Evidence-Based Self-Management for Spondyloarthritis Patients

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Abstract—We present a concept including a set of tools for self-management for patients suffering from axial spondyloarthritis (SpA). This concept involves patient-recorded outcome measures, both subjective assessment and clinical measurements, that are used to present recommendations. We report from experiences made while implementing a proof of this concept and analyse it from several perspectives. Our work resulted in proposing a self-management tool for the patient, improving the methodology for clinical measurements of rotation exercises, and proof the viability for using on-board sensors in smart phones. Further, since sensors collect data in a medical setting, we present ethical considerations.

Keywords—axial spondyloarthritis; self-management; health care; self-assessment; evidence-based; mobile applications; sensors; ethics.

I. INTRODUCTION

In our previous work [1], we presented a concept for evidence-based self-management of patients suffering from axial SpA. We have updated this concept and extended the implementation of a smart phone and sensor-based system that can give recommendations to the patients as support for self-managing their condition.

For a variety of chronic diseases, patients managing the condition themselves (self-management) can result in reduced costs in the health care sector and an improved clinical outcome [2]. Self-management encompasses methods where the patients participate in managing their disease through education and changes in behaviour and lifestyle [3] [4]. In evidence-based self-management, elements such as clinical assessment, collaborative priority and goal-setting, patient self-efficacy, and active follow-up are essential [5]. We look closer at self-management settings [6] where patients assess the status of their disease using sensors and questionnaires on their smart phones and report the results (i.e., patient-reported outcome measures) [7] [8]. Based on these measurements and self-reported outcomes patients receive non-pharmacological recommendations from the self-management system to increase their coping skills, help with pain management, adhere to their medication regime, improve self-care behaviours, and enact lifestyle changes.

Spondyloarthritis (SpA) describes a group of several related, but phenotypically distinct rheumatic diseases, such as ankylosing spondylitis (AS). The condition axial SpA is characterised by inflammatory back pain and mainly affects the axial skeleton, which is distinct from peripheral SpA where the symptoms are mainly arthritis, entesitis, or dactylitis. In axial SpA, the first appearance is mainly in young adulthood and can lead to structural and functional impairments and a decrease in health related quality of life. Although axial SpA is a chronic condition, the symptoms and disease activity vary over time [9] [10]. The primary goals for managing axial SpA are to maximise long term health-related quality of life by managing symptoms and inflammation, preventing progressive structural damage in the spine, and normalising function and social participation. Relevant medication and non-pharmacological treatment such as physical training are recommended as the foundation of the management of axial SpA [11] [12].

Currently, there are few evidence-based self-management tools for axial SpA. Some tools for subjective assessment exist, but sensor-based tools for objective assessment are not yet available to the wider public. Also, there are obstacles to let patient-assessed data be of use in a clinical setting [13].

This paper extends our concept for evidence-based self-management of axial SpA. This concept is supported by an implementation of a smart phone and sensor-based system that can give recommendations to the patients. We report from experiences from this implementation. We also perform an ethics assessment and risk analysis of our concept.

The remainder of this paper is organised as follows: After a brief presentation of related work (Section II) and presenting our concept of self-management for axial SpA patients (Section III), we show details from the proof of concept implementation involving subjective and sensor-based clinical assessment and recommendations to the patient (Section IV).
Fig. 1: Concept for managing the disease with the three parts: self-management, clinical assessment, and patient-health personnel communication.

Then, we present the results from a usability test (Section V). Further, we look into regulatory issues, ethical challenges, and perform an informal risk analysis that identifies functionality that needs to be implemented before productification of our concept can be done (Section VI). Finally, we discuss our findings (Section VII) and conclude in Section VIII.

II. RELATED WORK

For the management of most chronic illnesses the patients and their carers have an extensive responsibility regarding adherence to the treatment plan, lifestyle changes, taking preventive actions, etc. Newman et al. [14] presented a literature review of self-management interventions for chronic illnesses, here under arthritis, asthma, and diabetes. They reported about the content of interventions as well as outcomes. Note that since Newman et al.'s review in 2004 new concepts for self-management have been developed, specifically those that make use of emerging technologies, such as smart phones, sensors, and actuators.

A. Self-Management

We find multiple definitions of self-management in the literature. The term self-management covers all means of empowering individuals to cope with disease and experience a high quality of life by developing self-efficacy. Self-management also refers to an individual’s ability to manage the symptoms, treatment, physical, psychosocial, and lifestyle changes inherent in living with a chronic condition [15]. In this context, self-efficacy is the individual’s level of confidence in succeeding to cope with that individual’s chronic disease.

Intervention elements used in self-management often include education, follow-up strategies, motivational counseling, and individualised care plans. Johnston et al. [15] presented a literature review showing success factors and limitations of self-management.

Considerable work has been done on self-management programs for chronic diseases with good results in terms of quality of life, and reducing the need for care and cost efficiency [16]. Programs such as The Chronic Disease Self-Management Program have shown significant improvement in health distress and increased perceived self-efficacy [17]. The motivation for these programs is to provide people with chronic diseases the tool to efficiently manage their own condition.

We prefer the definition of self-management by Barlow et al. [18] “…the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition.” Barlow et al. stressed that monitoring one’s condition and the effect of responses to daily life can lead to a dynamic and continuous process of self-regulation.

B. Mobile eHealth Apps

The number of mobile health (mHealth) apps available to consumers exceeded 165 000 in 2015 [19] and is still growing. According to this report, two-thirds of these apps are related to wellness management, i.e., fitness, lifestyle, diet, and nutrition. Further, a quarter of these apps are related to disease and treatment management; about 9% of the total number of apps is disease-specific. About 6-7% of the disease-specific apps relate to musculo-skeletal diseases, where SpA is placed.

Dimensions of app-functionality include a) to inform, b) to instruct, c) to record, d) to display, e) to guide, f) to remind, and g) to communicate [19]. For evidence-based concepts, aspects c to g are of most relevance.

We have found management support for some chronic conditions using information and communication technology (ICT). These include: a self-management application called SoberDiary for alcoholism [20], a programme for quitting smoking [21], a programme for psychology support [22], a mobile application for diabetes that integrates with personal smart watches [23], a virtual coach for chronically ill elderly [24], a smart phone app for rheumatic diseases management [25]. There are also generic apps for integrating vital signs into personal health devices or electronic medical record systems [26].

A review of the effectiveness of multiple European eHealth initiatives concluded that while eHealth can be very effective, certain criteria need to be fulfilled for the success of such interventions [27].

Within axial SpA there are ICT apps like SpA Helper [28] that supports to monitor the disease. When SpA Helper is used, the results from the monitoring are not part of a feedback cycle, such as the treat-to-target principle (see Section III-A). There are also a variety of web-based calculators that implement the subjective clinical indices.

C. Sensors

There is extensive research on using sensors for tracking physical activity that ranges from physiological wearable sensors to the using mobile phones for tracking activities [29]. In recent years, we observed an increase in the number of dedicated activity trackers like FitBit Charge or Garmin Vivosmart. Research and user-testing have been conducted to monitor physical activity in a non-obtrusive manner, but more
research is needed to investigate which methods and devices work best for different demographics [30].

In general, sensors can only measure physical or physiological data that represent the patient’s physiological reactions or data from the environment, i.e., context information about the user. Subjective data still need be retrieved using questionnaires or similar methods. Note that technologies such as brain-computer interfaces (BCI) [31] are too obtrusive. Further, the BCI technology is still in an early state.

Often sensors measuring factors that can determine emotions (such as cameras, sound analysis, or skin conductance in the research field of affective computing [32]) can be used for well-being applications. Such technologies have been used to assess emotions of visitors in science centers [33]. However, for the purpose of assessing a single person’s state, there is only a statistical correlation between mood recognised by an algorithm and a person’s real state. Thus, such measurements cannot be used as input for medical decisions in the treatment of axial SpA.

III. A SYSTEM ARCHITECTURE FOR SELF-MANAGEMENT

Our concept is based on medical principles that are applied to a computer-based system with several components: sensors, smart phone, a health cloud, patient records and communication between these components. The system architecture addresses medical principles, restrictions caused by technical reasons, and policies by the stakeholders.

A. Integrating Treat-To-Target

A treat-to-target method [34] has been developed for treating axial SpA. This evidence-based method is used after diagnosis and early treatment, when the disease has reached a stable state (Fig. 1). At this stage, an individual treatment plan has been created for the patient. This method uses a treatment goal (target) for a treatment plan. Following the treatment plan and regularly assessing the patient’s status provides evidence about how the disease develops. When the patient’s status moves away from the treatment target to a worse condition, health personnel, in discussion with the patient, might adjust the treatment plan or target.

As part of an evidence-based, self-management setting, the treat-to-target method is extended so the patient can perform self-assessment to gather evidence about the current disease condition by performing assessments, answering questionnaires, and following the progress from the patient diary. The patient diary data can be used for patient-health personnel communication by making it available to the clinical personnel, either regularly or when needed (e.g., a patient visit).

Fig. 2 shows how treat-to-target can be aligned with self-management. The upper unshaded part of the drawing is the health personnel domain. This is where health personnel perform clinical assessments and decide the treatment target and treatment plan. The lower shaded part is the patient’s domain. This is where the patient can perform assessments, compare with the target, and adjust some elements of the treatment.

B. An Architecture for axial SpA Treatment

Our concept (Fig. 3) builds on a) a solution for self-management, b) better quality and effectiveness of clinical assessment, and c) enhanced patient-health personnel communication.

The solution for self-management lets the patients use tools at home to manage the disease. It includes patient-reported outcome measures [8], the assessment of ample parameters, the use of a patient diary [35], patient guidance with respect to the treat-to-target principles, and alerts in case of changes in the patient’s condition or physical function.

The concept also enhances the quality and effectiveness of clinical assessment; assessment methods developed for self-management are made available for clinical assessment.

The concept includes a foundation for patient-health personnel communication. Self-reported assessments can be used for patient-health personnel communication to explain or visualise the development of the disease and data transfer to the hospital.

C. The Health Cloud

Our concept uses a health cloud to facilitate persistent storage, and as a means to communicate data to the health care personnel. Although this is an extra component, there are several reasons for this health cloud: a) persistence and storage of health data and keep data consistent over several devices the patient might use; b) give the patient ownership over the patient data and the possibility to structure these after the patient’s own decisions; c) give the patient the possibility to exchange clean data to the health authority’s system (e.g., patient records) at the patient’s discretion; and d) give the
patient the possibility to store data also when health authorities have not (yet) implemented such possibilities.

Although we have considered exchanging data between the health cloud and the patient records, we have not implemented this functionality even though this would have been possible in Norway. Extra costs that were not funded during the research project are the main reason for this. However, issues like data quality, data ownership, security, privacy, policy, and standardisation need to be considered before implementing such data exchange.

Note that without such communication, the health personnel can get access to the patient data either by accessing the data on the patient’s smart phone or by accessing the health cloud via a specifically authorised interface. We also note that introducing a further interface beyond the patient records will probably not be a success criterion in the introduction of our concept. To our experience, health personnel will not be willing to take further interfaces into use. Colleagues of some of the authors at Diakonhjemmet Hospital and the Hospital of Southern Norway were interviewed, and they made it clear that introducing further special purpose interfaces would distract them from their daily work. Thus, implementing the API between the health cloud and the health records will be the only long-term option.

D. Development Methodology

The concept and implementation of our prototype was performed interdisciplinarily as an innovation project in the public sector, where major parts of the health care sector in Norway belong. The development team included health care personnel specialising in rheumatology and physiotherapy at hospitals. They could also draw on the expertise of their colleagues. The development team also included two representatives from the Norwegian Rheumatology Association to give the team a user-centred design focus. Further, computer scientists, programmers, and developers were involved in the work that also included technical and medical evaluations.

IV. PROOF OF CONCEPT FOR AXIAL SP A

The parts of this architecture that include data exchange between a health cloud or a patient’s devices and the electronic health record (EHR) system are beyond the scope of our work. These are parts that rely on policies defined by public health care providers. So, we focused on implementing tools for clinical assessment and self-management.

A. Medical Assessment Methods for axial SpA

Medical self-assessment is essential for evidence-based self-management. So, these self-assessment methods should be based on medical assessment methods since evidence for their effectiveness is documented.

The AS Disease Activity Score (ASDAS) is used for measuring and monitoring disease activity in axial SpA. It is based on a composite score of domains relevant to patients and clinicians, including both self-reported items and objective measures [36].

The Bath indices [37] present outcome measures for use with axial SpA patients, and consist of four indices: the Bath AS Metrology Index (BASMI), the Bath AS Functional Index (BASFI), the Bath AS Disease Activity Index (BASDAI), and the Bath AS Patient Global Score (BAS-G). These indices are designed to give a good clinical assessment using a minimum number of measurements or questions to be answered. The BASMI is five simple clinical measurements; the other indices consist of a number of questions that are answered on a numeric scale from zero to ten [38].

Østerås et al. [39] described a set of assessment tests as candidates for axial SpA self-assessment. These exercises are: lateral spinal flexion, modified Schober’s, cervical rotation, occiput to wall distance, tragus to wall distance, intermalleolar rotation around the vertical axis, lumbal and thoracic rotation, six-minutes walking test, stair climb test, sit-to-stand test, fingertip-to-floor test, and maximum grip strength test.

B. Requirements for Sensor-based Self-assessment

Clinical measurements for self-assessment must, ideally, be implemented in a way that allows the patient to operate the measurement at home and without assistance. As patients with axial SpA have or may develop a restricted range of motion, the equipment needs to be designed so that it is possible for the target group to use and setup any devices without assistance.

Further, the measurements must be designed so that incorrect operation by the patient is unlikely when performing the exercises and measuring. If possible, deviations should be recognised by the system, indicated to the patient, and transferred measurement results should be marked as invalid.

To implement these measurement processes, we can use a variety of sensor types, such as inertial sensors for movements, magnetic sensors, cameras, and microphones. Sensors built into, e.g., smart phones or smart-watches, can be used for such measurements if this is practical. External devices, often connected via a wireless medium, e.g., Bluetooth, can be better adapted to certain types of measurements and, thus, deliver more precise results. Further, there are specific external devices for measurements where suitable sensors are unavailable in standard smart phones, e.g., sensors for diabetes. For some exercises, training equipment with built-in sensors (spinning machine) could be used. Most specific sensors could be implemented with connectivity to a smart phone (e.g., communication protocols using Bluetooth, ANT+, or similar).

For some types of measurements, the built-in sensors of smart phones could be used, e.g., the measurement of the heart rate of a person using the LED-flash and camera of a smart phone [40]. Further, inertial and magnetic sensors, camera, and microphone could be used to implement measurements [41] [42]. There is a variety of training-related apps that make use of both internal sensors as well as external sensors and training armbands. As a note, the use of GPS-positioning seems less useful for self-management for axial SpA patients.

Consumer devices that are currently available include smart-watches and bracelets. Some of these are programmable and
have ample sensors on-board. Such devices are unobtrusive and can be used in most daily-life situations.

We foresee that new unobtrusive devices and sensors will be developed and integrated into textiles and spectacles that can be worn by the person. Alternatively, they may even implanted into the person. But with these new devices arise ethical problems that could violate the rights of the person or third parties. Thus, suitable counter-measures need to be taken to avoid this.

C. Implementing Exercises for Self-Assessment

Considering the exercises to assess axial SpA conditions, we can consider classes of exercises where the form factor needs to be adapted for the specific exercise.

1) Limb Movements and Position: Exercises that assess the relative position of limbs after a movement (e.g., the spinal lateral flexion or the fingertip-to-floor test) can be implemented using an inertial sensor. For the assessment, the sensor is attached to the limb; the position is assessed in the reference position, the movement is performed, and the position after the movement is assessed. The distance between these positions is reported. Challenges for such assessments is how to attach the sensors and the user interface (how to trigger the assessment).

Using a camera and employing image processing algorithms would be another solution [43]. Zhao et al. [44] presented such a system to track health workers’ positions while carrying out their work with patients. However, placement of the camera, lighting conditions, and physiological conditions (body shape) can result in challenges and reduced accuracy.

2) Rotation Exercises: Exercises that include circular movements of body or limbs (e.g., cervical, lumbar, thoracic movements; intermalleolar rotation around the vertical axis) can be implemented using an inertial sensor and, to a certain degree, a magnetic sensor. For the assessment, the sensor is attached to the body part to be rotated, a reference position is assessed, the movements are performed, and, at each of the extreme points, the relative movement is assessed.

3) Exercises that Need Specific Devices: For several of the exercises the assessment requires either specific sensors or external assistance. The modified Schober’s assessment measures differences in the length of the spine. This measurement cannot be performed without the assistance of a physiotherapist. However, the fingertip-to-floor test is correlated with the modified Schober’s test [45].

Assessment of the distances of the tragus or occiput to the wall could be implemented using some specific device, e.g., using a ruler; this, however, is beyond the scope of our project. Further, the assessor needs to ensure that both heels and back touch the wall for a correct assessment [38].

The maximum grip strength test is used to determine muscle strength. Currently, it can only be implemented using specific sensors or devices such as a dynamometer.

4) Tests for Health-Related Physical Fitness: Exercises that assess health-related physical fitness seem at first glance rather easy to implement. But as we shall see, there are several issues with these tests.

For the sit-to-stand test (also called the 30-second Chair Stand Test or 30s CST), the patient is given 30 seconds to complete as many full stands as possible starting from a seated position with arms folded across the chest. Such assessments can use the same principle as the limb movements, counting the number of up- and down movements. However, with this method it is not evident whether these movements have been only partially performed. We note that this test could be used for self-management due to its simplicity.

The six-minutes walking test (6MWT) is an inexpensive and simple walking test that can be used as a predictor of aerobic fitness or for assessing the sub-maximal level of functional capacity. Following the American Thoracic Society guidelines [46], patients are instructed to walk as fast as possible back and forth between two cones 15 meter apart on a flat, hard surface for six minutes. The walking distance is measured in meters. During the test, the heart rate is recorded with a heart rate monitor, and perceived exertion can be measured with Borg’s rating of perceived exertion (RPE) [47].

The test is claimed to be most useful in patients with at least moderately severe impairments while other more well-functioning populations may exhibit a ceiling effect since the test is limited to a patient’s walking speed.

While there is a variety of sensors that could be used to implement an assessment, including indoor positioning, inertial sensors, step counters, the most important question is whether the necessary space to perform such an exercise is available in the patient’s home. If available, e.g., some patients might have access to a corridor to perform the exercise, patients might not want to use this in a space that is not private.

In the stair climb test (ST) [48], the patient is asked to ascend and descend 50 normally sized steps with three landings in-between as quickly as possible, also measuring the heart rate. This test could be implemented using step counters or intertial sensors. Note that not all patients might have access to suitable stair steps.

D. Sensor-based Clinical Measurements

APERTUS developed a sensor that can measure rotation around the vertical axis such as cervical rotation, thoracic rotation and hip abduction (measured in the supine position). The Apertus sensor was developed by engineers in close collaboration with health professionals and patients with axial SpA in a process with discussions, development of prototypes and (re-)testing.

The result can be transmitted via a wireless connection to a receiver, such as PC, tablet, or smart phone. This inertial sensor is packaged in a small box (Fig. 4) that can be attached
to the body. The size of the device is 55mm × 35mm × 3mm. The sensor contains radio technology that follows Bluetooth standards that might influence electronic devices in 2.4 GHz ISM, but to a significantly lower degree than mobile phones.

Compared with other technology such as lasers or optical sensors, this sensor’s advantages include its high precision and being cheaper, smaller, and lighter than the other solutions. Compared to the traditional way of measuring rotation with a goniometer or myrinometer (e.g., compass) the sensor provides more precise measurements. The sensor is a simple way to achieve satisfactory measurements in acceptable use of time and without health personnel assisting.

The Apertus sensor was tested in a laboratory setting and the data collected was compared with Cybex 6000 simulation data as gold standard. The sensor was mounted to the cybex with a bracket in six different positions: 1) straight up; 2) straight down; 3) up, tilted 30° around the frontal axis; 4) down, tilted 30° around the frontal axis; 5) up, tilted 30° around the frontal axis, 20° around the sagittal axis; and 6) down, tilted 30° around the frontal axis, 20° around the sagittal axis. Reference angles were set at approximately 10, 30, 60, 90 and 120 degrees. From a center position the sensor was moved from left to right (one cycle) by manual force at the speed allowed (60° s⁻¹) until stop brackets were reached. Criterion validity and reliability for single measures and for the mean of three trials (left, right or cycle) was evaluated with two ways mixed interclass correlation coefficient (ICC).

Limits of agreement (LoA) (Bland and Altman method), and smallest detectable change (SDC95%) with 95% CI were calculated to evaluate the measurement error of the sensor. The sensor showed excellent criterion validity and reliability for rotation around the vertical axis in the range of motion from 10° to 120°. The angle can be measured with a precision of ±0.87 for one measure and 0.80 for the mean of three measures. When assessing a single cycle or the average of three cycles, a change of 1 degree is needed for real change beyond measurement error. These findings justify proceeding with further evaluations of the sensor for this kind of measurements [49] [50]. A clinical trial of the rotation measurements with 60 patients suffering from axial SpA is currently under evaluation.

We developed a suitable user interface for the assessment process with the sensor. The assessed data are stored locally in the patient diary and forwarded to the health cloud for permanent storage.

E. Smartphone-based Self-Management Measurements

Self-management based on smart phone platforms carries some benefits over dedicated third-party measuring devices. The user is likely to be more familiar interacting with a personal phone than any new measuring instruments. Moreover, the convenience of using a device already carried may significantly increase user acceptance and on-boarding. Further, by taking advantage of accurate high quality built-in sensors already available on smart phone platforms, the extra cost of acquiring measuring instruments can be avoided.

As a proof of concept, an Android app has been developed that allows the user to measure cervical rotation, thoracic rotation and hip abduction using the phone’s internal gyroscope. When starting a new measurement the phone can be positioned on the forehead (using, e.g., a regular head band) or in a pocket on the torso or on the hip. When activated, the app gives sound queues at regular intervals indicating when the user should turn forward, turn left, turn forward, turn right, and turn forward again. The sound queues allow for the use of the app during rotational exercises when the screen is not visible to the user. At the end of the measurement the user is presented with the results and given an option to save the data, allowing tracking of trends over time. The basic elements of the user interface are shown in Figure 5.

Low sensor accuracy and lack of uniformity represent potential drawbacks of the smart phone approach when compared to the use of dedicated sensors. A gyroscope sensor has been available on the Android platform since version 2.3 (API 9). In contrast to the iPhone, where hardware is largely homogeneous and standardised, the quality of sensors on an Android phone can differ greatly between manufacturers. However, some universal requirements exist for licensed Android smart phones. As of 2016, gyroscopes on licensed Android 7.0 devices are required to be calibrated, persistent between reboots, temperature compensated, have a resolution of at least 12 bits and a variance of no greater than 1 × 10⁻⁷ rad² s⁻¹ (or approximately 0.02 deg/√s). However, all gyroscopes will exhibit a drift over time, and on low-end devices this drift can potentially influence angle measurements.

To quantify the potential inaccuracy when using built-in smart phone gyroscopes for the measurement of cervical rotation, a simple experimental procedure was carried out. The prototype app was installed on four different smart phones of varying age: Sony D5803, Sony D6603, Samsung S3 and Samsung S8. The newest phone in the test was the Samsung S8 (released April 2017) and the oldest was the Samsung S3 (released May 2012). The phones were rotated 30°, 60°, and 90° at a radius of 0.1 m with a rotation time from the neutral...
TABLE I: The bias and standard deviation of the measurement error in degrees using the proof of concept Android app with gyroscope for measuring cervical rotation of 30°, 60°, and 90° with different phones.

<table>
<thead>
<tr>
<th>Phone</th>
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<td>0.68</td>
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<td>Samsung S8</td>
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<tr>
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<td>0.86</td>
<td>-0.72</td>
<td>1.00</td>
<td>-1.05</td>
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TABLE II: The bias and standard deviation of the measurement error in degrees using the proof of concept Android app with accelerometer for measuring cervical rotation of 30°, 60° and 90° with different phones.

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<td>14.26</td>
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position of about 1 s. The rotation was alternated between left and right and the experiment was repeated 10 times per device. In each case the difference in the angle measured by the app, \( \Theta_i \), and the known angle of rotation, \( \Theta_0 \), was recorded. Table I shows the bias

\[
\bar{\Theta} = \frac{1}{N} \sum_{i=1}^{N} (\Theta_i - \Theta_0)
\]  

(1)

and the standard deviation

\[
\text{STD} = \sqrt{\frac{1}{N} \sum_{i=1}^{N} (\Theta_i - \bar{\Theta})^2}
\]  

(2)

in degrees when using the different Android devices.

The results shown in Table I indicate that the overall measure error when using smart phone built-in gyroscope is of a comparable magnitude as the error reported in the sensor-based clinical measurements. Overall, the error was measured to be 0.61° to 1.48°. As expected, the error (STD) is somewhat larger for greater rotation angles and for the older of the phones tested (Samsung S3).

We observed also that some devices seem to produce useful results for angles up to 90°, but show large deviations for angles above. This is one of the reasons why we changed the measurement procedure for the rotation exercises to measure maximum 90°, rather than up to 180° as done in our first implementation.

While more rigorous testing is required before such a mobile application can be put into use, our tests indicate a clear potential of using smart phone built-in gyroscopes for measurement of cervical rotation.

Some (older or less sophisticated) smart phones come without a built-in gyroscope. For such cases one can consider using the phone’s accelerometer to estimate the arc length when rotating the phone, and calculating the rotation angle using an assumed radius. The angular inaccuracy for this approach was estimated using two different smart phones and the same experimental setup as used previously. Table II shows that the inaccuracy caused by accumulated accelerometer noise when using such a method renders this approach unfeasible. As a note, we also tested other smart phones such as the Samsung S3 and S8, but the results were entirely unusable and, thus, omitted from the table. It should be noted that the results when using accelerometer will to some degree depend on the algorithm used to compute the angle and may be improved upon. In this test a first-order Euler integration was carried out to get the arc length when rotating. The angle was obtained assuming the 0.1 m rotation radius.

In summary, a number of the self-assessment tests identified by Østerås et al. [39] can, potentially, be carried out using a smart phone platform. For example, one can envisage the measurement of the six-minutes walking test, the stair climb test and the sit-to-stand test using the phone’s built-in accelerometer combined with voice instructions. Future work includes extending the proof of concept self-management Android app to also include some of these features.

F. Self-Assessment of Subjective Conditions

For the assessment of the subjective conditions for BASDAI and BASFI we implemented suitable user interfaces in our prototype (Fig. 6). We also implemented a questionnaire for ASDAS, a composite score including subjective evaluation and the inflammatory markers C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). Patients answer the questions on a scale from zero to ten by tapping on the appropriate number. We did not choose sliders because we assumed that tapping on the appropriate field would be easier for the target group with their possible movement restrictions. Note that the use of a numeric rating scale is recommended by ASAS [12].

After the form is finished, the data are stored locally. An estimate of the current health condition is shown to give the patient feedback along with the possibility to report these data to the health cloud for permanent storage.

Questionnaires can be scheduled using the mobile device’s calendar by creating calendar entries with a specific syntax. The calendar then reminds patients to perform assessments at a given time.

G. Self-Management and Recommendation

Development of the self-management was based on the ASAS-EULAR management recommendation for axial SpA [12] taking into account the opinion of health professionals working within the field of rheumatology, patients with axial SpA, a psychologist and developers of the diary app.

A self-management system needs to support the patient in the following ways: a) deciding the type and degree of adjustments for non-pharmacological changes in a treatment plan, such as diet, training, lifestyle, or other minor adjustments; b) identifying significant deviations from the expected progress and present these deviations to the patient and health personnel; c) advising changes of treatment plan to the health personnel;
The diary shows the disease’s development visually, deviations from the treatment plan, and gives recommendations using trend labels. The patient view (Fig. 7b) shows the patient’s birth year, the current left and right cervical rotation, and the current scores for ASDAS, BASDAI, and BASFI, including their targets. Each of these scores can have historical data; this is shown in the patient history view (Fig. 7c) and summarised in the trend labels (Fig. 8) to the right of the value. There are five trend labels: (a) disease activity is increasing, but below target; (b) disease activity is increasing; (c) no change in disease activity; (d) disease activity is decreasing, either below or heading towards target; and (e) disease activity is decreasing, but still very high and needs more treatment.

H. Heuristic Decision Support Based on Medical Expertise

We created simple rules to guide patients and health personnel. These rules are based on the values from ASDAS, BASDAI, and BASFI.

The values derived in ASDAS and BASDAI indicate the amount of disease activity. Machado et al. [52] define cutoff values for disease activity measured using ASDAS: (a) under 1.3 – the disease is inactive; (b) between 1.3 and 2.1 – disease activity is moderate; (c) between 2.1 to 3.5 – disease activity is high; and (d) over 3.5 – disease activity is very high. A change on the ASDAS scale of 1.1 or more is considered a clinically important change while 2.0 or more is considered a major change. Based on this work, we indicate the trend of the scores (up, down, or steady), as well as the severity (colour). The thresholds can be personalised for patients where health personnel defines alternative values.

Braun et al. [53] propose a similar approach for BASDAI by calculating a trend line that uses BASDAI targets for cutoffs. Situations where the BASDAI is above 4.0 – indication of high disease activity – or changes of the BASDAI over 50% or a factor of two also generate a warning to contact health personnel.

BASFI indicates the disability level. Wariaghli et al. [54] ran a large survey with Moroccan patients and defined the target values depending on the patient’s age in three age ranges. We use similar rules as above for determining the trend based on the patient’s target or age information, depending on what is available.

Recently, Kviatkovsky et al. [55] proposed cutoff values for the patient-acceptable symptom state (PASS) for BASDAI and BASFI to be 4.1 and 3.8, respectively. For the minimum clinically important improvement (MCII), the values were 0.7 and 0.4, respectively. However, for patients with an active disease, the MCII values are 1.1 and 0.6, respectively.

V. Usability Test of the Prototypes

Usability, how easy something is to use, is an important factor for adoption and continuous use of a system or application. Motivated by this, we performed a usability test of the two developed prototypes. We wanted to see how appropriate the apps are for their purpose, and to get feedback on the usability. We employed the System Usability Scale (SUS) developed by Brooke [56]. The SUS consists of ten questions that are rated by the participants on a five point or a seven point Likert scale [57]. The ratings are used to calculate a score on a scale from 0 to 100 where 70 is the average score. Additionally, we added six questions on related matters that are not part of the SUS scale, e.g., the need for the apps, satisfaction, and whether participants would recommend the apps to others.

For the usability test, we recruited eighteen individuals with Android smartphones among members of the Norwegian...
TABLE III: SUS scores for the collection module app and patient diary app with highest and lowest scores removed.

<table>
<thead>
<tr>
<th></th>
<th>Average</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection module</td>
<td>73.73</td>
<td>80.20</td>
</tr>
<tr>
<td>Patient diary</td>
<td>74.05</td>
<td>74.35</td>
</tr>
</tbody>
</table>

Rheumatology Association (Norsk Revmatikerforbund). We asked the eighteen to download the two apps and sign up for the usability test. Of the invited participants, fourteen followed the procedure, downloaded the apps, and registered at the health cloud site. The individuals received the link to the surveys after they had downloaded the apps and a text message with instructions. Of the eighteen individuals, nine used the apps and completed the test.

With only nine respondents, the usability test is more a pilot study. If an application has major usability weaknesses, these will likely be revealed with small sample sizes also. Our test did not indicate major weaknesses. We did not perform statistical analysis of the data beyond calculating SUS scores.

We performed separate tests for each app. The average and median from the SUS are presented in Table III with the highest and lowest scores eliminated. The SUS scores of the apps are around 74, which is just above average. As the prototype apps have several known weaknesses, this is what we can expect. Note that the app for smartphone-based measurements of rotation exercises was developed after this test has been finished; thus, the SUS scores for the measurement app are not available.

VI. ETHICS, REGULATORY ISSUES, AND RISK ANALYSIS

Using devices, sensors, and supporting health care systems may create a variety of ethical issues that need to be analysed and addressed before a system using these is used by patients. Further, there is a variety of regulatory issues that must be addressed.

The ensemble of devices, sensors, and supporting health care systems is also referred to as the health-related Internet of Things (IoT) which refers to uniquely identifiable objects (things) and their virtual representations in an Internet-like structure. This term was first used in 1999 by Ashton [58]. Other definitions of IoT have appeared as technology progresses. A thing is a real or virtual object, e.g., a device or a web service, offering one or more services. The IoT is today a rather common platform for the deployment of health services. While our work makes use of sensors and networks, we focus on the concept for self-management rather than proposing a full deployment of our concept in the IoT.

A. Ethics Assessment

Mittelstadt [59] presents a literature review of ethics in the health-related IoT for devices, data protocols, and mediated care. These aspects can arise from both implementation and deployment. These aspects include: i) personal privacy; ii) obtrusiveness, stigma, and autonomy; iii) informational privacy; iv) data sharing and autonomy; v) consent and the uncertain value of data; vi) ownership and data access; vii) social isolation; viii) decontextualisation of health and well-being; ix) care quality and user well-being; and x) risks of non-professional care. Berman and Cerf [60] comment on rights to privacy in the IoT and accountability for decisions made by autonomous systems. Hence, the ethical properties of algorithms need to be investigated. Mittelstad et al. [61] categorise the ethical aspects of algorithms into xi) quality of evidence, divided into inconclusive, inscrutable, and misguided evidence; as well as xii) unfair outcomes; xiii) transformation effects; and xiv) traceability.

B. Regulatory Issues

Our presented framework consists of a variety of technical devices that are supposed to support the patient. As these devices and algorithms potentially could put the patient at risk, we need to consider the regulatory issues regarding medical devices. According to Boulos et al. [62], both the EU and the U.S. regulations define what a medical device is and whether certifications (e.g., according to the European Medical Device Directive MDD 93/42/ECC) would be required. Apps that archive and retrieve data from, e.g., patient records, support decisions informed by medical databases representing known facts, or perform straightforward simple calculations are usually not considered as medical devices. In contrast, apps for diagnosis, dosage calculation, interpretation and interpolation of assessed data outside a clinician’s supervision need to be certified as medical devices. Then, developers of such apps need to undertake a controlled test and risk assessment.

Considering the apps developed in our project for patients with axial SpA, the current implementation offers assessment of subjective and objective data, calculates indices according to the published definitions, transfer data to a health cloud, and presents trends for the patient to make a decision. According to the above considerations, these apps are not considered as medical devices. Note also that the patient recognises potential problems also without the apps; immediate danger for life due to the conditions cannot be expected.

We also note that the device for clinical measurements presented in Section IV-D would need certification as a medical devices once it is used in a clinical setting.

C. Ethics and Risk Analysis

We evaluate the fourteen ethics characteristics i to xiv for the currently implemented prototype. Table IV shows elements of this informal ethics assessment. According to this assessment, there are no critical issues; however, the implementation and deployment of the self-management system needs to be made carefully, and the issues mentioned in the assessment table need to be addressed.

We perform an informal risk analysis for our system that is similar to the work by Leister et al. [63]. From a system model, e.g., the one presented in Fig. 3, we can extract the functionality, communication channels, and list possible risks, sources of failure, weaknesses, exploits, and attacks.

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TABLE IV: Informal ethics assessment for characteristics i to xiv.

<table>
<thead>
<tr>
<th>#</th>
<th>Ethics aspect</th>
<th>Properties and comments</th>
</tr>
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<tbody>
<tr>
<td>i</td>
<td>Personal privacy</td>
<td>Make sure that only authorised persons can access device.</td>
</tr>
<tr>
<td>ii</td>
<td>Obtrusiveness, stigma, autonomy</td>
<td>Apps and sensors can be used in private space; smartphones and sensors are not obtrusive.</td>
</tr>
<tr>
<td>iii</td>
<td>Informational privacy</td>
<td>Make sure that information security measures are implemented.</td>
</tr>
<tr>
<td>iv</td>
<td>Data sharing</td>
<td>Data sharing only when client permits; controlled by regulations.</td>
</tr>
<tr>
<td>v</td>
<td>Consent</td>
<td>Patient can give consent.</td>
</tr>
<tr>
<td>vi</td>
<td>Data ownership, data access</td>
<td>Ownership by patient regulated by law in Europe; data access by regulations.</td>
</tr>
<tr>
<td>vii</td>
<td>Social isolation</td>
<td>Reduces number of clinical consultations; it is unlikely that this will lead to social isolation.</td>
</tr>
<tr>
<td>viii</td>
<td>Decontextualisation</td>
<td>Patient initiates questionnaires and assessments; patient can delete unwanted values; however, mishaps can occur.</td>
</tr>
<tr>
<td>ix</td>
<td>Care quality</td>
<td>Patients are under clinical supervision, but number of clinical consultations is reduced.</td>
</tr>
<tr>
<td>x</td>
<td>Non-professional care</td>
<td>Patients are under clinical supervision.</td>
</tr>
<tr>
<td>xi</td>
<td>Quality of evidence</td>
<td>Machine learning is not yet applied; system gives recommendations to educated patients; when patients enter wrong data or perform exercises in wrong manner, results and recommendations will be affected; hardware-dependence possible.</td>
</tr>
<tr>
<td>xii</td>
<td>Unfair outcomes</td>
<td>n/a</td>
</tr>
<tr>
<td>xiii</td>
<td>Transformation effects</td>
<td>Health-care system will change; number of planned consultations will be reduced in the long run.</td>
</tr>
<tr>
<td>xiv</td>
<td>Traceability</td>
<td>Yes, for current implementation; weaker when machine learning is applied.</td>
</tr>
</tbody>
</table>

For these, we consider severity and probability, as well as countermeasures. One could formalise this even more as demonstrated by Leister et al. [64], but we consider this not necessary for an overview.

Risks can occur due to various reasons, including the following: a) attacks on information security and privacy, affecting both devices and communication channels; b) issues with technical safety when operating the devices; c) issues with correctness of decisions and results; d) malfunction of device or algorithms; e) operation errors caused by the user; f) reduced availability; and g) organisational issues and policies.

D. Analysis of the MOSKUS Apps

Since the self-management system is complex, the results shown by the device might be wrong. For example, wrong input values might result in displaying an incorrect status and wrong recommendations. This, in turn, might result in non-optimal treatment. For recommendations for axial SpA, this will not cause life-threatening situations. Further, the patients using the MOSKUS apps are supposed to be educated to manage their own disease without the app and will seek for medical assistance also when technology should fail.

Reasons of the apps showing misleading results might be the following:

1) When using the questionnaires, the patient might enter wrong data. This may happen either voluntarily (cheating) or involuntarily by accident. In either case, when wrong values are entered, the resulting indices – such as ASDAS, BASDAI or BASFI – will be biased, leading eventually to wrong recommendations.

To avoid incorrect data, one can make a sanity check of the entered values and ask the patient when unusual data are entered. Such mechanisms have not been implemented in the prototypes, but this would be necessary for a final product. Further, educating the patient in the purpose and use of the apps would have a positive impact.

2) When performing the exercises, the patients might perform these in a wrong manner; e.g., they might move parts of the body that are supposed to be fixed or they might have misunderstood the exercise entirely. If this happens, the measurements from the exercises and the resulting indices (e.g., BASMI) will be biased.

To avoid this, educating the patients might be essential. Further, mechanical aids and fixtures, as well as sanity check of the exercises using extra sensors or recording more values might be necessary. Moreover, some patterns in movements during the exercises might indicate that exercises are not performed correctly. Such patterns can be detected in a preprocessing step to avoid submitting erroneous data. In the current prototypes, such measures have not been implemented.

3) Malfunction of the device or its sensors may happen. E.g., when using the smart phone as a measurement device for the exercises: the accelerometer could experience noise, the gyroscope could drift or be inaccurate, or the magnetometer might be influenced by magnetic fields. Indeed, in the tests carried out in this work, we observed that older smart phones may not be as accurate as required.

To avoid this, calibration steps and sanity checks of the sensors and devices need to be performed regularly and, if possible, without the intervention of the patient. If this is not possible, the apps should give out warnings in case of strange results during such calibration steps.

The consequences from malfunction of sensor or device will be no or unusable measurement values. This might result in incorrect recommendations given by the app.

There are further risks that can arise. Breaches of information security and privacy might compromise the privacy of the patient. Further, exploits might alter or destroy data and have an impact on the integrity of the data. As a consequence, this might lead to wrong recommendations or system failure (e.g., denial of service).
Suggested counter-measures are similar to those described by Leister et al. [63], i.e., to secure the communication channels by using security functions such as authentication, authorisation, access control, and encryption. Access to devices and sensors, as well as to the health cloud and the patient records by unauthorised persons needs to be restricted using the suitable measures. Note that security and privacy policies developed by the stakeholders are necessary, as for every other IT system.

Data loss can happen due to various reasons, e.g., unavailable services, destroyed hardware, power outage, theft, protocol errors, or routines not performed according to policies. The usual countermeasures for these situations apply, for example backing up important data.

Although smart phones and sensors can be considered as personal devices, it can happen that other persons, e.g., friends and family can get access to the MOSKUS app. For example, friends and family might be interested in the technology and try the app. To avoid that the data set is contaminated with data from other persons, the app needs to offer functionality to remove such data sets both from the smart phone, health cloud, and patient records. Additionally, a sanity check of the data can detect such unwanted data and suggest them for removal.

To summarise, the above informal analysis covers the some major risks that could lead to unusable data, privacy breach, data loss, and data inconsistency. However, there are several measures that can help avoid many of these risks becoming a threat to the patient. These measures include a) analysis of collected data and evaluation whether these data fit into the patient’s usual pattern; b) analysis of the quality of exercises using extra sensors and data analysis; c) implementation of warnings when data are inconsistent or do not fit into the patient’s pattern; d) possibility to remove data sets that are inconsistent, inaccurate or are form other sources than the patient; e) implementation of suitable security protocols; and f) possibility to back up data. Such measures and functionality need to be added before starting productification of the MOSKUS prototype.

VII. Discussion

The proposed concept for self-management is based on a feedback loop which involves the patient. Axial SpA does not require immediate attention when the condition worsens, but an appointment with a clinic needs to be scheduled. Also, not adhering to the self-management regime does not have other side-effects beyond not adhering to the treatment, and these patients need to keep the conventional frequency of clinical follow-ups. Note that other chronic diseases might require immediate attention in some situations or not adhering to the self-management regime might worsen the patient’s condition. Thus, an evaluation is needed for other conditions than axial SpA to see if our self-management architecture can be applied.

Data assessed in self-management are usually not complete or might be of a different nature in terms of the clinical indices. For example, the values extracted from blood samples might not be available, only selected values from the BASMI might be available, or the patient assesses alternative measurements that are not part of the established indices. To support recommendations in these cases, it is necessary to predict an individual’s axial SpA disease condition based on a combination of physiological, behavioural and subjective (self-reported) features. To achieve this, Schiboni et al. [65] have proposed a fuzzy rule-based evidential reasoning (FURBER) approach for multiple assessment fusion. But this approach requires enough real patient data as training data to be considered for real treatment.

The medical indices for axial SpA and the data retrieved from the FURBER method are only suited to give an indication of the disease conditions at one moment. For predicting the probable development of the patient’s health condition and whether actions need to be taken requires temporal reasoning. Modelling the disease development as a stochastic process to optimise the treatment recommendations could be done by a Markov Decision Process (MDP) [66]. Yet a large sample size could make this approach less viable [67]. Alternatively, the patient profiling method described by Lutz et al. [68], could be feasible.

The new assessment methodology for rotation exercises using sensor technology will also impact clinical use as it will save time and provide better results. Today, health personnel use goniometer or compass-based measurements that have acceptable accuracy. The trials in a clinic have shown this new methodology simplifies clinical measurements, greatly improves accuracy. The time saved and higher-quality data quickly make up for the cost of the sensors. Specifically, the much higher accuracy and easier handling of the sensor technology compared to the traditionally used methods is attractive to health professionals. Furthermore, the sensor will enable patients to perform the measurements themselves without the involvement of health personnel.

The use of sensor technology that comes in today’s smart phones for the assessment of the rotation exercises is viable. However, one has to keep in mind that the hardware is not standardised, and some models or brands could behave unexpectedly. Technical limitations might also have an impact on the implementation of the exercises, as our study has shown.

Our prototype does not implement all of the exercises that are recommended, and more studies and research will be necessary to find a suitable implementation of these. For some of these, e.g., the stair climb test or the sit-to-stand test, a solution seems obvious, unlike for others (e.g., the extended Schober’s test). Thus, replacement-exercises that are viable for implementation using sensors that are affordable need to be developed and clinically approved.

VIII. Conclusion

We presented an architecture for self-management of axial SpA patients that is based on self-assessment by these patients. We have performed a proof of concept by implementing vital parts of a self-management system including clinical measurements, patient-reported outcome measurements, feedback module, patient diary, and decision making software. For this, we used both specifically designed sensors that are suitable
for clinical settings as well as sensors that are on-board of smartphones.

Further user evaluations will be necessary before a system based on our architecture can be brought into clinical practice. In addition, communication modules to the EHR system of the clinics need to be implemented. Further, the development of suitable measurements for exercises beyond rotation exercises need to be developed in a way that allows patients to perform these at home. For some of the objective assessments, it must be considered to use replacement-exercises. This, however, will require evidence in clinical trials that these exercises are similar to the ones they replace.

Finally, since patient-reported data might not be of the best quality (e.g., they have not undergone quality assurance or might be incomplete) estimation methods both for the current disease status and for temporal prediction need to be developed. While we could show the viability of the methods, further implementation work needs to be done.

IX. ACKNOWLEDGMENTS

Parts of the work presented here has been carried out in the Mobile musculo SK eletal User Self-management (MOSKUS) project funded by the Research Council of Norway in the VERDIKT programme. grant number 227251.

REFERENCES


**List of Acronyms**

<table>
<thead>
<tr>
<th>Antonym</th>
<th>Definition</th>
<th>Antonym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANT+</td>
<td><em>an interoperable wireless transfer capability</em></td>
<td>BASMI</td>
<td>Bath AS Metrology Index</td>
</tr>
<tr>
<td>API</td>
<td>application program interface</td>
<td>BCI</td>
<td>brain-computer interface</td>
</tr>
<tr>
<td>AS</td>
<td>Ankylosing Spondylitis</td>
<td>CI</td>
<td>confidence interval</td>
</tr>
<tr>
<td>ASAS</td>
<td>Assessment of SpondyloArthritis international Society</td>
<td>CST</td>
<td>chair stands test</td>
</tr>
<tr>
<td>ASDAS</td>
<td>Ankylosing Spondylitis Disease Activity</td>
<td>CRP</td>
<td>C-reactive protein</td>
</tr>
<tr>
<td>aSpA</td>
<td>axial Spondyloarthritis</td>
<td>EHR</td>
<td>electronic health record</td>
</tr>
<tr>
<td>BASFI</td>
<td>Bath AS Disease Activity Index</td>
<td>ESRA</td>
<td>erythrocyte sedimentation rate</td>
</tr>
<tr>
<td>BASFI</td>
<td>Bath AS Functional Index</td>
<td>EULAR</td>
<td>European League Against Rheumatism</td>
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<td>BASG</td>
<td>Bath AS Patient Global Score</td>
<td>EU</td>
<td>European Union</td>
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<tr>
<td></td>
<td></td>
<td>FURBER</td>
<td>fuzzy rule-based evidential reasoning</td>
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<td></td>
<td></td>
<td>ICC</td>
<td>interclass correlation coefficient</td>
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<td></td>
<td></td>
<td>ICT</td>
<td>information and communication technology</td>
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<td></td>
<td></td>
<td>IoT</td>
<td>Internet of Things</td>
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<td></td>
<td></td>
<td>ISM</td>
<td>industrial, scientific, and medical</td>
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<td></td>
<td></td>
<td>LED</td>
<td>light emitting diode</td>
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<td></td>
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<td>LoA</td>
<td>limits of agreement</td>
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<td></td>
<td></td>
<td>MDP</td>
<td>Markov decision process</td>
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<td>mHealth</td>
<td>mobile health</td>
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<td></td>
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<td>MCII</td>
<td>minimum clinically important improvement</td>
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<td></td>
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<td>MOSKUS</td>
<td>mobile musculo-skeletal user self-management</td>
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<td></td>
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<td>PASS</td>
<td>patient-acceptable symptom state</td>
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<td></td>
<td></td>
<td>PC</td>
<td>personal computer</td>
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<td></td>
<td></td>
<td>RPE</td>
<td>rating of perceived exertion</td>
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<td></td>
<td></td>
<td>SDC</td>
<td>smallest detectable change</td>
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<td></td>
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<td>SpA</td>
<td>Spondyloarthritis</td>
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<td></td>
<td></td>
<td>ST</td>
<td>stair climb test</td>
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<td></td>
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<td>standard deviation</td>
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<td>United States</td>
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<tr>
<td></td>
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<td>six minutes walking test</td>
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