Sexual quality of life in patients with axial spondyloarthritis

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Summary in English

Background

Research on the impact of health status on sexual activity and sexual quality of life (QOL) in patients with axial spondyloarthritis (axSpA) is scarce.

Aim

The overall aim of the studies was to examine the impact of health status on sexual activity and sexual QOL in male and female patients with axSpA.

Methods

Three hundred and seventy-nine consecutive patients with axSpA, aged 18–81 years, who visited the outpatient rheumatology clinics at two Norwegian hospitals were included. Data on demographic factors, disease, treatment, and lifestyle variables were collected by doctors and nurses from questionnaires, laboratory test results, direct interviews, and physical examinations, at the baseline and after 5 years. At the follow-up, 245 patients participated. A broad-spectrum data collection method was used to obtain data for demographics, patient-reported outcome measures (PROMS), and disease activity/damage. PROMS measures included the Health Assessment Questionnaire (HAQ), Bath Ankylosing Spondylitis Patients Global Score (BAS-G), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Activity Index (BASDAI), 15D Measure of Health-Related Quality of Life (15D), Health Survey Short-Form-36 items (SF-36), and Sexual Quality of Life–Female (SQOL-F). Data on disease activity and damage were obtained from the Bath Ankylosing Spondylitis Metrology Index (BASMI) and the Maastricht Ankylosing Spondylitis Enthesis Score (MASES).

Results

The mean age of the patients at the baseline was 45.6 years (standard deviation, SD ± 11.9) and the mean disease duration was 13.9 years (SD ± 11.4); 66.5% were men. Of the study cohort, 81.1% had a sexual partner and 76.3% were married or cohabiting. Biological disease-modifying antirheumatic drugs (bDMARDs) were used

by 22% of the patients, and the mean comorbidity rate was low (0.7 per patient). A large percentage of patients with axSpA were working (70.7%), and 55.7% had more than 13 years of education.

At the baseline, one of five patients reported that their health status had a negative impact on sexual activity. Most patients had low disease activity and low disability. A large negative impact on sexual activity was independently associated with being a woman, high body mass index (BMI kg/m^2)), current smoking, and a reduced health-related QOL (HRQOL) (Paper I).

In the adjusted analysis, sexual QOL was impaired in patients with active axSpA, and impaired sexual QOL was associated with elevated BAS-G score, C-reactive protein (CRP)level, and use of bDMARDs. Being a woman and increased BMI were also independently associated with a decreased sexual QOL (Paper II).

At the 5-year follow-up, significant increases were observed in the number of comorbidities and use of bDMARDs. The patients displayed better disease control (e.g., lower scores on the CRP, MASES, BASFI, and BAS-G) but no significant changes in sexual QOL. The frequencies of negative lifestyle factors such as smoking had decreased. In patients older than 65 years and in those who exercised <1 h/week, a decreased sexual QOL was reported (Paper III).

Conclusions

This cohort of outpatient patients with axSpA reported a low impact of health status on sexual activity and sexual QOL. Sexual QOL did not seem to worsen over time and remained stable through the 5-year follow-up despite an increase in the number of comorbidities. Effective disease control and changes in healthy lifestyle habits may help to improve the outcomes for these patients.

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Norsk sammendrag

Bakgrunn

Det finnes lite forskningen på hvilken innvirkning helsestatus har på seksuell aktivitet og seksuell livskvalitet hos pasienter med axSpA.

Hensikt

Det overordnede målet med studien var å undersøke hvilken påvirkning helsestatus har på seksuell aktivitet og seksuell livskvalitet hos mannlige og kvinnelige pasienter med axSpA.

Metode

Trehundre og syttini pasienter med axSpA i alderen 18–81 år ble fortløpende inkludert i studien ved besøk på polikliniske revmatologiske klinikker ved to norske sykehus. Data på demografiske faktorer, sykdom, behandling og livsstils variabler ble samlet inn av leger og sykepleiere ved å bruke spørreskjemaer, laboratorietester, direkte intervjuer og fysiske undersøkelser. Dette ble gjort ved baseline og etter 5 år. Ved oppfølgingen deltok tohundre og førtifem pasienter. Det ble samlet data på: demografi variabler, pasientrapporterte utfallsmål (PROMS) og sykdomsaktivitet/skade. PROMS som ble brukt var, HAQ, BAS-G, BASFI, BASDAI, 15D, SF-36 og SOQL-F. Data på sykdomsaktivitet og skade ble samlet ved å benytte spørreskjemaet BASMI og MASES.

Funn

Ved basseline hadde pasientene en gjennomsnittsalder på 45,6 år (standardavvik, SD ±11,9), med en gjennomsnittlig sykdomsvarighet på 13,9 år, (SD ±11,4), og 66,5 % var menn. Av studiekohorten hadde 81,1 % en seksuell partner og 76,3 % var gift eller samboer. Biologiske sykdomsmodifiserende antireumatiske legemidler (bDMARD) ble brukt av 22 % av pasientene, og det var få tilleggssykdommer (gjennomsnitt 0,7 per pasient). En stor andel av pasientene med axSpA var i arbeid (70,7 %) og 55,7 % hadde mer enn 13 års utdanning. Ved

baseline rapporterte én av fem pasienter at helsestatusen deres hadde en negativ innvirkning på seksuell aktivitet. De fleste pasientene hadde lav sykdomsaktivitet og rapporterte om god fysisk funksjon. En stor negativ innvirkning på seksuell aktivitet var uavhengig assosiert med kvinnelig kjønn, høy kroppsmasseindeks (BMI), røyking og redusert helserelatert livskvalitet (HRQOL) (artikkel I). I de justerte analysene var seksuell QOL redusert hos pasienter med aktiv axSpA, (målt ved hjelp av forhøyet BAS-G og CRP, og med bruk av bDMARDs). Kvinnelig kjønn og økt BMI var også uavhengig assosiert med redusert seksuell QOL (papir II). Ved 5-års oppfølgingen ble det funnet en signifikant økning i antall tilleggssykdommer, mer bruk av bDMARDs, bedre sykdomskontroll (vises ved lavere skår på CRP, MASES, BASFI og BAS-G), men ingen signifikante endringer i seksuell livskvalitet. Negative livsstilsfaktorer som røyking var redusert. Hos pasienter eldre enn 65 år og hos de som trente mindre enn 1 time/uke ble det rapportert en reduksjon i seksuell livskvalitet (artikkel III).

Konklusjon

Pasienter med axSpA i våre studier rapporterte en lav innvirkning av helsestatus på seksuell aktivitet og seksuell livskvalitet. Seksuell livskvalitet så ikke ut til å forverres over tid og forble stabil gjennom 5-års oppfølgingen til tross for en økning i antall tilleggssykdommer. Effektiv sykdomskontroll og endring til en sunnere livsstilsvaner kan ha bidratt til å forbedre resultatene for denne pasientgruppen.

Abbreviations

AS	Ankylosing spondylitis
ASAS	Assessment of SpondyloArthritis international Society
AxSpA	Axial SpondyloArthritis
BASDAI	Bath Ankylosing Spondylitis Activity Index
BASFI	Bath Ankylosing Spondylitis Functional Index
BASMI	Bath Ankylosing Spondylitis Metrology Index
BAS-G	Bath Ankylosing Spondylitis Patients Global Score
bDMARD	Biological disease-modifying antirheumatic drug
BMI	Body mass index
CRP	C-reactive protein
CsDMARD	Conventional synthetic disease-modifying antirheumatic drug
EULAR	European Alliance of Associations for Rheumatology
HAQ	Health Assessment Questionnaire
HLA-B27	Human leukocyte antigen – B27
HP	Health Personnel
HRQOL	Health-related quality of life
MASES	Maastricht Ankylosing Spondylitis Enthesitis Score
MHH	Martina Hansen's Hospital
MRI	Magnetic resonance imaging
Nr-axSpA	Non-radiographic axial spondyloarthritis
NSAID	Non-steroidal anti-inflammatory drug
PROMS	Patient-reported outcome measures

PsA	Psoriatic arthritis
QOL	Quality of life
RA	Rheumatoid arthritis
R-axSpA	Radiographic axial spondyloarthritis
Sexual QOL	Sexual quality of life
SF-36	Health Survey Short-Form-36 items
SpA	Spondyloarthritis
SQOL-F	Sexual quality of life – Female
SSHF	Sørlandet Hospital
TNF	Tumour necrosis factor
T2T	Treat-to-target
UIA	University of Agder
WHO	World Health Organization
15D	The 15D Measure of Health-Related Quality of Life

Innhold

List of figures and tables

List of papers

I. Berg, K.H., Rohde G, Prøven, A., Almås, E., Benestad, E.E.P., Østensen, M., Haugeberg, G. Exploring the relationship between demographic and disease-related variables and perceived effect of health status on sexual activity in patients with axial spondyloarthritis: associations found only with non-disease variables. *Scandinavian Journal of Rheumatology*, 2017; *46*(6), 461-467. doi:10.1080/03009742.2017.1279684

II. Berg, K.H., Rohde, G., Prøven, A., Benestad, E.E.P., Østensen, M., Haugeberg, G. Sexual Quality of Life in Patients with Axial Spondyloarthritis in the Biologic Treatment Era. *The Journal of rheumatology*, 2019; doi:10.3899/jrheum.180413

III. Berg, K.H., Rohde, G., Pripp, A., Prøven, A., Benestad, E.E.P., Østensen, M., Haugeberg, G. Increased proportion of comorbidities but no deterioration of sexual QOL during a 5-year follow-up in patients with axSpA in the biologic treatment era. *Rheumatology*, 2021; doi.org/10.1093/rheumatology/keaa887

1 Background

1.1 Introduction

In 2007, a prospective longitudinal observational study of axial inflammatory rheumatic disorders, including ankylosing spondylitis (AS), was designed, with the title: 'Inflammatory back pain and Bechterew's disease in Norway'. The project was designed by Professor Glenn Haugeberg at Sørlandet Hospital (SSHF). The overall aim of the study was to explore the epidemiology, demographics, disease presentation, morbidity, health-related quality of life (HRQOL), including sexual QOL, treatment, and health-care economics for these patients. For questions on sexuality, Professor Esben Ester Pirelli Benestad and Professor Elsa Almås at the University of Agder (UIA) were consulted. Although the study was planned as a multicentre study in Norway, only two clinics were able to participate. The two rheumatology outpatient clinics were located at SSHF in Kristiansand and Martina Hansen's Hospital (MHH) in Bærum. This thesis is part of the above-mentioned project, with a cross-sectional longitudinal design.

Through working in a rheumatology outpatient clinic as a nurse and team leader for over 25 years, I have developed a personal and professional interest in axSpA and the impact of axSpA on a patient's life, ability to work, social life, relationships, and sexual QOL. I have noted that patients with axSpA have stated that their disease has impacted their sexual QOL. During this time, my interest in research matured. In October 2010 I started to work at the Rheumatology Department at SSHF and was involved in data collection as one of the study nurses for this project, later taking on a leading role for all data collection. When I was given an opportunity to use part of the collected data focusing on the impact of health status on sexual activity and sexual QOL in male and female patients with axSpA over a 5-year period in the framework of a PhD funded by the University of Agder, I made the decision driven by curiosity to challenge myself and to move into the world of health-care research.

The disease burden for patients with axSpA has been reported to be extensive, in the past (Boonen et al., 2015; Garrido-Cumbrera et al., 2019; Sieper et al., 2016).

However, in the new millennium with new treatment strategies and improved patient management, disease outcomes have improved (Smolen et al., 2014; Smolen et al., 2018). The improvement has been driven by the introduction of biological disease-modifying antirheumatic drugs (bDMARDs) from around 2005. Furthermore, a treat-to-target (T2T) strategy, which has been documented to improve outcomes for patients with rheumatoid arthritis (RA) since 2012 (Smolen et al., 2010) has also been recommended for the follow-up of patients with axSpA (Smolen et al. (2014). The T2T strategy defines remission as the target and assesses patients' preferences in the decision-making process of treatment (Smolen et al., 2014; Smolen et al., 2018). In addition, programmes on self-management of the disease, focusing on its physical, emotional, and social consequences have proven to be beneficial for coping with axSpA (Molto et al., 2021). The emergence of both better and more powerful medications and the change to a patient-centred approach, as a partner in their own care and given the opportunity to be involved in decision-making, has given patients with axSpA the possibility of coping better in living with this chronic disease (Agrawal & Machado, 2020; Torre-Alonso, Queiro, Comellas, Lizán, & Blanch, 2018).

PROMs are important for obtaining the patients' perception of health, HRQOL, and sexual QOL in a clinical setting. PROMs include any reports that patients have given on their health condition (Cappelleri et al., 2014). PROMs are also recognized as important outcome tools to identify any disease activity and functional impairments (Khanna et al., 2011; Madsen, 2018). In a study by Rohde et al. on the same patient population as the current studies, patients having axSpA reported decreased HRQOL, including reduced physical functioning, compared with published norm-based data for the general population (Rohde, Berg, Prøven, & Haugeberg, 2017).

One of the key functions in human beings is sexual activity, which affects both quality of life (QOL) and sexual QOL (Gallinaro, Akagawa, Otuzi, Sampaio-Barros, & Gonçalves, 2012). However, in general, sexual QOL remains an unexplored area of research, including patients with axSpA. So far, the research focus has been on sexual activity, functioning, and dysfunction, which are all related to sexual QOL, but little

attention has been given to this topic (Akkurt et al., 2016; Christensen et al., 2011; Shen et al., 2013). Despite the importance of sexual QOL, sexual issues and sexual health among patients with rheumatic diseases, including axSpA, are often unaddressed or neglected by health personnel (HP) and are rarely raised in consultations with rheumatology specialists (Helland, Garratt, Kjeken, Kvien, & Dagfinrud, 2013; Josefsson & Gard, 2012). Therefore, in this thesis, the focus is on the significance of the patient's state of health on sexual activity and perception of sexual QOL in those with axSpA.

1.2 Axial spondyloarthritis

In this section, I will give a brief overview of axSpA in the context of spondyloarthritis (SpA) disorders, diagnosing and classification of axSpA with its different phenotypes of axial inflammatory disease, the epidemiology of axSpA, disease characteristics and course, its burden, and implications for the individual living with axSpA. Finally, the T2T strategy and medical treatment of patients with axSpA will be described.

1.2.1. Axial spondyloarthritis as part of the spondyloarthritis concept

In 1974, Moll et al. defined the SpA concept as a group of disorders with common features that may affect several organs including the spine, the sacroiliac joints, peripheral joints, and peri-articular structures (Moll, Haslock, Macrae, & Wright, 1974). This included the diagnosis of axial spondyloarthritis (AS) (previously also called Bechterew's disease), psoriatic arthritis (PsA), reactive arthritis, inflammatory bowel disease-related arthritis, and undifferentiated arthritis. It is important to emphasize that all these disorders can present with axial inflammatory involvement, but only for AS, axial skeleton involvement is mandatory.

1.2.2. Characteristics of axSpA and its disease course

From the axial skeleton involvement perspective in SpA, axSpA can be defined as a chronic, inflammatory rheumatic disease affecting the axial skeleton, causing severe pain, stiffness, and fatigue (Bal et al., 2011). AxSpA is divided into two sub-phenotypes: one characterized by signs of inflammation on radiographs (radiographic

axSpA), in patients and one with axial skeleton inflammation without signs of inflammation on radiographs (non-radiographic axSpA). During the disease course, patients with axSpA may suffer structural damage in their spine due to the development of osteophytes in the intervertebral joints which contributes to disease burden and disease severeness (Garg, van den Bosch, & Deodhar, 2014).

1.2.3. Epidemiology of axSpA

Obviously, the use of different criteria for axial inflammatory disease will also impact the epidemiology of axSpA (Bakland & Nossent, 2013). In a study from Northern Norway in a population with chronic back pain and with a high prevalence of human leucocyte antigen (HLA)-B27, 8.4% met the Assessment of SpondyloArthritis international Society (ASAS) classification criteria for axSpA, whereas only 2.4% met the modified New York criteria (Bakland & Nossent, 2013). The estimated prevalence of axSpA in Norway is 0.3% to 1.2% (Bakland & Nossent, 2013). Among the types of SpA, axSpA is the most common diagnosis found among 0.15% to 1.8% of people of European origin and is more frequent in populations with a high prevalence of human leukocyte antigen-B27 (HLA-B27), as seen in northern latitudes (Zochling & Smith, 2010).

1.2.4. Diagnosing and classification of axSpA in a historical context

Different criteria have been developed to diagnose AS (radiographic sacroiliitis) (van der Linden, Valkenburg, & Cats, 1984). For this phenotype of axSpA, the Rome criteria were developed in 1961, which were later modified and reformulated as the New York criteria in 1966 and in 1984 the modified New York criteria were developed. To fulfil these criteria, signs of sacroiliitis must be present on X-rays, termed radiographic axial spondyloarthritis (r-axSpA). With the introduction of magnetic resonance imaging (MRI), visualization of the axial inflammatory disease process before bone damage was visible on X-rays—defined as non-radiographic axial spondyloarthritis (nr-axSpA)—became possible (Bennett et al., 2008).

In 2009, the ASAS and the European Alliance of Associations for Rheumatology (EULAR) published new classification criteria for axSpA, (Rudwaleit et al., 2009b). These criteria were applied in the present study to select patients

according to their inclusion criteria Figure 1. The new ASAS criteria for axial inflammatory disease include both radiographic (sacroiliitis on X-rays) and non-radiographic axial inflammatory (sacroiliitis on MRI) phenotypes. They also included a non-imaging arm for patients with chronic back pain being HLA-B27 positive and with various SpA features as shown in Figure 1.

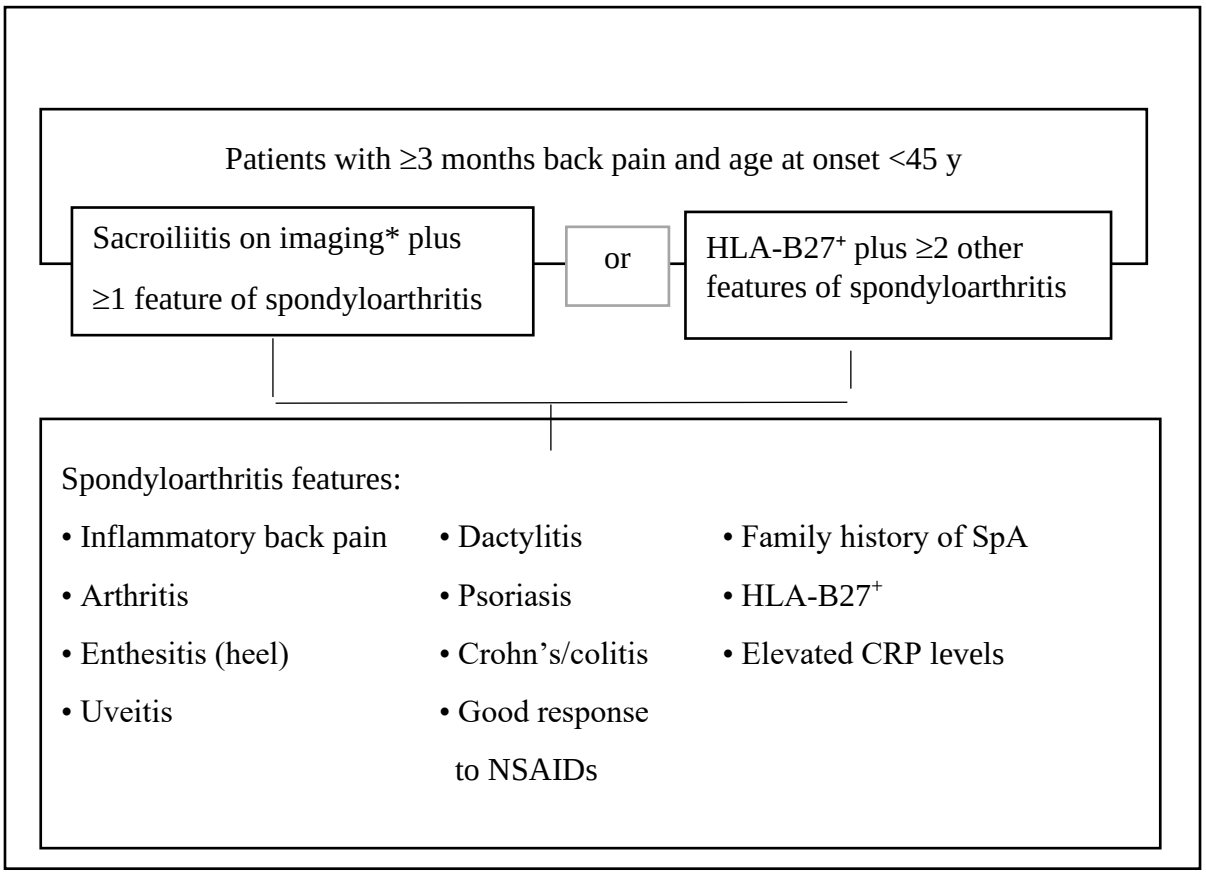

Figure 1. The ASAS classification criteria for axial spondyloarthritis

ASAS, Assessment of SpondyloArthritis international Society; CRP, C-reactive protein; NSAIDs, non-steroidal anti-inflammatory drugs; SpA, spondyloarthritis. *Sacroiliitis on imaging refers to definite radiographic sacroiliitis according to the modified New York criteria or sacroiliitis on MRI according to the ASAS consensus definition. Adapted from (Rudwaleit et al., 2009b).

The new ASAS criteria for axial inflammatory disease thus include patients at an earlier stage in the disease course as when sacroiliitis first was diagnosed after beeing visible on X-rays (Feldtkeller, Bruckel, & Khan, 2000).

Patients with nr-axSpA and r-axSpA share common clinical features such as uveitis, enthesitis, peripheral arthritis, psoriasis, irritable bowel disorder and dactylitis which all significantly impact HRQOL (Sieper & Poddubnyy, 2017; Strand & Singh, 2017; Taurog, Chhabra, & Colbert, 2016). However, there are differences. Risk factors for developing AS have been identified and include smoking, male gender, the HLA-B27^{+} genotype and sacroiliitis on MRI (Bakland, Nossent, & Gran, 2005; Bennett et al., 2008; Videm, Cortes, Thomas, & Brown, 2014).

Historically, axSpA has been considered a disease that predominantly affects men, and the ratio between men and women has varied from 2:1 to 4:1 (Bakland & Nossent, 2013; Zochling & Smith, 2010). However, better diagnostic procedures revealed that a significant proportion of women also suffer from axSpA. Using MRI and ASAS criteria for diagnosis has now narrowed the gap in the ratio between men and women (Baumberger & Khan, 2017; Rusman, van Vollenhoven, & van der Horst-Bruinsma, 2018). Although the time to diagnosis of axSpA has decreased for men over the years, women still experience a much longer diagnostic delay than men because of differences in the rate of disease manifestation (Rusman et al., 2018).

1.2.5. The impact of axSpA on the patient's daily life

AxSpA is a chronic disease and patients living with it can experience the disease in different ways. It typically starts in early adulthood (<40 y), which is a critical period of life when most people finish their education and move on to a career and might have started a family (Sieper et al., 2009). The inflammation may lead to structural damage in both the spine and the sacroiliac joints and lead to a great impact on patients' mobility, physical function, and ability to work as well as lifestyle (J. T. Rosenbaum, Pisenti, Park, & Howard, 2019). All the symptoms caused by axSpA might also lead to difficulties in relationships and have a negative impact on HRQOL, including sexual relationships and sexual QOL (Strand & Singh, 2017).

The persistence of inflammation in the sacroiliac joints and the spine causes pain, develops into chronic back pain, and may lead to postural changes. Severely reduced mobility of the spine causes stiffness and pain, and hampers performing daily activities, such as personal care, dressing, and housework, regardless of whether

patients have r-axSpA or nr-axSpA (Singh & Strand, 2009; Strand & Singh, 2017; Özdemir, 2011). Working ability can be affected, depending on the person's type of work. Heavy work may be more difficult than working in an office and living in rural areas is more difficult than in the cities. Difficulties with working might further affect a person's economic situation (Hollick et al., 2020; Nikiphorou & Ramiro, 2020). Furthermore, engaging in leisure activities can be difficult, and it might be necessary to change focus and find other types of leisure activities (Hamilton-West & Quine, 2009; Özdemir, 2011).

The impact of axSpA varies between patients and influences men and women in different ways (Hwang, Ridley, & Reveille, 2021; Landi et al., 2016). Women tend to report more negative impacts of the disease than men in physical, discomfort, emotional, and social areas (T. Y. Rosenbaum, 2010). Men are often diagnosed earlier in life and have more radiographic damage. However, women have longer delay in getting a diagnosis; they have a higher disease burden, higher disease activity, respond significantly less well to tumour necrosis factor (TNF) inhibitors, and do not have the same treatment responses as men (Hwang et al., 2021; Rusman et al., 2018).

Fatigue can also be a major problem caused by inflammatory processes in the body. Sleep disturbances, such as insomnia and waking several times during the night, can have major negative effects on patients' sleep quality and can lead to daytime fatigue, as well as influencing all other activities (Aissaoui et al., 2012; Kotsis, Voulgari, Drosos, Carvalho, & Hyphantis, 2014).

One additional problem is the unpredictability of disease activity and rapid change in the disease course, which makes it difficult to plan activities ahead. Some patients manage living well with the disease, even though the disease is active; they adapt positively and adjust how to manage their illness by using strategies to optimize their QOL. Some persons tend to 'deny' limitations caused by the disease (Essers et al., 2015; Sirgy, 2012), whereas others experience that high disease activity might harm the quality of sleep, increase pain, and reduce their QOL (Macfarlane, Rotariu, Jones, Pathan, & Dean, 2020). Because of the nature of axSpA, and possible implications for the patients with this disease, it is important to provide an early

diagnosis and start treatment without delay so that disease perception, loss of function, and impairment can be minimized (Garg et al., 2014; Shim, Jones, Pathan, & Macfarlane, 2018).

1.2.6. Treatment strategies and drugs used to treat patients with axSpA

To manage axSpA successfully, a combination of non-pharmacological and pharmacological treatments is required (Regel et al., 2017; Ward et al., 2019). Treatment should be individualized and based on the whole person; thus, not only the disease symptoms should be considered but also other aspects, such as comorbidities, QOL, and medication use (Smolen et al., 2018; van der Heijde et al., 2017). An important point is that patients need to participate in the decision process, so it is important to give information on a level that is understandable regardless of literacy ability and level of education (Wittink & Oosterhaven, 2018). The treatment goal for pharmacological treatment is to eliminate or reduce symptoms, achieve clinical remission, prevent worsening of the disease, and reduce damage (van der Heijde et al., 2017). Pharmacological treatment relies on the treatment recommendations of the 2016 ASAS-EULAR management for axSpA (van der Heijde et al., 2017). These include non-steroidal anti-inflammatory drugs (NSAIDs), local glucocorticoid injections, conventional synthetic disease-modifying antirheumatic drugs (csDMARDs), and bDMARDs (van der Heijde et al., 2017). The bDMARDs including antitumour necrosis factor agents are an effective option for patients with high disease activity where NSAIDs and exercise are not sufficient to reduce pain and inflammation. The most frequently used csDMARDs are methotrexate and Salazopyrin, they have been used for many years and mostly for patients who have peripheral arthritis (Caso et al., 2015).

Non-pharmacological treatments such as regular exercise aim to maintain physical functioning (Agrawal & Machado, 2020; Rausch Osthoff, Juhl, et al., 2018; Regel et al., 2017). Another important non-pharmacological treatment is a change in lifestyle: stopping smoking (Chung, Machado, van der Heijde, Agostino, & Dougados, 2012; Poddubnyy et al., 2012; Ramiro et al., 2015); losing weight (van der Heijde et al.,

2017); and education to understand better the disease and its management (Candelas et al., 2016; Zangi et al., 2015).

The concept of ‘T2T’, defined for axSpA and peripheral SpA in 2012 (Smolen et al., 2014; Smolen et al., 2018) and reviewed in 2017, aims at early clinical remission or achieving an inactive disease, with an improvement in the BASDAI of 50%, less pain, and better scores on the Bath Ankylosing Spondylitis Metrology Index (BASMI) and BASFI as well as normalization of CRP levels and of the erythrocyte sedimentation rate. The concept considers the patient’s treatment goals and individualizes the treatment to prevent structural damage (Smolen et al., 2018).

1.2.7. Previous research

A literature search was performed to obtain an overview of research on the impact of axSpA on sexual QOL in patients from the start of the study 2009 to 2022. For inclusion, papers in the English language was chosen. The search was performed with the following terms: words for Quality of life or well-being, and sexual*, and ‘ankylosing spondylos’ or ‘bechterew’ and free text terms and terms from the databases subject headings, in the following databases: CINAHL, MEDLINE (EBSCOhost) and APA PsycInfo (Ovid), up to 30th of March 2022 (Figure 2). In addition, hand searching was performed in reference list and cited by articles.

The literature search resulted in 23 papers and five research areas: sexual activity (n = 4), sexual QOL (n = 1), sexual relationships (n = 1), sexual satisfaction (n = 1), and sexual dysfunction and function (n = 16) (Appendix 4).

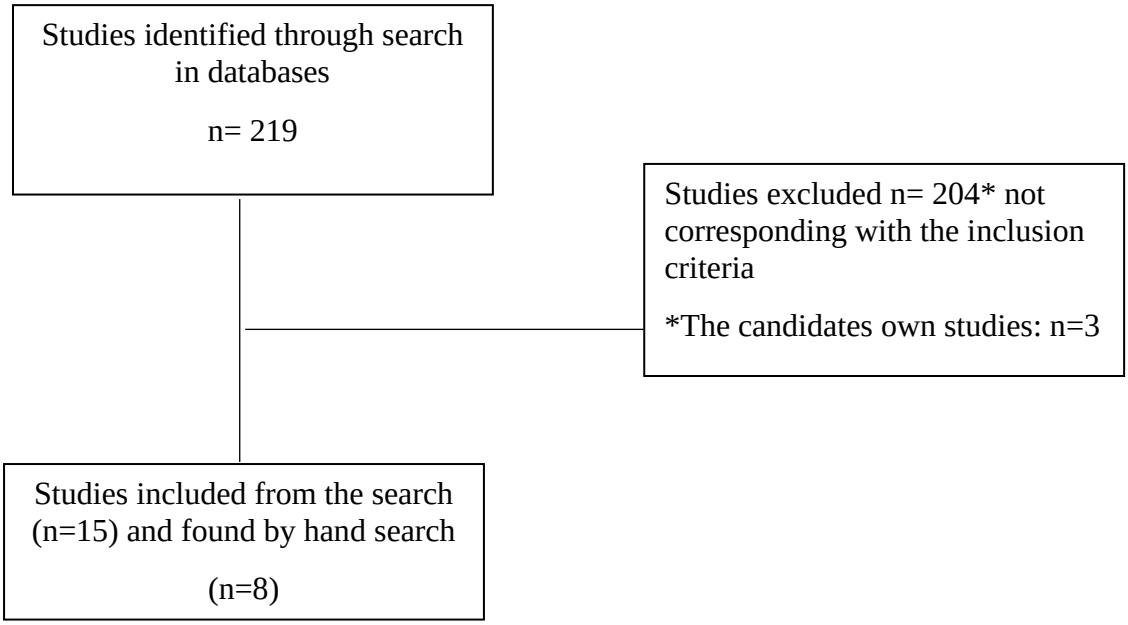

Figure 2. Search history for publications on sexual activity and sexual QOL

The search resulted in four papers on sexual activity, showing that AS, with its chronic nature and associated poor function, has a considerable influence on patients' sexual activity (Fu et al., 2018; Gallinaro et al., 2012; Rostom et al., 2013; Yao et al., 2016). As for the perceptions of sexual QOL among patients with axSpA, only one study was identified, showing that sexual QOL and disease activity improved after treatment with a bDMARD (Dong, Zheng, Shi, & Liu, 2015). One study was found on sexual relationships: it revealed a substantial impact, regarding physical outcomes and psychological state (Healey et al., 2009). Patients with axSpA reported that their sexual satisfaction declined after being diagnosed with axSpA (Akkuş, Nakas, & Kalyoncu, 2010). Studies on sexual dysfunction and function in patients with rheumatic diseases (including patients with axSpA) show impaired sexual function related to the functional status and disease activity including erectile dysfunction, decreased functionality, joint involvement, poor HRQOL, and depression with a negative impact on sexual intercourse (Dhakad et al., 2015; Erdem, Ortac, & Salabas, 2020; Fan et al., 2015; Oh et al., 2009; Rezvani, Ök, & Demir, 2012; Santana et al., 2017; Sariyildiz et al., 2013; Shen et al., 2013; Tristano, 2009; Özkorumak, Karkucak, Civil, Tiryaki, & Özden, 2011). Another study, (Bal et al., 2011) showed problems with satisfaction from intercourse, while Nisihara et al. (2021) reported worse sexual performance. In two other studies, sexual dysfunction was more common for women

with AS compared with the normal population and another study found that the impact seemed to be worse for men than for women with AS (Akkurt et al., 2016; Liu, Dong, Chen, Wang, & Tu, 2015). Increased smoking had a negative impact on sexual functioning in men with AS (Aykurt Karlıbel et al., 2019). No difference was found on sexual functioning and psychological burden between r-axSpA and nr-axSpA (Gözüküçük et al., 2021). For more details, see Appendix 4.

1.3 Theoretical framework

In this chapter, the theoretical framework of the thesis will be elaborated: the concepts of sexuality, sexual health, and sexual activity as an integrated part of health, HRQOL, QOL, and sexual QOL.

1.3.1 Sexuality

Sexuality is a person's ability to experience or express sexual feelings. It is unique to every person and does not exist alone: it is a part of the biopsychosocial perspective. Moreover, it is a broad term that affects a person in many ways and is affected by biological, physical, social, erotic, and spiritual dimensions (Graugaard, Giraldi, & Møhl, 2019). The motive for sexual activity is both complex and unpredictable. Sexuality is part of human life and has different purposes, such as reproduction, feelings of love, relief of tensions, intimacy, relations between people, and respect of people's own and other boundaries. Sexuality can also be used as a component of rehabilitation, recreation, and relaxation (Graugaard et al., 2019; J. S. Greenberg, Bruess, & Oswalt, 2016). Every person is a sexual being, but sexuality in terms of how it affects the body and intimacy has varied over time and has been influenced and affected by cultural and value systems. One of the key points in maintaining QOL, as defined by the World Health Organization (WHO), is sexuality, defined as:

> '… a central aspect of being human throughout life encompasses sex, gender identities and roles, sexual orientation, eroticism, pleasure, intimacy and reproduction. Sexuality is experienced and expressed in thoughts, fantasies, desires, beliefs, attitudes, values, behaviours, practices, roles and relationships. While sexuality can include all these dimensions, not all of them are always

> experienced or expressed. Sexuality is influenced by the interaction of biological, psychological, social, economic, political, cultural, legal, historical, religious and spiritual factors.' (WHO, 2006b)

Human sexuality encompasses a network of feelings that is unique for every person. This unique feeling is built by a person's individual experience and inherent properties. Sexuality is affected by biological, psychological, socio-cultural, moral, spiritual, and ethical and legal factors. How this network is composed on the individual level is unknown (Almås & Benestad, 2010; Graugaard et al., 2019; J. S. Greenberg et al., 2016).

The relationship between chronic disease and human sexuality has many aspects. Verschuren et al. propose a generic conceptual framework to present a conceptualization of chronic disease, where the chronic disease has implications on the physical condition (such as disease activity, treatment, and complications) and the psychological well-being (such as acceptance) which further influence sexual functioning and sexual well-being as a part of sexuality (Verschuren, Enzlin, Dijkstra, Geertzen, & Dekker, 2010). At the same time, it is important to consider different aspects such as the person's age and changing health conditions, and how the chronic disease progresses and which type of function or dysfunction the patients have that is linked to their sexuality (Carrillo-González, Sánchez-Herrera, & Chaparro-Díaz, 2013; Verschuren et al., 2010). Further, it might be important to consider that there is a difference between acute and chronic diseases. Whereas sudden progression of the disease requires immediate adaptation, progressive chronic disease requires continuous adaptation. The impact on these adaptations is affected by the person's place in life (Carrillo-González et al., 2013; Verschuren et al., 2010).

From an early age, we learn the socio-cultural meaning of gender, often being defined as either a boy or girl and our community will influence our perception of gender both psychologically, socially, and culturally (J. S. Greenberg et al., 2016). Gender differences in sexuality are pervasive and affect our thoughts and feelings, and is important to take into consideration for patients with axSpA (Graugaard et al., 2019; J. M. Greenberg, Smith, Kim, Naghdechi, & IsHak, 2017; Prairie, Scheier, Matthews,

Chang, & Hess, 2011). The effect of having a chronic disease—such as axSpA—can also lead to psychological distress, loss of self-esteem, fatigue, depression and grief, and affect sexual outcomes and further sexuality (Özkorumak et al., 2011). AxSpA can cause physical changes where activity can cause pain, leading to poor functional capacity; thus, it can interfere with sexual activity (Fu et al., 2018).

1.3.2 Sexual health

Sexual health is an important part of overall health, consisting of psychological (attention and communication), physiological (hormones, the impact of drug use, and medical problems), moral, and cultural aspects (J. S. Greenberg et al., 2016). Because all individuals are sexual beings and sexuality is part of the individual identity, sexual health concerns everyone (J. M. Greenberg et al., 2017; J. S. Greenberg et al., 2016). A definition of sexual health was given in 2006 by the WHO (WHO, 2006a).

> '… a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled.'

Sexual health is a relatively new concept and was first taken into the International Statistical Classification of Disease and Related Health Problems in 2019 (Epstein, 2021).

Good sexual health is a resource and can promote one's QOL and how a person copes with a disease (J. M. Greenberg et al., 2017). Education on sexuality and sexual health given by HPs is an important source for obtaining sexual health because it also implies respect for the person's sexual rights (Ministry of Health and Care Services, 2016; Starrs et al., 2018). Sexual health issues are one of many areas for HP to address in consultations (Ministry of Health and Care Services, 2016). Helland et al. (2013) found that HP accepted sexual health as an important issue for patients and relevant for health care in the field of rheumatology. At the same time, they identified some barriers to addressing sexual health, such as the feeling of being uncomfortable with the topic and lack of knowledge and education on how to address sexual health issues

(Helland et al., 2013). Areskoug-Josefsson et al. also identified barriers among Swedish social work students who considered themselves uncomfortable and not prepared sufficiently for dealing with patients' sexual health (Areskoug-Josefsson, Rolander, & Bülow, 2019).

1.3.3. Sexual activity

Sexual activity is part of good sexual health and QOL and an aspect of life affected by personal characteristics, interpersonal relationships, family circumstances, socio-cultural conditions, environment, and records of sexual activity of the couple, and one's own physical and mental health and hormonal status (J. M. Greenberg et al., 2017). Physical difficulties (Fu et al., 2018; Gallinaro et al., 2012; Yao et al., 2016), fatigue, and sleep disturbance (Rostom et al., 2013), can reduce sexual activity. Furthermore, the frequencies of sexual activity and level of intimacy might also change in different phases of life and be affected by a person's view of their body image, having a partner, culture, society, and health (Graugaard et al., 2019; J. S. Greenberg et al., 2016).

1.3.4. Health

Different definitions of health have been promoted during the last decades and the meaning has changed over the years (Larson, 1999; Leonardi, 2018). How we define health might have implications for clinical practice, policy making, and health-care services (Leonardi, 2018). The medical model has been used widely in the USA, the WHO model has gained popularity and newer models such as the wellness model and the environmental model have added new meaning to the definition of health (Larson, 1999).

The 'medical model' has a view of the body as a machine that is possible to fix: also referred to as the 'old medical model'. Georg Engel proposed in a series of papers from 1960 to 1980 to add the psychosocial dimension to broaden the biomedical approach calling it the 'biopsychosocial model' also referred to as the 'the new medical model' (Farre & Rapley, 2017). The intention is to give HP the opportunity to evaluate all factors that could contribute to illness, not the biological factors alone (Farre & Rapley, 2017; Larson, 1999).

The ‘holistic model’, with a broader perspective than the medical model, introduced positive health as an idea. This was exemplified by the WHO definition of health as, ‘…a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’ (WHO, 1948). The definition has been criticized for stating that health and disease cannot coexist, even though some studies report that people with severe chronic diseases have reported their QOL as being equal or superior to people with no chronic disease (Wahl, Rustoen, Hanestad, Gjengedal, & Moum, 2005). The holistic model has the advantage of allowing for discrimination of people at the higher end of functioning; it focuses on mental as well as physical health, and on broader issues of active participation in life (World Health Organization, 1984). Therefore, in 1984, a WHO discussion document proposed moving away from viewing health as a state, towards a dynamic model that presented it as a process or a force. The new suggestion was:

> ‘The extent to which an individual or group is able to realize aspirations and satisfy needs, and to change or cope with the environment. Health is a resource for everyday life, not the objective of living; it is a positive concept, emphasizing social and personal resources, as well as physical capacities.’ (World Health Organization, 1984)

This definition of health is a resource for living and incorporates both social and personal resources as well as physical capacities (World Health Organization, 1984). This definition has been chosen in this thesis even though it has met some criticisms as not meeting the challenges in today’s health-care systems and for not meeting needs in clinical and scientific fields. The definition is in line with the approach and philosophy of care as T2T in patients with axSpA. So far, no new attempts for a definition have reached consensus (Leonardi, 2018).

1.3.5. QOL in a health context

As for health, many definitions of QOL have been suggested and it can mean different things for different people (Fayers & Machin, 2016, p. 4; Post, 2014). However, there is agreement that QOL is a multidimensional concept, which in different contexts may comprise different characteristics, meanings, and perspectives, including multiple aspects of people’s lives, such as good health, comfort in

relationships, material comfort, and safety. Other aspects of QOL are the opportunity to learn, creative expression, the opportunity to help and encourage others, and socializing in all stages of life (Fayers & Machin, 2007; Spilker, 1996). The WHO definition of QOL from 1997 is chosen in this thesis, it encompasses a personal assessment of the person, their physical health status (e.g. daily physical functioning), and their psychological and social status (e.g. mood, companionship, and recreational activities), and is defined as:

> 'An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.' (WHO, 1997)

QOL may be viewed at several levels. Spilker divides QOL into three levels (Spilker, 1996) (Figure 3). The top level is global QOL and contains overall well-being and satisfaction with life. HRQOL might be defined as health status, components placed in the middle level, and single aspects of HRQOL are defined as the level of specific parts of QOL in the pyramid's lowest level. We have included measures of concepts on levels one and two of Spilker's model.

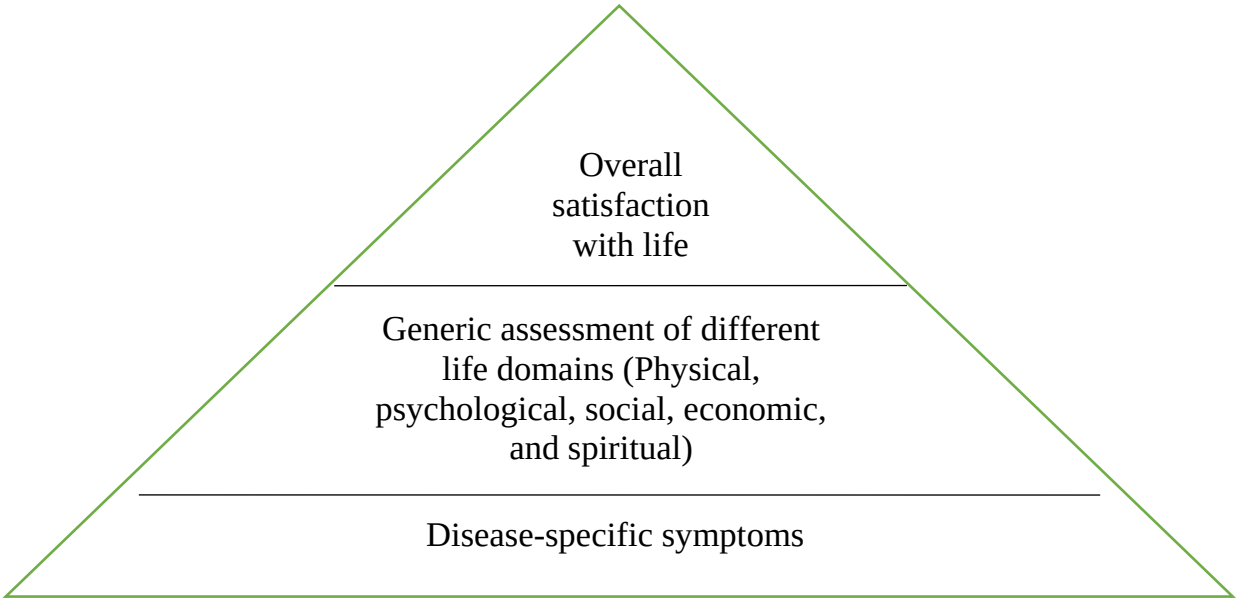

Figure 3. Spilker's model combining measurements of the overall, generic, and disease-related aspects of QOL (Spilker, 1996)

The levels are not mutually exclusive: one level might affect another and can also impact domains within the same level (Ferrans, 1990; Ferrans, Zerwic, Wilbur, & Larson, 2005; Spilker, 1996). Sirgy has suggested that the different domains both within and between the three levels of QOL often affect each other in a positive way (Sirgy, 2012). QOL and HRQOL are recognized and well-accepted among researchers. These concepts have also been used for many years to estimate both positive and negative aspects in terms of the impact of specific diseases. The two terms have also been used to measure the efficacy of interventions in clinical trials and have become valid indicators in assessing whether a particular treatment benefits patients (Spilker, 1996). Furthermore, QOL and HRQOL have been incorporated into strategic documents nationally and internationally. Nationally, the Norwegian Ministry of Health has used the terms to make national plans and uses QOL as an important goal (Ministry of Health and Care Services, 2016).

1.3.6. Health-related quality of life (HRQOL)

Both Ferrans (1990) and Spilker (1996) note that the terms QOL and HRQOL have been used interchangeably. In addition, for HRQOL there is no consensus on the definition (Ferrans, 1990; Karimi & Brazier, 2016; Spilker, 1996). We use the definition of HRQOL proposed by Cappelleri et al., who define HRQOL as a concept with multiple domains representing a person's general perception of the effect of illness and treatment on the physical, psychological, and social aspects of life (Cappelleri et al., 2014). HRQOL is recognized as an important issue in understanding the impact of a disease on a person's life (Ferrans et al., 2005). Because QOL has been used to describe many different aspects over time such as physical functioning, health status, symptoms, psychosocial adjustment, well-being, happiness, and life satisfaction, HRQOL was introduced 'to narrow the focus on the effect of health, illness and treatment on QOL' (Ferrans et al., 2005). The theoretical framework of HRQOL is based on a multidimensional perspective of health, as it covers the patient's own experiences. HRQOL focuses on a person's level of ability, daily functioning, and ability to experience a fulfilling life (Spilker, 1996).

1.3.7. Linking objective variables with HRQOL

The model of linking objective variables with HRQOL by Wilson and Cleary (1995)—later revised by Ferrans et al. (2005)—includes a taxonomy of variables that has a connection with and influences HRQOL. The revised model will be used as a framework for this study (Ferrans et al., 2005; Wilson & Cleary, 1995). The model divides the health outcomes on a continuum with five types of measures, each measuring patient outcomes. The five boxes in the middle of the model, describe biological factors, symptoms, functional status, general health perceptions, and overall HRQOL (Figure 4).

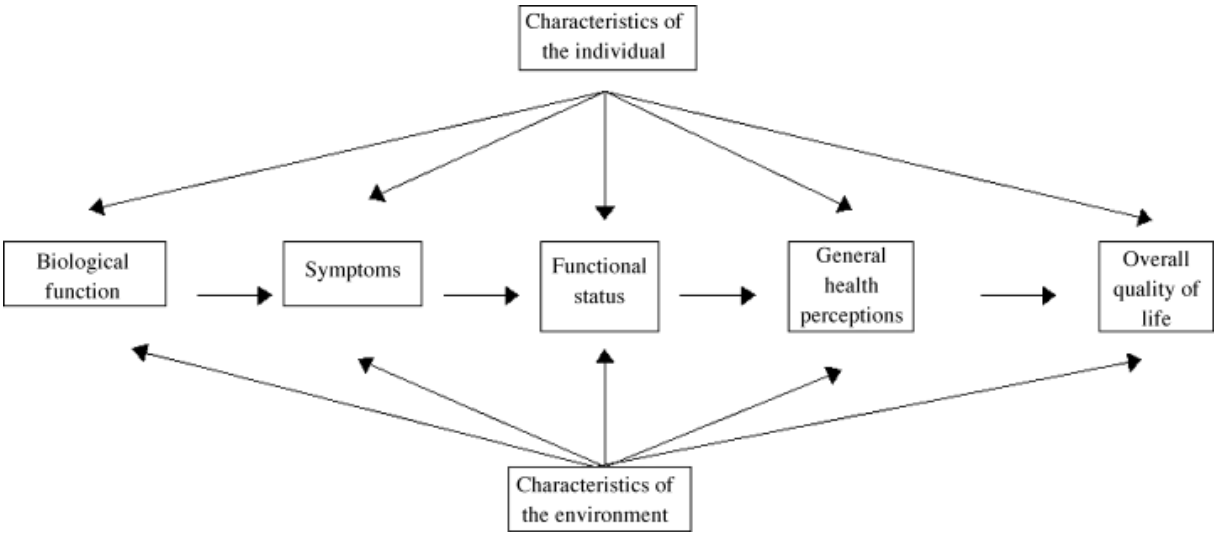

Figure 4. Conceptual framework of HRQOL (Ferrans et al., 2005)
(Used with permission from John Wiley & Sons, Inc.)

The first box in Wilson and Cleary's model is 'biological function'; originally called biological and physiological variables, with pathological function at one end and optimal function at the other. It includes the dynamic processes that support life and the whole organism, including molecular and cellular processes. In the revised model, both individual and environmental characteristics are considered to affect biological function (Ferrans et al., 2005). Individuals have genetic characteristics and compositions that predispose them to develop diseases such as axSpA. How people act, and their knowledge, lifestyle, and attitudes serve as psychological characteristics affecting biological functioning. In the model, 'symptoms' focus on the entire organism, related to the individual's physical, psychological, and psychophysical aspects rather than on the cellular and organism levels (Ferrans et al., 2005).

The functional status comprises four domains of functions: physical function, social function, role function, and psychological function. The fourth box, 'general health perception' integrates all the aspects of health described earlier in the model and at the same time evaluates all aspects of health. These causal pathways in this model are important for clinical practice and can be used in clinical treatment and care of patients with axSpA. Here, objective, and subjective health outcomes and factors were included to identify causal pathways in patients with axSpA, by collecting data on

demographic and clinical variables, functional status, damage, comorbidity, HRQOL, and the disease's impact on sexual activity and sexual QOL. The fifth box in the middle of the model, overall QOL, described as subjective well-being, is how happy and satisfied a person is with life overall. It is a synthesis of experiences and feelings that people have (Ferrans et al., 2005). Overall QOL was not measured in the present study. Often included in QOL studies are several characteristics identified as determinants or associates of QOL, such as educational level, personality, coping mechanisms, and marital status, which also are included in this study (Loge, Kaasa, Hjermstad, & Kvien, 1998).

1.3.8. Sexual quality of life

Sexual QOL is defined as the status that describes the individual's subjective evaluation of the positive and negative aspects of one's sexual relationship, and his/her subsequent affective response to this evaluation (Koh & Sewell, 2015). Sexual QOL includes both sexual health and sexuality involving communication, culture, ethical, and global areas (Graugaard et al., 2019; J. S. Greenberg et al., 2016). To have a fulfilling sex life is important for sexual QOL at all ages. Forbes et al. found that being older was a negative factor for sexual QOL, but learned strategies—also called sexual wisdom—together with a positive relationship with a partner was positive for sexual QOL (Forbes, Eaton, & Krueger, 2017). Therefore, measuring sexual QOL is an important issue for assessing short- and long-term outcomes of disease, especially when having a disease that can cause sexual problems (Hwang et al., 2021; Symonds, Boolell, & Quirk, 2005). To have good sexual QOL and satisfactory HRQOL, it is important to focus on both subjective and objective perspectives associated with axSpA, such as demographic and clinical variables, functional status, damage, comorbidity, the disease impact on sexual activity and sexual QOL. In this thesis, HRQOL and sexual QOL refer to Spilker's second level for patients with axSpA (Spilker, 1996).

1.3.9. Psychology of QOL and 'response shift'

The psychology of QOL includes mechanisms of how patients tend to adjust and manage their illness and how they use strategies to optimize all aspects of their

QOL (Sirgy, 2012). One of these strategies is ‘response shift’, defined as a change in internal standards and values and a redefinition of what is important in the patient’s life in relation to their QOL (Schwartz et al., 2006; Sirgy, 2012). The response shift has been described as recalibrating (by changes in internal standards of measurements), reprioritizing (by changes in the priority of components of the target construct), and reconceptualizing (by redefinition of the target construct) (Sprangers & Schwartz, 1999; Yang et al., 2016).

Developing a chronic disease such as axSpA requires recalibration of the perceived QOL. There can be differences in how a person can or cannot shift focus. Some patients are ‘decliners’ of the response shift, and some are ‘improvers’. A decliner does not adapt to the situation, whereas an improver achieves a response shift with or without help from others, and decliners might use a strategy of somatization or hypochondriasis, leading to a lack of response shift (Wilson, 1999; Yang et al., 2016). The process might be influenced by a person’s social and structural context, which can promote or inhibit changes (Yang et al., 2016). For example, affective understanding and practical support from family and friends can promote changes, which can help the person to achieve new goals and thereby improve QOL and sexual QOL (Sirgy, 2012).

2 Aims of the study

The overall aim of this thesis was to examine the impact of health status on sexual activity and sexual QOL in male and female patients with axSpA. The specific aims were:

In Paper I (a cross-sectional study) the aim was to explore the relationship between demographic and disease-related variables and the perceived effect of health status on sexual activity in patients with axSpA and answer the following specific research questions:

In Paper II (a cross-sectional study) the aim was to examine the relationship between demographics, disease-related variables, treatment, and sexual QOL in men and women with axSpA and to answer the following specific research questions:

In Paper III (a prospective cohort study with a 5-year follow-up) the aim was to explore whether a follow-up would reveal long-term changes in perception of sexual QOL in male and female patients with axSpA and to answer the following specific research questions:

3 Materials and methods

In this chapter, ethical considerations will be elaborated, followed by study description, study design, patient recruitment, data collection, PROMs, and finally a presentation of the statistical analyses used in the three sub-studies.

3.1 Ethics

The aim of the Norwegian Health Research Act is to 'promote good and ethically sound medical and health research' (The Health Research Act, 2008). To achieve this, people who are willing to participate in research are needed. The research should be of some benefit for the participants and possible factors of risk and harm should be calculated. Further, respect for human dignity as self-determination and justice includes fair treatment and the right to anonymity (Polit & Beck, 2008). To be able to fulfil these all patients received written information about the study (Appendix 7) together with a letter with the time for the consultation appointment. When the patients were coming to the consultation, the were given oral information and informed consent was obtained from all patients. When given their consent to participating, all data set was given a number with connection to a master list. All procedures performed were done in accordance with the ethical standards set by the Declaration of Helsinki (World Medical Association, 2013).

A research protocol was sent to the Regional Committee for Medical Research Ethics of South-East Norway and approved under the number IRB 4.2007.2152).

3.1.1. Collecting sensitive data

Collecting data on sexual activity and sexual QOL in patients with axSpA is sensitive and closely related to 'vulnerable groups'. Furthermore, Liamputtong (2007) defines several groups as being vulnerable, including chronically ill people, who were the target of our research (Liamputtong, 2007). On the other hand, patients with axSpA might be considered not to be especially vulnerable, but the issue of sexual activity and sexual QOL can be sensitive for patients and has to be taken into onsideration (Liamputtong, 2007).

To be both clinician and researcher at the same time, like me in the current study, can present some challenges and causes ethical considerations, and involves all three principles in the Belmont Report 1979: first, respect for the person's autonomy; second, beneficence (protecting the patients from harm); third, justice providing the same fairness for all participants (HHS, 1979). Loyalty to and trust in the researcher can lead to the patient agreeing to participate in research without being fully aware of all the implications of the project. In the present study, the nurses were both clinicians and researchers, which could put the patients in a conflict between loyalty to the health-care providers and their own wishes. Patients should be aware of the type of data they are agreeing to provide, especially concerning sensitive data such as data on sexual health. To accommodate the three principles in the Belmont Report, the patients were given written and oral information about the study, the type of data collected, how the data were stored and made anonymous as soon as they were collected (HHS, 1979; Lovdata, 2017). They were also informed about how the data would be used for research and publications and their right to withdraw from the study at any time (World Medical Association, 2013).

3.2 Study description and study design

The present study was a prospective cohort study that comprised three sub-studies presenting objective and self-reported data of patients with axSpA (Table 1). In Papers I and II, a cross-sectional study design was used (Polit & Beck, 2008). In Paper III, a prospective cohort study with a 5-year follow-up design was used, where data were collected at two time points, which allowed us to make comparisons over time and to determine whether changes had occurred (Polit & Beck, 2008). In the last paper, the patients were followed over a period of 5-years. Papers I and II include baseline data on the same sample of patients with axSpA, whereas Paper III includes patients with data available at both the baseline and at the 5-year follow-up. Across the different sub-studies in Papers I–III, sample size, study design, dependent and independent variables, and analyses varied. Table 1 gives an overview.

Table 1. Study design, dependent and independent variables, and analyses used in Papers I–III

	Paper I	**Paper II**	**Paper III**
Sample (n)	n = 379	n = 360	n = 245*
Study	Cross-sectional	Cross-sectional	Prospective cohort with 5-year follow-up
Dependent variable	15D (question 15)	SQOL-F	SQOL-F
Independent variables: **Demographics** **Health status** Clinical measures Damage Self-reported HRQOL Treatment	Age, gender BMI (kg/m^2), Smoker, employment Exercise CRP, 68 tender joints, 66 swollen joints, BASDAI, MASES BASMI BASFI, HAQ, BAS-G SF-36 NSAID, csDMARD, bDMARD	Age, gender BMI (kg/m^2), Smoker, employment Exercise CRP, 68 tender joints, 66 swollen joints, BASDAI, MASES BASMI BASFI, HAQ, BAS-G SF-36 NSAID, csDMARD, bDMARD	Age, gender BMI (kg/m^2), Smoker, employment Exercise CRP, 68 tender joints, 66 swollen joints, BASDAI, MASES BASMI BASFI, HAQ, BAS-G SF-36 NSAID, csDMARD, bDMARD
Analyses	Chi-squared Independent *t* tests Univariate and multivariate logistic regression Nagelkerke R^2	Chi-squared Independent *t* tests Linear regression (GLM) Cronbach's α Pearson correlation Nagelkerke R^2	McNemar's tests Paired-samples *t* tests Univariable and multivariable regression (GLM) Cohen's effect size Nagelkerke R^2

* Not all patients from MHH were invited for the 5-year follow-up because of a lack of financial resources. 15D, a generic, comprehensive, 15-dimensional, standardized, self-administered measure of HRQOL; SF-36, Health Survey Short-Form-36 items; GLM, General Linear Model; SQOL-F, Sexual Quality of Life – Female; BASFI, Bath Ankylosing Spondylitis Functional Index; HAQ, Health Assessment Questionnaire; BAS-G, Bath Ankylosing Spondylitis Patients Global Score; BASDAI, Bath Ankylosing Spondylitis Activity Index; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; BMI, body mass index; BASMI, Bath Ankylosing Spondylitis Metrology Index; csDMARD, synthetic disease-modifying antirheumatic drug; bDMARD; biological disease-modifying antirheumatic drug.

3.3 Patient recruitment and data collecting

Patients with axSpA were recruited from the outpatient clinics at two hospitals in Norway: SSHF and MHH. Patients had to be aged ≥18 years with no upper limit. In addition, they had to speak and understand Norwegian and be in a physical and mental condition suitable to give informed consent. When the study was designed, the modified New York criteria were applied (van der Linden et al., 1984). The ASAS classification criteria for axSpA published in 2009 (Rudwaleit et al., 2009a; Rudwaleit et al., 2009b) including both patients with radiographic axSpA (AS) and non-radiographic axSpA was not available. After inclusion of patients in the present study, all patients were checked that they fulfilled these criteria (Rudwaleit et al., 2009a; Rudwaleit et al., 2009b).

The patients were identified by the study nurses, who used the list for planned patient interviews at the outpatient rheumatology clinics. The patients were contacted by telephone before the appointment and informed about the study, invited to participate, and were then included consecutively. During the baseline consultation, the patients were informed that they would get an invitation to a 5-year follow-up. Baseline data collection was performed from 2008 to 2011 and after five years from 2013 to 2016, which enabled the exploration of data related to health and disease-related issues over time. At the beginning of the data collection, no power calculation of size was done. The aim was to recruit all patients with axSpA visiting the outpatient clinics, fulfilling the inclusion criteria, who were scheduled for control appointments in a timeframe from 2008 to 2011. In total, 397 patients with axSpA were invited to participate. Eight patients declined the invitation without giving any reason, which led to data collection from 389 patients (Figure 5). In the middle of the process of inviting patients for the 5-year follow-up, the inclusion of patients at MHH was stopped because of a lack of financial resources. This meant that 109 patients were not invited to participate in the follow-up. In total, 280 patients at the two hospitals were invited to the follow-up, 35 did not accept the invitation, 31 had moved and four had died.

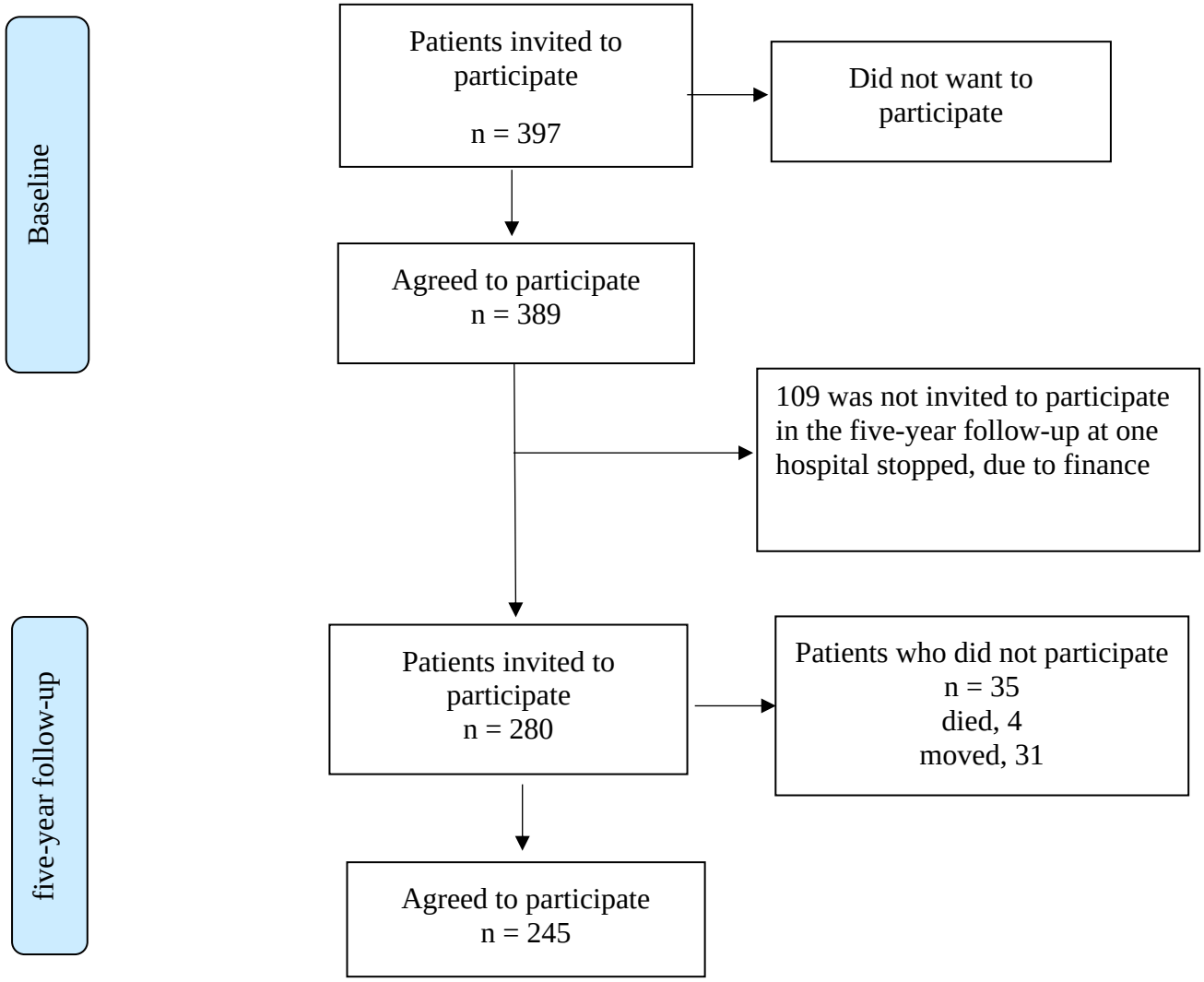

Figure 5: Flow chart describing the sample of patients with axSpA included at baseline and five-year follow-up.

3.4 Demographic variables, medication, and physical examinations

Doctors and nurses assigned to the project obtained demographic data from patients such as age, weight, employment, education, married or cohabiting, and if they had a partner with whom to have sex. We also collected data on exercise, alcohol use, smoking, sex (categorized as man or woman), weight in kg and height in centimetres to calculate the body mass index (BMI kg/m^2). Data on educational level

were organized into three groups: <10, 11–13, and >13 years. Employment was categorized as working, on sick leave, on disability benefits, or as retired. This was recoded into working or unemployed (on sick leave, disability benefits, and retired) in the analyses. Exercise was organized into >3 h/week, 1–3 h/week, <1 h/week, seldom or never, these were further recoded to >1 h/week and <1 h/week in the analyses.

Data on alcohol use were collected by asking how often the patient had drunk alcohol during the last 30 days, organized into five groups: never, 2–6 glasses/week, 7–14 glasses/week, 14–21 glasses/week, and more than 21 glasses/week. For statistical purposes, these groups were recoded to never, 1–6 glasses/week and ≥7 glasses/week. Smoking status was organized as non-smoker, previous smoker, and current smoker, and for statistical purposes recoded to smoker and non-smoker (non-smoker and previous smoker). In addition, disease duration was calculated as the time from when the ASAS criteria were fulfilled until the date of inclusion. Information regarding current medication was collected by asking the patients and checking patients' hospital files. The doctors and nurses assigned to the project obtaining data also performed physical examinations such as the MASES Score, which is an examination of tender points, showing inflammation in the tendons (Heuft-Dorenbosch et al., 2003). Further, the BASMI, which is a test of function and an expression for disease damage (Jenkinson et al., 1994), and examination of tenderness and swelling in 68/66 joints were performed (Duarte-García et al., 2019). Objective measures such as the CRP level was obtained from laboratory tests (Table 2).

Table 2. An overview of the measures of disease activity and damage

Measures	Reported by	Description	Papers
MASES	Physician/nurse	Disease activity	I, II, and III
CRP	Laboratory	Disease activity	I, II, and III
68 tender and 66 swollen joints counts	Physician/nurse	Disease activity	I, II, and III
BASMI	Physician/nurse	Damage	I, II, and III

MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; CRP, C-reactive protein level; BASMI, Bath Ankylosing Spondylitis Metrology Index.

3.5 Patient-reported outcome measures (PROMs) used in the study

PROMs measure a patient's perceptions of health, sickness, and effect of treatment, and encompass measures of symptoms, functions, health, and QOL (Fayers & Machin, 2016). The PROMS used in this thesis were HAQ, BAS-G, BASFI, BASDAI, 15D, SF-36, and SQOL-F (Table 3).

Table 3. Patient-reported outcome measures used in this study

Measures	Reported by:	Description	Paper
HAQ	Patients ≥18 years	Physical ability	I, II, and III
BAS-G	Patients ≥18 years	Effect of AS on patients' well-being	I, II, and III
BASFI	Patients ≥18 years	Daily activity	I, II, and III
BASDAI	Patients ≥18 years	Disease activity	I, II, and III
15D	Patients ≥18 years	QOL	I
SF-36	Patients ≥18 years	HRQOL	I and II
SQOL-F	Patients ≥18 years	Sexual QOL	II and III

HAQ, Health Assessment Questionnaire; BAS-G, Bath Ankylosing Spondylitis Patients Global Score; BASFI, Bath Ankylosing Spondylitis Functional Index; BASDAI, Bath Ankylosing Spondylitis Activity Index; 15D, A generic, comprehensive, 15-dimensional, standardized, self-administered measure of HRQOL; SF-36, Health Survey Short-Form-36 items; SQOL-F, Sexual Quality of Life – Female.

3.5.1. The Health Assessment Questionnaire (HAQ)

This tool was used to measure physical disability. The questionnaire comprises 20 questions about the performance of physical activity over the last week and covers eight areas: dressing and getting ready, arising, eating, walking, personal hygiene, reach, grip, and common daily activity. Each item has a four-level response scale from 0 to 3, where 0 is no difficulty, 1 is some difficulty, 2 is much difficulty, and 3 indicates inability to do the activity (Fries, Spitz, Kraines, & Holman, 1980). HAQs

are used frequently to measure physical disability in patient groups. The questionnaire has established validity and reliability, internationally and in Norway (Bruce & Fries, 2003; Uhlig, Haavardsholm, & Kvien, 2005).

3.5.2. The Bath Ankylosing Spondylitis Patients Global Score (BAS-G)

This tool was used to measure the effect of axSpA on a patient's well-being during the last week and in the last 6 months (Jones, Steiner, Garrett, & Calin, 1996). Each question has a numerical rating scale range of 0–10, where 0 is the most positive and 10 the most negative. It was tested for reliability, validity, and sensibility in the original and Swedish versions (Jones et al., 1996; Waldner, H., & C.H., 1999). It was translated and validated into Norwegian by the medical company MSD-Norway, using standardized translation procedures according to an international cross-cultural translation manual (Fayers & Machin, 2016). However, the translation procedure has not been published.

3.5.3. Bath Ankylosing Spondylitis Functional Index (BASFI)

This questionnaire comprises 10 questions about how the patient has managed daily activity over the last week and focuses on axial pain, peripheral joint pain, fatigue/tiredness, enthesitis, and morning stiffness. Each question has a visual analogue scale of 0 to 10, with 0 being the most positive and 10 the most negative score. It has been found to be a valid and appropriate composite to define disease activity in patients with AS (Calin et al., 1994). The questionnaire was translated into Norwegian by the medical company MSD-Norway (see above), using standardized translation procedures according to an international cross-cultural translation manual (Fayers & Machin, 2016). However, the translation procedure has not been published.

3.5.4. Bath Ankylosing Spondylitis Activity Index (BASDAI)

This was used to measure disease activity. It is a self-reported questionnaire measuring disease activity with six questions about how the patient has felt over the last week concerning tiredness, pain, and morning stiffness. Each question has a score from 0 (nothing to report) to 10 (the most negative answer) in the other end, this is a numerical ranking scale. The patient chooses the number suitable for their situation: a

lower number shows lower disease activity. The BASDAI was developed and validated by Garrett et al., with established validity and reliability (Garrett et al., 1994). It has been translated into Norwegian and validated by MSD-Norway (see above), using standardized translation procedures according to an international cross-cultural translation manual (Fayers & Machin, 2016). However, the translation procedure has not been published.

3.5.5. Measure of Health-Related Quality of Life (15D)

This was used to measure the impact of health status on sexual activity. It is a generic, multidimensional, standardized tool for evaluating HRQOL and is primarily used as a single-index measure but can be used as a profile utility measure. The questionnaire captures the health status by assessing 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. Each dimension is assessed by one question using five response categories with the following response options for sexual activity: no adverse effect, has a slight effect, has a considerable effect, makes it almost impossible, and makes it impossible.

In the current study, we used only question 15 in the 15D questionnaire and for analysis, the five response options were dichotomized as follows: no adverse effect/slight effect to ‘no/little effect’, and considerable effect/almost impossible/sexual activity impossible to ‘large effect’.

The self-administered questionnaire was independently translated into Norwegian from an English version by the physicians, who discussed the translations and agreed on a consensus version. The Norwegian version had also been compared with the original Finnish version (Stavem, 1999). The 15D instrument has been used in different patient groups when the focus is on HRQOL (Helland, Dagfinrud, & Kvien, 2008; Rohde, Berg, Pripp, Prøven, & Haugeberg, 2019; Rohde et al., 2017) and has favourable validity and reliability (Sintonen, 2001; Saarni et al., 2006).

3.5.6. Health Survey Short-Form-36 items (SF-36)

This was used to measure HRQOL. The SF-36 is a self-reported generic health status questionnaire (Ware & Kosinski, 2005). It is widely used internationally and is not specific to age, treatment, or disease group. It comprises 36 questions and eight

domains: general health, bodily pain, physical function, role limitations (physical), mental health, vitality, social function, and role limitations (emotional). The eight domains can be combined into a Physical Component Summary score (PCS) and a Mental Component Summary score (MCS) measuring distinct components of health, physical, and mental health. The PCS and MCS scales were used in this study (Ware & Kosinski, 2005). The SF-36 was scored according to published procedures. Each question has a response range of 0–100 with 100 representing excellent health. Imputation for missing data was included in scoring, in accordance with the original guidelines (Ware & Kosinski, 2005). Reliability and validity in the SF-36 are satisfactory, as indicated in earlier Norwegian studies (Loge et al., 1998).

3.5.7. Sexual quality of life-Female questionnaire

The Sexual quality of life-Female questionnaire (SQOL-F) was chosen to measure sexual QOL. In 2005, Symonds, Boolell, and Quirk developed the SQOL-F, based on the work of Abraham and co-workers, which again was based on Spitzer's QOL measure. The SQOL-F is a generic self-reporting questionnaire for assessing the relationship between female sexual dysfunction and QOL (Symonds et al., 2005). It comprises 18 positive and negative items, rated on a 6-point response: completely agree, moderately agree, slightly agree, slightly disagree, moderately disagree, and completely disagree. The response categories are scored 1–6, giving a total score range of 18–108. A higher score indicates better sexual QOL (Symonds et al., 2005). The questionnaire has shown good psychometric properties according to convergent validity, discriminant validity, and test–retest validity (Symonds et al., 2012; Symonds et al., 2005). SQOl-F has not been validated in a Norwegian population. The questionnaire was translated into Norwegian by the MAPI Research Institute in 2006 for use in clinical trials (Downey, CA, USA; not published). To our knowledge, no other studies has used SQOL-F in patients with axSpA but used other questionnaire on SQOL (Dong et al., 2015).

Maasoumi et al. (2013) translated SQOL-F into Persian and identified four categories: psychosexual feelings (range 7–42), sexual and relationship satisfaction (range 5–30), self-worthlessness (range 3–18), and sexual repression (range 3–18). These reflect various aspects or dimensions of sexual QOL and showed good

psychometric properties in the Iranian population. These categories were also used in this study. We applied Cronbach's α test for evaluating the reliability of the questionnaire and its subcategories. The results were 0.77 for total sexual QOL, 0.91 for psychosexual feelings, 0.81 for sexual and relationship satisfaction, 0.84 for self-worthlessness, and 0.87 for sexual repression, which were considered as acceptable reliability for the patients in the current study (Fayers & Machin, 2007).

3.6 Analyses

For statistical analysis, IBM SPSS Statistics v. 22.0 was used in Paper I; v. 24.0 in Paper II, and v. 25.0 in Paper III (IBM Corp., Armonk, NY, USA). In all three papers, descriptive statistics were used to describe the samples, which are presented as the mean and standard deviation (±SD) for continuous variables and as number and percentage (%) for categorical variables. In Papers I and II, comparisons between groups were applied using chi-squared tests for categorical variables and independent-sample Student's *t* tests for continuous variables. In Paper III, the comparison between baseline and 5-year follow-up, McNemar's test was used for categorical variables and paired-samples Student's *t* tests for continuous variables (Table 1) (Altman, 2006).

To explore the relationship between demographic and disease-related variables and the perceived effect of health status on sexual activity in patients with axSpA (question 15 in Paper I) the 15D questionnaire was dichotomized into no/little or a large effect of health status on sexual activity in patients with axSpA. To identify associations with the dependent variable (question 15 in the 15D questionnaire), we included demographic variables and variables on disease activity, health status, damage, comorbidity, and treatment centre, in univariate and multivariate logistic regression analyses (enter procedure). Variables with $p < 0.20$ tested in the univariate analysis were included in the multivariate model, and a backward procedure was used to test for robustness (Table 1).

In Paper II, to examine the adjusted association between demographic, disease-related variables and sexual QOL, for both the total score and for the four categories, a

general linear model (GLM) was used in SPSS. The independent variables in the multiple analyses were chosen based on $p < 0.1$ in the univariate analyses and adjusted for age and gender. In the final multivariate model, we included the impact of demographic variables and variables on disease activity, health status, damage, comorbidity, and treatment centre. To explore the reliability of the SQOL-F questionnaire with its total score and sub-scores, we used Cronbach's α test (Table 1).

In Paper III, changes in the sexual QOL score were calculated by subtracting the baseline score from the score at the 5-year follow-up. The effect size was calculated by subtracting the mean sexual QOL score (and its categories) at baseline from the mean score at the 5-year follow-up and divided by the SD at baseline within the groups. Cohen's effect size index was used to interpret and estimate the proportion of patients with clinically significant changes in sexual QOL over the studied period (Fayers & Machin, 2007; Polit & Beck, 2008, 2018). Multivariable regression (GLM) analyses were used to identify associations between demographic variables and variables on disease activity, health status, damage, comorbidity, and treatment centre at baseline and at the 5-year changes in sexual QOL sum score and its sub-scores (Fayers & Machin, 2007). The level of significance was set to $p < 0.05$.

4 Main findings

This section gives a summary of the findings in papers I–III. More detailed information can be found in the original paper attached at the end of this thesis.

4.1 Papers I and II

4.1.1 Demographic data at baseline

In all, 397 patients with axSpA were invited to participate in the study, of whom 389 completed the questionnaires (Figure 5). The participants had a mean age of 45.6 years, SD ±11.9), 66.5% were men, and 55.7% reported having more than 13 years of education. Their mean disease duration was 13.9 years, SD (±11.4) and the patients reported to have few other co-morbidities (mean = 0.7; SD ±0.9). A high proportion of the patients were married, or cohabiting (76.3%) and the majority (81.1%) said that they had a partner with whom to have sex. Most of the patients (84.8%) exercised for >1 h/week.

4.1.2. Paper I

Most of the 379 patients with axSpA answered the question of how their state of health had an impact on their sexual activity (15D). The 10 patients who did not answer the question had a mean age of 52.2 years, vs. 46.6 years in the group who answered the question ($p = 0.09$). In addition, those who did not answer the question had a longer disease duration: 28.8 years vs. 13.9 years ($p = 0.016$). Most (82.3%) of the patients who answered the question, reported that their health status had little or no impact on their sexual activity. There were some differences between genders, where more women than men reported their health status to have had a large impact on sexual activity (23.6% vs. 14.7% ($p = 0.031$)). Furthermore, there were some additional differences between men and women: men had higher BMI (27.6 kg/m^2 vs. 25.6 kg/m^2; $p = 0.001$), higher alcohol consumption (1–6 glasses per week 73.5% vs. 65.9%, more than 7 glasses per week 11.6% vs. 7.1%; $p = 0.012$), higher employment rate (76.6% vs. 66.9%, $p = 0.048$), reported lower disease activity (BASDAI score 3.03 SD ±2.10 vs. 3.5 SD ±2.1; $p = 0.037$) and lower health status (HAQ 0.52 SD ±0.47 vs. 0.65 SD ±0.54; $p = 0.012$) than women. Physical examinations revealed that

men had lower inflammation in the tendons (by MASES), but more damage on the skeleton (by BASMI), than women.

In the adjusted analyses, the characteristics that were significantly associated with a large negative effect on health status on sexual activity were being a woman, having a high BMI, being a current smoker, and reduced HRQOL (measured by SF-36, PCS, and MCS).

4.1.3. Paper II

Here, 360 out of the 389 patients responded to questions on sexual QOL. The responders reported to have a higher consumption of alcohol (82.0% vs. 62.1%; p = 0.033), higher employment rate (72.2% vs. 48.3%; p = 0.003), exercised more (86.6% vs. 72.4%; p = 0.038), and more were cohabitant (78.6% vs. 37.9%; $p < 0.001$) than non-responders to the questionnaire. Some differences between gender were identified for sexual QOL; men reported better on total sexual QOL (78, SD ±10.9 vs. 75, SD ±11.9; p = 0.026), and on the subgroup, sexual repression (16, SD ±3.4 vs. 14, SD ±4.1; p = 0.005). Furthermore, women had lower BMI, more inflammation in the tendons, and lower physical function than men. In the adjusted analyses, low BAS-G and CRP scores and use of bDMARDs were associated with higher sexual QOL, whereas female gender and increased BMI were independently associated with lower sexual QOL.

4.1.4 Paper III

In all, 280 patients with axSpA were invited to participate at 5-year follow-up; 245 agreed to take part, and 221 completed the questionnaires on sexual QOL both at baseline and at the 5-year follow-up (Figure 5).

The 221 patients with axSpA who answered the question on sexual QOL were significantly younger (mean 45.4 years, SD ±10.8) vs. 50.9, SD ±10.8; p = 0.025) and more were married or cohabiting (81% vs. 42%; $p < 0.001$) than the non-responders. Among the responders fewer reported smoking (26% vs. 46%; p = 0.046), and they exercised more (89% vs. 75%; p = 0.046) than those who did not answer the questionnaire. Over the 5-year period, no significant changes in sexual QOL were revealed. However, the patients used more bDMARDs and there was a significant

increase in the incidence of comorbidities from 0.58 to 0.95. In the multivariate analysis, a decrease in sexual QOL after 5 years was observed in patients exercising <1 h/week at baseline (p = 0.048) and in patients aged >65 years.

5 Discussion

In this section, the main findings will be discussed across the three papers according to the following topics: significance of the state of health for sexual activity, sexual quality in life in patients with axSpA, differences between men and women related to sexual activity and sexual quality of life and sexual quality of life in a social context, followed by methodological considerations.

5.1 Significance of the state of health for sexual activity

Sexual activity is an important part of being a person and has multiple purposes, such as pleasure, bonding to a partner, showing love and affection, and reproduction (Graugaard et al., 2019). Health status has been reported to have a negative impact on sexual activity in patients with axSpA (Helland et al., 2008). Although few studies have examined the impact of health status on sexual activity in men and women with axSpA, health status has been reported to have a negative impact on sexual activity in patients with AS (Fu et al., 2018; Gallinaro et al., 2012; Rostom et al., 2013; Yao et al., 2016). However, it is difficult to compare our studies with these earlier studies because of differences in the settings, measurements, and timing: for example, for data collected before and after surgery (Fu et al., 2018; Gallinaro et al., 2012; Rostom et al., 2013; Yao et al., 2016).

In the thesis study population of patients with axSpA, with a mean age of 46 years and 33% as women, about 18% reported their health status to have a large impact on sexual activity. A Norwegian study of outpatients with PsA, a prototype of peripheral SpA, with a mean age of 52 years and 49% as women that used the 15D questionnaire, a similar percentage (18%) reported that their health status had a large impact on sexual activity (Haugeberg, Michelsen, Østensen, & Kavanaugh, 2020). In another Norwegian study that used the same questionnaire in patients with RA, 31% reported that their health status had a considerable influence on their sexual activity (Helland et al., 2008). The study by Helland et al. (2008) included a higher percentage of women (74%) with a mean age of 58 years (Helland et al., 2008). By contrast, slightly different results were reported in a Norwegian study of 181 patients with wrist fracture, aged 50 years and

older (mean age 65 years, 84% women), in which only 13% reported that their health status had a large negative impact on sexual activity (Rohde, Berg, & Haugeberg, 2014).

From the studies mentioned above, it seems that a lower percentage of patients with inflammatory joint disorders, including axSpA, perceive that their health status has a more negative impact on sexual activity than that seen in the Norwegian background population (Haugeberg, Michelsen, & Kavanaugh, 2020; Helland et al., 2008; Rohde et al., 2014). The reason why fewer patients with axSpA report that their disease has a large impact on sexual activity may reflect the influence of various factors. Patients reporting little or no impact in the studies presented here may differ on lifestyle factors. For example, fewer patients in this cohort smoked, more exercised regularly, 78% were married or cohabiting, and their disease activity was low, as indicated by less inflammation in the tendons and better self-reported health status.

5.1.1. Lifestyle factors important for health status

Both smoking and obesity are important lifestyle factors related to health status (Bindesbøll, Garrido-Cumbrera, Bakland, & Dagfinrud, 2020; Zhao et al., 2019). These factors as well as physical activity are important for patients with axSpA because they have a strong impact on health status, which may be even stronger than that of the disease itself (Chimenti et al., 2021). Obesity in patients with axSpA can increase the disease activity (Bindesbøll et al., 2020), and obesity (BMI >30 kg/m^2) is more common in patients with axSpA than in the general population (Maas et al., 2016). The findings of the present studies are to some degree consistent with those described above. For example, in Paper I, overweight patients (BMI 28.5 kg/m^2) reported that their health status negatively impacted their sexual activity; these patients also had lower scores for well-being (BAS-G), physical disability (HAQ), and HRQOL (measured by the SF-36; PCS, and MCS), and more problems managing daily activities (BASFI).

Smoking and obesity can interfere with and lead to poorer responses to treatment. In a large study from England of 758 participants (66% men, mean age 45 years), smoking was associated with worse disease severity but had no impact on discontinuation of anti-TNF therapy (Zhao et al., 2019). In the current cohort, smoking

and obesity has been reported to reduce patients' HRQOL and impact their sexual activity (Berg et al., 2017). A review article from Spain found that, in two studies, smokers had a negative response to anti-TNF therapy but that four other studies identified no differences in the clinical response to such treatment (Zurita Prada, Urrego Laurín, Guillén Astete, Kanaffo Caltelblanco, & Navarro-Compán, 2021). In the same review, five of six studies found that obesity had a negative impact on the response to anti-TNF therapy (Zurita Prada et al., 2021). In the present studies, no disease- or treatment-related variables were independently associated with a negative impact of health status on sexual activity.

5.1.2 Disease activity in patients with axSpA

Patients who reported that health status had a large impact on sexual activity reported higher disease activity, lower physical HRQOL and less exercise, were more likely to be unemployed, used more alcohol, smoked more, had a higher BMI, and had more comorbidities (Berg et al., 2017). High disease activity along with inflammation in the axial skeleton leads to pain and restrictions in mobility, which can impair sexual activity, limit physical activity, and impair physical HRQOL (Agrawal & Machado, 2020; Rausch Osthoff, Niedermann, et al., 2018; Regel et al., 2017).

Health status is also influenced by physical activity and lifestyle (Regel et al., 2017). Exercise is important for managing daily activities and for disease control, general well-being, and preventing other diseases, and is an essential part of the non-pharmacological treatment in patients with axSpA. (Agrawal & Machado, 2020; Regel et al., 2017). The National Norwegian (2014) recommendation for daily physical activity is 150 min/week for adults. In the studies presented here, 84.8% of patients exercised more than 1 hour/week. In previous studies, smoking was negatively associated with disease activity, functional status, and HRQOL (Chung et al., 2012; Mattey, Dawson, Healey, & Packham, 2011). In our studies, current smoking also had a negative impact on sexual activity (Paper I).

In general, the disease activity in the current study cohort was low, and the long disease duration (mean disease duration 13.9 years) probably reflects that most of the patients were middle-aged (mean age 46.6 years). Different results may have been

obtained from a cohort with a younger mean age and shorter disease duration. Young patients tend to report more pain and have had less time to adjust to the disease because axSpA often occurs in early adulthood (Sieper et al., 2009). For example, in a study of a large group of patients with early axSpA, those with high disease activity had worse physical HRQOL but not mental HRQOL (van Lunteren et al., 2018). Low disease activity in the current cohort most likely reflects good disease control because a higher percentage (23%) of patients used bDMARDs at the baseline and 40% used these drugs at the 5-year follow-up. High disease activity and damage, as assessed by the BASMI, are associated with worse physical and mental HRQOL (Rohde et al., 2017). Studies of men with axSpA have found that high disease activity and disease manifestations, such as damage to the hip joints and spine, can negatively interfere with sexual activity (Fu et al., 2018; Gallinaro et al., 2012; Yao et al., 2016).

In addition to lifestyle factors and pathophysiological processes, health status is also influenced by psychosocial factors, as discussed below. Some patients manage to live well with the disease, even when it is active, because they adapt positively and adjust their strategies to optimize their HRQOL as a way to manage their illness (Sirgy, 2012).

5.1.3 Psychosocial and environmental factors

Social influences of a partner, family, friends, and HPs are important environmental factors to HRQOL and sexual QOL (Ferrans et al., 2005; Graugaard et al., 2019). Living with a partner can provide social and psychological support, although feedback from a partner can increase awareness of the influences of axSpA on sexual activity (Starrs et al., 2018). In our studies, high percentages of patients reported having a partner to have sex with (81.1%) and being married or cohabiting (76.3%). Living in a social context with a close partner may be important for managing living with axSpA as a lifelong condition (Raybone, Family, Sengupta, & Jordan, 2019). This may partly explain why as high as 80% of the patients in our studies reported that their health status had little or no impact on their sexual activity. After living with the disease for many years, the patients had probably adapted and developed strategies to make sexual activity satisfactory, possibly through

recalibration of their mindset to optimize their sex life (Sprangers & Schwartz, 1999; Yang et al., 2016).

5.2 Sexual quality of life in patients with axSpA

At the baseline in these studies, impaired sexual QOL was independently associated with being a woman, high BMI, high disease activity, and use of bDMARDs (Paper II). The same associations with being a woman and BMI were observed in the study of the impact of health status on sexual activity, as discussed above (Paper I). By contrast, markers of inflammation were associated with impaired sexual QOL but not with health status and had no impact on sexual activity (Berg et al., 2017). Interestingly, the current use of bDMARDs was associated with impaired sexual QOL. Use of bDMARDs may be considered to be a surrogate marker for disease activity, and these drugs are prescribed for patients with more severe disease, high disease activity, insufficient exercise, and poor response to NSAIDs (van der Heijde et al., 2017).

The treatment of patients with axSpA has changed during the last 20 years. The main change in treatment appeared around 2000 with the introduction of TNF inhibitors (i.e., bDMARDs) (Agrawal & Machado, 2020). Previously, patients with axSpA experienced greater impairment, especially functionally, because the treatments were less effective in controlling the disease. Medications such as bDMARDs improve disease outcomes significantly and bring more patients with axSpA into remission (Agrawal & Machado, 2020). A study from China of 42 male patients with AS found that sexual QOL and sexual activity improved when patients used a TNF-α inhibitor (Dong et al., 2015). This is consistent with the 5-year data in our studies, in which the disease activity was lower and bDMARDs were used more frequently than at the baseline, which may indicate better disease control. Good disease control improves disease activity and, by reducing pain and inflammation, has a positive effect on sexual QOL (Dong et al., 2015). However, our studies are the only ones to use the SQOL-F in patients with axSpA. The only previous study of sexual QOL from China, found that sexual QOL improved in men when using bDMARDs (Dong et al., 2015).

Comorbidities can be experienced as an additional burden for patients with axSpA. In general, our patients reported few comorbidities, but the number of comorbidities increased from the baseline to the 5-year follow-up, although there was no significant change in sexual QOL. Good disease control, low disease activity, and better physical functioning may explain the lack of changes in these other variables. Our findings contrast with recent studies in which overall comorbidity was associated with worse outcomes of disease severity, work production, mortality, and QOL (Nikiphorou et al., 2018; Zhao et al., 2020).

The current cohort of patients with axSpA had a large age range (18–81 years). Most of the patients were aged between 31 and 65 years, and few of the patients were younger than 30 years. The mean disease duration of the cohort was about 14 years. Younger patients with early and active disease can experience greater impairment of sexual function, which leads to lower sexual QOL (van Lunteren et al., 2018). We compared sexual QOL in those over and under 30 years of age in this cohort. The 23 patients aged <30 years showed few differences, and had lower scores on the BASMI scale (damage), shorter disease duration, higher scores for sexual repression (loss of joy with sexual activity, being embarrassed, and avoiding sexual activity), and lower scores on comorbidity than the patients >30 years.

The research on axSpA and sexual QOL is scarce, and minimal data are available for comparison with studies from other countries. The only other study is from China and involved 42 AS patients with mean age of 32 ± 7 years and shorter disease duration (7.8 ± 8.0 years)(Dong et al., 2015). In that study, sexual QOL improved while the men used bDMARDs. The Chinese health-care system, social and economic systems are different from those in Norway. No longitudinal data on healthy controls are available for comparison with our findings. In another study of the present cohort, comparison of HRQOL between patients and the normal population showed lower HRQOL among patients with axSpA (Rohde et al., 2017). However, during the 5-year follow-up of the present cohort, improvements in the physical dimension of HRQOL were observed, and these changes indicated better physical function (Rohde et al., 2019).

Sexual QOL is not routinely discussed with patients in rheumatology outpatient clinics in Norway (Helland et al., 2013) or in Sweden (Areskoug-Josefsson et al., 2019). Addressing sexual concerns is important to sexual QOL. One useful method is to implement a model for communication such as the Permission, Limited Information, Specific Suggestions, and Intensive Therapy model (PLISSIT). When asking patients to participate in a study of sexual activity and sexual QOL, HPs need to give patients the permission to talk about such topics. Giving permission is the first step in the PLISSIT model (Annon, 1976; de Almeida, Britto, Figueiredo, Moreira, & de Carvalho, 2019), which was not used explicitly in the current study. However, by inviting patients to participate in a study, HPs acknowledge that sexual activity and sexual QOL are important subjects to address. Giving patients the opportunity to express their concerns about and thoughts on their sexual activity and sexual QOL is part of the recognition of the patient as a whole person and not just a person with a disease. As seen in a Norwegian study, HPs in rheumatology with more knowledge and education about sexuality addressed sexual issues more frequently (Helland et al., 2013). The PLISSIT is a good tool for structuring patient–HP conversations and may render HPs more confident in discussing sexual activity and sexual QOL, which may be a sensitive area for both people.

The goal for medical treatment for patients with axSpA is to reduce disease activity, obtain remission, and improve and maintain flexibility in the spine to produce a normal posture and reduce functional limitations (Strand & Singh, 2017). Combining treatment strategies, implementing management programmes, and including patients in the decision-making may help to reduce disability and improve HRQOL (Smolen et al., 2018; van der Heijde et al., 2017). Maintaining the ability to work and reducing other complications related to the disease, such as comorbidities, are also important (Nikiphorou & Ramiro, 2020). These factors all influence the overarching goal of supporting QOL, including HRQOL and sexual QOL, as identified in our studies.

5.3 Differences in disease perceptions between men and women related to sexual activity and sexual QOL

Although both men and women tend to receive their diagnosis of axSpA earlier now than just a few years ago, the time from the onset to diagnosis is still longer for women (8.8 years) than for men (6.5 years), and more men than women are diagnosed with axSpA, which is consistent with the current study where 67% of the patients with axSpA were men (Baumberger & Khan, 2017; Jovaní, Blasco-Blasco, Ruiz-Cantero, & Pascual, 2017). This is in contrast with a study by Landi et al. (2017) that found that men reported a longer diagnostic delay than women (Landi et al., 2016). Such a delay in diagnosis may create a greater disease burden for women and may delay the onset of treatment (Rusman et al., 2018). The delay in diagnosis may reflect the greater disease severity in men, as seen as radiological damage and progression (Baraliakos, Listing, von der Recke, & Braun, 2011; Landi et al., 2016; Roussou & Sultana, 2011; Rusman et al., 2018; Östlund et al., 2014). Radiological damage and progression in our studies could not be explored because radiographs and MRI scans were not available. In a study by Rusman et al. (2018), women reported greater disease burden, as shown by a delay in diagnosis, higher disease activity, and lower response to TNF inhibitors. Our studies found similar trends; that is, the female patients had higher self-reported disease activity, worse health status, less ability to manage their daily activities, and greater inflammation in the tendons than did male patients.

Sexuality is a crucial part of a person's identity and sexual identity, and has a psychological, physiological, moral, and cultural/social context. People's perception of their place in a social context and other aspects of life, including their disease, affects their QOL and HRQOL (Cappelleri et al., 2014; Ferrans et al., 2005). A higher percentage of female than male patients in our studies reported that their health status had a negative impact on sexual activity. This finding contrasts with the findings of another study that found no gender differences regarding the impact of health status on sexual activity in patients with PsA (Haugeberg, Michelsen, & Kavanaugh, 2020). Men with RA report a greater impact of health status on sexual activity than women with the disease (Helland et al., 2008). The differences between earlier studies and our studies may be explained by the inclusion of different patient groups—patients with axSpA,

PsA, and RA. It is known that women exhibit greater inflammation in tendons, which may elicit greater pain and worsen physical function and self-reported disease activity (Landi et al., 2016). It is also known that increased pain leads to difficulties in sexual activity and that pain and discomfort caused by disease activity affect both physical and psychosocial relationships and may further impact sexual activity. Pain that impairs sexual activity may have a negative impact on sexual QOL (T. Y. Rosenbaum, 2010).

Disease activity, as measured by the BASDAI at the baseline in our studies, was lower for men than for women, and men had less enthesitis than women. This is consistent with findings from a study of Ibero-American men and women, which found that men had lower disease activity (BASDAI), were younger, had higher work disability rates, more structural damage, lower disease activity, and better QOL than women (Landi et al., 2016). For HRQOL, men in the present cohort reported better scores on vitality, bodily pain, and physical role limitations than women but had lower HRQOL (SF-36) scores than the norm-based SF-36 score in another study from Norway (Rohde et al., 2017). One explanation may be differences in how men and women respond to the questions asked. In general, women tend to encourage more conversation than men and to disclose more information about themselves. Simultaneously, women tend to equalize their status, whereas men tend to assert differences (Schneider & Stone, 2014). These differences can influence patients' responses both when completing PROMS and when reporting to doctors and nurses. How patients evaluate their health and communicate health problems is connected to emotions and the influence of cultural gender differences. Women and men express emotions differently; women tend to report both positive and negative affect more intensively but not more often than men (Schneider & Stone, 2014). These differences may also have affected the findings of the present studies.

5.4 The impact of employment on sexual QOL

There is a close connection between education and employment because higher educational achievement provides opportunities for a larger range of work (Shim et al., 2018). Employment can influence health habits and may also be important for sexual

QOL. Employment is important in the social context because participating in working life is important both economically and socially, and it can positively affect a person's psychological health (Bryngelson, 2009; Ramonda et al., 2016). Employment generates groups and networks that can influence health habits; it also generates income and increases the ability to perform disease prevention behaviours (Shim et al., 2018). The state of health is important for sexual activity and sexual QOL.

The employment rate in our studies was high (71%). A positive influence of being in paid work has also been reported in a previous study showing significant improvements in work productivity in patients with axSpA using bDMARDs (Shim et al., 2018). In our studies, we had no data on work productivity, which could have been useful for providing a broader picture about the differences between patients who work and do not work. Even if patients with axSpA are well treated, having a chronic long-term disease increases the risk of withdrawal from the labour force (Boonen, Boone, Albert, & Mielants, 2018). Low disease activity and use of bDMARDs, as observed in the current cohort, were associated with the high employment rate in a study from Italy that found that high disease activity correlated with decreased work productivity (de Hooge et al., 2016). Hagelund et al. suggested that impaired functioning outside work is likely to also cause problems at work. However, these data were from 2003 to 2007, when bDMARDs were not prescribed widely (Haglund, Petersson, Bremander, & Bergman, 2015).

5.5 Methodological considerations

In this section I will discuss methodological considerations related to study design and, psychometric properties of the questionnaire, external validity, and statistical considerations.

5.5.1 Study design

To address the overall aim of the studies, a cross-sectional design was applied in Papers I and II, and a prospective cohort study with a 5-year follow-up in Paper III (Polit & Beck, 2018). A major limitation of cross-sectional studies is that they do not permit causal interpretation but can only identify associations between dependent and

independent variables (Polit & Beck, 2008). The rationale for choosing these designs for the present studies was that we wanted to describe relationships between phenomena at a fixed point in time (Polit & Beck, 2018) to examine the impact of health status on sexual activity and sexual QOL (Table 1) .

The advantage of using a follow-up design, as in Paper III, is that it allows the researcher to follow a group of people over time, to identify the predictors of changes, and to explore the effects of changes on the outcomes measured. It is also important because no other follow-up studies have been reported for patients with axSpA after introduction of a new treatment such as bDMARDs. Here, the interval between the baseline and follow-up was 5 years. There are challenges if the intervals between the data collecting time points are too long because there is a risk of attrition, such as loss of patients, which can reduce the representativeness of the results (Polit & Beck, 2018). Only data from patients who had participated at the baseline and at the 5-year follow-up were included in these analyses. Among the 289 patients invited to the follow-up, only 35 were lost to follow-up. There were minor differences between those who were invited and those who were not: fewer of the patients without 5-year data were cohabiting, were not current users of bDMARDs, and exercised for less than 1 h/week, which could indicate that their disease was less active.

5.5.2 Psychometric properties of the questionnaires

Most of the outcome measures used in these studies are used widely in studies of axSpA and were recommended by the ASAS working group (Che et al., 2015; Sieper et al., 2009), and all have been tested psychometrically. In addition, the PROMS information provided by the patients, and questionnaires collected by doctors and nurses have been used in previous studies and been shown to have satisfactory reliability and validity (Kiltz, Gossec, Baraliakos, & Braun, 2016). The PROMS used in these studies is part of the daily routine in the outpatient clinic at the two hospitals. A more detailed discussion of the specific PROMS used as the main outcome measures in the three sub-studies is given below.

The 15D instrument is considered to be suitable both as a profile and single-index score measure. Its psychometric properties are satisfactory and, when used as a single

index, represents the overall HRQOL (Sintonen, 2001). Here, we used one question, number 15, of the entire questionnaire. The completion rate of the 15D questionnaire and question number 15 in particular in our studies was high (97%) compared with the 75% completion rate for question 15 in a previous study of patients with RA (Helland et al., 2008). Discrepancies can occur when the measures are clustered around a high score (ceiling) or a low score (floor) (question 15 in 15D) and can further reduce the validity and reliability (Polit & Beck, 2008; Polit & Yang, 2016).

The SQOL-F questionnaire is a validated instrument shown to have good psychometric properties (Symonds et al., 2005). We also used the sub-scores introduced and validated by Maasoumi et al. (2013), which have been shown to have good psychometric properties in the Iranian population. It is a limitation that no other studies were available for comparison for the responses to this questionnaire and for a specific disease such as axSpA or other rheumatological diseases. Another limitation is the lack of data for comparison with the Norwegian population. However, as a part of these studies, we performed factor analysis and confirmed the sub-scores identified by Maasoumi et al. We calculated Cronbach's α for the total score and sub-scores as a part of the reliability testing.

In the present study, we chose to use the SQOL-F in men and women although, to our knowledge, it has not been used on men in scientific studies (Symonds et al., 2005). Given the gender differences in the perception of sexual matters, we changed question 4 from "women" to "men and women". This decision was based on the suggestion of the developer of the questionnaire that "the questionnaire can also be used on partners and on male partners with minor modifications" (Symonds et al., 2005). Abraham et al. (2008) stated that the items of the SQOL-F are also applicable to men with only a small change needed to question 4, "When I think about my sexual life, I feel less of a man" (Abraham, Symonds, & Morris, 2008), as we did in the current study.

5.5.3 External validity

External validity pertains to the generalization of research results where findings from one setting can be transferred to other populations and settings (Polit & Beck, 2018). The patients who participated in the present studies were referred and

recruited from the outpatient clinics in two hospitals. This may have led to sample bias because patients referred to hospital clinics tend to have more severe disease than a population-based cohort, such as patients treated by general practitioners. Another threat to external validity is the differences in age and use of bDMARDs between participants, which may have influenced the results for other variables. However, these characteristics of the patient cohort reflect the real-life population of the patients attending the hospital outpatient clinics.

Data were collected by both doctors and nurses at the two hospitals, and this is both a strength and a weakness. The data collection from two hospitals could be considered as a strength, and the involvement of different people to collect data could be considered as a weakness. However, these patterns reflected the real-life situation in the clinics, although we do not know to what extent these differences impacted the results. Loss of data may have hindered generalization (Polit & Beck, 2018) ; for example, in Paper III, only patients with data at both the baseline and the 5-year follow-up were included in the analyses.

Because of funding restrictions at one of the hospitals (MHH), not all patients from the baseline were invited to the 5-year assessment. In a follow-up study, loss of patients who leave during the study can be a challenge, and attrition can be a threat to internal validity (Polit & Beck, 2018). A high drop-out rate could influence the representativeness of the results if those who drop out differ from those who continue being part of the study. However, in the present studies, the drop-out rate after 5 years was only 35 of 280 (12.5%), and it was random and caused by death (n = 4) or moving to another place (n = 31; Figure 5). None of the participants decided to leave the study after 5 years for other reasons, possibly because talking about sexual QOL in relation to their disease may have met a need in these patients.

5.5.4 Statistical considerations

In our studies, we chose to present scores on instruments such as the HAQ, BASFI, MASES, CRP, and BASDAI as the mean ± SD instead of the median and interquartile range, although some of the scores are somewhat skewed with an excess of zeros. However, the dependent and independent variables do not need to be

normally distributed in a regression model. The assumption about normal distribution in linear regression analyses relates to the residuals, and we assessed the distribution of the residuals. Linear regression models tend to be robust for moderate deviations from the assumptions of a normal distribution and especially with a high number of observations. Transformation of variables or use of statistical models with other distributional assumptions can address these issues, but their interpretation is more difficult and not commonly used. In our experience, the overall results and conclusions tend to be similar between such approaches and the findings of linear regression analyses in a large sample. For statistical modelling in the multiple analysis, we used a clinically driven approach to select the relevant independent variables and performed further comparisons using multiple analysis.

Throughout the study each patients had to answer nearly 100 questions (Table 3), this may be seen as a burden for the patients and hamper validity of the data(Polit & Beck, 2008). At the same time answering many questions is routine in every consultation at these outpatients' clinics. There was a high response rate on answering questions in the study.

More patients did not answer some of the questionnaire items in Paper II (n = 29) than in Paper I (n = 10) at the baseline. The patients who did not answer some of the questions in Paper I were older and had been ill for a longer time than the responders. For the non-responders on the SQOL-F, fewer were married, and they worked and exercised less. The non-responders in Paper III were older, tended not to be married or cohabiting, smoked more, and exercised less. It is possible that answering questions about how axSpA affects sexual activity may have been easier than answering questions about sexual QOL.

Data on comorbidity were collected by interviewing the patients and from the patients' files. The data were collected as specific entities and were further aggregated into groups of related diseases using the following categories: cardiovascular, pulmonary, neurological, endocrine, haematological, gastrointestinal, urogenital, malignant, mental disorders, and other. A summary score was calculated (Sarfati, 2016). This coding could have been more thoroughly described or used in other ways. For

example, the Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987) could have been used as a prognostic tool for assessing the risk of mortality in our patients.

6 Conclusions

A chronic disease, such as axSpA, can impair HRQOL, including sexual activity and sexual QOL. Sexual QOL, which is part of HRQOL but reflects a broader concept than sexual activity, includes both psychological and social dimensions. Only a small percentage of the patients with axSpA in our studies (~20%) reported that their health status had a large negative effect on their sexual activity. Women reported a larger effect of health status on sexual activity than men. In these studies, gender and lifestyle factors, but not disease-related variables, negatively influenced sexual activity. Only being a woman, high BMI, current smoking, and poor HRQOL were associated with the impact of health status on sexual activity. This is promising because lifestyle factors such as smoking and BMI are modifiable. In the adjusted analyses, being a woman, high BMI, disease activity measured by the BAS-G and CRP, and the use of bDMARDs were negatively associated with sexual QOL. Compared with men, women reported better sexual QOL on the sub-score sexual repression. Sexual repression includes factors such as losing the pleasure of sexual activity and feeling uncomfortable and embarrassed, which lead to avoiding sexual activity.

Sexual QOL in our patients with axSpA remained stable through a 5-year follow-up despite an increase in the number of comorbidities. Simultaneously, intensification of medical treatment (e.g., use of bDMARDs) led to better disease control and reduction in some of the negative lifestyle factors such as smoking habits. Patients who exercised less and were aged >65 years reported lower psychosexual feelings of being frustrated, depressed, worried about their partner's rejection, and feelings. Women had a lower BMI and BASMI score, and higher MASES and HAQ scores than men.

These encouraging findings indicate that both effective control of disease activity and changes initiated by patients with axSpA, such as a reduction in smoking, weight loss, and more exercise, might contribute to improved sexual QOL. In addition, these findings raise awareness of the need to focus on comorbidities in daily practice because these can hamper achieving the target of remission of axSpA.

In the clinical context, the word “burden” is often used. The words chosen to describe the implications of having axSpA can affect patients and their spouse and family. The characterization of axSpA can affect how HPs communicate with the patients and how patients look upon themselves. Because there are few studies on sexual QOL, it is important to move the focus from burden to sexual QOL and to focus on how to live well in a social context when having axSpA.

6.1 Implications for clinical practice

- Knowing about the patient’s experience of having axSpA and its effect on sexual activity and sexual QOL is important to the ability of HPs in clinical practice to meet the patient and be better prepared to answer questions on these topics.
- The findings from these studies add valuable information about the impact of health status on sexual activity and sexual QOL because earlier research on these topics is scarce.
- The results of these studies will be of interest to HPs working with patients with axSpA by enabling them to become more aware of the influence axSpA can have on sexual activity and sexual QOL.
- This knowledge should be significant in patient-centred care according to the T2T strategy.
- A holistic approach to disease activity and the implications of having axSpA should be adopted and should include a focus on lifestyle factors, treatment, and comorbidities.
- When discussing sexual QOL, it is important to regard each patient as an individual and to understand the spectra of diseases and challenges in sexual activity and the implications for sexual QOL.

6.2 Further research

- Including partners in research when exploring the impact of health status on sexual activity and sexual QOL will added valuable information for HPs.
- Interviewing the patients and their partners will provide additional information about how they perceive axSpA and what types of relationships are important to them. Because many of the patients in this cohort were cohabiting, we know little about those who were not married or cohabiting. Interviewing such patients will provide important information on what is important to them.

- It will be useful to examine the different education programmes and to what extent sexual education is a part of education programmes for patients and partners. Qualitative research is needed to examine how patients understand all the information given (i.e., their health literacy).
- It will be useful to conduct further follow-up studies of patients with axSpA on sexual activity and sexual QOL, to illuminate this topic further.
- It will be important to continue to focus on exercise and lifestyle factors such as obesity as comorbidities because these can increase disease activity and impair sexual QOL.
- Other measures that could be used in further research include a questionnaire on depression, a measure of pain using scales such as the visual analogue scale, and a standardized assessment of fibromyalgia tender points to address pain in a wider context.

Further research would also benefit from having X-rays of all patients, which would allow the differentiation between non-radiographic and radiographic axSpA.

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Appendices

1. Paper I
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Paper I

This is an Accepted Manuscript of an article published by Taylor & Francis in Scandinavian Journal of Rheumatology on 15/03/2017, available online:
Berg, K.H., Rohde, G., Prøven, A., Benestad, E.E.P., Østensen, M., Haugeberg, G. Sexual Quality of Life in Patients with Axial Spondyloarthritis in the Biologic Treatment Era. *The Journal of rheumatology*, 2019; doi:10.3899/jrheum.180413

http://www.tandfonline.com/10.1080/03009742.2017.1279684.

Paper II

Paper III

This is an article published in Rheumatology following peer review: Berg, K.H., Rohde, G., Pripp, A., Prøven, A., Benestad, E.E.P., Østensen, M., Haugeberg, G. Increased proportion of comorbidities but no deterioration of sexual QOL during a 5-year follow-up in patients with axSpA in the biologic treatment era. *Rheumatology*, 2021; doi.org/10.1093/rheumatology/keaa887

https://pubmed.ncbi.nlm.nih.gov/33410472/#:~:text=Rheumatology%20(Oxford),10.1093/rheumatology/keaa887.

Appendix 4

An overview of studies on sexual activity, sexual QOL, sexual relationships. Sexual satisfaction, and sexual dysfunction and function.

Table 1. An overview of studies on sexual activity, sexual QOL, sexual relationships, sexual satisfaction, and sexual dysfunction and function

	N	**Research question**	**Method and instruments**	**Main findings**
Sexual activity				
Gallinaro, A.L. et al. 2012 Brazil	32 patients 32 controls 28 mal2 4 women	Sexual activity in **AS**	Case-control HAQ-S, BASFI, BASDAI, VAS	The chronic nature of AS, associated with poor functional capacity and high activity, interferes with sexual intercourse. When sexual activity was possible, no difference was found between patients and controls.
Fu, J et al. 2019 China	31 male	Sexual activity in male AS patients before and after total hip arthroplasty (THA)	Longitudinal International Index of Erectile Function (IIEF)	Successful THA may improve sexual activity and better movement (flexion-extension range motion ROM, adduction-abduction ROM) improved sexual activity.
Yao, Z. et all. 2016 China	45 male	Assessment of changes in sexual activity after surgical treatment for AS-induced kyphosis	Retrospectively reviewed IIEF	Showed surgery may improve sexual functioning .

Rostom, s. et al. 2013 Marocco	110 male	The impact of AS on sexual activity	Modified New York criterias	2atigue and sleep disturbance was independently associated with perceived problems and sexual activity.
Sexual QOL				
Dong, X. et al. 2015 China	42 patients over 3 months	To investigate the therapeutic effect of a tumour necrosis factor-alpha (TNF-α) antagonist on the sexual quality of life of male patients with **AS**	Open label/longitudinal mSLQQ-QOL BASDAI	No significant differences in baseline data were found between the two groups. After treatment, disease activity and quality of life were improved in these two groups. Sexual quality of life and disease activity were improved after treatment with TNF-α antagonists in male patients with AS. The extent of improvement in sexual quality and disease activity are positively related.
Sexual relationships				
Healey, E. et al. 2009 United Kingdom	612 patients from 10 sites	To explore the impact of **AS** on sexual relationships in a large cohort of patients across the UK.	Multicenter cross-sectional HADS-d, BASFI, BASDAI ASES, VAS	AS substantially impacts patients' sexual relationships, both for physical outcomes and psychological state. 37.6% of males and 37.7% females reported that the disease impacts sexual relationships.
Sexual satisfaction				
Akkus, Y. 2010 Turkey	18 RA 15 AS 33 patients	Factors affecting the sexual satisfaction of patients with RA and **AS**	Descriptive DAS 28, HAQ, BASDAI, BASFI	Statistically significant difference in satisfaction before diagnosis compared to after. Sexual satisfaction was lower in RA patients; sexual satisfaction was negatively correlated with DAS 28 and HAQ. Nurses should be aware of sexual lifestyle and functioning.

Sexual dysfunction/function				
Erdem, IH. et al. 2020 Turkey	50 males 50 controls With AS patients	To investigate the incidence of erectile dysfunction (ED) in patients with AS with a control group and to investigate the risk factors for ED.	Case-control BASDAI, BASFI, ASOQOL	Erectile function scores slightly lower in the AS group than the control group. Risk of ED was shown as disease activity and psychological factors increased.
Rezvani, E.A. et al. 2012 Turkey	39 male AS 27 healthy controls	To investigate the impact of **AS** on sexual functions in male patients compared with the healthy controls. Identify the associations with disease-related variables.	Cross-sectional IIEF BDI ASQOL	Sexual dysfunction is common in male patients with AS. No statistically significant differences between AS and controls in terms of sexual functions. Sexual dysfunction is associated with an unfavorable psychological status.
Dhakad, U. et al. 2015 India	100 males and 100 controls with AS	To determine sexual dysfunctions and urinary symptoms in male **AS** patients and their association with various disease and patient factors	Case-control IIEF IPSS HADS BASFI. BASDAI	AS is associated with higher incidence of sexual dysfunction in male patients. ED is associated with anxiety, depression, longer duration of disease, higher BASFI score and higher age in AS patients.
Gözukücük, M. et al. 2021 Turkey	98 women (62 AS and 36 patients with nr.axSpA) 99 Healthy controls	Evaluate sexual functioning and disease related variables, physical and psychogenic states in female patients with nr-axSpA	Case-control FSFI, SF-36, HADS, Gynecological evaluation	No difference between AS and nr-axSpA related sexual functioning and psychological burden. Elderly women with axSpA disease duration and limitations in movement are more affected in genital arthropathy and sexual functioning.

Akkurt. HE, et al. 2016 Turkey		This study aimed to evaluate sexual function in females with **AS**, compare them with healthy controls, and demonstrate the effects of AS on female sexual functions.	Case-control FSFI VAS BASDAI	Sexual dysfunction was more common in female AS patients without marked impairment in body image and hip involvement when compared to normal population.
Nisihara, R. et al. 2021 Brazil	35 male patients with AS and 104 controls	To study erectile dysfunction in male patients and correlation to sexual hormonal profile and disease activity	Transversal observational, single center IIEF, FT, BT, SHBG, ASDAS,	Patients with AS had worse sexual performance than controls linked to disease activity, not to hormonal profile.
Sariyildiz, MA. et al. 2013 Turkey	37 females	To explore the impact of **AS** and the disease-related variables, psychological status, and the QOL on the female patients' sexual function	Cross-sectional FSFI	No significant correlation was observed with the disease duration, smoking status, depression, anxiety, pain, and ESR when the total scores and the scores from the domains of the FSFI were compared. The sexual function is impaired in female patients with AS. This impairment in the sexual function is especially related to the functional status and disease activity among the clinical and laboratory parameters.
Shen, B. et al. 2013 China	103 AS patients 78 males 25 females	A primary analysis of sexual problems in Chinese patients with **AS**	Single-center cross-sectional BIDQ SF-36 VAS HAQ	Both physical and psychological factors were shown to impact sexual relationship and function. Disease activity, physical function, and psychological well-being impact sexual health. To examine associations with demographic parameters, physical impairments, psychological problems.

Demir, S.E. et al. 2013 Turkey	23 AS patients 27 Controls	Assessment of sexual functions in female patients with **AS** compared with healthy controls	Case-control FSFI BDI Short-Form-36	Sexual problems in female patients with AS appear to be associated with higher depression levels, increased disease activity, decreased functionality, higher pain scores and decreased quality of life.
BAL, S. et al. 2011 Turkey	37 male patients 67 controls	Sexual functioning in **AS**	Case-control SF-36, disease duration, VAS, ESR, CRP, BASDAI, BASFI BASMI, BAS-G IIEF	Prevalence of ED like that for controls. AS patients have problems with satisfaction from intercourse.
Oh. JS, et al. 2009 Korea	22 males	The effect of antitumor necrosis factor agents on sexual dysfunction in male patients with **AS**: a pilot study	Open label without placebo BASDAI IIEF RAND-36	Anti-TNF therapy may improve sexual dysfunction in men with AS, in addition to reducing disease activity. Decreased ED. Only intercourse showed significant correlation with BASDAI..
Ôzkorumak. E, et al. 2011 Turkey	43 men recruited consecutively: matched control group	Sexual function in male patients with **AS**	Case-control Questionnaire on socio-demographic data BDI, GRSSS, BASDAI BASFI, BASMI, VAS	Sexual health of patients with AS appears to be based on two interrelated factors: psychological status (depression and anxiety) and disease activity.
Fan. D, et all. 2015 China	535 men with AS 430 male controls from 11 studies	TO drive a more precise estimation of the Sexual function and its clinical correlation in men with AS	Meta analysis	Sexual functioning is impaired in male patients with AS.

Santana. T, et al. 2017 Brasil	40 male patients with AS and 40 healthy controls	To study erectile dysfunction in ankylosing spondylitis patients	Case-control BASDAI, ASDAS, Sr, CRP, MASES, SPARCC, BASFI, HAQ, BASMI, IIEF.	High prevalence of erectile dysfunction among patients with AS, associated with disease activity measured with BASDAI.
Aykurt Karibel.I, 2019 Turky	67 mail patients with AS	Investigate the effect of smoking on sexual functioning	Prospective observational BASDAI, BASMI, BASFI, ASQoL, Fatigue and pain VAS scale, BDI, FTND, IIEF-5, Exh.CO	Sexual function in patients with AS is associated with, pain, fatigue, disease activity, functional status, QOL, depression and cumulative exposure to smoking. Sexual functioning tends to decline with increasing degree of smoking.
Liu. Y.F. 2015 China	484 cases from 5 studies	Investigate the impact of AS on sexual functioning, regardless of gender	Review, mata-analysis BASFI, BASDAI; ASQoL, IIEF, FSFI	AS has a certain impact on sexual functioning of male patients. And the impact seems to be greater for men than for women.

BASFI - Bath Ankylosing Spondylitis Functional Index; BASDAI - Bath Ankylosing Spondylitis Activity Index; ESR – erythrocyte sedimentation rate; BAS-G - Bath Ankylosing Spondylitis Patients Global Score; BASMI - Bath Ankylosing Spondylitis Metrology Index; CRP - C-reactive protein ; ROM – range of motion; FSFI – Depression Inventory and Female Sexual Function Index; VAS – visual analogue scale for pain; IIEF – International Index of Erectile Function; IIEF-5 - International Index of Erectile Function classified into 5 categories; BDI – Beck Depression Inventory; ASES – Arthritis-Specific Self-Efficacy questionnaire; IPSS – International Prostate Symptom Score; HADS – Hospital Anxiety and Depression Scale; SD – Sexual Dysfunction; BIDQ – Body Image Disturbance Questionnaire; GRSSS – Glombok-Rust Sexual Satisfaction Scale; ROM – Range of Motion; AIMS2 – Arthritis Impact Measurement Scale; SF-12 – 12-Item Short-Form Health Survey; RAND- ; SF-36 – Medical Outcomes Short-Form-36 questionnaire; BMSFI – Brief Male Sexual Functioning Inventory; HADS-d – Hospital Anxiety and Depression Scale; mSLQQ-QOL – The Modified Sexual Life Quality Questionnaire; ASQoL – Ankylosing Spondylitis Quality of Life; VAS – visual analog scale; ASDAS – Ankylosing Spondylitis disease Activity Score; SPARCC – Spondyloarthritis Research Consortium of Canada; FTND – Fagerstrøm Test for Nicotine Dependence; Exh.CO – Carbon-monoxide in exhaled air;

Appendix 5

Approval Norwegian Center for Research Data

NTNU
Norges teknisk-naturvitenskapelige universitet

Det medisinske fakultet
Regional komite for medisinsk forskningsetikk
Helseregion Midt-Norge

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Vår dato:	Vår ref.:	Deres dato:	Deres ref.:
02.10.07	4.2007.2152		

Inflammatorisk ryggsykdom og etablert Bekhterevs sykdom i Norge. - En klinisk epidemiologisk studie av forekomst, sykelighet, klinisk presentasjon, livskvalitet seksualitet, og helseøkonomi og effekt av biologisk behandling.

Med hjemmel i lov om behandling av etikk og redelighet i forskning § 4 har Regional komité for medisinsk og helsefaglig forskningsetikk, Midt-Norge vurdert prosjektet i sitt møte 14. september 2007 med følgende vilkår og vurdering:

Hovedbegrunnelsen for å gjennomføre denne studien er at det er et stort behov for økt kunnskap om denne sykdommen (både tidlig og etablert stadium) baserte på populasjonsbasert studie design. Dette gjelder både klinisk epidemiologiske forhold, livskvalitet og helseøkonomi. Dataene fra denne studien vil således kunne bli en viktig kunnskaps kilde for leger og øke deres forståelse til hjelp i diagnostisering, behandling og oppfølging av pasienter med Bektherev sykdom. For helse byråkrater og helsepolitikere vil den studien gi viktig bakgrunnsinformasjon når beslutninger skal tas knyttet til bestemmelser om ressursbruk og rettigheter overfor denne pasientgruppen. Videre er det også et behov for å finne ut hvordan moderne og dyr behandling ("biologisk behandling") virker i den daglige bruk av disse medikamentene.

Metode:
Prospektiv klinisk epidemiologisk populasjonsbasert studie med et tverrsnitt og en longitudinel design. Pasienter med etablert Bektherevs sykdom vil bli identifisert ved hjelp av sykehusenes elektroniske diagnoseliste systemer. Det samme vil bli gjort ved å innhente diagnose lister fra deltagende privat praktiserende revmatologer og deltagende private Røntgensentra.
Allmennpraktikere vil i brevs form bli oppfordret til å henvise pasienter med Bekhterevs sykdom til undersøkelse ved de deltagende revmatologiske avdelinger. Pasientens diagnose vil bli verifisert og innkalt til undersøkelse og inklusjon i studien etter at pasienten har avgitt muntlig og skriftlig samtykke.
Pasienter som starter opp med biologisk behandling vil bli fulgt med objektive og subjektive effektmål.

For delstudien som omfatter undersøkelse av pasienter med tidlig Bektherev sykdom så vil denne basere seg på at primærleger vil bli oppfordret til å henvise pasienter med mistanke om Bektherev sykdom tidlig til revmatologisk avdeling for undersøkelse. Pasienter som har sagt seg villige til å delta i tverrsnittsstudien vil også bli forspurt om å ville delta i en prospektiv studie. Det vil ved hjelp av spørre skjema bli innhentet et bredt spekter av data knyttet til sosiodemografi, kliniske forhold, livskvalitet og helseøkonomi.

Komiteen har følgende merknader til prosjektet:

- Komiteen viser til prosjektprotokollen og det er uklart hvordan deltakerne skal inkluderes og hvordan dette finansieres. Komiteen stiller spørsmål om pasienter blir henvist for studiedeltakelsen, eller er det de som er henvist uavhengig av denne studien som skal inkluderes? Det kan være et forskningsetisk problem hvis henvisning er begrunnet i forskning og ikke begrunnet i vanlig klinisk praksis. Vil deltakere som eventuelt trekker seg fra studien underveis kunne fortsatte å gå til kontroller? Komiteen ber om tilbakemelding om dette.
- Det må utarbeides et informasjonsskriv som de aktuelle studiedeltakerne får før de blir henvist til senter for deltakelsen, slik at de som eventuelt henvises for studien og ikke for medisinsk vurdering og behandling kan få tatt standpunkt til dette på forhånd. Den første henvendelsen om deltakelse i studien må skje gjennom den som er klinisk ansvarlig overfor den konkrete pasienten, slik at taushetsplikt er bevart.
- Komiteen viser til informasjonsskrivet og det må utarbeides et totrinns skriv. Ett skriv må først informere om den overordnede studien og deretter må det utformes skriv som informerer direkte om understudier.
- Komiteen mener det er uheldig at det flere steder blir understreket at dette er dyre medisiner. Det bør være pasienten uvedkommende om dette er dyrt eller billig, dette aspektet bør ikke være noe om pasienten bør bekymre seg om.
- Det skal tas biologisk materiale. I henhold til Biobankloven må det søkes spesielt om dette, jf. § 4 i loven, og dette skal vurderes av Regional komité for medisinsk forskningsetikk før det meldes til Sosial- og helsedirektoratet. Komiteens sekretariat vil oversende meldingen til direktoratet så snart den er oversendt komiteen og vurdert. Komiteen må forelegges en punkt for punkt redegjørelse for de momentene som skal svares på etter lovens § 4. Det må opplyses i informasjonsskrivet til forsøkspersonene at det blir opprettet en biobank.
- Komiteens sekretariat vil oversende biobankmeldingen til direktoratet.

Komiteen ber om å få tilsendt artikkel/rapport når studien er fullført.

Vedtak:
"Komiteen godkjenner at prosjektet gjennomføres med de merknader som er gitt."

Vedtaket kan påklages og klagefristen er tre uker fra mottagelsen av dette brev, jf. fvl. §§ 28 og 29. Klageinstans er Den nasjonale forskningsetiske komité for medisin og helsefag (NEM), men en eventuell klage skal rettes til REK Midt-Norge. Avgjørelsen i NEM er endelig. Det følger av fvl. § 18

at en part har rett til å gjøre seg kjent med sakens dokumenter, med mindre annet følger av de unntak loven oppstiller i §§ 18 og 19.

Vi viser til dette.

Med hilsen

Arne Sandvik
Professor
Leder i komiteen

Arild Hals
Seniorrådgiver
Sekretær i komiteen

Appendix 6

Norwegian Social Science Data Service

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

Harald Hårfagres gate 29
N-5007 Bergen
Norway
Tel: +47-55 58 21 17
Fax: +47-55 58 96 50
nsd@nsd.uib.no
www.nsd.uib.no
Org.nr. 985 321 884

Glenn Haugeberg
Revmatologisk avdeling
Sørlandet sykehus HF
Serviceboks 416
4604 KRISTIANSAND S

Vår dato: 28.11.2007 Vår ref: 17602 / 3 / SF Deres dato: Deres ref:

TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 01.10.2007. Meldingen gjelder prosjektet:

17602	*Inflammatorisk ryggsykdom og etablert Bekhterevs sykdom i Norge*
Behandlingsansvarlig	*Sørlandet sykehus HF, ved institusjonens øverste leder*
Daglig ansvarlig	*Glenn Haugeberg*

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/-helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/melding/pvo_endringsskjema.cfm. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://www.nsd.uib.no/personvern/register/.

Personvernombudet vil ved prosjektets avslutning, 17.10.2008, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Bjørn Henrichsen

Sølve Fauskevåg

Kontaktperson: Sølve Fauskevåg tlf: 55 58 25 83
Vedlegg: Prosjektvurdering

Appendix 7

Information and declaration of consent

Informasjonsskriv til pasienter med etablert Bekhterevs sykdom og ”tidlig Bekhterev” som ønsker å delta i en studien - Bekhterev i Norge

Forespørsel om å delta i forskningsprosjekt:

Om Bekhterevs sykdom:
Bekhterev sykdom er en kronisk systemisk leddbetennelsesykdom som hovedsakelig rammer små ledd i ryggen og som fører til smerte og stivhet. Over år kan sykdommen føre til tilstivning av ryggsøylen. Sykdommen kan også ramme andre organer i kroppen som f.eks tarmen, hjerte, skjelettet og øynene. Sykdommen er forbundet med stor sykelighet, redusert livskvalitet og fører ofte til redusert arbeidsevne og dermed økt risiko for tidlig uførhet. Sykdommen fører til store helsekostnader for både pasient og samfunn. Det er et stort behov for å øke vår kunnskap om denne sykdommen, blant annet fordi nye dyre medikamenter er tilgjengelige.
Diagnosen Bekhterevs sykdom er vanskelig å stille på et tidlig tidspunkt. Pasienter kan gå i flere år med plagene sine uten at riktig diagnose stilles. Dette fører ofte til stor frustrasjon hos pasienten og gir pasienten ofte en følelse av at han/hun ikke blir tatt på alvor. Vi ønsker derfor også å undersøke dem som har tidlig symptomer på Bekhterevs sykdom hvor sykdommen kan mistenkes, men hvor diagnosen ikke kan stilles helt sikkert. Dette er viktig fordi vi har som mål å komme tidlig i gang med behandling av sykdommen.

Denne studien:
Denne undersøkelsen som du har mulighet til å delta i, er planlagt som en førstegangsundersøkelse nå og så ny undersøkelse om 5 år dersom du har sikker sykdom og om 3 år dersom du har tidlig Bekhterev. Dersom du ønsker å delta, er det ingen forpliktelse om også å delta senere. Du kan når som helst trekke deg fra undersøkelsen.

Hva ønsker vi å oppnå med studien:
Undersøkelsen har som formål å undersøke hvordan pasienter med Bekhterevs sykdom har det og hvordan det går med dem. Vi ønsker blant annet å kartlegge hvor mange som har sykdommen, hvilke behandling som gis, sykdomsalvorlighet, grad av organskade, livskvalitet og kostnader. Videre ønsker vi å få oversikt over hvor mange pasienter som vil kunne være kandidater for annen behandling enn fysioterapi og betennelsesdempende (NSAID/COXIB).
Det er mangelfulle data på dette området og økt kunnskap trengs for om mulig å bedre tilbudet til denne pasientgruppen og kunne møte de utfordringer som vi i fremtiden står overfor for å kunne gi riktig behandling til riktig pasient.

Gjennomføring av undersøkelsen:
Pasienter med ”mistenkt/tidlig Bekhterev” og sikker Bekhterev sykdom som behandles/henvises revmatologiske avdelinger, privatpraktiserende revmatologer, eller som er blitt diagnostisert til å ha sykdommen ved Røntgenavdelingen eller private røntgensentre vil bli invitert til å ta del i undersøkelsen. Informasjon om studien gis både skriftlig og muntlig.
Det presiseres at det hele tiden er fullt mulig å gå ut av studien dersom man ikke ønsker videre deltagelse også uten å måtte angi grunn. Undersøkelsen vil inkludere utfylling av protokoll hvor man i hovedtrekk svarer på spørsmål, klinisk undersøkelse, røntgen undersøkelse, bentetthetsmåling med tanke på osteoporose og rutine blodprøver. Deltagelse i studien vil for deg ikke være forbundet med økte utgifter. Reisekostnader vil vi dessverre ikke kunne dekke dersom de ikke er en del av en rutinekontroll ved en Revmatologisk avdeling.

<u>Fordeler / ulemper for deg med å delta i undersøkelsen:</u>

Fordeler: Du vil bli grundigere undersøkt og fulgt opp enn det som er gjeldende ut fra dagens rutiner. Dette er ikke en sammenlignende undersøkelse av behandlingseffekt, det betyr at om du velger å delta eller ikke, vil du få samme type behandling som behandlende lege finner riktig å gi deg.
Ulemper: Du vil måtte bruke tid på utfylling av spørreskjema, klinisk undersøkelse, røntgenundersøkelser og blodprøver. Vi regner med at du vil måtte bruke ca 30-40 minutter ekstra på å besvare spørsmålene i spørreskjemaene som brukes. Du vil dersom du ønsker få full innsikt i helseopplysninger som registreres om deg ved å kontakte din lokale kontaktperson ved det sykehuset hvor du følges opp (se nedenfor). Opplysninger som er spesifikke for prosjktet vil bli lagret i prosjektmapper og lagret anonymt på datafiler. Medisinsk informasjon som er en del av rutine undersøkelsen vil bli lagret i din medisinske sykehusjournal og i din prosjektmappe.

Samtykkeerklæring:

Jeg har lest og fått utlevert et eksemplar av denne informasjonen, og i tillegg fått muntlig informasjon om forskningsprosjektet.
Jeg samtykker i å være med i forsøket, og er klar over at mitt samtykke ikke hindrer meg i når som helst å trekke meg fra forsøket uten å måtte oppgi grunn.

Jeg er informert om at alle opplysninger om meg vil behandles konfidensielt av forskningskvalifisert personale under ledelse av prosjektleder. Ved prosjektets slutt vil alle innsamlede opplysninger bli anonymisert. Det vil bli beholdt en navneliste separat som kan kobles til den anonymiserte databasen.
Jeg er informert om at jeg til enhver tid har mulighet til å se dataene som er lagret om meg.

Pasient / forsøksperson: _____

□ Sørlandet Sykehus
□ Revmatismesykehuset i Lillehammer
□ St.Olavs Hospital
□ Martina Hansen
□ Betanien Hospital
□ Andre deltagende sentra:_____

Med vennlig hilsen prosjektleder
professor dr.med Glenn Haugeberg
INM, DMF, NTNU, Trondheim
Overlege ved Revmatologisk avdeling, Sørlandet Sykehus HF

Appendix 8

Addition information to participants

Til deltagere i forskningsprojsektet – Bekhterev i Norge

Tilleggsinformasjon til deltagere i forskningsprosjektet – Bekhterev i Norge

Av NSD (Norsk samfunnsvitenskapelig datatjeneste AS Personvernombud for forskning) er vi gjort oppmerksom på at informasjonsbrevet som du fikk om studien også må inneholde konkret informasjon om hvilken institusjon som er ansvarlig for studien og hvem du skal kontakte dersom du ønsker å trekke deg fra studien. Dette gikk ikke tydelig frem i det informasjonsskrivet som du fikk da du ble med i studien. Denne studien er et sammarbeidsprosjekt mellom revmatologisk avdeling ved Sørlandet sykehus HF og revmatologisk avdeling ved Martina Hansens Hospital, der Sørlandet sykehus HF er databehandlingsansvarlig institusjon

Dersom du ønsker å trekke deg fra studien og også ønsker å få slettet data som er lagret må du kontakte følgende personer nedenfor:

- De som er inkludert i studien fra Sørlandet sykehus HF må kontakte Overlege Glenn Haugeberg (Tlf 38073142).
- De som er inkludert på Martina Hansens Hospital må kontakte Overlege Anne Prøven (Tlf 67521736).

Kontakperson for hele forskningsprosjektet er som tidligere anført i informasjonsskrivet: Professor dr.med. Glenn Haugeberg (Tlf 38073142).

Som du ble informert om har vi ønske om å gjøre en oppfølgingsstudie fem år etter at du ble med i denne studien. Til denne oppfølgingsundersøkelsen vil det bli sent ut en ny invitasjon. Selv om du nå er med i denne studien er det viktig å presisere at det er ingen forpliktelse i å delta senere.

I informasjonsskrivet brukte vi feilaktig begrepet anonymiserte data. Den riktige betegnelsen er avidentifiserte personopplysninger. Forskjellen er at så lenge prosjektet pågår så oppbevares det en koblingsnøkkel mellom persondata (som navn f.dato) og forskningsdatafilene.

Ved prosjektslutt vil datafilene bli anonymisert. Det vil si at koblingsnøkkelen mellom persondata og forskningsdatafilene vil bli slettet.

Prosjektslutt er satt til 01.01.2017.

Med vennlig hilsen

Prosjektleder
Professor dr.med. Glenn Haugeberg

Adresse:
Revmatologisk avdeling
Sørlandet sykehus HF
Serviceboks 416
4632 Kristiansand.S

Appendix 9

Patients` questionnaire

Protokoll - Inflammatorisk ryggsykdom og etablert Bekhterevs sykdom i Norge

Protokoll nr:_____ **Dato for utfylling av spørreskjema**: _____ **Sykehus**:_____

Navn:_____ **F.dato (pnr)**:_____

Adresse:_____

Postnr:_____ **Poststed**:_____ **Kommune**:_____

☐ **KONTROLL GRUPPE "MEKANISK RYGG".**

☐ **Klinisk Mistanke om Bekhterev (IBP): Enten IBP symptomer eller MR IS ledd positiv.**

☐ **Klinisk Bekhterev med røntgen funn tolkett som forenlig med AS.**

☐ **Etablert Bekhterev, d.v.s. oppfyller New York kriteriene.**

☐ **Bekhterevs sykdom – samtidig oppstart biologisk behandling ved inklusjon.**

IS-ledd billeddiagnostikk, rtg funn breskrevet i journalen:

☐ Rtg: Erosjoner J/N, sklerosering J/N
☐ MR: Inflammasjonstegn J/N (ødem J/N, synovitt J/N), Erosjoner J/N
☐ CT: Erosjoner J/N
☐ Skjelettscintigrafi: Sykdomsaktivitetstegn J/N

Kolumna:

☐ MR av kolumna. Inflammasjonstegn J/N

*New-York kriteriene for Bekhterev:

Symptom debut dato	Symptom ved debut	Klinisk diagnosedato	Diagnosedato
		(Mod. NY krit. ikke oppfylt)	(Mod. NY krit.

Modifiserte New York kriterier

Kliniske kriterier:

☐ 1. Karakteristiske lave ryggsmerter og stivhet > 3 mnd (Smerter som lindres ved bevegelse og ikke ved hvile)

☐ 2. Nedsatt bevegelse i nedre del av ryggsøyle i frontal og sideplan

☐ 3. Nedsatt thoraxbevegelse i forhold til normale verdier for samme alder og kjønn

Radiologisk kriterium:

☐ 4. Bilateral sakroilitt grad 2 eller mer ELLER unilateral grad 3 - 4

Sakroilittgradering

0: Normal 1: Mistenkelig (ingen entydig endring)
2: Minimal (minimal sakroilitt, definert ved begynnende uklarhet ved kanten av SI-leddene, noe juxtaartikulær sklerose, små begynnende erosjoner, og mulig leddspaltereduksjon)
3: Moderat (moderat sakroilitt, definert ved entydig sklerose på begge sider, uklare og utydelige kanter, og tydelige erosjoner med tap av leddspalte)
4: Alvorlig (fullstendig fusjon eller ankylose av leddene)

Diagnosegradering

Bekreftet AS hvis kriterium 4 OG minst en av kriteriene 1 - 3 er oppfylt
Sannsynlig AS hvis kriteriene 1, 2 og 3 ELLER bare kriterium 4 er oppfylt

HLA-B27 indikasjon

HLA-B27 tilstede? ○ Ja ○ Nei ◉ Ingen data Dato:

Inflammatorisk rygg plager siste uken:

IBP (inflammatory back pain) kriterier (kryss av):

- **Morgen stivhet:**
  a. Ingen morgenstivhet
  b. < 10 min
  c. 10-30 min
  d. 31-60 min
  e. >60 min
  f. >30 min
- Varighet av morgenstivhet: timer_____ minutter:_____
- **Ryggsmertene bedres ved:**
  a. Hvile
  b. Fysisk aktivitet
  c. Fysisk aktivitet men ikke med hvile
- **Rygg smertene forverres ved:**
  a. Hvile
  b. Fysisk aktivitet
  c. Fysisk aktivitet men ikke med hvile
- **Nattlig oppvåkning p.g.a. ryggsmerter:**
  a. Tidspunkt for oppvåkning om natten:____ Når legger du deg: Når står du opp:____
  b. Våkner når som helst på natten
  c. Bare i første halvdel av natten
  d. Bare i andre halvdel av natten
  e. I begge halvdeler av natten
- **Setesmerter:**
  a. Hatt en eller annen gang
  b. Ensidig
  c. Bilateral
  d. Vekslende
- Var det en forutgående hendelse som du husker før du fikk plagene?:
  a. Traume (ulykke, løfting, bæring etc....)
  b. Infeksjon
  c. Mentalt/emosjonelt stress
- Hvor lang tid tok det fra du fikk plagene og til du kontaktet en doktor: År:___, Måneder:____

Andre fenomener som hyppig ses ved Bekhterev (kryss av):

- Helsmerter (entesitt, akillestendinitt eller plantarfasciitt)
- Dactylitt ("pølsetå/finger")
- God respons på NSAID/COXIB

Demografiske data:

Kjønn: Mann: Kvinne:

Nåværende høyde: _____meter

Høyde som ung: _____ meter

Vekt:_____kg

Livvidde mål: _____ cm **BT**:_____ mmHg **Puls**:_____min

***Sivilstatus**: Enslig, gift/samboer, separert, skilt, enke/enkemann.

***Utdannelse**: <10år, 11-13, >13år,

***Arbeidsstatus:** Jobb :_____%, Sykemeldt: , Uføretrygdet: , Pensjonert:

Røyking: Aldri Røykte tidligere Røyker, Antall sigaretter pr dag:____.

Hvor ofte har du drukket alkohol de siste 30 dagene? Aldri, Ikke mer enn et glass per uke

2-6 glass per uke 7-14 glass per uke 14-21 glass per uke, Mer enn 21 glass per uke

***Noen i familien med Bekhterev sykdom? J/N, usikker, sannsynlig sikker**

Noen i familien med psoriasisleddgikt? J/N, usikker, sannsynlig sikker

Noen i familien med "IBD-relatert leddgikt" J/N, usikker, sannsynlig sikker

Andre revmatiske sykdommer i familien?: _____

Fysisk trening:

>3 timer/uke	o
1-3 timer/uke	o
mindre enn 1 time/uke	o
sjelden eller aldri	o

*Sykdomsaktivitet (selvrapportering) målt med:

*BASDAI (skala 0-10 for hvert spørsmål, 0 ingen problemer/plager)

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

I løpet av den siste uken, hvordan vil du beskrive

den generelle graden av utmattelse/tretthet du har erfart?

den generelle graden av smerter i nakke-, rygg eller hofter i forbindelse med Bekhterev sykdom?

det generelle nivået av smerte/hevelse du har hatt i ANDRE LEDD enn nakken-, ryggen eller hoftene?

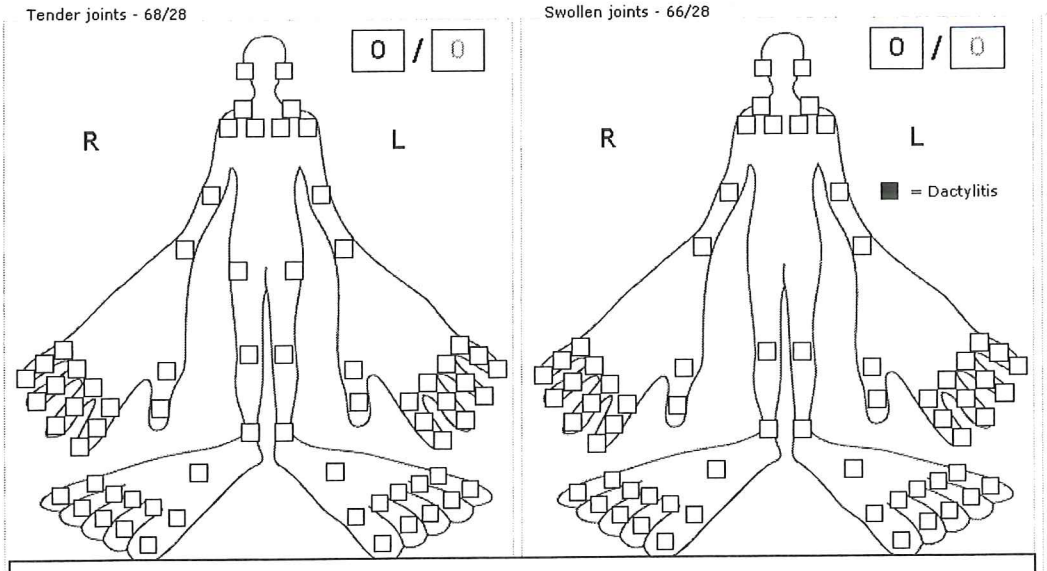
den generelle graden av ubehag du har hatt på eventuelle steder som gjør vondt ved berøring eller trykk?

den generelle graden av stivhet du har opplevd om morgenen fra det tidspunkt du våkner?

Hvor lenge varer morgenstivheten fra det tidspunktet du våkner?

BASDAI verdi:_____ Hentes fra selvrapportering i GTI!

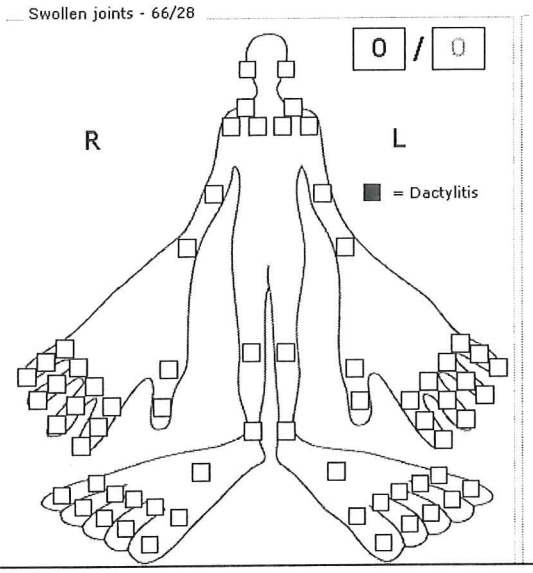
*Ømme og hovne perifere ledd ved aktuell u.s., (utføres av undersøker)



68 ømme ledd:_____ **66 hovne ledd:_____**

NB! registreres i GTI og på arket total sum føres opp!

Hovne perifere ledd (X) eller daktylitt (*) (historisk)?



66 hovne ledd:_____ registreres ikke i GTI kun her!
NB! sett kryss i figuren og merk event daktylitt! Total antall telles og føres opp.

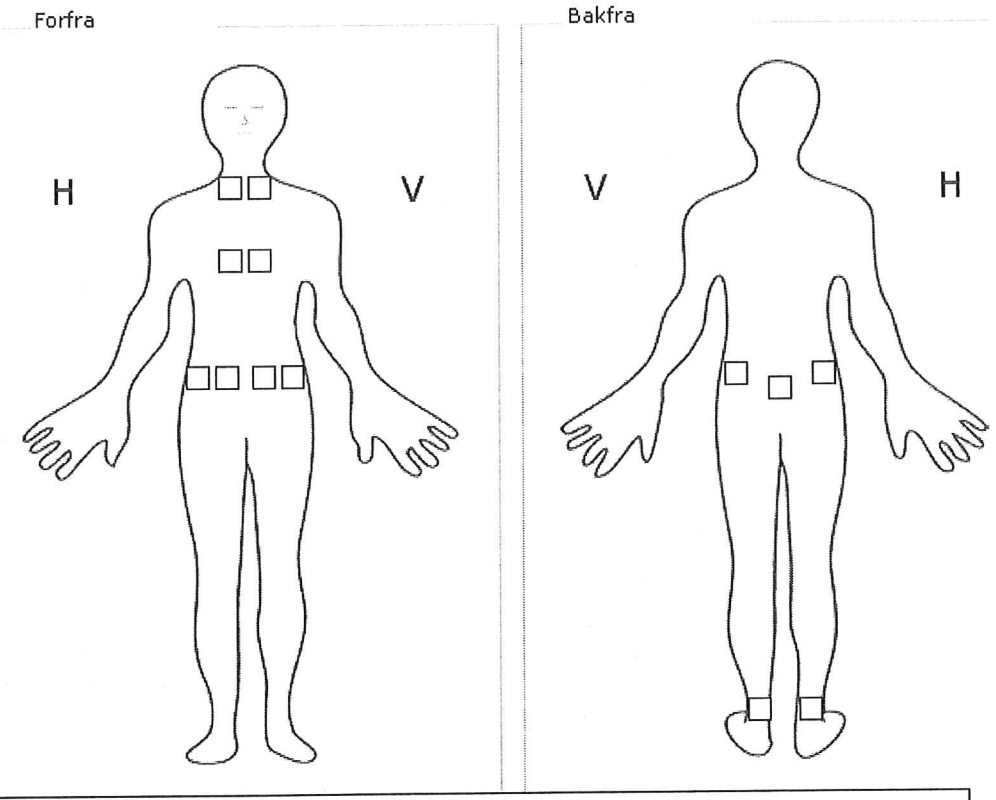
***Blodprøver:**
Følgende blodprøver tas også:

SR
CRP
Kolesterol
LDL
HDL
Triglyserider
HbA1C

BT systolisk
BT diastolisk

HLA-B27 (dersom det ikke er tatt!)

***Smerte i senefester (utføres av undersøker)**



Hjelpetekst kommer opp på GTI om du holder markør over u.s. stedet!
NB! registreres i GTI og på arket total sum føres opp!

Totalsum (0-13):_____

*Helsestatus (selvrapportering)

*Spørreskjema (HAQ, illustrasjon her er MHAQ)

I løpet av den siste uken, kunne du...	Uten problemer (0)	Med visse problemer (1)	Med store problemer (2)	Kunne ikke (3)
kle på deg selv, inkl. å knytte skolisser og å kneppe knapper?				
vaske håret?				
reise deg fra en stol m/rett rygg uten armlener?				
komme opp i og ut av sengen?				
skjære opp kjøtt?				
løfte en full kopp eller et fullt glass til munnen?				
åpne en ny melkekartong?				
gå utendørs på flat mark?				
gå opp 5 trappetrinn?				

HAQ verdi:_____ Hentes fra selvrapportering i GTI!

*Spørreskjema selvrapportering (skala 0-10 for hvert spørsmål, 0 ingen problemer/plager)

(BASFI)

BASFI Bath Ankylosing Spondylitis Functional Index

Siste uke hvordan klarte du å...

ta på strømper eller strømpebukser uten assistanse eller ved bruk av hjelpemiddel (for eksempel strømpe påtrekker)?

bøye deg forover fra midjen for å plukke opp en penn fra gulvet uten å bruke et hjelpemiddel?

nå opp til en høythengende hylle uten bruk av hjelpemidler (for eksempel gripetang)?

reise deg fra en spisebordsstol uten armlener eller annen hjelp?

reise deg opp fra liggende stilling på gulvet uten hjelp?

stå oppreist uten støtte i 10 min. uten å få ubehag?

gå opp 12-15 trappetrinn uten å bruke rekkverk eller gåstøtte (en fot på hvert trinn)?

se deg over skulderen uten å vri kroppen?

utføre fysisk krevende aktiviteter (for eksempel fysioterapiøvelser, hagearbeid eller sport)?

utføre en hel dags aktiviteter enten hjemme eller på arbeid?

BASFI verdi:_____
Hentes fra selvrapportering i GTI!

BAS-G Bath Ankylosing Spondylitis Global

Hvilken innvirkning har sykdommen hatt på ditt velbefinnende den siste uken?

Hvilken innvirkning har sykdommen hatt på ditt velbefinnen
månedene?

BAS-G verdi:_____
Hentes fra selvrapportering i GTI!

*Skade på skjelettet

***Funksjonsmål undersøkelse (trenet helsepersonell, registreres i GTI og her):**

Bath Ankylosing Spondylitis Metrology Index (BASMI)

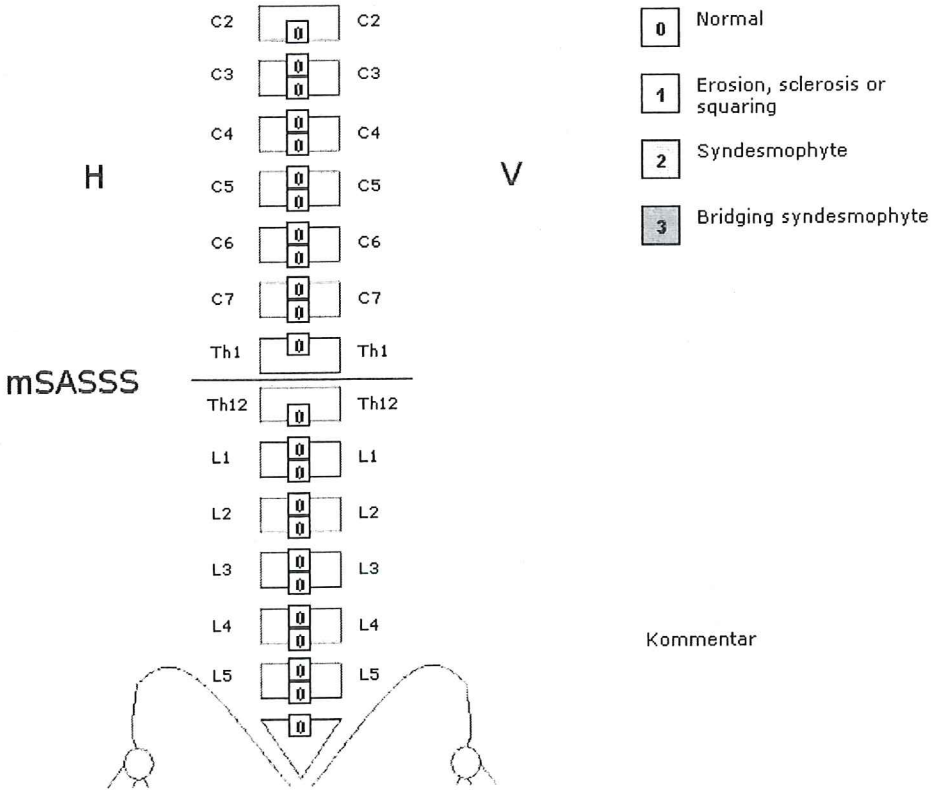
Cervical rotasjon:	°
Tragus (øregang) til vegg:	cm
Lumbal fleksjon (modifisert Schober's):	cm
Lumbal sidebøy:	cm
Intermalleolær avstand:	cm

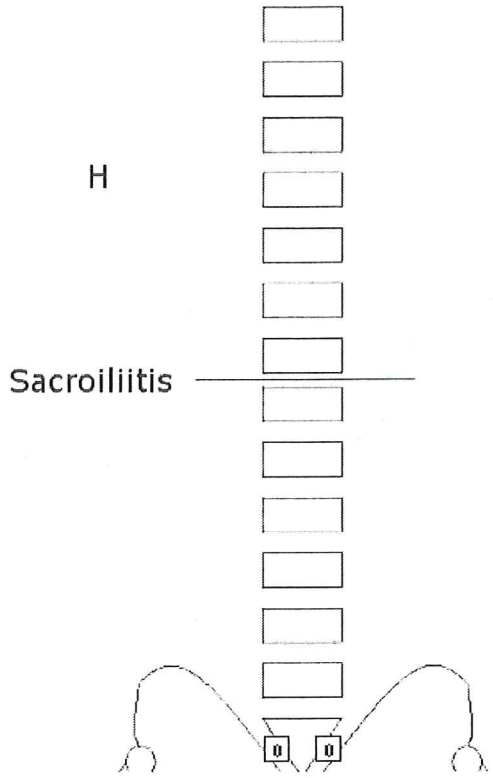
BASMI verdi:_____
Hentes fra selvrapportering i GTI!

Spinal mobilitet

Brystkasseutvidelse	Bakhode-til-vegg avstand	Schober's test
cm	cm	cm

***Rtg undersøkelse av ryggsøyle (cervical, thoracal lumbal i sideplan) og ileosakralledd**





0 Normal

1 Suspicious (no definite change)

2 Minimal (minimal sacroiliitis, defined as the loss of definition at the edge of the SI joints, some juxtaarticular sclerosis, minimal erosions, and possible joint space narrowing)

3 Moderate (moderate sacroiliitis, defined as definite sclerosis on both sides, blurring and indistinct margins, and erosive changes, with loss of joint space)

4 Severe (complete fusion or ankylosis of the joints)

Kommentar

*Andre manifestasjoner (regsitreres både her og i GTI):

Hvor mange ganger hatt uveitt/iridocyklitt:_____ Subjektivt visustap: J/N

Tilstedeværelse

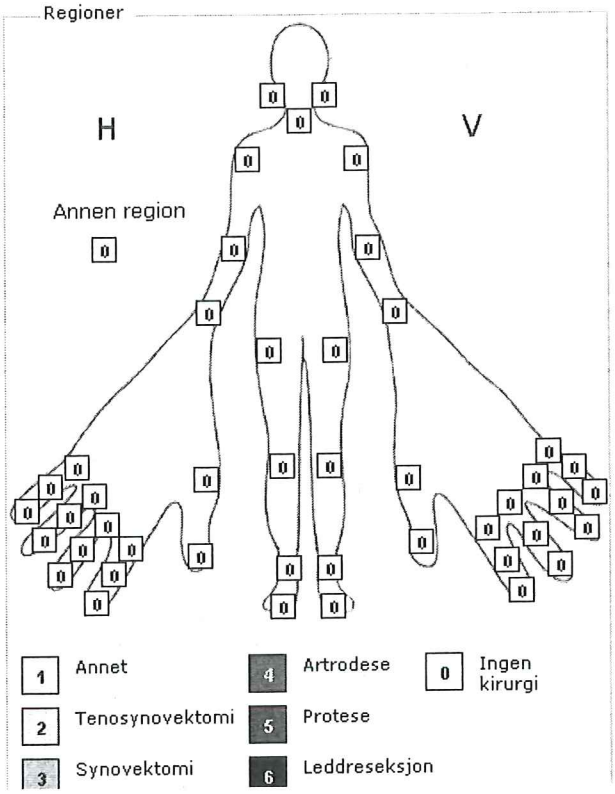
Ikke tilstede/ undersøkt 0

Mulig tilstede 1

Sikkert tilstede 2

Ak		Andre manifestasjoner	Kommentarer
0	0	Akutt fremre uveitt/iridocyclitt	
0	0	Aortitt/aortaklaffe insuffisiens	
0	0	Hjerterytmeforstyrrelse	
0	0	Inflammat. tarmsykdom (IBD)	
0	0	Psoriasis	
0	0	Lungefibrose/alveolitt	
0	0	Sekundær amyloidose	
0	0	Annet	

*Kirurgi status (regsitreres både her og i GTI)



Hvilke behandling har du fått for sykdommen (Oppdater også GTI!):

NSAID: Oppstart:_____ COXIB: Oppstart:_____ DMARD: Oppstart:_____

Biologiske medikamenter: Oppstart:_____ Omega-3 fettsyrer:

Paracet: Opiater: Fysioterapi: Egentrening: Varmtvannsbasseng trening:

Organisert gruppe fysioterapi i Norge: Behandlingsreiser i utlandet: Kiropraktikk:

Manuell terapi: Akupunktur: Homeopati: Annet: _____

Har du tilfredsstillende behandlingseffekt av NSAID/COXIB og eller fysioterapi: J/N

Synes du at du trenger bedre symptomlindrende effekt av behandlingen?: J/N

Hvor god symptomlindring gir NSAID/COXIB (0=ingen lindring, 10 komplett symptomlindring):__

Hvor god symptomlindring gir fysioterapi (0=ingen lindring, 10 komplett symptomlindring):__

Har du brukt eller bruker du noen av disse andre medikamentene:

o Folsyre oppstart:_____
o ACE hemmere oppstart:_____
o Statiner oppstart:_____
o Acetylsalicylsyre oppstart:_____
o Betablokker oppstart:_____
o Østrogener oppstart:_____

Hvilke medisiner har du brukt siste 10 dager?: _____

_____

_____

Annen sykdom (Komorbiditet, Oppdater også i GTI)

Angi hvilke av sykdommene nedenfor du har:

Hjertekarsykdom: Angina pectoris/bryst smerter: Diagnose når?:_____
Hjerteinfarkt: Antall:_____ Når:_____
Hjertesvikt
Arteriell hypertensjon: Når ble diagnosen stilt_____
Hyperkolesterolemi eller behandling for hyperkolesterolemi
Hjerteoperert, Dersom ja når (år):_____
Type operasjon:
Aortokoronar bypass, evt. antall operasjoner _____
PTCA/ Stenting, evt. antall ganger _____
Hjerteklaffoperasjon
Annet: :_____

Har du arvelighet for hjertekarsykdom? Angina pectoris, hjerteinfarkt eller akutt hjertedød hos

Kvinnelige 1. gradsslektninger <65 år
Mannlige 1. gradsslektninger < 50 år

Lungesykdom: Astma, KOLS, Annet:_____

Nevr. sykdom: Hjerneslag: Antall:_____ Når:_____
MS
Parkinson
Epilepsi
Annet:

Endokrin sykdom:
Stoffskiftesykdom: hypotyreose, hypertyreose
Diabetes mellitus: Når ble diagnosen stilt_____
Bruker insulin: ja o nei o

Hyperparathyreodisme
Annet:

Hemat. sykdom:_____

GI sykdommer:

Ulcus sykdom:
ulcus ventriculi, ulcus duodeni, ulcus duodeni og ventriculi
Inflamatorisk tarmsykdom: Mb.Crohn, Ulcerøs colitt)
Refluks sykdom
Annet:

Urogen sykdom: Nyresykdom, Annet: _____

Revm. sykdom: Inflam.leddsykdom:
RA, Bechterev, Psoriasis, Reaktiv, IBD, udiff.spondyl.
Andre: Collagenose Fibromylagi Urinsyregikt Artrose Annet ____

Kreftsykdom:
Første kreftdiagnose
Andre kreftdiagnose
Tredje kreftdiagnose

Mental lidelse:
Depresjon Manisk-depresiv Schizofreni Demens
Psyk. Utviklingshemmet
Annet:

Annet:
Alkoholisme
Synshemmet

Transplantasjon: _____

Osteoporose:

Arv

Har din mor hatt brudd etter 45-årsalderen? Ja Nei Ikke opplyst

Har din far hatt brudd etter 40-årsaldereren? Ja Nei Ikke opplyst

Hvor mange søsken har du? Antall: _____

Har en eller flere av dine søsken hatt brudd etter 40-årsalderen? Ja Nei Ikke opplyst

(Andre forhold?)

Spørsmål om kost

Hvor mye melk drikker du?:

Mer enn 0,5 liter daglig Mindre enn 0,5 liter daglig Sjeldent eller aldri

Ikke opplyst

Hvor ofte spiser du ost (antall høvlede osteskiver):

mer enn 3 skiver daglig , mindre enn 3 skiver daglig , sjeldent eller aldri □□, Ikke opplyst

Tar du vitamintilskudd Ja Nei Ikke opplyst

Tar du kalk Ja Nei Ikke opplyst □

Tar du D-vitaminer Ja Nei Ikke opplyst

Hormoner (Kun for kvinner)

Hvor gammel var du da du fikk din første menstruasjon? _____ år

Har du hatt uregelmessig menstruasjon? (manglende menstruasjon i lengre enn 3 måneder utenom graviditet) Ja Nei

Har du gjennomgått underlivsoperasjon? Ja □ Nei □

- I hvilken alder? _____ år

- Ble eggstokkene fjernet? Ja □ Nei □□□□□ vet ikke□□□□

Har du passert overgangsalderen? Ja, >6 måneder □ Ja, >12 måneder □□

□□□□□□Nei □□□□□□

□□Usikker□□

- Ved hvilken alder? _____ år

Har du tidligere hatt lavenergi brudd? Ja □ Nei □

Hva brakk du? Brudd 1:_____Alder:_____Brudd 2:_____Alder:_____

Brudd 3:_____Alder:_____Brudd 4:_____Alder:_____

Fall anamnese:
Antall fall siste år: □ Ingen, □ 1-3, □ 4 eller mer
Antall fall:_____

DEXA BMD målinger (Dato for u.s.:_____)

Lumbal kolumna (L2-4): _____g/cm2.T-score :_____ Z-score :_____
Lumbal kolumna (L1-4): _____g/cm2.T-score :_____ Z-score :_____
Venstre total hofte: _____g/cm2.T-score :_____ Z-score :_____
Høyre total hofte: _____g/cm2.T-score :_____ Z-score :_____

Rtg av ryggsøyle tatt □ (skores etter Genants semikvantitative metode)

Steroidebehandling

Har du brukt/bruker du steroider (mer enn 3 måneder):

Aldri Tidligere Nåværende Brukt siste året

Hvor lenge har du brukt Prednisolon? _____måneder

Høyeste dose som er brukt: _____mg

Vedlikeholdsdose:_____mg

Bruk av helsetjenester, ressurser:

Spørsmål knyttet blant annet til bosted og behov for helsetjenester:

Bosted siste året: Enebolig, Leilighet, Aldersbolig, Sykehjem, Pleie og omsorgs institusjon. Beskriv:_____

Bolig med: Trapper Heis

Hjelpebehov siste året (Helse ressursbruk):

Opphold i rehab. eller opptreningsinstitusjon: J / N, dager:_____

Almennpraktiserende lege: J / N: antall ganger:_____

Annen spesialist: J / N: antall ganger:_____Hvem:_____

Sykepleier på legekontor: J / N: antall ganger:_____

Fysioterapeut: J / N: antall enkelt behandlinger:_____

Ergoterapeut: J / N: antall enkelt ganger:_____

Sosionom: J / N: antall ganger:_____

Bassengtrening: J / N: antall enkelt ganger:_____

Trygghetsalarm: J / N

Sykehusinnleggelse siste år (telles ikke aktuell): J / N: ganger:____dager:____

Sykehjemsopphold siste år: J / N: antall dager:_____

Annen rehabiliterings institusjon J / N: antall dager:_____

Dagsenter: J / N: antall ganger pr uke :_____

Matombringing: J / N: antall ganger pr uke :_____

Blodprøver i løpet av siste år: J / N: antall:_____

Hjemmehjelp siste år: J / N: antall ganger pr uke :_____timer pr uke:_____

Hjemmesykepleier siste år: J / N: antall ganger pr uke :____timer pr uke:____

Hjelp av pårørende: J / N, Til hva:?_____

QUALITY OF LIFE

New 15D/Harri Sintonen

Pasient spørreskjema

Vennligst les gjennom alle svaralternativene til hvert spørsmål før du plasserer et kryss (x) for det alternativet som best beskriver din nåværende tilstand. Fortsett på samme måte for alle 15 spørsmålene. Gi bare ett svar på hvert spørsmål.

SPØRSMÅL 1. **BEVEGELIGHET**

1 ( ) Jeg er i stand til å gå normalt (uten vanskelighet) innendørs, utendørs og i trapper
2 ( ) Jeg er i stand til å gå uten vanskelighet innendørs, men utendørs og/eller i trapper har jeg litt problemer.
3 ( ) Jeg er i stand til å gå uten hjelp innendørs (med eller uten et hjelpemiddel), men utendørs og/eller i trapper bare med betydelig vanskelighet eller med hjelp fra andre.
4 ( ) Jeg er i stand til å gå innendørs kun med hjelp fra andre.
5 ( ) Jeg er fullstendig sengeliggende og ute av stand til å bevege meg omkring.

SPØRSMÅL 2. **SYN**

1 ( ) Jeg ser normalt, dvs. jeg kan lese aviser og tekst på TV uten vanskelighet (med eller uten briller).
2 ( ) Jeg kan lese aviser og/eller tekst på TV med litt vansker (med eller uten briller).
3 ( ) Jeg kan lese aviser og/eller tekst på TV med betydelige vansker (med eller uten briller).
4 ( ) Jeg kan ikke lese aviser eller tekst på TV hverken med briller eller uten, men jeg kan se godt nok til å gå omkring uten hjelp.
5 ( ) Jeg kan ikke se godt nok til å gå omkring uten en hjelper, dvs. jeg er nesten eller helt blind.

SPØRSMÅL 3. **HØRSEL**

1 ( ) Jeg hører normalt, dvs. normal tale (med eller uten et høreapparat).
2 ( ) Jeg hører normal tale med litt vansker.
3 ( ) Jeg hører normal tale med betydelige vansker; i samtaler må stemmer være høyere enn normalt.
4 ( ) Jeg hører selv sterke stemmer dårlig; jeg er nesten døv.
5 ( ) Jeg er helt døv.

SPØRSMÅL 4. **PUST**

1 ( ) Jeg er i stand til å puste normalt, dvs. uten å være kortpustet eller ha andre pustevansker.
2 ( ) Jeg er kortpustet under tungt arbeid eller sport, eller når jeg går raskt på flat mark eller i slak motbakke.
3 ( ) Jeg er kortpustet når jeg går på flat mark med samme tempo som andre på min alder.
4 ( ) Jeg blir kortpustet selv etter lett aktivitet, f.eks. når jeg vasker meg eller kler på meg.
5 ( ) Jeg har pustevansker nesten hele tiden, selv i hvile.

SPØRSMÅL 5. **SØVN**

1 ( ) Jeg er i stand til å sove normalt, dvs. jeg har ingen problemer med å sove.
2 ( ) Jeg har lette søvnproblemer, f.eks. vanskelig for å falle i søvn eller våkner av og til om natte
3 ( ) Jeg har moderate søvnproblemer, f.eks. forstyrret søvn eller føler jeg ikke har sovet nok.
4 ( ) Jeg har store søvnproblemer, f.eks. må bruke sovemedisiner ofte eller rutinemessig, eller våkner om natten og/eller for tidlig om morgenen.
5 ( ) Jeg lider av alvorlig søvnløshet, f.eks. er søvn nesten umulig selv med bruk av sovemedisiner, eller jeg forblir våken det meste av natten.

SPØRSMÅL 6. **SPISING**

1 ( ) Jeg er i stand til å spise normalt, dvs. uten hjelp fra andre.
2 ( ) Jeg er i stand til å spise selv med mindre vansker (f.eks. langsomt, kløhete, skjelvende, eller med spesielle hjelpemidler).
3 ( ) Jeg trenger noe hjelp fra en annen person for å spise.
4 ( ) Jeg er ute av stand til å spise selv i det hele tatt, slik at jeg må mates av en annen person.
5 ( ) Jeg er ute av stand til å spise i det hele tatt, slik at jeg mates enten med slange eller intravenøst.

SPØRSMÅL 7. **TALE**

1 ( ) Jeg er i stand til å snakke normalt, dvs. klart, hørbart og flytende.
2 ( ) Jeg har lette vansker med å snakke, f.eks. famler av og til etter ord, mumler eller endrer stemmeleiet.
3 ( ) Jeg kan gjøre meg forstått, men min tale er f.eks. oppstykket, nølende, stotrende eller stammende.
4 ( ) De fleste mennesker har store vansker med å forstå hva jeg sier.
5 ( ) Jeg kan bare gjøre meg forstått med fakter.

SPØRSMÅL 8. **VANNLATING/AVFØRING**

1 ( ) Min blære og tarm fungerer normalt og uten problemer.
2 ( ) Jeg har lette problemer med min blære- og/eller tarmfunksjon, f.eks. vansker med å urinere, eller løs eller hard avføring.
3 ( ) Jeg har betydelige problemer med min blære- og/eller tarmfunksjon, f.eks. "uhell" av og til, eller alvorlig forstoppelse eller diaré.
4 ( ) Jeg har alvorlige problemer med min blære- og/eller tarmfunksjon, f.eks. regelmessig "uhell", eller behov for kateterisering eller klyster.
5 ( ) Jeg har ikke kontroll over min blære- og/eller tarmfunksjon.

SPØRSMÅL 9. **VANLIGE AKTIVITETER**

1 ( ) Jeg er i stand til å utføre mine vanlige aktiviteter (f.eks. arbeid, studier, husarbeid, fritidsaktiviteter) uten vanskelighet.
2 ( ) Jeg er i stand til å utføre mine vanlige aktiviteter noe mindre effektivt eller med litt vanskelighet.
3 ( ) Jeg er i stand til å utføre mine vanlige aktiviteter mye mindre effektivt, med betydelig vanskelighet, eller ikke fullt ut.
4 ( ) Jeg kan bare klare en liten del av mine vanlige aktiviteter fra tidligere.
5 ( ) Jeg er ute av stand til å klare noen av mine vanlige aktiviteter fra tidligere.

SPØRSMÅL 10. **MENTAL FUNKSJON**

1 ( ) Jeg er i stand til å tenke klart og logisk, min hukommelse fungerer godt.
2 ( ) Jeg har litt vansker med å tenke klart og logisk, min hukommelse svikter meg av og til.
3 ( ) Jeg har merkbare vansker med å tenke klart og logisk, min hukommelse er noe redusert.
4 ( ) Jeg har store vansker med å tenke klart og logisk, min hukommelse er betydelig nedsatt.
5 ( ) Jeg er stadig forvirret og desorientert for sted og tid.

SPØRSMÅL 11. **UBEHAG OG SYMPTOMER**

1 ( ) Jeg har ikke fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
2 ( ) Jeg har lett fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
3 ( ) Jeg har tydelig fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
4 ( ) Jeg har alvorlig fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.
5 ( ) Jeg har uholdbart fysisk ubehag eller plager, f.eks. smerte, verk, kvalme, kløe etc.

SPØRSMÅL 12. **DEPRESJON**

1 ( ) Jeg føler meg overhodet ikke trist, melankolsk eller deprimert.
2 ( ) Jeg føler meg litt trist, melankolsk eller deprimert.
3 ( ) Jeg føler meg middels trist, melankolsk eller deprimert.
4 ( ) Jeg føler meg svært trist, melankolsk eller deprimert.
5 ( ) Jeg føler meg ekstremt trist, melankolsk eller deprimert.

SPØRSMÅL 13. **STRESS**

1 ( ) Jeg føler meg overhodet ikke engstelig, stresset eller nervøs.
2 ( ) Jeg føler meg litt engstelig, stresset eller nervøs.
3 ( ) Jeg føler meg middels engstelig, stresset eller nervøs.
4 ( ) Jeg føler meg svært engstelig, stresset eller nervøs.
5 ( ) Jeg føler meg ekstremt engstelig, stresset eller nervøs.

SPØRSMÅL 14. **LIVSKRAFT**

1 ( ) Jeg føler meg frisk og energisk.
2 ( ) Jeg føler meg litt sliten, trett eller svak.
3 ( ) Jeg føler meg middels sliten, trett eller svak.
4 ( ) Jeg føler meg svært sliten, trett eller svak, nesten utslitt.
5 ( ) Jeg føler meg ekstremt sliten, trett eller svak, totalt utslitt.

SPØRSMÅL 15. **SEKSUELL AKTIVITET**

1 ( ) Min helsetilstand har ingen ugunstig virkning på min seksuelle aktivitet.
2 ( ) Min helsetilstand har en liten virkning på min seksuelle aktivitet.
3 ( ) Min helsetilstand har en betydelig virkning på min seksuelle aktivitet.
4 ( ) Min helsetilstand gjør seksuell aktivitet nesten umulig
5 ( ) Min helsetilstand gjør seksuell aktivitet umulig.

SF-36 SPØRRESKJEMA OM HELSE

INSTRUKSJON: Dette spørreskjemaet spør om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å krysse av det alternativet som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1 Stort sett, vil du si helsen din er:

(Kryss av ett alternativ)
1 ☐ Utmerket
2 ☐ Meget god
3 ☐ God
4 ☐ Ganske god
5 ☐ Dårlig

2 Sammenlignet med for ett år siden, hvordan vil du si helsen din stort sett er nå?

(Kryss av ett alternativ)
1 ☐ Mye bedre nå enn for ett år siden
2 ☐ Litt bedre nå enn for ett år siden
3 ☐ Omtrent den samme som for ett år siden
4 ☐ Litt dårligere nå enn for ett år siden
5 ☐ Mye dårligere nå enn for ett år siden

3 De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er helsen din slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye?

	(Kryss av ett alternativ på hver linje) Ja, begrenser meg mye	Ja, begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a. Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	1 ☐	2 ☐	3 ☐
b. Moderate aktiviteter som å flytte et bord, støvsuge, gå tur eller drive med hagearbeid	1 ☐	2 ☐	3 ☐
c. Løfte eller bære en handlekurv	1 ☐	2 ☐	3 ☐
d. Gå opp trappen flere etasjer	1 ☐	2 ☐	3 ☐
e. Gå opp trappen en etasje	1 ☐	2 ☐	3 ☐
f. Bøye deg eller sitte på huk	1 ☐	2 ☐	3 ☐
g. Gå mer enn to kilometer	1 ☐	2 ☐	3 ☐
h. Gå noen hundre meter	1 ☐	2 ☐	3 ☐
i. Gå hundre meter	1 ☐	2 ☐	3 ☐
j. Vaske deg eller kle på deg	1 ☐	2 ☐	3 ☐

4 I løpet av de siste 4 ukene, har du hatt noen av følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	(Kryss av ett alternativ på hver linje) JA	NEI
a. Har du redusert tiden du har brukt på arbeidet ditt eller andre aktiviteter	1 ☐	0 ☐
b. Har du utrettet mindre enn du hadde ønsket	1 ☐	0 ☐
c. Har du vært hindret i visse typer arbeid eller andre aktiviteter	1 ☐	0 ☐
d. Har du hatt vanskeligheter med å utføre arbeidet ditt eller andre aktiviteter (f.eks. fordi det krevde ekstra anstrengelser)	1 ☐	0 ☐

5 I løpet av de siste 4 ukene, har du hatt noen av følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (f.eks. fordi du har følt deg deprimert eller engstelig)?

	(Kryss av ett alternativ på hver linje) JA	NEI
a. Har du redusert tiden du har brukt på arbeidet ditt eller andre aktiviteter	1 ☐	0 ☐
b. Har du utrettet mindre enn du hadde ønsket	1 ☐	0 ☐
c. Har ikke arbeidet eller utført andre aktiviteter like nøye som vanlig	1 ☐	0 ☐

6 I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

(Kryss av ett alternativ)
1 ☐ Ikke i det hele tatt
2 ☐ Litt
3 ☐ En del
4 ☐ Mye
5 ☐ Svært mye

7 Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene?

(Kryss av ett alternativ)
1 ☐ Ingen
2 ☐ Meget svake
3 ☐ Svake
4 ☐ Moderate
5 ☐ Sterke
6 ☐ Meget sterke

8 I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt vanlige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

(Kryss av ett alternativ)
1 ☐ Ikke i det hele tatt
2 ☐ Litt
3 ☐ En del
4 ☐ Mye
5 ☐ Svært mye

9 De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

(Kryss av ett alternativ på hver linje)

	Hele tiden	Nes-ten hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Følt deg full av tiltakslyst?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
b. Følt deg veldig nervøs?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
c. Vært så langt nede at ingenting har kunnet muntre deg opp?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
d. Følt deg rolig og harmonisk?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
e. Hatt mye overskudd?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
f. Følt deg nedfor og trist?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
g. Følt deg sliten?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
h. Følt deg glad?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
i. Følt deg trett?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

10 I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsesmessige problemer påvirket din sosiale omgang (som det å besøke venner, slektninger osv.)?

(Kryss av ett alternativ)
1 ☐ Hele tiden
2 ☐ Nesten hele tiden
3 ☐ En del av tiden
4 ☐ Litt av tiden
5 ☐ Ikke i det hele tatt

11 Hvor RIKTIG eller GAL er hver av de følgende påstander for deg?

(Kryss av ett alternativ på hver linje)

Påstander om din helse	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a. Det virker som om jeg blir lettere syk enn andre	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
b. Jeg er like frisk som de fleste jeg kjenner	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
c. Jeg forventer at helsen min vil bli dårligere	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
d. Helsen min er utmerket	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Spørsmål om seksualitet

Alle svarene dine vil bli behandlet strengt konfidensielt!

Hvor viktig eller uviktig er det å ha sex/seksualitet for at du skal være fornøyd med den daglige tilværelsen?

□ Meget viktig
□ Ganske viktig
□ Mindre viktig
□ Uten betydning

Har du større eller mindre glede av seksuallivet ditt nå enn tidligere, eller har du like stor glede av det?

□ Større
□ Mindre
□ Like stor glede
□ Tvil/vet ikke

Har du partner som du har sex med?

□ Nei □ Ja

Dersom du svarte Nei på spørsmålet "Har du partner som du har sex med?" vær så snill å svare på følgende spørsmål:
Jeg er ikke seksuelt aktiv for tiden av følgende grunner:
(sett kryss ved så mange svar som passer for deg)

□ Jeg har ingen partner for tiden
□ Jeg er for trett
□ Min partner er for trett
□ Jer er ikke interessert i sex
□ Min partner er ikke interessert i sex
□ Jeg har et fysisk problem som gjør seksuelle forhold vanskelig eller ubehagelig
□ Min partner har et fysisk problem som gjør seksuelle forhold vanskelig eller ubehagelig
□ Andre grunner

Dersom du svarte Ja på spørsmålet "Har du partner som du har sex med?" vær så snill å svare på følgende spørsmål:
Hvem tar vanligvis initiativet til og starter når du har seksuell kontakt/samleie?

□ Alltid jeg som gjør det
□ Som regel jeg
□ Like ofte jeg og den andre
□ Som regel den andre
□ Alltid den andre

Svar vennligst videre på spørsmålene nedenfor

Hvor mange ganger har du hatt seksuell kontakt/samleie de siste 4 uker?

□ Ingen ganger
□ 1 gang
□ 2-4 ganger
□ 5-10 ganger
□ 11 ganger eller flere

Synes du at du har seksuell kontakt samleie for ofte, passe eller for sjelden

□ For ofte
□ Passe
□ For sjelden

Alt i alt – hvor fornøyd er du med ditt seksualliv ?

□ Veldig fornøyd
□ Ganske fornøyd
□ Verken fornøyd eller misfornøyd
□ Litt misfornøyd
□ Misfornøyd

Hvor fornøyd er du med ditt seksualliv i dag med hvordan det var for fem år siden, er det da

□ Mye bedre
□ Noe bedre
□ Uforandret
□ Noe dårligere
□ Mye dårligere

Har du noen gang hatt seksuelle problemer som du har trengt hjelp til å løse **?**

□ Nei
□ Ja

Hva slags seksuelle problemer var det ? ***(sett så mange kryss du trenger)***

□ Manglende/lite lyst
□ Ogasmeproblemer
□ For tidlig utløsning
□ For sen utløsning
□ Smerter ved samleie
□ Reisnings-/potensproblemer
□ Tørrhet i skjeden
□ Følte med seksuelt avvikende
□ Manglende/liten seksuell interesse
□ Følelse av ikke å være attraktiv
□ Annet

Har du hatt noen av disse samme problemer den siste måneden, i så fall hvilke? ***(sett så mange kryss du trenger)***

□ Ingen problemer
□ Manglende/lite lyst
□ Orgasmeproblemer
□ For tidlig utløsning
□ For sen utløsning
□ Smerter ved samleie
□ Reisnings-/potensproblemer
□ Tørrhet i skjeden
□ Følte meg seksuelt avvikende
□ Manglende/liten seksuell interesse
□ Følelse av ikke å være attraktiv
□ Annet

Dersom du har/har hatt noen av problemene nevnt ovenfor, i hvilken grad vil du knytte dem til den sykdommen/tilstanden du har?

□ I meget stor grad
□ I noen grad
□ Ikke i det hele tatt.

Dersom du har/har hatt seksuelle problemer knyttet til sykdommen/tilstanden, skyldes de noe av det følgende (sett så mange kryss du trenger).

□ Tretthet
□ Stivhet
□ Smerter
□ Endring av kroppen
□ Endring i hvordan jeg føler andre oppfatter meg.
□ Bivirkning av medikamenter.

Spørreskjema om seksuell livskvalitet
(SQoL-F)

Dette spørreskjemaet består av en rekke utsagn som alle dreier seg om tanker og følelser som du kan ha om ditt seksualliv. Utsagnet kan dreie seg om enten positive eller negative sider ved seksuallivet ditt.

Du bes om å vurdere hvert utsagn etter hvor enig eller uenig du er i det ved å sette en ring rundt ett av seks svaralternativer.

Ved vurderingen av disse utsagnene, gjelder de følgende definisjoner:

Seksualliv: er både fysiske seksuelle aktiviteter og det følelsesmessige seksuelle forhold du har til din partner.

Seksuell aktivitet: omfatter enhver aktivitet som kan føre til seksuell stimulering eller seksuell nytelse, for eksempel samleie, kjærtegn, forspill, masturbasjon (dvs. at du selv masturberer eller at partneren masturberer deg) og munnsex (dvs. at din partner stimulerer dine kjønnsorganer med munnen).

Vanligvis er det første svaret som faller deg inn også det beste, så ikke bruk for lang tid på hvert spørsmål.

1. Når jeg tenker på seksuallivet mitt, er det en del av livet mitt generelt sett som jeg har glede av	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
2. Når jeg tenker på seksuallivet mitt, føler jeg meg frustrert	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
3. Når jeg tenker på seksuallivet mitt, føler jeg meg nedtrykt	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
4. Når jeg tenker på seksuallivet mitt, føler jeg meg mindre verd som kvinne/mann	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
5. Når jeg tenker på seksuallivet mitt, føler jeg meg fornøyd	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
6. Jeg har mistet tiltroen til meg selv som en seksualpartner	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
7. Når jeg tenker på seksuallivet mitt, føler jeg meg engstelig	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
8. Når jeg tenker på seksuallivet mitt, føler jeg meg sint	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
9. Når jeg tenker på seksuallivet mitt, føler jeg meg nær partneren min	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
10. Jeg er bekymret for hvordan det skal gå med seksuallivet mitt i fremtiden	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
11. Jeg har mistet gleden ved seksuell aktivitet	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
12. Når jeg tenker på seksuallivet mitt, føler jeg meg utilpass	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
13. Når jeg tenker på seksuallivet mitt, opplever jeg at jeg kan snakke med partneren min om ting som dreier seg om seksuallivet	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
14. Jeg prøver å unngå seksuell aktivitet	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
15. Når jeg tenker på seksuallivet mitt, føler jeg meg skyldig	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*

16. Når jeg tenker på seksuallivet mitt, er jeg bekymret for at partneren min føler seg såret eller avvist	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
17. Når jeg tenker på seksuallivet mitt, opplever jeg det som om jeg har mistet noe	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*
18. Når jeg tenker på seksuallivet mitt, er jeg tilfreds med hyppigheten på seksuell aktivitet	*helt enig*	*ganske enig*	*litt enig*	*litt uenig*	*ganske uenig*	*helt uenig*

Hvordan har du det?

Når smerter og andre plager har vart en tid, blir en gjerne sliten og oppgitt. Dette gir ofte slike plager som nevnt nedenfor. Samlet blir disse her brukt som mål på at en er legemlig og psykisk presset.
Vurder hvor mye hvert symptom har vært til plage eller ulempe for deg de siste 14 dagene (til og med i dag).
Sett ring rundt tallet som passer best. Husk å sette *en ring utenfor hver plage/hvert symptom.*

(sett ring rundt tallet)	Ikke i det hele tatt	Litt	En god del	Svært mye
1. Anklager deg selv for ting.	1	2	3	4
2. Følelse av håpløshet m.h.t. fremtiden	1	2	3	4
3. Føler deg nedfor.	1	2	3	4
4. Føler deg ensom.	1	2	3	4
5. Har tanker om å ta ditt eget liv.	1	2	3	4
6. Følelse av å være fanget.	1	2	3	4
7. Bekymrer deg for mye.	1	2	3	4
8. Føler ikke interesse for noe.	1	2	3	4
9. Føler at du ikke er noe verd.	1	2	3	4
10. Plutselig skremt uten grunn.	1	2	3	4
11. Føler du deg engstelig.	1	2	3	4
12. Nervøs eller urolig.	1	2	3	4
13. Hjertebank.	1	2	3	4
14. Skjelving.	1	2	3	4
15. Føler deg anspent eller opphisset.	1	2	3	4
16. Anfall av redsel eller panikk.	1	2	3	4
17. Rastløshet, kan ikke sitte rolig.	1	2	3	4
18. Har lett for å gråte.	1	2	3	4
19. Føler du deg svimmel eller kraftløs.	1	2	3	4
20. Hodepine.	1	2	3	4
21. Føler deg slapp og uten energi.	1	2	3	4
22. Tap av seksuell interesse/opplevelse.	1	2	3	4
23. Dårlig appetitt.	1	2	3	4
24. Vanskelig for å sove.	1	2	3	4
25. Føler at alt krever stor anstrengelse.	1	2	3	4

HSCL-25