PROJECT DELIVERABLE REPORT

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Advanced personalised, multi-scale computer models preventing osteoarthritis

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1.4	27/04/18	LEITAT	Review of first draft
1.5	27/04/18	HULAFE, KULeuven	Review of first draft
1.6	27/04/18	HULAFE	Final version
1.7	03/08/18	ALL	Modification of DCP. Final version

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Abbreviations

BMI	Body mass index
BSHHD	Belt-stabilized handheld dynamometer
CSI	Central Sensitization Inventory
DCP	Data collection protocol
FACHS	Functional Ambulation Classification of the Hospital at Sagunto
FPAQ	Flemish Physical Activity Questionnaire
GADS	Goldberg Anxiety and Depression Inventory
HAD	Hospital Anxiety and Depression Scale
ICF	International Classification of Functioning, Disability and Health
KL	Kellgren and Lawrence
KOOS	Knee Injury and Osteoarthritis Outcome Score
LLI	Leg-length inequality
MOAKS	MRI Osteoarthritis Knee Score
MS	Metabolic syndrome
NHANES	National Health and Nutrition Examination Survey
OA	Osteoarthritis
ROM	Range of motion
VAS	Visual Analogue Scale
WHO	World Health Organization
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
WORMS	Whole-organ MRI score
WP	Work Package

1. Summary

This report refers to Deliverable 2.2, which relates to the OActive WP 2, "System Architecture Requirements and Use cases", and specifically Task 2.2, "Design of the Data Collection Protocol and user requirements", led by ANIMUS.

The Data Collection Protocol (DCP) defines the optimal plan for collecting data from the different populations, including the timing, content, screening, assessment, and evaluation tests and other rules relating to the collection of data, to ensure the holistic evaluation of OACTIVE.

On this report we define this DCP and the evaluation data.

2. Introduction

Deliverable 2.2 consists of the description of the DCP and the system of data evaluation.

In order to ensure a holistic and thorough evaluation, the DCP has been created supported by literature concerning the risk factors of knee osteoarthritis (OA).

As physical medicine and rehabilitation clinicians, we've taken into consideration the aspects of the International Classification of Functioning, Disability and Health (ICF) and we have emphasised the importance of a correct characterization of pain, an exhaustive physical examination scientifically endorsed, and the evaluation and consideration of the patient's activity, and other functional aspects.

2.1. Purpose and Scope

There are known medical risk factors that influence the development and progression of OA. They can be divided into non-modifiable and modifiable risk factors.

The non-modifiable factors analysed in literature include age and gender [1, 2, 3, 4], familial history of OA [1], personal OA history [1, 2, 3, 4] and hormonal status in women [3].

The modifiable factors described are overweight and obesity, usually quantified using body mass index (BMI) [1, 4, 5, 6, 7], occupational risks [1, 7], vitamine D, PTH [8], vitamine K, psychological factors [7], components of metabolic syndrome (MS) [9], knee extensor muscle weakness [10], knee injuries, synovitis [7, 11, 12], leg-length inequalities, malalignment [7] and previous knee trauma [4].

All of these risk factors have been included in the DCP as it is presented in detail below.

We also comment in this report the measurement methods for these items, supported by literature, and the way the data must be collected at the DCP in order to achieve the standardization, and to facilitate the identification of matching data elements in different sources supporting the data integration.

3. Elaboration of the data collection protocol

For the purpose of the DCP, we divided it into the five sections in which a medical visit is structured: demographics, anamnesis, physical examination, body fluid tests, and functional and psychological scales.

3.1. Demographics

We included in this section general demographic information included in other big databases, and well-established conventional predictors, such as birth country, sex, age, ethnicity, level of education, marital status, residency, household income, housing status and occupation [1, 2, 3, 4, 7].

3.2. Anamnesis

On this section we have compiled the usual questions of a clinical interview and symptoms of the disease, including the items described as risk factors in literature:

Familial OA, defined as parents, siblings or grandparents having a diagnosis of OA, having undergone arthroplasty of the knee or hip, or if they were reported to have Heberden's nodes [1].

Personal OA history has been studied, with controversial results. Some studies have found the hand and/or hip OA history as one of the main factors consistently associated with knee OA [3, 4], while other authors found it non-significant [2].

It has been also studied the association of occupational activities with the development of knee OA, finding an increased risk in floor layers or in frequent occupational kneeling and lifting [1, 7].

We will collect information about drinking alcohol and smoking, which have been found not to be statistically significant as either risk or protective factors [2, 3].

Women have consistently been shown to be at higher risk of hip, knee, and hand OA, and it has been studied if this increase in risk is constant with age and changes in relation with endogenous oestrogen production and menopause [3].

It has been described that knee injuries, in terms of cartilage lesions, meniscal damage, synovitis and bone marrow lesions, are all risk factors for OA and are related with the prediction of progression [1, 7]. Meniscal damage, which can be related to sports or to repetitive use of a joint associated, for example, with occupational activities, has been found to confer a 4-fold increased risk of knee OA. In knees without any cartilage lesions at baseline, meniscal damage was found to increase the risk for developing knee OA over 30 months [7]. And synovitis, especially when there is a substantial volume within the knee, has been reported as an independent cause of OA [12].

Sport activities, defined as regular leisure activities, have been found to predict the progression of knee OA [1].

It's been recently published that there has been a shift toward the importance of pain as a driving factor in the definition of OA, rather than structural factors alone. However, due to the risk of misclassification it was felt that the combination of symptoms and structural features would provide the most accurate definition. Experts agreed to use symptomatic radiographic OA as the primary criteria to classify OA for

the purpose of combining OA classifications across cohort studies. Pain alone was suggested as a secondary criterion [13]. Recommendations suggest to use National Health and Nutrition Examination Survey (NHANES)-type pain questions where duration of pain is indicated as 'most days in a month' (NHANES A and NHANES C) [13].

The relation between knee pain and knee OA has been widely studied. There is not always a good clinical and radiographic correlation. Sometimes it may appear *incident knee OA* without pain, and other cases it is associated with concurrent knee pain, then it is named *symptomatic knee OA*. The association of risk factors with onset of knee pain has also been studied, establishing knee pain not as a predictor, but part of outcome measures for knee OA [1, 2, 6, 7]. It is recommended the use of multiple pain assessments (i.e., NHANES pain questions, WOMAC, clinical assessment, etc.) at multiple time-points to provide better comparability with existing cohorts and to use as outcome measures, as well as the inclusion of self-reported/physician-diagnosed OA[13]. It is also important to define the type of pain, and which phenotype is the most prevalent. To that end we have included the validated Central Sensitization Inventory (CSI) in the protocol [14] (See appendix 2).

3.3. Physical examination

To be able to correctly detect and classify patients with knee OA or those in high risk of presenting it, it is crucial to carry out a thorough physical examination, identifying and characterising all the signs of the disease, in order to determine an accurate diagnosis.

A general physical examination, and a knee specific exploration will be performed, including the items described as risk factors at the literature:

Changes in knee morphology, such as swelling, joint effusion, Baker's cyst, or any other, need to be explored and documented [7].

Knee extensor muscle weakness has been found associated with an overall increased risk of developing symptomatic knee OA [7, 10].

Leg-length inequality (LLI) is an easily modifiable abnormality that can also affect lower extremity biomechanics. LLI of at least 2 cm has been shown almost twice as likely to have prevalent radiographic knee OA, but no such association was noted for incident knee OA [7].

Knee alignment, both static and dynamic, has important implications for load distribution within the knee. There have been conflicting findings regarding the effects of alignment on incident OA, and a best evidence synthesis concluded there was lack of sufficient evidence to draw a conclusion. It is possible that malalignment may be a reflection of the severity of the disease, with joint space loss due to cartilage and meniscal abnormalities, and bone contour alterations occurring as part of the OA disease process contributing to malalignment. Recently it was found that varus malalignment increased the incidence of knee OA. No study to date has evaluated the effects of malalignment on incident OA among knees without any MRI-based lesions [7].

There are a number of scoring methods to semi-quantitatively assess radiographic OA. Two of the most used in population-based cohorts are the Kellgren and Lawrence (KL) (a global grade) and the OARSI atlas of individual features. All experts agreed that using the established cut-off for radiographic OA, KL greater than or equal to 2 was appropriate to define more advanced stages of OA, rather than an alternate cut-off or individual features [13, 15, 16]. It is recommended the use of additional X-ray views, especially for the patellofemoral compartment, to improve diagnosis of radiographic knee OA [13].

Table 1. Radiographic grading of knee OA according to the Kellgren-Lawrence score [16]	
Osteophyte formation	none: 0 definite: 1 large: 2
Joint space width	normal: 0 narrowing: 1 advanced narrowing: 2 gone: 3
Subchondral sclerosis	none: 0 discrete: 1 discrete sclerosis with cyst formation: 2 severe sclerosis with cyst formation: 3
Deformation	none: 0 discrete: 1 strong: 2
Grade 0 = 0 points; grade 1 = 1 – 2 points; grade 2 = 3 – 4 points; grade 3 = 5 – 9 points; grade 4 = 10 points.	

3.4. Complementary information

Cartilage lesions, meniscal damage and synovitis have been found as risk factors for OA [7, 12].

In cases in which a complementary test, such as ultrasound or MRI, is performed, we will also collect information regarding synovitis and meniscal and cartilage damage.

3.5. Body fluid tests

The extraction of blood samples from the patients is needed for the search of biomarkers. Having this in mind, and supported by literature, we have included the examination of these items, which have been described as risk factors for development or progression of OA:

Low vitamin D [25(OH)D] (< 15 mg/L) has been associated with a 2-fold elevated risk of knee OA progression, and both low vitamin D and high PTH (>73 pg/mL) with a 3-fold increased risk of progression [8].

Accumulation of MS components, including overweight, hypertension, dyslipidemia, and high glycated hemoglobin, is significantly related to both occurrence and progression of knee OA [9].

Vitamin K, which has potential bone and cartilage effects, has been associated with OA, and recently with incident radiographic knee OA and MRI-based cartilage lesions [7].

Also, it is expected to search for new biomarkers by studying exosome content (nucleic acids and proteins) in fluid samples that will include blood, urine and, in cases that will be possible, synovial liquid. Exosomes from these samples will be extracted for further proteomic and genomic analysis.

3.6. Faecal samples

Recently, it has been observed a relationship between the microbiota and Osteoarthritis. Disbiosis has been associated to many diseases, as obesity, diabetes, inflammatory bowel disease, or related to age, diet, among others. Then, microbiota could be considered, as stated by Li et al. [17], as a hidden risk factor for OA, so its characterization could give some insights and use them as a potential biomarkers for OA. Thus, samples will be obtained from the same set of patients as the ones for exosome isolation for microbiome research.

3.7. Functional and psychological evaluation

OA is a leading cause of global disability. In fact, the Global Burden of Disease Study ranked OA 11th in terms of global disability. OA is the most frequent cause of limitations in walking one mile and stair climbing. Quality of life is also reduced in OA due to pain and participation restrictions, as the disease limits outdoor activities, family activities and social interactions. For the assessment of limitations in functioning among patients with OA of the lower extremities, reliable patient-related outcome measures, such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or the Knee Injury and Osteoarthritis Outcome Score (KOOS), along with some others, have been developed [18] (See appendixes 2 and 3). It has been demonstrated that a cut-point of 3 in the WOMAC pain subscale had the best sensitivity and specificity against the gold standard NHANES question [13].

Functional Ambulation Classification of the Hospital at Sagunto (FACHS) is a validated scale to assess gait and categorizing patients into different walking abilities, with a simple and quick management [19, 20] (See table 2).

Table 2. Functional Ambulation Classification of the Hospital at Sagunto (FACHS) [19, 20]	
Level 0	Non-ambulation.
Level 1	Non-functional or dependent ambulation.
Level 2	Household ambulation.
Level 3	Surroundings of the house ambulation (neighborhood).
Level 4	Community ambulation.

Level 5	Normal ambulation.

As we mentioned above, a "structure-symptom" discordance is often described in OA, and it has been suggested that it may exist an important link between the pain experience and psychological state [7]. To evaluate these psychological factors, in terms of anxiety and depression, we have included two auto-administered scales, Hospital Anxiety and Depression Scale (HAD) and Goldberg Anxiety and Depression Inventory (GADS) (See appendixes 4 and 5).

4. Measurement methods

In terms of comparability among the clinical partners, we have tried to standardise the measurement methods for the items included in this protocol, as it figures in annex 1. Some items, however, deserve a special comment:

The most commonly accepted method of evaluating general muscle strength is the Medical Research Council Manual Muscle Testing scale. This method involves testing key muscles from the upper and lower extremities against the examiner's resistance and grading the patient's strength on a 0 to 5 scale (see table 3). To have a holistic evaluation of lower limb muscles, the muscles to explore should include hip flexors, hip abductors, knee extensors and flexors, and plantar flexors [21].

Table 3. Medical Research Council Manual Muscle Testing scale [21]
0 = No muscle activation
1 = Trace muscle activation, such as a twitch, without achieving full range of motion
2 = Muscle activation with gravity eliminated, achieving full range of motion
3 = Muscle activation against gravity, full range of motion
4 = Muscle activation against some resistance, full range of motion
5 = Muscle activation against examiner's full resistance, full range of motion

For the specific evaluation of muscle strength in OA the most used method is testing the isometric thigh muscle strength [22, 23, 24]. It could be used a belt-stabilized handheld dynamometer (BSHHD), as described by Bohannon et al. [25]: "BSHHD was conducted while subjects were seated on an elevated commercially available chair with foam padding and stabilizing straps for their proximal thighs and waist. Their knees were at about 90 degrees of flexion (i.e., their legs were vertical). A dynamometer stabilizing belt passed around a bar secured behind the back legs of the chair and over a calibrated MicroFET HHD that was placed against the anterior legs of participants just proximal to the malleoli. Participants were asked to take a second or two to come to maximal effort and to then continue trying to straighten their knee as hard as possible until the tester asked them to stop (about 4 seconds later). (...) Consistent with previous studies, the reliability coefficients of the present investigation support the reliability of the 3 measures used to quantify muscle strength (...)"

Knee alignment should be measured based on bilateral standard anterior-posterior weight-bearing radiographs. It should be measured as the angle formed by the intersection of the mechanical axes of the femur (the line from femoral head center to femoral intercondylar notch center) and the tibia (the line

from ankle talus center to the center of the tibial spine tips). A knee should be defined as varus when alignment is more than 0° in the varus direction, valgus when it is more than 0° in the valgus direction, and neutral when alignment is 0° (The angle made by the femur and tibia on a knee x-ray does not consider the proximal femur, femoral or tibial shafts, or ankle, so it is highly variable as opposed to full-limb measurements) [26].

For flexion deformity, the patient should be viewed from the side and the long axis of the thigh and the leg should be determined, and the angle between them measured with the goniometer [27].

For the assessment of muscle atrophy we should use manual circumference measurements at specific intervals, with a standard, non–elastic, bendable tape with a sensitivity level of 0.1 cm, and using one-centimeter width for the measurements. The tape should be enclosured around the limb while the observer should be holding the zero end of the tape with one hand and the other end of the tape with the other hand. Measurement results should be observed from the point where the tape intersects with number zero. Measurements should be recorded in centimeters to achieve the standardization [28].

To obtain knee range of motion (ROM) measurements, particular care should be taken to align the goniometer to the femur by palpating the greater trochanter and then aligning the proximal arm of the goniometer close to the femur. The distal arm of the goniometer should be parallel to the tibia [29].

To assess knee laxity we will use the traditional passive tests including the Lachman test, the anterior/posterior drawer test, the pivot shift test, the quadriceps active test, and the varus/valgus stress test. The primary structures being tested are the anterior cruciate ligament, posterior cruciate ligament and medial and lateral collateral ligaments[31].

For measuring knee joint propioception, patient will be in bed side sitting position with legs out of the plinth and thigh fully supported. Subject will be blind folded to avoid any visual cues. Examiner will passively flex knee joint from extended position to the target angle of 30 degree at very slow speed (about10 degree/second). Subject will attempt to identify test position whilst holding it actively for 4 seconds and then passively return to the starting position. Then subject will be asked to reproduce target position actively using the same limb[32].5 sit-to-stand test and 10-meter walk test will be conducted as explained in appendixes 7 and 8, respectively.

5. Conclusions

In order to standardise the evaluation of OA patients and the data collection to facilitate the data integration, this DCP was elaborated, scientifically endorsed, taking into account the recommendations of the WHO with the ICF concepts. It encompasses an exhaustive history and physical examination, compiling a considerable amount of risk factors, with special care in the determination of OA's pain syndrome (rhythm, intensity, frequency, etc.) and the OA's impact on the person, such as activity limitations, functional consequences and social participation.

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7. Appendix

7.1. Data Collection Protocol

OACTIVE Data Collection Protocol

Participant Notes (including the Exclusion/Inclusion Criteria used):

Inclusion criteria:	**Exclusion criteria:**
1. 2. 3. 4. 5. (e.g. Knee pain, Radiological evidence of OA on plain film, Crepitus audible/palpable, Stiffness lasting under 30 mins, Patient age >50 years, etc)	1. 2. 3. 4. 5. (e.g. Post traumatic OA, Autoimmune OA, Infective/inflammatory OA, Rheumatologic conditions, Patient age <50 years)

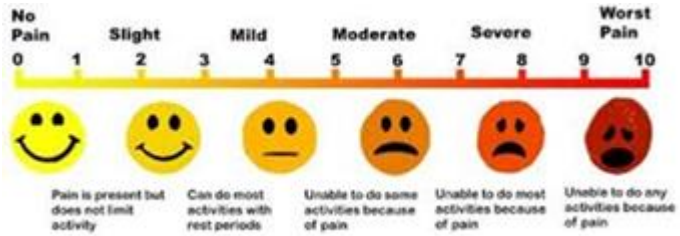
Participant Record

DEMOGRAPHICS:	
Sex	
Male	
Female	
Age (years)	
Birth country	
Spain	
Cyprus	
Greece	
Other European countries	
Other non-European countries	
Ethnicity	
White	
Black	

Hispanic American		
American Indian		
Asian		
Pacific Islander		
Other Race		
Two or More Races		
Level of education (level of studies completed)	Individual	Parents
Elementary school not completed		
Elementary school completed		
Vocational education or general secondary education		
College or university education		
Marital status		
Single		
Married/Civil partnership		
Separated/Divorced		
Widow		
Residency		
Living independently		
Living with family		
Living in institution		
Household income: Thinking of your household's total monthly income, would you say that your household is able to make ends meet?		
With great difficulty		
With some difficulty		
Fairly easily		
Easily		
Housing status		
Renting		
Owning		

Occupation	
MEDICAL & FAMILY HISTORY:	
Any Current Medication	
Family history of OA	
No	
Yes	
Personal history of hand OA	
No	
Yes	
Personal history of hip OA	
No	
Yes	
Do you have knee osteoarthritis?	
No	
Yes	
Have you ever been told that you have OA of your knee by a doctor?	
No	
Yes	
Occupational risk (Occupational kneeling and lifting)	
Never	
Seldom	
Once-twice/month	
Once-twice/week	
Once a day	
Always	
Alcohol	
Never	
Seldom	
Once-twice/month	

Once-twice/week		
Once a day		
> once a day		
Smoking		
No		
Yes (number of cigarettes per day or week)		
Ex-smoker		
Hormonal status (women)		
Premenopause		
Postmenopause		
Previous knee injuries (indicate L: Left; R: Right; B: Bilateral)		
No/Yes		
Ligament		
Meniscus		
Cartilage		
Bone		
Athlete		
No		
Yes		
Regular sport leisure activity		
No		
Yes: type of sport		
Once-twice/month		
Once-twice/week		
Once a day		
Physical Activity (FPAQ)[36]		
Knee pain (NHANES-type questions)	L	R
NHANES A: Knee pain on most days in the last month		
NHANES C: Knee pain lasting at least a month in the last year		

No pain		
 Resting VAS (Visual Analogue Scale)		
Walking VAS		
Pain rhythm	L	R
Mechanical		
Inflammatory		
Neuropathic component	L	R
No		
Yes		
Time since pain start (months, ages)		
SOCIAL PARTICIPATION How often in the past four weeks…		
Have you taken part in a club, interest group or activity group, church or other similar activity?		
Not		
Less than once a week		
Once or twice a week		
More than twice a week		
Have you been to a cultural or educational event such as the cinema, theatre, museum, talk or course		
Not		
Less than once a week		
Once or twice a week		
More than twice a week		
Have you eaten out?		
Not		
Less than once a week		
Once or twice a week		

More than twice a week	
Have you been out to a pub, café or tearoom?	
Not	
Less than once a week	
Once or twice a week	
More than twice a week	
Have you been to a public event?	
Not	
Less than once a week	
Once or twice a week	
More than twice a week	
Have you taken part in an organised games afternoon or evening? For instance, bingo, quiz or card games	
Not	
Less than once a week	
Once or twice a week	
More than twice a week	
Have you been on a day trip organised by a club or society?	
Not	
Less than once a week	
Once or twice a week	
More than twice a week	
Have you carried out committee work for a club, society or other group?	
Not	
Less than once a week	
Once or twice a week	
More than twice a week	
Have you done any organised voluntary work?	
Not	
Less than once a week	
Once or twice a week	
More than twice a week	
PHYSICAL EXAMINATION:	
Mass (Kg)	
Height (cm)	
BMI	

Knee morphology	L	R
Normal		
Altered		
Joint effusion	L	R
No		
Yes		
Increased local temperature	L	R
No		
Yes		
Local redness	L	R
No		
Yes		
Baker's cyst	L	R
No		
Yes		
Muscle strength (MRC Manual Muscle Testing scale: 0-5)	L	R
Hip flexors (0-5)		
Hip abductors (0-5)		
Knee extensors (0-5)		
Knee flexors (0-5)		
Plantar flexors (0-5)		
Dynamometric/HHD evaluation of knee extension strength		
Dynamometric/HHD evaluation of knee flexion strength		
Leg-length inequality		
No		
Yes		
Knee alignment	L	R
Radiographic angle		

Flexion deformity (angle)		
Knee ROM	L	R
Flexion (angle)		
Extension (angle)		
Knee Instability (Buckling-Any knee buckling, shifting or giving away during the past 3 months)		
No		
Yes		
Knee Laxity	L	R
Anterior		
Posterior		
Varus		
Valgus		
Joint Proprioception (Joint Positioning Sense)	L	R
Normal		
Altered		
5 Sit-to-stand test: Time(sec)		
Muscle atrophy (difference of circumference between both thighs, in centimeters)		
High blood pressure		
No		
Yes		
Kellgren & Lawrence (KL)	L	R
0=0 points		
1=1-2 points		
2=3-4 points		
3=5-9 points		
4=10 points		
X-ray 30º view of patellofemoral compartment	L	R
Patellofemoral lateral angle		

Lateral deviation patella		
Congruence angle		
Synovitis (by complementary tests: radiograph/ MRI/ US)	L	R
No		
Yes		
Not applicable		
Cartilage damage (by complementary tests: radiograph/ MRI/ US)	L	R
No		
Yes		
Not applicable		
Meniscal damage (by complementary tests: radiograph/ MRI/ US)	L	R
No		
Yes		
Not applicable		
MRI Examination (Specify affected area: Tibia M/L Femur M/L, Patella, Overall Joint)		
T2		
T1ϱ		
WORMS (whole-organ MRI score)		
MOAKS (MRI Osteoarthritis Knee Score)[34]		
Gait Examination (3D Gait Analysis)	L	R
Walking Speed: 10 meter walk test (m/s)		
Symmetry index (SI)		
KAM & KAM Impulse		
Progression Angle		
Knee Forces (specify details)		
Cartilage Pressure		
BLOOD TEST:		
PTH (pg/mL)		

Vitamine D (mg/L)	
Total cholesterol (mg/dL)	
HDL-cholesterol (mg/dL)	
LDL-cholesterol (mg/dL)	
Vitamine K (ng/mL)	
Glycated hemoglobin (%)	
Serum COMP	
Serum HA	
Serum CPII	
IL-1β	
TNF-α	
IL-6	
SCALES:	
CSI: Central Sensitization Inventory	
Part A (total)	
Part B (mark if positive for one or more disorders)	
WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index (%)	
KOOS: Knee injury and Osteoarthritis Outcome Score (%)	
FACHS: Functional Ambulation Classification of the Hospital at Sagunto	
0=Non-ambulation	
1=Non-functional or dependent ambulation	
2=Household ambulation	
3=Surroundings of the house ambulation (neighborhood)	
4=Community ambulation	
5= Normal ambulation	
HAD: Hospital Anxiety and Depression Scale	
0-7 points, Normal	
8-10 points, Borderline abnormal (borderline case)	
11-21 points, Abnormal (case)	

GADS: Goldberg Anxiety and Depression Inventory	
No anxiety or depression	
Anxiety, scores of five or more	
Depression, scores of two or more	
FPAQ: Flemish Physical Activity Questionnaire	

7.2. Central Sensitization Inventory (CSI)

Central Sensitization Inventory: Part A

Please circle the best response to the right of each statement.						
1	I feel unrefreshed when I wake up in the morning	Never	Rarely	Sometimes	Often	Always
2	My muscles feel stiff and achy	Never	Rarely	Sometimes	Often	Always
3	I have anxiety attacks	Never	Rarely	Sometimes	Often	Always
4	I grind or clench my teeth	Never	Rarely	Sometimes	Often	Always
5	I have problems with diarrhea and/or constipation	Never	Rarely	Sometimes	Often	Always
6	I need help in performing my daily activities	Never	Rarely	Sometimes	Often	Always
7	I am sensitive to bright lights	Never	Rarely	Sometimes	Often	Always
8	I get tired very easily when I am physically active	Never	Rarely	Sometimes	Often	Always
9	I feel pain all over my body	Never	Rarely	Sometimes	Often	Always
10	I have headaches	Never	Rarely	Sometimes	Often	Always
11	I feel discomfort in my bladder and/or burning when I urinate	Never	Rarely	Sometimes	Often	Always
12	I do not sleep well.	Never	Rarely	Sometimes	Often	Always
13	I have difficulty concentrating	Never	Rarely	Sometimes	Often	Always
14	I have skin problems such as dryness, itchiness or rashes	Never	Rarely	Sometimes	Often	Always
15	Stress makes my physical symptoms get worse	Never	Rarely	Sometimes	Often	Always
16	I feel sad or depressed	Never	Rarely	Sometimes	Often	Always
17	I have low energy	Never	Rarely	Sometimes	Often	Always
18	I have muscle tension in my neck and shoulders	Never	Rarely	Sometimes	Often	Always
19	I have pain in my jaw	Never	Rarely	Sometimes	Often	Always
20	Certain smells, such as perfumes, make me feel dizzy and nauseated	Never	Rarely	Sometimes	Often	Always
21	I have to urinate frequently	Never	Rarely	Sometimes	Often	Always

22	My legs feel uncomfortable and restless when I am trying to go to sleep at night	Never	Rarely	Sometimes	Often	Always
23	I have difficulty remembering things	Never	Rarely	Sometimes	Often	Always
24	I suffered trauma as a child	Never	Rarely	Sometimes	Often	Always
25	I have pain in my pelvic area	Never	Rarely	Sometimes	Often	Always
					Total=	

Central Sensitization Inventory: Part B

Have you been diagnosed by a doctor with any of the following disorders? Please check the box to the right for each diagnosis and write the year of the diagnosis.				
		NO	**YES**	**Year Diagnosed**
1	Restless Leg Syndrome			
2	Chronic Fatigue Syndrome			
3	Fibromyalgia			
4	Temporomandibular Joint Disorder (TMJ)			
5	Migraine or tension headaches			
6	Irritable Bowel Syndrome			
7	Multiple Chemical Sensitivities			
8	Neck Injury (including whiplash)			
9	Anxiety or Panic Attacks			
10	Depression			

7.3. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Name:_____ Date:_____

Instructions: Please rate the activities in each category according to the following scale of difficulty:
0 = None, 1 = Slight, 2 = Moderate, 3 = Very, 4 = Extremely

Circle one number for each activity.

Pain

1. Walking	0 1 2 3 4
2. Stair Climbing	0 1 2 3 4
3. Nocturnal	0 1 2 3 4
4. Rest	0 1 2 3 4
5. Weight bearing	0 1 2 3 4

Stiffness

1. Morning stiffness	0 1 2 3 4
2. Stiffness occurring later in the day	0 1 2 3 4

Physical Function

1. Descending stairs	0 1 2 3 4
2. Ascending stairs	0 1 2 3 4
3. Rising from sitting	0 1 2 3 4
4. Standing	0 1 2 3 4
5. Bending to floor	0 1 2 3 4
6. Walking on flat surface	0 1 2 3 4
7. Getting in / out of car	0 1 2 3 4
8. Going shopping	0 1 2 3 4
9. Putting on socks	0 1 2 3 4
10. Lying in bed	0 1 2 3 4
11. Taking off socks	0 1 2 3 4
12. Rising from bed	0 1 2 3 4
13. Getting in/out of bath	0 1 2 3 4
14. Sitting	0 1 2 3 4
15. Getting on/off toilet	0 1 2 3 4
16. Heavy domestic duties	0 1 2 3 4
17. Light domestic duties	0 1 2 3 4

Total Score: _____ / 96 = _____%
Comments / Interpretation (to be completed by therapist only):

7.4. Knee Injury and Osteoarthritis Outcome Score (KOOS)

Today's date: _____/_____/_____ Date of birth: _____/_____/_____
Name: _____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities. Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Symptoms
These questions should be answered thinking of your knee symptoms during the **last week**.

S1. Do you have swelling in your knee?
Never ___ Rarely ___ Sometimes ___ Often ___ Always ___
S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?
Never ___ Rarely ___ Sometimes ___ Often ___ Always ___
S3. Does your knee catch or hang up when moving?
Never ___ Rarely ___ Sometimes ___ Often ___ Always ___
S4. Can you straighten your knee fully?
Always ___ Often ___ Sometimes ___ Rarely ___ Never ___
S5. Can you bend your knee fully?
Always ___ Often ___ Sometimes ___ Rarely ___ Never ___

Stiffness
The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

S6. How severe is your knee joint stiffness after first wakening in the morning?
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
S7. How severe is your knee stiffness after sitting, lying or resting later in the day?
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___

Pain

P1. How often do you experience knee pain?
Never ___ Monthly ___ Weekly ___ Daily ___ Always ___

What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
P3. Straightening knee fully
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
P4. Bending knee fully
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
P5. Walking on flat surface
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___

P6. Going up or down stairs
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
P7. At night while in bed
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
P8. Sitting or lying
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
P9. Standing upright
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___

Function, daily living
The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A1. Descending stairs
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A2. Ascending stairs
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A3. Rising from sitting
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A4. Standing
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A5. Bending to floor/pick up an object
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A6. Walking on flat surface
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A7. Getting in/out of car
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A8. Going shopping
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A9. Putting on socks/stockings
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A10. Rising from bed
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A11. Taking off socks/stockings
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A12. Lying in bed (turning over, maintaining knee position)
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A13. Getting in/out of bath
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A14. Sitting
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A15. Getting on/off toilet
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
A17. Light domestic duties (cooking, dusting, etc)
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.

SP1. Squatting
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
SP2. Running
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
SP3. Jumping
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
SP4. Twisting/pivoting on your injured knee
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___
SP5. Kneeling
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___

Quality of Life

Q1. How often are you aware of your knee problem?
Never ___ Monthly ___ Weekly ___ Daily ___ Constantly ___
Q2. Have you modified your life style to avoid potentially damaging activities to your knee?
Not at all ___ Mildly ___ Moderately ___ Severely ___ Totally ___
Q3. How much are you troubled with lack of confidence in your knee?
Not at all ___ Mildly ___ Moderately ___ Severely ___ Extremely ___
Q4. In general, how much difficulty do you have with your knee?
None ___ Mild ___ Moderate ___ Severe ___ Extreme ___

Thank you very much for completing all the questions in this questionnaire.

7.5. Hospital Anxiety and Depression Scale (HAD)

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all

		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:

Total score: Depression (D) _____ Anxiety (A) _____

0-7 = Normal

8-10 = Borderline abnormal (borderline case)

11-21 = Abnormal (case)

7.6. Goldberg Anxiety and Depression Inventory (GADS)

The following is an adaptation of Dr. Goldberg's Depression Screening Questionnaire developed in 1993. You may self score this test with the instructions at the bottom of the screening questions. **A simple screening test such as this will not provide a diagnosis or treatment for symptoms of depression or other mood disorders. It is best if you use the results to identify possible symptoms and for seeking professional assistance.**

When answering the questions think back over the last ten to fourteen days and reflect on the relevance of each statement for your personal experience.

0 = Not at all 1 = Just a little 2 = Somewhat 3 = Moderately 4 = Quite a lot 5 = Very much

1. I do things slowly.	0 1 2 3 4 5
2. My future seems hopeless.	0 1 2 3 4 5
3. It is hard for me to concentrate on reading or other tasks.	0 1 2 3 4 5
4. The pleasure and joy has gone out of my life.	0 1 2 3 4 5
5. I have difficulty making decisions.	0 1 2 3 4 5
6. I have lost interest in aspects of life that used to be important to me.	0 1 2 3 4 5
7. I feel sad, blue, and unhappy most of the time.	0 1 2 3 4 5
8. I am agitated and restless much of the time.	0 1 2 3 4 5
9. I feel fatigued.	0 1 2 3 4 5
10. It takes great effort for me to do simple things.	0 1 2 3 4 5
11. I feel that I am a guilty person who deserves to be punished.	0 1 2 3 4 5
12. I feel like a failure.	0 1 2 3 4 5
13. I feel lifeless - - - more dead than alive.	0 1 2 3 4 5
14. My sleep has been disturbed: too little, too much, or broken sleep.	0 1 2 3 4 5
15. I spend time thinking about how I might kill myself.	0 1 2 3 4 5
16. I feel trapped or caught.	0 1 2 3 4 5
17. I feel depressed even when good things happen to me.	0 1 2 3 4 5
18. Without trying to diet, I have lost, or gained, weight.	0 1 2 3 4 5

Screening test scoring ranges:
0 – 9 No depression likely.
10 – 21 Possible symptoms that may be due to depression or other medical issues.
22 – 35 Mild to Moderate Depression.
36 – 53 Moderate to Severe Depression.
54 and up Severely Depressed.

The higher the number, the more severe your depression is likely to be. **Please seek professional assistance for symptoms of depression and if your symptoms are severe or life threatening please stay safe and call 911 or go to your nearest emergency room.**

Dr. Ivan Goldberg was a well-known and respected psychiatrist in New York City for over fifty years. He was best known for innovative treatments of medication resistant depression and bipolar disorder. He served on the staff of the National Institute of Mental Health, in the Departments of Psychiatry at the Columbia-Presbyterian Medical Center and Columbia University's College of Physicians and Surgeons. He also founded PsyCom.net in 1997, an online resource site for clinicians and consumers.

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7.7. 5 Sit-to-stand test[33]

Description: Assesses functional lower extremity strength, transitional movements, balance, and fall risk.

Equipment: Stopwatch; standard height chair with straight back (16 inches high).

Therapist Instructions: Have the patient sit with their back against the back of the chair. Count each stand aloud so that the patient remains oriented. Stop the test when the patient achieves the standing position on the 5th repetition.

Patient Instructions: "Please stand up straight as quickly as you can 5 times, without stopping in between. Keep your arms folded across your chest. I'll be timing you with a stopwatch. Ready, begin."

Interpretation:
- Lower times = better scores
- MDC: 3.6-4.2 sec [1, 2]
- MCID: 2.3 sec [3]

Age-Matched Norms[4]:

Age Bracket	Time (sec)
60-69 yo	11.4
70-79 yo	12.6
80-89 yo	14.8

Fall Risk:
- Geriatrics
  - -need for further assessment of fall risk: ≥ 12 sec[5]
  - -recurrent falls: > 15 sec[6]
- Vestibular Disorders
  - -fall risk: > 15 sec[7]
- Parkinson's Disease
  - -fall risk: > 16 sec[8]

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7. Buatois, S., Miljkovic, D., et al. (2008). "Five times sit to stand test is a predictor of recurrent falls in healthy community-living subjects aged 65 and older." Journal of the American Geriatrics Society 56(8): 1575-1577.
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7.8. 10 Meter walk test[35]

General Information:

- individual walks without assistance 10 meters (32.8 feet) and the time is measured for the intermediate 6 meters (19.7 feet) to allow for acceleration and deceleration
    - start timing when the toes of the leading foot crosses the 2-meter mark
    - stop timing when the toes of the leading foot crosses the 8-meter mark
    - assistive devices can be used but should be kept consistent and documented from test to test
    - if physical assistance is required to walk, this should not be performed
- can be performed at preferred walking speed or fastest speed possible
    - documentation should include the speed tested (preferred vs. fast)
- collect three trials and calculate the average of the three trials

Set-up (derived from the reference articles):

- measure and mark a 10-meter walkway
- add a mark at 2-meters
- add a mark at 8-meters

Patient Instructions (derived from the reference articles):

- Normal comfortable speed: "I will say ready, set, go. When I say go, walk at your normal comfortable speed until I say stop"
- Maximum speed trials: "I will say ready, set, go. When I say go, walk as fast as you safely can until I say stop"

10 Meter Walk Testing Form

Name:_____
Assistive Device and/or Bracing Used:_____
Date:_____

Seconds to ambulate 10 meters (only the middle 6 meters are timed)

Self-Selected Velocity: Trial 1_____sec.___	Fast Velocity: Trial 1_____sec.___
Self-Selected Velocity: Trial 2_____sec.___	Fast Velocity: Trial 2_____sec.___
Self-Selected Velocity: Trial 3 _____sec.___	Fast Velocity: Trial 3_____sec.___
Self-Selected Velocity: Average time___sec.__	Fast Velocity: Average time___sec.__

Actual velocity: Divide 6 by the average seconds
Average Self-Selected Velocity:_____m/s
Average Fast-Velocity:_____m/s

References:

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