted a systematic literature review (SLR), identifying a comprehensive list of candidate self-reported symptomatic side effects reported in RCTs within RMDs (16). However, using the Patient-Reported Outcomes version of The Common Terminology Criteria For Adverse Events (PRO-CTCAE), a Canadian study found that patients with RA report frequent side effects with their medications, which are associated with a substantial burden (17). Several of these self-reported side effects (e.g., “concentration” [symptom term]/”problems with concentration” [question term] and “painful urination” [symptom term]/”pain or burning with urination” [question term]) along with additional symptomatic side effects (e.g., “brain fog” and “dry eyes”) described by the included patients in the study were not identified in our SLR. Further, from quantitative and qualitative studies of patient’s perspective of side effects in glucocorticoid use within a broad range of inflammatory diseases, the OMERACT Glucocorticoid Impact Working Group (GCWG) identified physical and psychological symptomatic outcomes related to side effects, which affect participation and health-related quality of life (18). However, some of these side effects (e.g., “change in taste” and “loss of teeth”) were also lacking in our SLR.

Our results emphasize the urgent need to develop a patient-reported framework for side effects to complement clinicians’ reports, and it was suggested that such framework should include measures of severity of side effects (16), patient satisfaction with their medication (13), and how patients view the balance between benefit and side effects of their treatment (13). However, it is unclear what patients want to know about side effects prior to medical treatment. Thus, further research is needed to identify patient-relevant questions on side effects and to evaluate the relevance and comprehension of candidate self-reported side effects identified in different studies.

Objectives

First, we will explore what patients consider important to measure in RCTs in relation to side effects. Second, we will seek to understand which, if any, of the candidate self-reported symptomatic side effects are relevant to patients. We will further explore patients’ comprehension of the candidate self-reported symptomatic side effects, and how patients classify these.

METHODS

Protocol

This protocol will be published online on the Parker Institute web page (www.parkerinst.dk) prior to conducting any interviews. The study will be reported according to the Consolidated criteria for reporting qualitative research (COREQ) (19).

Study design

Qualitative research is the most appropriate method to explore patients' experiences and opinions. This study will use both focus groups (phase A) and interviews (phase B) with people with IA. Focus groups will enable us to seek a broad perspective from patients' point of view and promote discussion among participants, allowing common experiences to be clarified and exploring diversity among participants. One to one semi-structured interviews will enable us to explore individual's understanding of the candidate self-reported harms in more depth. To minimize risk of bias caused by the investigator's preconceptions of patients' experiences and beliefs of harms, DBB will continually engage in reflexivity throughout the research process.

Participants and setting

We will invite patients attending outpatient clinics with confirmed IA (RA, PsA or AxSpA) for focus groups. To be eligible, participants must be at least 18 years of age and have been taking one or more prescribed drug (e.g., NSAID, DMARD, glucocorticoid) for their inflammatory arthritis for at least 12 months. We intend to include a broad sample of participants with IA, and purposive sampling will be used as we aim to include a range of age, gender, ethnicity, employment status, condition, disease duration, current use of rheumatological medication, prior use of rheumatological medication, other conditions than IA and medications currently taken for other conditions than IA as described in Appendix Table 3. The participants will be included from three continents (Europe, US/Canada, and Australia), and will be identified through our co-authors, the OMERACT SWG, and social media. To emphasize equality among participants and encouraging participants to tell their personal story, we will value to create a safe and respectful environment during the focus groups.

Initially, co-authors and members in the SWG or their colleagues will invite potential participants to participate in our interview. Potential participants will be given an information sheet including an explanation of the purpose of the study and the participant's role (Appendix Box 1). The potential participants will further be informed that participation is voluntary, and their clinicians

won't be informed of their decision. Potential participants will be given the opportunity of a personal - or a tele-meeting with a researcher if further information on participation is needed. Upon acceptance to participate, an interview will be scheduled, and participants will be asked to complete an informed consent form (Appendix Box 2) and a pre-study questionnaire identifying patients' demographics and clinical characteristics (Appendix Box 3). All information will be confidential.

We will further recruit patients through social media (e.g., Twitter, Facebook) posting a short information summery of the study and including a researcher's institutional e-mail to response to. On responding, potential participants will be sent the information sheet (Appendix Box 1) containing the same information as potential participants invited by clinicians. Likewise, the opportunity of a personal - or a tele-meeting with a researcher will be given if further information on participation is needed. For potential participants recruited through social media screening questions will be used to confirm diagnosis when a researcher contacts them to arrange to attend the focus group. They will be asked to confirm they have received a diagnosis of IA, and the name of their rheumatologist and treating hospital. This will be a verbal discussion to confirm eligibility. If further validation of potential participants' diagnosis is needed, a rheumatologist (PMB, PT) will be consulted, before the interview will be scheduled and before the participant will be asked to complete the informed consent form (Appendix Box 2) and the pre-study questionnaire (Appendix Box 3).

All participants will be advised they can withdraw their data for up to two weeks after data collection, after this time the transcripts will be fully anonymized. Participants in the focus groups will be advised that some of their data may be retained after withdrawal if it is needed to provide context to other participants' data, but it will be fully anonymized.

At the end of the phase A focus groups, participants will be invited to participate in an interview for phase B, which will be scheduled on a new date. To be familiar with English terms of symptoms, potential non-native English-speaking participants will review the list of candidate side effects and their classifications (Appendix Table 4) prior to phase B interviews.

Materials

Phase A: A draft focus group schedule will be used, which has been developed in cooperation with PRPs (MV and PR: Box 1). Discussions will be iterative and build on themes raised in previous groups.

Phase B: An interview schedule will be developed based on the resulting discussion from phase A focus groups. A first draft has been developed in discussion with PRPs (MV and PR: Box 1).

Participants will be presented with the list of candidate side effects and their classifications (Appendix Table 4). Prior to the interviews, we will adjust our list of side effects judged to be appropriate for patient self-reporting in our SLR (16). As these side effects were reported in RCTs, they are most likely reported by healthcare professionals and researchers. To broaden this perspective, we will merge our list of candidate self-reported side effects with symptomatic side effects reported by patients with RA using the PRO-CTCAE (17), and with outcomes related to side effect identified by the OMERACT GCWG from quantitative and qualitative studies of patient's perspective of side effects in glucocorticoid use (18).

First, side effects extracted from our SLR, that according to the Medical Dictionary for Regulatory Activities (MedDRA), are reflecting system organ classes (such as "psychiatric disorders"), high-level group terms (such as "musculoskeletal and connective tissue signs and symptoms") and high-level terms (such as "gastrointestinal symptoms") or side effects that are not symptoms or diagnoses (such as "hospitalized") will be excluded as we consider them unspecific. Second, two reviewers (DBB and TGW) will categorize side effects from our SLR as symptoms or diagnoses. If side effects can be considered both a symptom and a diagnosis, we will categorize according to the parent-description provided in the International Statistical Classification of Diseases and Related Health Problems 11 (ICD-11) (20); side effects not described in the ICD-11 will be considered symptoms. Third, two investigators (DBB and GSH) will compare side effects extracted from our SLR and symptoms included in PRO-CTCAE to identify overlapping symptom terms, for which we initially will select the question-term provided in the PRO-CTCAE, as these have been validated even though validation was aimed at patients with cancer (21,22). Symptoms identified from our SLR, but not included in PRO-CTCAE, will be listed in the lay language terms used in our SLR, and when no lay language term is available, medical terms from the SLR will be used. As only symptomatic side effects will be included in our list, side effects from our SLR that are diagnoses will be excluded if they can reasonably be covered by items reflecting symptom terms usually occurring from the diagnoses, e.g., the diagnosis "asthma" will be excluded as patients would usually report symptoms such as wheezing and shortness of breath, which are already included in the list. Fourth, additional side effects suggested by participants from the PRO-CTCAE evaluation in RA (17), will be extracted if the suggested term reflects a symptom. We will group terms covering the same symptom (e.g., diarrhea and loose stool) and give each group an overall symptom term. Additional symptoms from the PRO-CTCAE evaluation in RA will be included, if not already included in a previous stage. Fifth, symptomatic outcomes related to side effects extracted from the OMERACT GCWG study (18) and listed as individual symptoms (e.g., "muscle weakness [myopathy, pain, cramps, difficulty standing]" will be listed as "myopathy", "pain", "cramps", and "difficulty standing") will be merged with symptoms in the list, though

excluding doublets and overlapping symptom terms. Sixth, further adjustment of wording, merging, and grouping of symptom terms in the list from patients' point of view, will be based on input from two experienced OMERACT PRPs (MV and PR).

Candidate self-reported side effects will be grouped - according to 12 modified categories of body areas in the PRO-CTCAE item library version 1.0 (23) adding lay-language terms inspired by de Vries et al. (20) in cooperation with and further adjusted by PRPs (MV and PR) - as: oral (mouth, nose and/or throat); gastrointestinal (intestines, stomach and/or bowel movements); cardio/circulatory and respiratory (chest, breathing, excess bleeding and/or swelling); cutaneous (skin, hair and/or nails); neurological and attention/memory (brain and/or nerves); musculoskeletal (muscles, bones and/or joints); visual/perceptual (ears and/or eyes); sleep/wake (sleep); mood (mood and/or emotions); gynecologic/urinary (bladder, genitals and/or hormones); sexual (intimate relationships); miscellaneous internal (internal bodily effects); and miscellaneous external (external bodily effects). A list of adjustments leading to 135 included symptomatic side effects and their classification is shown in Appendix Table 1, while 151 excluded side effects and reasons for exclusion are shown in Appendix Table 2.

Box 1: Pre-defined interview guide

Phase A: Identifying relevant side effect domains to measure

(I) What side effect(s) have you experienced with your medical treatment for your inflammatory arthritis?
  (a) How did the side effect(s) impact you?

(II) What is the potential side effect(s) that worry you the most?
  (a) Why does this(/these) side effect(s) worry you more than other side effects?

(III) What is the worst side effect(s) you've ever experienced?
  (a) What made that side effect worse than the other side effect(s) you have experienced?

(IV) If we could rate the cumulative burden of all combined side effects on a scale, what would the points on the scale say?
(Probing: 0-10 [with 0 being no impact/bother and 10 being worst ever impact/bother], have no side effects/ can manage daily living without problems from side effects/can manage daily living with some problems from side effects/cannot manage daily living because of side effects)

(V) Before you decide about a new medical treatment for your disease, what would you like to know about potential side effects?

(Probing: type of specific side effects, number of side effects, severity, impact on life/physical function/work/family/social interactions, fluctuation, duration)

(a) Which of these items/outcomes related to side effects are most important to you?

(b) What makes that item/outcome related to side effects most important?

(c) Which one is the next most important to you?

(VI) Do you have anything else you would like to mention that we've not discussed?

Phase B: Relevance and comprehension of candidate self-reported symptomatic side effects and their classification.

This list (Appendix Table 3) represents symptoms and classifications of potential side effects, that we consider appropriate for patients' self-reports.

(VII) Looking at the symptoms mentioned in first category of chest, breathing, excess bleeding and/or swelling:

(a) Are all the symptoms relevant for patients' self-report?

(b) Are there any of these symptoms that need to be removed or changed or was any important symptom left out?

(c) Do the category cover the symptoms, or do anything needs to be changed?

(VIII) Looking at the symptoms mentioned in second category of…….*(same questions as in VII for all 12 categories)*.

Data collection

The interviews will be conducted using Teams internet calls by DBB supported by CF. We anticipate interviews to last for 60-90 minutes. All interviews will be recorded, and data will be kept in a locked file or secure computer with access only by the immediate research team. Interviews will further be verbatim transcribed, anonymized, and analyzed in the language of origin. Data will be fully anonymized before being given to anyone in the study team other than the researchers collecting the data. To enable analysis across English and Danish, themes identified from Danish interviews will be translated into English. Data analysis will be iterative, with subsequent focus groups building on findings from previous groups.

Interviews will be conducted in either English or Danish. Interviews with participants from Denmark will be conducted in Danish. We will not translate the list of symptoms for phase B interviews, thus Danish participants will only be encouraged to participate in phase B if they feel confident with the English terms of the symptomatic side effects. However, we will conduct phase B interviews with Danish participants in Danish. For phase A interviews, we will mix participants

from English-speaking countries and conduct these interviews in English, although due to different time-zones it is possible that focus groups will be country specific. Participants from countries of non-English or non-Danish languages will be invited to participate in the English interviews, if they feel confident with spoken and written English language.

Data analysis and sample size

Reflexive thematic analysis will be used to analyze the data (24). This flexible method ensures that findings are grounded using a bottom-up approach to search for common patterns (themes) within data without trying to fit the data into any pre-existing coding frame or the researcher's preconceptions (25). In the first stage, the transcripts from the interviews will be read multiple times, searching for units of meaning to generate descriptive codes. In the second stage, moving back and forth between the entire data set, we will explore codes for links, and group them into larger concepts and sub-concepts - subsequently leading to overall main themes (25). Danish transcripts will be analyzed by DBB supported by SMN and MUR, while CF will provide support for English transcripts. To ensure agreements with similar themes, SMN/MUR/CF and DBB will code at least two transcripts for rigor. Likewise, at least one PRP (MV or PR) and DBB will code transcripts to ensure agreements from patients' point of view. NVIVO will be used to manage the data. For publication of our results, we will make sure to include a range of representative statements from both Danish and English interviews, however, all published statements will be translated into English.

There are no robust standards for the sample size of interview studies or diversity of included participants (26). Thus, we anticipate 6 focus groups (a minimum of two from each continent) with 5 to 7 participants in each, which is sufficient participants to promote discussion, but not too many to ensure all voices are heard. However, we will conduct interviews until we reach data saturation, i.e., the point where no new themes, findings, concepts, or problems are evident in the data (26). For phase B, we anticipate saturation to occur at 10-15 interviews (26).

Patient involvement

Following common practice of involvement of patient research partners (PRPs) within OMERACT (27), we involved a minimum of two PRPs (MSV and PR) in all phases of the project. Both PRPs are well experienced in the OMERACT methodology, and hence, will not receive any training. OMERACT-PRPs have been involved in the design and conceptualization stages of this work including designing the interview schedules and will contribute to data analysis and as co-authors on any resulting papers. Further, local Danish PRPs will be involved ad hoc e.g., in the design

stage and when translating interview schedules. We will report the involvement of the PRPs by following the guidelines from OMERACT (27), EULAR (28), and GRIPP2 (29).

Ethics, permissions, and consent

This study will be carried out in accordance with the Helsinki Declaration. Permission will be obtained from the Data Protection Agency of the capital region in Denmark, and data will be handled according to agreements. Patients will be asked to provide written informed consent to participate in this study. Investigational Review Board/Ethics Committee consensus will be obtained according to local regulations. The study does not require permission from the Health Research Ethics Committee in Denmark. Investigators, who will obtain local permissions and/or recruit patients are DBB, TE, SJB, GSH, OS, DEF, PMB and CF.

PERSPECTIVES AND DISSEMINATION

This study will collect important information from patients, which will provide background for the next step which will include an anonymous online questionnaire-based survey among a large sample of patients with various RMDs. The survey will identify patients' priorities of individual side effects and the impact of side effects on patients' life. Subsequently, results of this qualitative study and the anonymous online questionnaire-based survey is anticipated to lead to a Delphi survey to gain consensus among relevant stakeholder groups (patients, clinicians, and 'others' [e.g., regulatory or pharma]) on which side effect domains are important to measure in clinical trials within RMDs. The results of the Delphi survey will inform the development of an RMD-specific framework for side effects, and if endorsed by policy makers, this will guide regulatory actions and decision making relating to patient-centered rheumatology RCTs. Thus, the framework will allow results of trials to be compared and combined, and thereby increase usable and patient-relevant information for decision-making when deciding on a new medical treatment. An increased focus on patients' perspective on side effects from their treatment will potentially lead to better wellbeing for all patients with RMDs at all ages, as side effects important to patients might be less obvious to clinicians, who systematically downgrade the severity of patients' symptoms (6). A more mutual understanding between clinician and patient will improve the patient-clinician relationship and better accede to patients individualized therapy needs - further leading to reducing health inequity in rheumatology care (30).

Results of this study will be disseminated through presentations at rheumatology meetings, including OMERACT meetings, and a publication in an international peer-reviewed journal.

Conflicts of interest and funding

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APPENDIX

Appendix. Table 1. List of included candidate self-reported symptomatic harms.

Table 1. List of included candidate self-reported symptomatic harms.						
Lay language term	**Medical term**	**Type of outcome**	**Source**	**Body area category**	**Lay language category**	**Reason for change of lay language wording**
Chest pain	Chest pain	Symptom	SR	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	
Cough	Cough	Symptom	PRO-CTCAE	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	
Excess bleeding for cuts		Symptom	Additional	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	
Limp swelling	Swelling	Symptom	PRO-CTCAE	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	PRPs: Changed from "arm or leg swelling" (to also cover "swelling of feet or ankles" from GC)
Pounding or racing heartbeat (palpitations)	Heart palpitations	Symptom	PRO-CTCAE	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	
Shortness of breath	Shortness of breath	Symptom	PRO-CTCAE	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	
Wheezing (whistling noise in the chest with breathing)	Wheezing	Symptom	PRO-CTCAE	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	
Acne or pimples on the face or chest	Acne	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Bed sores	Bed/pressure sores	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Brittle fingernails or toenails	Nail loss	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	PRPs: Changed from "lose any fingernails or toenails" (inspired by "brittle skin/fingernails" from GC) - "brittle" covers wider than "lose"
Bruise easily (black and blue marks)	Bruising	Symptom	PRO-CTCAE	Miscellaneous	Skin, hair and/or nails	
Change in the color of your fingernails or toenails	Nail discoloration	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Dry or oily skin	Skin dryness	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	PRPs: Changed from "dry skin" (to also cover "oily skin" from GC)
Flushing	Flushing	Symptom	SR	Cutaneous	Skin, hair and/or nails	
Fragile skin		Symptom	GC	Cutaneous	Skin, hair and/or nails	

Gone from straight hair to wavy/ curly hair		Symptom	Additional	Cutaneous	Skin, hair and/or nails	
Hair loss	Hair loss	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Hives (itchy red bumps on the skin)	Hives	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Impaired wound healing		Symptom	GC	Cutaneous	Skin, hair and/or nails	
Increased hair growth	Hirsuitism	Symptom	GC	Cutaneous	Skin, hair and/or nails	
Increased skin sensitivity to sunlight	Sensitivity to sunlight	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Itchy skin	Itching	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Pain, swelling, or redness at a site of drug injection or iv	Pain and swelling at injection site	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Rash	Rash	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Redness	Erythema	Symptom	SR	Cutaneous	Skin, hair and/or nails	
Ridges or bumps on your fingernails or toenails	Nail ridging	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Skin burns from radiation	Radiation skin reaction	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Skin peeling	Skin peeling	Symptom	SR	Cutaneous	Skin, hair and/or nails	
Stretch marks	Stretch marks	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Thin skin		Symptom	GC	Cutaneous	Skin, hair and/or nails	
Unusual darkening of the skin	Skin darkening	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	
Bleed after a bowel movement		Symptom	Additional	Gastrointestinal	Intestines, stomach and/or bowel movements	
Bloating of the abdomen (belly)	Bloating	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	
Change of bowel habit	Change of bowel habit	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	
Changed appetite	Decreased appetite	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	PRPs: Changed from "decreased appetite" (to also cover "increased appetite" from GC and SR)
Constipation	Constipation	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	

Diarrhea/diarrhoea (loose or watery stools)	Diarrhea	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	PRPs: Changed from "loose or watery stools (diarrhea/diarrhoea)" as "diarrhea/diarrhoea" is more common wording
Gastric pain		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	PRPs: Changed from "heart burn or gastric pain" to separate them ("heart burn" already included")
Reflux/heartburn	Heartburn	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	PRPs: Changed from "heartburn" (to also cover "stomach upset or acid reflux")
Hiccups	Hiccups	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	
Increased passing of gas (flatulence)	Gas	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	
Indigestion	Dyspepsia	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	
Lose control of bowel movements	Fecal incontinence	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	
Nausea	Nausea	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	
Pain in rectum	Pain in rectum	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	
Pain in the abdomen (belly area)	Abdominal pain	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	
Vomiting	Vomiting	Symptom	PRO-CTCAE	Gastrointestinal	Intestines, stomach and/or bowel movements	
Irregular menstrual periods	Irregular periods/vaginal bleeding	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	
Long term absence of menstrual period		Symptom	GC	Gynecologic/Urinary	Bladder, genitals and/or hormones	PRPs: Changed from "amenorrhea/altered menstrual cycle" (for better understanding)
Loss of control of urine (leakage)	Urinary incontinence	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	
Pain or burning with urination	Painful urination	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	
Unusual vaginal discharge	Vaginal discharge	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	
Urge to urinate all of a sudden	Urinary urgency	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	
Urinate frequently	Urinary frequency	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	

Urine color change	Change in usual urine color	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	
Vaginal dryness	Vaginal dryness	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	PRPs: Changed from "vaginal dryness at its worst" (as "at its worst" is only specified for this symptom)
Decreased sexual interest	Decreased libido	Symptom	PRO-CTCAE	Sexual	Intimate relationships	
Difficulty getting or keeping an erection	Achieve and maintain erection	Symptom	PRO-CTCAE	Sexual	Intimate relationships	
Ejaculation problems	Ejaculation	Symptom	PRO-CTCAE	Sexual	Intimate relationships	
Pain during vaginal sex	Pain w/sexual intercourse	Symptom	PRO-CTCAE	Sexual	Intimate relationships	
Took too long to have an orgasm or climax	Delayed orgasm	Symptom	PRO-CTCAE	Sexual	Intimate relationships	
Unable to have an orgasm or climax	Unable to have orgasm	Symptom	PRO-CTCAE	Sexual	Intimate relationships	
Body odor	Body odor	Symptom	PRO-CTCAE	Miscellaneous	Internal and/or external bodily effects	
Breast area enlargement or tenderness	Breast swelling and tenderness	Symptom	PRO-CTCAE	Miscellaneous	Internal and/or external bodily effects	
Change in body shape		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	
Change in facial features		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: Changed from "bloated face" (as the original category of "change in facial features" was judged not to need specification)
Feeling badly	Malaise	Symptom	SR	Miscellaneous	Internal and/or external bodily effects	
Feeling of warmth	Feeling of warmth	Symptom	SR	Miscellaneous	Internal and/or external bodily effects	
Feeling weak	Asthenia	Symptom	SR	Miscellaneous	Internal and/or external bodily effects	
Fever	Pyrexia	Symptom	SR	Miscellaneous	Internal and/or external bodily effects	
Hot flashes/flushes	Hot flashes	Symptom	PRO-CTCAE	Miscellaneous	Internal and/or external bodily effects	
Lump in back		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	

Not recognizing oneself physically		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: Changed from "not recognizing oneself" (to make wording more clear)
Shivering or shaking chills	Chills	Symptom	PRO-CTCAE	Miscellaneous	Internal and/or external bodily effects	
Unexpected decrease in sweating	Decreased sweating	Symptom	PRO-CTCAE	Miscellaneous	Internal and/or external bodily effects	
Unexpected or excessive sweating during the day or nighttime (not related to hot flashes/flushes)	Increased sweating	Symptom	PRO-CTCAE	Miscellaneous	Internal and/or external bodily effects	
Weight changes		Symptom	Additional	Miscellaneous	Internal and/or external bodily effects	PRPs: Changed from "weight loss" (to also cover "weight gain" from GC and "increased body weight" from SR)
Anxiety	Anxious	Symptom	PRO-CTCAE	Mood	Mood and/or emotions	
Negative feelings	Sad	Symptom	PRO-CTCAE	Mood	Mood and/or emotions	PRPs: Changed from "sad or unhappy feelings" as negative feelings cover wider (and can thereby include "feel that nothing could cheer you up", "feeling of futility", and "anger")
Irritability and mood swings (agitation, mood disturbances)		Symptom	GC	Mood	Mood and/or emotions	
Hyperactivity/ euphoria (over optimistic feelings, manic, full of ideas)		Symptom	GC	Mood	Mood and/or emotions	
Personality change/ not feeling oneself (behavioral changes)		Symptom	GC	Mood	Mood and/or emotions	
Back pain	Back pain	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	
Flare-up	Flare	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	
Joint stiffness	Joint stiffness	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	
Joint swelling	Joint effusion	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	
Muscular weakness	Muscular weakness	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	
Straining	Straining	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	

Painful joints (such as elbows, knees, shoulders)	Joint pain	Symptom	PRO-CTCAE	Musculoskeletal	Muscles, bones and/or joints	
Painful muscles	Muscle pain	Symptom	PRO-CTCAE	Musculoskeletal	Muscles, bones and/or joints	
Muscle cramp		Symptom	GC	Musculoskeletal	Muscles, bones and/or joints	
Pain	General pain	Symptom	PRO-CTCAE	Musculoskeletal	Muscles, bones and/or joints	
Tendon pain	Tendon pain	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	
Difficulty standing		Symptom	GC	Musculoskeletal	Muscles, bones and/or joints	
Dizziness	Dizziness	Symptom	PRO-CTCAE	Neurological and attention/memory	Brain and/or nerves	
Fainting, losing consciousness	Syncope	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Recurrent falls	Recurrent falls	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Impaired coordination	Ataxia	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Increased sensitivity of any sense	Hyperesthesia	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Nerve pain	Neuralgia	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Numbness or tingling in your hands or feet	Numbness & tingling	Symptom	PRO-CTCAE	Neurological and attention/memory	Brain and/or nerves	
Paranoia		Symptom	Additional	Neurological and attention/memory	Brain and/or nerves	
Reduced sensitivity of any sense	Hypoesthesia	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Restless legs	Restless legs syndrome	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Sensing things that are not real	Hallucination	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Stinging	Stinging	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Tremor	Tremor	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	
Brain fog		Symptom	Additional	Neurological and attention/memory	Brain and/or nerves	
Problems with concentration	Concentration	Symptom	PRO-CTCAE	Neurological and attention/memory	Brain and/or nerves	

Problems with memory	Memory	Symptom	PRO-CTCAE	Neurological and attention/memory	Brain and/or nerves	
Headache	Headache	Symptom	PRO-CTCAE	Neurological and attention/memory	Brain and/or nerves	
Loss of identity		Symptom	GC	Neurological and attention/memory	Brain and/or nerves	PRPs: Changed from "loss of identity, embarrassment" - and "embarrassment" is a "negative feeling" ("negative feeling" already included)
Dental pain	Dental pain	Symptom	SR	Oral and respiratory	Mouth, nose and/or throat	
Difficulty swallowing	Difficulty swallowing	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	
Dry mouth	Dry mouth	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	
Hoarse voice	Hoarseness	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	
Jaw pain		Symptom	Additional	Oral and respiratory	Mouth, nose and/or throat	
Lips, mouth or throat sores	Mouth/throat sores	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	PRPs: Changed from "mouth or throat sores" to also include lips (as indicated by "sores on lips/mouth" from GC-study)
Runny nose	Rhinitis	Symptom	SR	Oral and respiratory	Mouth, nose and/or throat	
Stuffy nose		Symptom	Additional	Oral and respiratory	Mouth, nose and/or throat	
Voice changes	Voice quality changes	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	
Change in taste		Symptom	GC	Oral and respiratory	Mouth, nose and/or throat	PRPs: Changed from "change in taste (metallic taste)" as "change in taste" can cover more than just "metallic" taste
Nosebleeds	Nosebleed	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	
Loss of teeth		Symptom	GC	Oral and respiratory	Mouth, nose and/or throat	
Fatigue, tiredness, or lack of energy	Fatigue	Symptom	PRO-CTCAE	Sleep/Wake	Sleep	
Sleepiness	Somnolence	Symptom	SR	Sleep/Wake	Sleep	
Sleep difficulties (including difficulty falling asleep, staying a sleep, or waking up early)	Insomnia	Symptom	PRO-CTCAE	Sleep/Wake	Sleep	PRPs: Changed from "insomnia (including difficulty falling asleep, staying a sleep, or waking up early)"

Weird dreams		Symptom	Additional	Sleep/Wake	Sleep	
Droopy eyelid	Ptosis	Symptom	SR	Visual/Perceptual	Ears and/or eyes	
Dry eyes		Symptom	Additional	Visual/Perceptual	Ears and/or eyes	
Light sensitivity (eyes)		Symptom	Additional	Visual/Perceptual	Ears and/or eyes	
Ringing in your ears	Ringing ears	Symptom	PRO-CTCAE	Visual/Perceptual	Ears and/or eyes	
Watery eyes (tearing)	Watery eyes	Symptom	PRO-CTCAE	Visual/Perceptual	Ears and/or eyes	
Ear pain	Ear pain	Symptom	SR	Visual/Perceptual	Ears and/or eyes	
Vision affected		Symptom	GC	Visual/Perceptual	Ears and/or eyes	PRPs: Changed from" difficulty seeing well" to also cover "blurry vision", "each eye saw different colours","flashing lights in front of your eyes", and "spots or lines (floaters) that drift in front of your eyes".

SR = systematic review; PRO-CTCAE = patient-reported outcomes version of the common terminology criteria for adverse events; GC = glucocorticoid; PRPs = Patient research partners

1

Appendix. Table 2. List of excluded harms.

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Lay language term	**Medical term**	**Type of outcome**	**Source**	**Body area category**	**Lay language category**	**Reason for exclusion**	**Coding (reason for exclusion)**
Injury, poisoning, and procedural complications	Injury, poisoning, and procedural complications	SOC/HLGT/HLT	SR			Exclusion-criteria: type of outcome is system organ class/high level group term/high level term	SOC/HLGT/HLT
Skin injuries	Skin injuries	SOC/HLGT/HLT	SR			Exclusion-criteria: type of outcome is system organ class/high level group term/high level term	SOC/HLGT/HLT
	Gastrointestinal symptoms	SOC/HLGT/HLT	SR			Exclusion-criteria: type of outcome is system organ class/high level group term/high level term	SOC/HLGT/HLT
	Joint-related signs and symptoms	SOC/HLGT/HLT	SR			Exclusion-criteria: type of outcome is system organ class/high level group term/high level term	SOC/HLGT/HLT
	Muscle-related signs and symptoms (muscle cramps, muscle twitching, night cramps)	SOC/HLGT/HLT	SR			Exclusion-criteria: type of outcome is system organ class/high level group term/high level term	SOC/HLGT/HLT
	Musculoskeletal and connective tissue signs and symptoms	SOC/HLGT/HLT	SR			Exclusion-criteria: type of outcome is system organ class/high level group term/high level term	SOC/HLGT/HLT
	Psychiatric disorders	SOC/HLGT/HLT	SR			Exclusion-criteria: type of outcome is system organ class/high level group term/high level term	SOC/HLGT/HLT
Burning	Burning	Symptom	SR	Miscellaneous	Internal and/or external bodily effects	PRPs: "burning" can have diverse understandings: feeling of warm, skin burning, hot flushes - we are not sure, what it means, therefore exclude	PRP feedback
Face swelling		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: better to keep the original category "Change in facial features" from GC and include the specific side effects in that	PRP feedback
Flushing in face		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: better to keep the original category "Change in facial features" from GC and include the specific side effects in that	PRP feedback

Moon face		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: better to keep the original category "Change in facial features" from GC and include the specific side effects in that	PRP feedback
Puffy face		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: better to keep the original category "Change in facial features" from GC and include the specific side effects in that	PRP feedback
Round face		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: better to keep the original category "Change in facial features" from GC and include the specific side effects in that	PRP feedback
Pain in extremity	Pain in extremity	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	PRPs: Can be misinterpreted: "extremity" can be either e.g. finger/arm/leg or an intense feeling (extreme pain). Painful joints/painful muscles/pain will cover pain in e.g. finger/arm/leg.	PRP feedback
Dyspnea		Symptom	GC	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	"Shortness of breath" already included from PRO-CTCAE	Overlap
Palpitations		Symptom	GC	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	"Pounding or racing heartbeat (palpitations)" already included from PRO-CTCAE	Overlap
Swelling of feet or ankles		Symptom	GC	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	"Limp swelling" already included	Overlap
Palpitations	Palpitations	Symptom	SR	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	"Pounding or racing heartbeat (palpitations)" already included from PRO-CTCAE	Overlap
Swelling	Peripheral oedema	Symptom	SR	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	"Arm or leg swelling" already included from PRO-CTCAE	Overlap
Acne		Symptom	GC	Cutaneous	Skin, hair and/or nails	"Acne or pimples on the face or chest" already included from PRO-CTCAE	Overlap
Brittle skin/fingernails		Symptom	GC	Cutaneous	Skin, hair and/or nails	"Brittle fingernails or toenails" already included	Overlap
Bruising		Symptom	GC	Cutaneous	Skin, hair and/or nails	"Bruise easily (black and blue marks)" already included from PRO-CTCAE	Overlap
Oily skin		Symptom	GC	Cutaneous	Skin, hair and/or nails	Included under "dry or oily skin"	Overlap
Hives	Urticaria	Symptom	SR	Cutaneous	Skin, hair and/or nails	"Hives (itchy red bumps on the skin)" already included from PRO-CTCAE	Overlap
Injection site pain	Injection site pain	Symptom	SR	Cutaneous	Skin, hair and/or nails	"Pain, swelling, or redness at a site of drug injection or iv" already included from PRO-CTCAE	Overlap

Injection-site reactions	Injection-site reactions	Symptom	SR	Cutaneous	Skin, hair and/or nails	Already covered by "pain, swelling, or redness at a site of drug injection or iv" from PRO-CTCAE	Overlap
Itching	Pruritus	Symptom	SR	Cutaneous	Skin, hair and/or nails	"Itchy skin" already included from PRO-CTCAE	Overlap
Sun sensitivity	Sun sensitivity	Symptom	SR	Cutaneous	Skin, hair and/or nails	"Increased skin sensitivity to sunlight" already included from PRO-CTCAE	Overlap
Bloating		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	"Bloating of the abdomen (belly)" already included from PRO-CTCAE	Overlap
Constipation-related bloating	Constipation-related bloating	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	PRPs: "Bloating of the abdomen (belly)" and "constipation-related bloating" are diffucult to distinguish. "Constipation-related bloating" should be excluded, and "bloating of the abdomen" should be to refrased to "bloating".	Overlap
Diarrhea		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	"Diarrhea/diarrhoea (loose or watery stools)" already included	Overlap
Dyspepsia		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	"indigestion" already included from PRO-CTCAE	Overlap
Epigastric pain		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	"Gastric pain" included from GC	Overlap
Increased appetite	Increased appetite	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	Covered by "changed appetite"	Overlap
Increased appetite		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	Included under "changed appetite"	Overlap
Reduced appetite		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	Included under "changed appetite"	Overlap
Stomach upset or acid reflux		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	PRPs: will be included under "reflux/heartburn"	Overlap
Abdominal pain	Abdominal pain	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	"Pain in the abdomen (belly area)" already included from PRO-CTCAE	Overlap

Bloating	Abdominal distension	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	"Bloating of the abdomen (belly)" already included from PRO-CTCAE	Overlap
Diarrhea	Diarrhea	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	"Loose or watery stools (diarrhea/diarrhoea)" already included from PRO-CTCAE	Overlap
Lack of appetite	Lack of appetite	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	"Decreased appetite" already included from PRO-CTCAE	Overlap
Passing gas	Flatulence	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	"Increased passing of gas (flatulence)" already included from PRO-CTCAE	Overlap
Miss an expected menstrual period	Missed expected menstrual period	Symptom	PRO-CTCAE	Gynecologic/Urinary	Bladder, genitals and/or hormones	PRPs: covered by "irregular menstrual periods" from PRO-CTCAE	Overlap
Abnormally heavy, prolonged, and irregular uterine bleeding	Menometrorrhagia	Symptom	SR	Gynecologic/Urinary	Bladder, genitals and/or hormones	"Irregular menstrual periods" already included from PRO-CTCAE	Overlap
Yellow discoloration of urine	Yellow discoloration of urine	Symptom	SR	Gynecologic/Urinary	Bladder, genitals and/or hormones	"Urine color change" is already included from PRO-CTCAE	Overlap
Excessive sweating		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	"Unexpected or excessive sweating during the day or nighttime (not related to hot flashes/flushes)" already included	Overlap
Fat redistribution		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	PRPs: Can go under "change in body shape"	Overlap
Hot flushes		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	"Hot flashes/flushes" already included from PRO-CTCAE	Overlap
Increased body weight	Increased body weight	Symptom	SR	Miscellaneous	Internal and/or external bodily effects	Covered by "weight changes" adjusted from additional harms in PRO-CTCAE-survey	Overlap
Larger breasts		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	"Breast area enlargement or tenderness" already included from PRO-CTCAE	Overlap
Weight gain		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	"Weight changes" already included	Overlap
Bruise	Contusion	Symptom	SR	Miscellaneous	Skin, hair and/or nails	"Bruise easily" already included from PRO-CTCAE	Overlap
Anger		Symptom	GC	Mood	Mood and/or emotions	PRPs: Covered by "negative feelings"	Overlap

Depression or low mood (suicide attempt)		Symptom	GC	Mood	Mood and/or emotions	PRPs: "depression" is a diagnosis. Low mood could be covered by "negative feelings"	Overlap
Feel that nothing could cheer you up	Discouraged	Symptom	PRO-CTCAE	Mood	Mood and/or emotions	PRPs: Covered by "negative feelings" already included from PRO-CTCAE	Overlap
Feeling of futility		Symptom	Additional	Mood	Mood and/or emotions	PRPs: Covered by "negative feelings" already included from PRO-CTCAE	Overlap
Mood swings		Symptom	Additional	Mood	Mood and/or emotions	PRPs: "irritability and mood swings (agitation, mood disturbances)" included from GC	Overlap
Anxiety attack	Anxiety attack	Symptom	SR	Mood	Mood and/or emotions	"anxiety" is already included from PRO-CTCAE	Overlap
Depression	Depression	Symptom	SR	Mood	Mood and/or emotions	"Feel that nothing could cheer you up" is already included from PRO-CTCAE	Overlap
Gout flare	Gout flare	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	PRPs: Keep "Flare" and leave out "RA flare" and "gout flare" - flare of your disease (whatever disease) is important	Overlap
Pain in the study joint	Pain in the study joint	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	PRPs: Can be covered by "painful joints"	Overlap
RA flare	RA flare	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	PRPs: Keep "Flare" and leave out "RA flare" and "gout flare" - flare of your disease (whatever disease) is important	Overlap
Painful joints		Symptom	GC	Musculoskeletal	Muscles, bones and/or joints	PRPs: "painful joints (such as elbows, knees, shoulders)" already included from PRO-CTCAE	Overlap
Joint pain	Arthralgia	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	"Painful joints (such as elbows, knees, shoulders)" already included from PRO-CTCAE	Overlap
Muscle pain	Myalgia	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	"Painful muscles" is already included from PRO-CTCAE	Overlap
Being perceived as different by friends or family		Symptom	GC	Neurological and attention/memory	Brain and/or nerves	PRPs: Can go under "loss of identity, embarrassment" - and is observed by others (therefor "being perceived as different by friends or family" is only indirectly reported by the pt)	Overlap
Hallucinations (strange/frightening thoughts)		Symptom	GC	Neurological and attention/memory	Brain and/or nerves	PRPs: Covered by "sensing things that are not real" included from PRO-CTCAE (PRO-CTCAE symptom is "hallucination")	Overlap
'Pins and needles'	Paresthesia	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	"Numbness or tingling in your hands or feet" already included from PRO-CTCAE	Overlap
Spinning sensation	Vertigo	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	"dizziness" is already included from both SR and PRO-CTCAE	Overlap

Dryness of the mouth		Symptom	GC	Oral and respiratory	Mouth, nose and/or throat	PRPs: "dry mouth" already included	Overlap
Problems with tasting food or drink	Taste changes	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	PRPs: Covered by "change in taste"	Overlap
Skin cracking at the corners of your mouth	Cracking at the corners of the mouth (cheilosis/cheilitis)	Symptom	PRO-CTCAE	Oral and respiratory	Mouth, nose and/or throat	PRPs: Covered by "lips, mouth or throat sores"	Overlap
Sore mouth or throat		Symptom	GC	Oral and respiratory	Mouth, nose and/or throat	PRPs: "mouth or throat sores" already included from PRO-CTCAE (adjusted to "lips, mouth or throat sores")	Overlap
Sores on lips/mouth		Symptom	GC	Oral and respiratory	Mouth, nose and/or throat	PRPs: "mouth or throat sores" already included from PRO-CTCAE (adjusted to "lips, mouth or throat sores")	Overlap
Difficulty in swallowing	Dysphagia	Symptom	SR	Oral and respiratory	Mouth, nose and/or throat	"Difficulty swallowing" already included from PRO-CTCAE	Overlap
Mouth ulcers	Mouth ulcers	Symptom	SR	Oral and respiratory	Mouth, nose and/or throat	"Mouth or throat sores" already included from PRO-CTCAE	Overlap
Sore throat	Pharyngitis	Symptom	SR	Oral and respiratory	Mouth, nose and/or throat	"Mouth or throat sores" already included from PRO-CTCAE	Overlap
Loss of libido		Symptom	GC	Sexual	Intimate relationships	"Decreased sexual interest" already included from PRO-CTCAE	Overlap
Reduced interest in sex		Symptom	GC	Sexual	Intimate relationships	"Decreased sexual interest" already included from PRO-CTCAE	Overlap
Drowsiness		Symptom	GC	Sleep/Wake	Sleep	PRPs: covered by "fatigue, tiredness, or lack of energy"	Overlap
Fatigue (asthenia, generalized weakness)		Symptom	GC	Sleep/Wake	Sleep	PRPs: "fatigue, tiredness, or lack of energy" already included	Overlap
Insomnia		Symptom	GC	Sleep/Wake	Sleep	PRPs: "sleep difficulties (including difficulty falling asleep, staying a sleep, or waking up early)" already included	Overlap
Nightmares		Symptom	GC	Sleep/Wake	Sleep	PRPs: Covered by "sleep difficulties (including difficulty falling asleep, staying a sleep, or waking up early)"	Overlap
Restless sleep		Symptom	GC	Sleep/Wake	Sleep	PRPs: Covered by "sleep difficulties (including difficulty falling asleep, staying a sleep, or waking up early)"	Overlap
Sleeping difficulty		Symptom	GC	Sleep/Wake	Sleep	PRPs: Covered by "sleep difficulties (including difficulty falling asleep, staying a sleep, or waking up early)"	Overlap

Sleeping disturbance		Symptom	GC	Sleep/Wake	Sleep	PRPs: Covered by "insomnia (including difficulty falling asleep, staying a sleep, or waking up early)"	Overlap
Sleeping trouble		Symptom	GC	Sleep/Wake	Sleep	PRPs: Covered by "sleep difficulties (including difficulty falling asleep, staying a sleep, or waking up early)"	Overlap
Difficulty sleeping	Insomnia	Symptom	SR	Sleep/Wake	Sleep	"Insomnia (including difficulty falling asleep, staying asleep, or waking up early)" already included from PRO-CTCAE	Overlap
Fatigue	Fatigue	Symptom	SR	Sleep/Wake	Sleep	"Fatigue, tiredness, or lack of energy" already included from PRO-CTCAE	Overlap
Blurry vision	Blurred vision	Symptom	PRO-CTCAE	Visual/Perceptual	Ears and/or eyes	PRPs: Covered by "vision affected"	Overlap
Each eye saw different colours		Symptom	Additional	Visual/Perceptual	Ears and/or eyes	PRPs: Covered by "vision affected"	Overlap
Flashing lights in front of your eyes	Flashing lights	Symptom	PRO-CTCAE	Visual/Perceptual	Ears and/or eyes	PRPs: Covered by "vision affected"	Overlap
Spots or lines (floaters) that drift in front of your eyes	Visual floaters	Symptom	PRO-CTCAE	Visual/Perceptual	Ears and/or eyes	PRPs: Covered by "vision affected"	Overlap
Hospitalized	Hospitalized	Other	SR			Exclusion-criteria: type of outcome is "other"	Ex-crit. other
Itch or dizziness	Itch or dizziness	Other	SR			Exclusion-criteria: type of outcome is "other"	Ex-crit. other
Chest pain		Symptom	GC	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	Duplicate of lay language term	Duplicate
Cough	Cough	Symptom	SR	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	Duplicate of lay language term	Duplicate
Hair loss	Alopecia	Symptom	GC	Cutaneous	Skin, hair and/or nails	Duplicate of lay language term	Duplicate
Rash	Rash	Symptom	SR	Cutaneous	Skin, hair and/or nails	Duplicate of lay language term	Duplicate
Stretch marks		Symptom	GC	Cutaneous	Skin, hair and/or nails	Duplicate of lay language term	Duplicate
Constipation	Constipation	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	Duplicate of lay language term	Duplicate
Constipation		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	Duplicate of lay language term	Duplicate

Hiccups		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	Duplicate of lay language term	Duplicate
Indigestion		Symptom	GC	Gastrointestinal	Intestines, stomach and/or bowel movements	Duplicate of lay language term	Duplicate
Nausea	Nausea	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	Duplicate of lay language term	Duplicate
Vomiting	Vomiting	Symptom	SR	Gastrointestinal	Intestines, stomach and/or bowel movements	Duplicate of lay language term	Duplicate
Weight loss		Symptom	GC	Miscellaneous	Internal and/or external bodily effects	Duplicate of lay language term	Duplicate
Anxiety		Symptom	GC	Mood	Mood and/or emotions	Duplicate of lay language term	Duplicate
Back pain		Symptom	GC	Musculoskeletal	Muscles, bones and/or joints	Duplicate of lay language term	Duplicate
Painful muscles		Symptom	GC	Musculoskeletal	Muscles, bones and/or joints	Duplicate of lay language term	Duplicate
Dizziness		Symptom	GC	Neurological and attention/memory	Brain and/or nerves	Duplicate of lay language term	Duplicate
Dizziness	Dizziness	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	Duplicate of lay language term	Duplicate
Headache		Symptom	GC	Neurological and attention/memory	Brain and/or nerves	Duplicate of lay language term	Duplicate
Headache	Headache	Symptom	SR	Neurological and attention/memory	Brain and/or nerves	Duplicate of lay language term	Duplicate
Tremor		Symptom	GC	Neurological and attention/memory	Brain and/or nerves	Duplicate of lay language term	Duplicate
Dry mouth	Dry mouth	Symptom	SR	Oral and respiratory	Mouth, nose and/or throat	Duplicate of lay language term	Duplicate
Hoarse voice		Symptom	GC	Oral and respiratory	Mouth, nose and/or throat	Duplicate of lay language term	Duplicate
Hair loss	Alopecia	Symptom	SR	Cutaneous	Skin, hair and/or nails	Duplicate of lay language term	Duplicate
Pain	Pain	Symptom	SR	Musculoskeletal	Muscles, bones and/or joints	Duplicate of lay language term	Duplicate
Shortness of breath	Dyspnea	Symptom	SR	Cardio/Circulatory and respiratory	Chest, breathing, excess bleeding and/or swelling	Duplicate of lay language term	Duplicate

Hand-foot syndrome (a rash of the hands or feet that can cause cracking, peeling, redness or pain)	Hand-foot syndrome	Symptom	PRO-CTCAE	Cutaneous	Skin, hair and/or nails	PRPs: "hand-foot syndrome" is more a diagnosis (symptoms mentioned in parenthesis are already included)	Diagnosis
Abdominal wall abscess	Abdominal wall abscess	Diagnosis	SR			"Abdominal wall abscess" is a diagnosis, and pts would report symptoms such as abdominal pain (already included)	Diagnosis
Allergic reactions	Allergic reactions	Diagnosis	SR			"Allergy reactions" is a diagnosis, and can affect e.g. Airways, sinuses and nasal passages, skin, and digestive system and can lead to multible symptoms such as hvies, itching, rash, runny nose, watery eyes, shortness of breath, wheezing, cough (already included)	Diagnosis
Angina	Angina pectoris	Diagnosis	SR			"Chest pain" is already included from SR, and is more appropriate - further, "angina" is a diagnosis	Diagnosis
Asthma	Asthma	Diagnosis	SR			"Astma" is a diagnosis, and pts would report symptoms such as wheezing, shortness of breath (already included)	Diagnosis
Bladder inflammation	Cystitis	Diagnosis	SR			"Bladder inflammation" is a diagnosis, and pts would report symptoms such as pain or burning with urination (already included)	Diagnosis
Bronchitis	Lower respiratory tract infection	Diagnosis	SR			LRTI is a diagnosis, and pts will report e.g. cough, wheezing, shortness of breath, chest pain (already included)	Diagnosis
Common cold	Nasopharyngitis	Diagnosis	SR			"Nasopharyngitis" is diagnosis, and pts would report symptoms such as runny or stuffy nose, cough, sore throat, headache (already included)	Diagnosis
Eczema	Eczema	Diagnosis	SR			"Eczema" is diagnosis, and pts would report symptoms such as itching and red skin (included already)	Diagnosis
Eyelid inflammation	Blepharitis	Diagnosis	SR			"Eyelid inflammation" is a diagnosis, and pts would report symptoms such as watery eyes (already included)	Diagnosis
Flu syndrome	Influenza	Diagnosis	SR			"Influenza" is diagnosis, and pts would report symptoms such as fever/chills, cough, sore throat, headache, fatigue (already included)	Diagnosis

Gastritis	Gastritis	Diagnosis	SR			"Gastritis" is diagnosis, and pts would report symptoms such as abdominal pain (already included)	Diagnosis
Inflamed breast	Mastitis	Diagnosis	SR			"Mastitis" is a diagnosis, and pts would report symptoms such as breast tenderness/painfulness (already included)	Diagnosis
Infusion reaction	Infusion reaction	Diagnosis	SR			Already covered by "pain, swelling, or redness at a site of drug injection or iv" from PRO-CTCAE	Diagnosis
Irritable bowel syndrome	Irritable bowel syndrome	Diagnosis	SR			IBS is diagnosis, and pts with IBS will suffer from several of the symptoms included in PRO-CTCAE: e.g. bloating, diarrhea and constipation, abdominal pain	Diagnosis
Renal colic	Nephrolithiasis	Diagnosis	SR			"Renal colic" is diagnosis, and pts would report symptoms such as fever/chills, cough, sore throat, headache, fatigue (already included)	Diagnosis
Sinusitis	Sinusitis	Diagnosis	SR			"Sinusitis" is diagnosis, and pts would report symptoms such as runny or stuffy nose, headache, sore throat, cough (already included)	Diagnosis
Stomach flu	Gastroenteritis	Diagnosis	SR			Several symptoms will categorize gastroenteritis: diarrhea, vomiting, abdominal pain (already included)	Diagnosis
Tooth abscess	Tooth abscess	Diagnosis	SR			"Tooth abscess" is a diagnosis, and pts would report symptoms such as dental pain (already included)	Diagnosis
Upper respiratory tract infection	Upper respiratory tract infections	Diagnosis	SR			URTI is a diagnosis, and will include several symptoms e.g. cough, fever, fatigue, difficulty in swallowing, headache (already included)	Diagnosis
	Abdominal hernia, obstructive	Diagnosis	SR			"Abdominal hernia" is a diagnosis, and all though pts will visually notice a bulge, they would also report abdominal pain (already included) when e.g. Coughing	Diagnosis
	Allergic conjunctivitis	Diagnosis	SR			"Allergic conjunctivitis" is a diagnosis, and pts would report symptoms such as watery eyes	Diagnosis
	Anal fistula	Diagnosis	SR			"Anal fistula" is a diagnosis, and pts would report symptoms such as pain in rectum (already included)	Diagnosis
	Colitis	Diagnosis	SR			"Colitis" is diagnosis, and pts would report symptoms such as bloating, diarrhoea and	Diagnosis

						constipation, abdorminal pain (already included)	
	Effusion	Diagnosis	SR			"Effusion" is a diagnosis, and can be related to pleura or joints and can cause symptoms such as chest pain, cough, shortness of breath (pleura) and such as joint swelling, joint pain, joint stiffness (already included)	Diagnosis
	Induration	Diagnosis	SR			"Induration" is a diagnosis leading to hardening of (e.g.) The skin, which pts would report as a symptom	Diagnosis
	Infected tophus	Diagnosis	SR			"Infected tophus" is a diagnosis, and if infected pts would usually report symptoms such as pain, stiffness (already included)	Diagnosis
	Inguinal hernia	Diagnosis	SR			"Inguinal hernia" is a diagnosis, and all though pts will visually notice a bulge, they would also report abdominal pain (already included) when e.g. coughing	Diagnosis
	Optic neuritis	Diagnosis	SR			Several symptoms (included in the PRO-CTCAE) can cover this: Flashing lights, Visual floaters, Watery eyes	Diagnosis
	Osteoarthritis	Diagnosis	SR			"Osteoarthritis" is a diagnosis, and pts would report symptoms such as joint pain, joint stiffness, joint swelling, flare (already included)	Diagnosis
	Pleurisy	Diagnosis	SR			"Pleurisy" is a diagnosis, and pts would report symptoms such as chest pain, cough, sortness of breath (already included)	Diagnosis

SOC/HLGT/HLT = organ class/high level group term/high level term; SR = systematic review; PRO-CTCAE = patient-reported outcomes version of the common terminology criteria for adverse events; GC = glucocorticoid; PRPs = Patient research partners;

1

Appendix. Table 3. Categories for purposive sampling and reporting of included participants

Table 3. Categories for purposive sampling and reporting of included participants	
Age	Mean (±SD)
<40 years	n (%)
40-59 years	n (%)
≥60 years	n (%)
Gender	
Female	n (%)
Male	n (%)
Diverse	n (%)
Ethnicity	
Arabian	n (%)
Asian	n (%)
Black	n (%)
Hispanic	n (%)
Mixed/multiple ethnic groups	n (%)
White	n (%)
Other	n (%)
Employment status	
Working, full time (paid/unpaid)	n (%)
Working, part time (paid/unpaid)	n (%)
Sickleave	n (%)
Unemployed (due to arthritis)	n (%)
Unemployed (for other reasons)	n (%)
Student	n (%)
Retired	n (%)
Other	n (%)
Condition	
RA	n (%)
PsA	n (%)
AxSpA	n (%)
Disease duration of IA	Mean (±SD)
1-4 years	n (%)

5-9 years	n (%)
≥10 years	n (%)
Current use of rheumatological medication	
Nonsteroidal anti-inflammatory drugs [NSAIDs]	n (%)
Conventional Synthetic Disease-Modifying Anti-Rheumatic	n (%)
Drug [DMARDs]	n (%)
Target synthetic DMARDs	n (%)
bDMARDs	n (%)
Glucocorticoid	n (%)
Other	n (%)
No of prior rheumatological medication	
Nonsteroidal anti-inflammatory drugs [NSAIDs]	n (%)
Conventional Synthetic Disease-Modifying Anti-Rheumatic	n (%)
Drug [DMARDs]	n (%)
Target synthetic DMARDs	n (%)
bDMARDs	n (%)
Glucocorticoid	n (%)
Other	n (%)
Other conditions than IA	
None	n (%)
Cardiovascular disease	n (%)
Type 2 diabetes	n (%)
Other	n (%)
No of medications currently taken for other conditions than IA	
None	n (%)
1-2	n (%)
3-4	n (%)
≥5	n (%)

1

Appendix. Table 4. Candidate self-reported side effects.

Table 4. Candidate self-reported side effects

Chest, breathing, excess bleeding and/or swelling

- chest pain
- cough
- excess bleeding for cuts
- limp swelling
- pounding or racing heartbeat (palpitations)
- shortness of breath
- wheezing (whistling noise in the chest with breathing)

Skin, hair and/or nails

- acne or pimples on the face or chest
- bed sores
- brittle fingernails or toenails
- bruise easily (black and blue marks)
- change in the color of your fingernails or toenails
- dry or oily skin
- flushing
- fragile skin
- gone from straight hair to wavy/ curly hair
- hair loss
- hives (itchy red bumps on the skin)
- impaired wound healing
- increased hair growth
- increased skin sensitivity to sunlight
- itchy skin
- pain, swelling, or redness at a site of drug injection or iv
- rash
- redness
- ridges or bumps on your fingernails or toenails
- skin burns from radiation
- skin peeling
- stretch marks
- thin skin
- unusual darkening of the skin

Intestines, stomach and/or bowel movements

- bleed after a bowel movement
- bloating of the abdomen (belly)
- change of bowel habit
- changed appetite
- constipation
- diarrhea/diarrhoea (loose or watery stools)
- gastric pain
- reflux/heartburn
- hiccups
- increased passing of gas (flatulence)

- indigestion
- lose control of bowel movements
- nausea
- pain in rectum
- pain in the abdomen (belly area)
- vomiting

Bladder, genitals and/or hormones

- irregular menstrual periods
- long term absence of menstrual period
- loss of control of urine (leakage)
- pain or burning with urination
- unusual vaginal discharge
- urge to urinate all of a sudden
- urinate frequently
- urine color change
- vaginal dryness

Intimate relationships

- decreased sexual interest
- difficulty getting or keeping an erection
- ejaculation problems
- pain during vaginal sex
- took too long to have an orgasm or climax
- unable to have an orgasm or climax

Internal and/or external bodily effects

- body odor
- breast area enlargement or tenderness
- change in body shape
- change in facial features
- feeling badly
- feeling of warmth
- feeling weak
- fever
- hot flashes/flushes
- lump in back
- not recognizing oneself physically
- shivering or shaking chills
- unexpected decrease in sweating
- unexpected or excessive sweating during the day or nighttime (not related to hot flashes/flushes)
- weight changes

Mood and/or emotions

- anxiety
- negative feelings
- irritability and mood swings (agitation, mood disturbances)
- hyperactivity/ euphoria (over optimistic feelings, manic, full of ideas)
- personality change/ not feeling oneself (behavioral changes)

Muscles, bones and/or joints

- back pain
- flare-up
- joint stiffness
- joint swelling
- muscular weakness
- straining
- painful joints (such as elbows, knees, shoulders)
- painful muscles
- muscle cramp
- pain
- tendon pain
- difficulty standing

Brain and/or nerves

- dizziness
- fainting, losing consciousness
- recurrent falls
- impaired coordination
- increased sensitivity of any sense
- nerve pain
- numbness or tingling in your hands or feet
- paranoia
- reduced sensitivity of any sense
- restless legs
- sensing things that are not real
- stinging
- tremor
- brain fog
- problems with concentration
- problems with memory
- headache
- loss of identity

Mouth, nose and/or throat

- dental pain
- difficulty swallowing
- dry mouth
- hoarse voice
- jaw pain
- lips, mouth or throat sores
- runny nose
- stuffy nose
- voice changes
- change in taste
- nosebleeds
- loss of teeth

Sleep

- fatigue, tiredness, or lack of energy
- sleepiness
- sleep difficulties (including difficulty falling asleep, staying a sleep, or waking up early)
- weird dreams

Ears and/or eyes

- droopy eyelid
- dry eyes
- light sensitivity (eyes)
- ringing in your ears
- watery eyes (tearing)
- ear pain
- vision affected

Appendix. Box 1. Information sheet

Box 1. Information sheet

Symptoms, classifications, and themes related to harms in rheumatology: Qualitative semi-structured interviews with patients with inflammatory arthritis

Patient information sheet
Version 1.0 (10/11/2021)

We would like to invite you 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 read the following information carefully and discuss it with friends and relatives if you wish. Ask us if anything is not clear or if you would like more information.

What is the purpose of the study?
Side effects from medication are the direct opposite of benefits, and at the moment, most information on side effects from rheumatological medication comes from the perspective of the clinician instead of the perspective of the patient. Thus, we would like to find out more about patients' experiences of side effects from their rheumatological medication, the impact of side effects on patients´ life, and what patients would like to know about potential side effects before deciding about a new medical treatment.

Why have I been chosen?
You have been invited to take part because you are at least 18 years of age, have been diagnosed with either rheumatoid arthritis, psoriatic arthritis, or axial spondyloarthritis, and have used one or more prescribed medication for your arthritis for at least 12 months. We are inviting at least 30 patients to take part from Europe, USA/Canada and Australia.

What will I be asked to do if I take part?
You will be invited to take part in a focus group. This will be an online discussion with a group of around 4-6 other patients with either rheumatoid arthritis, psoriatic arthritis, or axial spondyloarthritis.

In the focus group you will be asked questions that will enable you to discuss your experience of side effects from your medication. We will talk about how the burden of one or more side effects impacts patients, and what you think is important to know about side effects before deciding about a new medical treatment for your disease. The focus group will be run by PhD-student Dorthe B. Berthelsen with support from Dr Caroline Flurey, who are both bound by confidentiality agreements.

You can say as much or as little as you like, you will not be 'picked on' to speak. There's no such thing as a wrong answer – everyone will have their own individual experiences. Participating in the discussion will require 60-90 minutes of your time. The discussion will be conducted using a secure Teams internet group call. Thus, you will need a device (PC, tablet or mobile) with a microphone, camera and internet access to participate.

From the focus groups, we will also invite 10-15 patients for a secondary interview to discuss further some relevant side effects from patients' point of view. We will tell you more about that during the focus group.

We will audio record the discussion, type it up and then analyze it. This means that we will examine the typed-up discussions to look for different themes. To check our findings, we will ask two or three other project members to review several discussions. These project members include a patient representative. When the discussions are typed up they will be made completely anonymous, which means that statements cannot be tracked to the person. A report will be written on how patients experiences side effects from their rheumatological medication, and we will be happy to send you a copy of the final report.

Do I have to take part?
Taking part is voluntary. If you decide to take part, we will ask you to complete an online consent form. If you take part, you are still free to withdraw at any time. If you decide not to take part you do not have to give a reason, nobody will be upset and the care you receive will not be affected. Your clinician will not be informed of your decision to participate or not.

What are the possible risks of taking part?
We do not anticipate any risk or discomfort in talking about your experiences.

What are my responsibilities?
We would be grateful if you agree to take part and treat everything discussed in the group as confidential. We would also like you to complete a brief questionnaire about yourself (such as age, gender etc.), so that we can make sure we have a wide range of patients taking part.

Will my taking part in this study be kept confidential?
Yes. When the audio-recording is typed up, your name will be replaced with a code. No one will be able to identify you from the typed discussion. Although the report will include quotations from the focus groups, no names will be used. The audio-recording will be kept securely for 5 years and then destroyed, in accordance with good practice guidelines.

What will happen to the results of the research study?
The results will be reported in professional publications and conferences (but patients will not be identifiable). The results will help us to better understand side effects from the point of view of patients. Additionally, this research will inform the design of our future research studies. The results will further enable us to decide which side effects are most important to measure in clinical trials from patients' point of view and to develop a patient-reported framework for side effects.

Who is funding the study and who has reviewed the research?
The research is part of a PhD-study, and the study is part of a global Outcome Measures in Rheumatology (OMERACT) initiative - an independent international organization of health care professionals and patient research partners striving to improve outcome measurement and instrument methodology in rheumatology. This research has not received any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

What do I do now?
Thank you for considering taking part in this research. Please e-mail PhD-student Dorthe B. Berthelsen dorthe.bang.berthelsen@regionh.dk if you are interested. We will then contact you with further information. If you have questions or concerns about participating in this interview, please contact us. We will be happy to answer your questions and explain more about the interview.

We hope you will be willing to participate in our interview. In that case, your participation will be a step forward in a more patient-centered care approach.

On behalf on the OMERACT Safety Working Group,

Yours sincerely,

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1

Appendix. Box 2. Consent form

Box 2. Consent form

Symptoms, classifications, and themes related to harms in rheumatology: Qualitative semi-structured interviews with patients with inflammatory arthritis

Consent form for research study

		Please initial each box
1	I confirm that I have read and understand the information sheet dated 09/11/2021 for the above study.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	☐
3	I agree that the focus group will be audio-recorded.	☐
4	I understand that anonymized quotes from the discussions may be used in publications and conference presentations.	☐
5	I agree to take part in the above study.	☐

Name of patient	Date	Signature
Name of researcher	Date	Signature

Appendix. Box 3. Collection form – demographics and characteristics of included participants

Box 3. Collection form – demographics and characteristics of included participants

Symptoms, classifications, and themes related to harms in rheumatology: Qualitative semi-structured interviews with patients with inflammatory arthritis

Name:_____ Date (dd/mm/yyyy):_____

Year of birth (yyyy):_____

Gender:
- ☐ Female
- ☐ Male
- ☐ Diverse

Ethnicity:
- ☐ Arabian
- ☐ Asian
- ☐ Black
- ☐ Hispanic
- ☐ Mixed/multiple ethnic groups
- ☐ White
- ☐ Other, please specify:_____

Employment status:
- ☐ Working, full time (paid/unpaid)
- ☐ Working, part time (paid/unpaid)
- ☐ Sickleave
- ☐ Unemployed (due to arthritis)
- ☐ Unemployed (for other reasons)
- ☐ Student
- ☐ Retired
- ☐ Other, please specify:_____

Clinical diagnosis of inflammatory arthritis:
- ☐ Rheumatoid arthritis
- ☐ Psoriatic arthritis
- ☐ Axial spondyloarthritis

Year of diagnoses (yyyy):_____

Please, list your current use of prescribed medication for your inflammatory arthritis:

_____

_____

_____

Please, list your prior use of prescribed medication for your inflammatory arthritis (if any):

_____

_____

_____

_____

_____

Please, list if you have other conditions than inflammatory arthritis:

_____

_____

_____

Please, list if you currently take medications for other conditions than your inflammatory arthritis:

_____

_____

_____

_____

_____

1