

# ASSESSMENT OF OVERALL FUNCTIONING IN PATIENTS WITH COMPLEX HEALTH ISSUES

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## INTRODUCTION

Assessment of overall functioning including the ability to perform activities of daily living (ADL) is a key assignment at the Department of Social Medicine. The impact on each patient is great, as the outcomes of the assessment are used in the evaluation of work ability and social insurance performed by municipal authorities. Current practice is an assessment of the patient based on a clinical examination, medical records and in some cases the Work Rehabilitation Questionnaire (WORQ) and physical performance tests. Thus, the assessment depends greatly on the physician's expertise and knowledge as is the case in other comparable units.<sup>1</sup> As also reported by comparable units<sup>2</sup> we find a need to enhance uniformity and quality of the assessment of overall functioning at our Department of Social Medicine as part of evidence-based practice. Therefore, the overall aim of this project is to develop a standard for assessing overall functioning at the Department of Social Medicine.

To enhance quality and uniformity, guidelines for the medical evaluation of functioning and work disability based on ICD-10 diagnoses have been implemented in comparable units<sup>3</sup>. However, as stated by others<sup>4 5</sup> the assessment of work ability should be multifactorial.

According to the International Classification of Functioning, Disability and Health (ICF), developed by the World Health Organization (WHO), functioning is an umbrella term for body function, body structures, activities, and participation. The ICF model describes functioning, and disability based on an interaction between body structures, health conditions, environmental factors, and personal factors. The ICF-model is used as a framework by physicians in the assessment of social insurance across Europe<sup>7</sup> and supplements the well-known ICD-10 system by having a biopsychosocial approach. Thus, the ICF together with the ICD-10 provides "*a broader and more meaningful picture of the health of people or populations which can then be used for decision-making purposes*".<sup>8</sup>

We have found no studies presenting a set of instruments or standard procedures for evaluating overall functioning, as presented in the ICF-model, in an unemployed population. Accordingly, we plan to develop a standard procedure including a set of instruments to evaluate overall functioning including relevant aspects of body function, activities, and participation among persons unemployed due to complex health issues.

The first step in this process, was to identify aspects of functioning relevant in this particular clinical context. Patients referred to the Department of Social Medicine most often are affected by several somatic and/or psychiatric disorders and their health can be affected by social circumstances e.g. substance abuse or homelessness. The examination should both be able to describe the patient as well as uncover special needs relevant for workability. Therefore, an examination of overall functioning needs to describe impairments in body functions, especially movement-related functions, as well as the ability to engage in activities and participate. After identifying these relevant aspects, we secondly started the process to find instruments covering these aspects. During this process different instruments investigating functioning, which has previously been found associated with workability, was identified.

The Assessment of Motor and Process Skills (AMPS) is a performance-based test describing the safety and independence of overall ADL task performance. During an AMPS evaluation ADL motor skills and ADL process skills are evaluated. In general ADL skills are defined as small and observable parts of performance (i.e. actions).<sup>9</sup> In a Belgian study AMPS ADL ability measures were found to predict workability in 75% of chronically unemployed men<sup>10</sup>. Another study found a moderate correlation between current level of employment and ADL ability as measured by AMPS in adult with schizophrenia<sup>11</sup>.

We have found several studies investigating simple physical performance tests and their relation to work ability. Generally, a good correlation between physical performance tests and work ability has been found<sup>12-15</sup>. However, all these studies are either based on specific diagnoses<sup>13,15</sup> or a population in current employment<sup>12,14</sup>. Although, a wide range of physical performance tests have been investigated but we have found no consent on which tests to use.

Self-reported measurements have previously proven to be efficient in predicting workability and disability pension<sup>16,17</sup>. However, in a Danish study investigating functioning in women with chronic pain only a weak association between self-reported functioning and functioning measured by AMPS was found and it was concluded that both methods of assessment were necessary for a fulfilling description of functioning<sup>9</sup>. In another study<sup>18</sup> the combination of self-reported work ability and a physical performance test was found to increase the prognostic value of sustainable return to work in construction workers with musculoskeletal disorders.

As our patients generally have been unemployed for a longer period and often are affected by more complex health issues, we do not find the former studies applicable to our group of patients. Thus, although an association between the different instruments and workability has been established, we find a need to investigate feasible methods in a population corresponding to our patients and clinical needs. As displayed in table 1 we find that the abovementioned tests altogether represent different aspects of overall functioning as described in the ICF-model. Furthermore, the instruments represent different methods of assessing overall functioning.

<b>Format ICF-Classification</b>	<b>Body Functions</b>	<b>Activities and Participation</b>
<b>Questionnaire</b>	WORQ	WORQ, ADL-Q
<b>Interview</b>		ADL-I
<b>Observation</b>		AMPS
<b>Physical performance tests</b>	30sCST, HGS,	30sCST, CAS

*Table 1: Classification of the implemented instruments according to format and ICF-classification. WORQ (Work Rehabilitation Questionnaire), ADL-Q (Activities of Daily Living Questionnaire), ADL-I (Activities of Daily Living Interview), 30sCST (30 Seconds Chair Stand Test), HGS (Hand Grip Strength), CAS (Cumulated Ambulation Score), AMPS (Assessment of Motor and Process Skills).*

### **Overall, we hypothesize:**

- Patients being evaluated at the Department of Social medicine have a lower overall functioning, when compared with healthy adults.
- The implementation of each single instrument is feasible.
- Implementation of different methods ensures both the patients and the healthcare professionals' perspective on overall functioning.

### **Aim**

We want to investigate whether a combination of AMPS, physical performance measurements, and

questionnaires all together can be used in the assessment of overall functioning in an unemployed population with complex health issues.

The overall aim of the study is to determine whether each instrument examines the same aspect of overall functioning or contributes with different aspects.

## METHODS

### Study design

A cross-sectional study employing a combination of physical performance tests, questionnaires, and an observational test in all patients referred to the department who consent to participate in the study.

### Setting

The study will be conducted at the Department of Social Medicine at Bispebjerg and Frederiksberg Hospital, in the Capital Region of Denmark. The department receives patients referred by the municipality for a general clinical examination and an assessment of overall functioning (Klinisk Funktion). The criteria of referral are a need of a medical assessment of complex health issues and the impact on functioning and/or symptoms with no equivalent objective findings. Generally, the patients referred are characterized by complex health issues and several years of unemployment. The conclusion, which consists of a medical review and an assessment of overall functioning, is sent to the municipality and used e.g., in their assessment of workability and social insurance (førtidspension, fleksjob e.g.).

### Study period

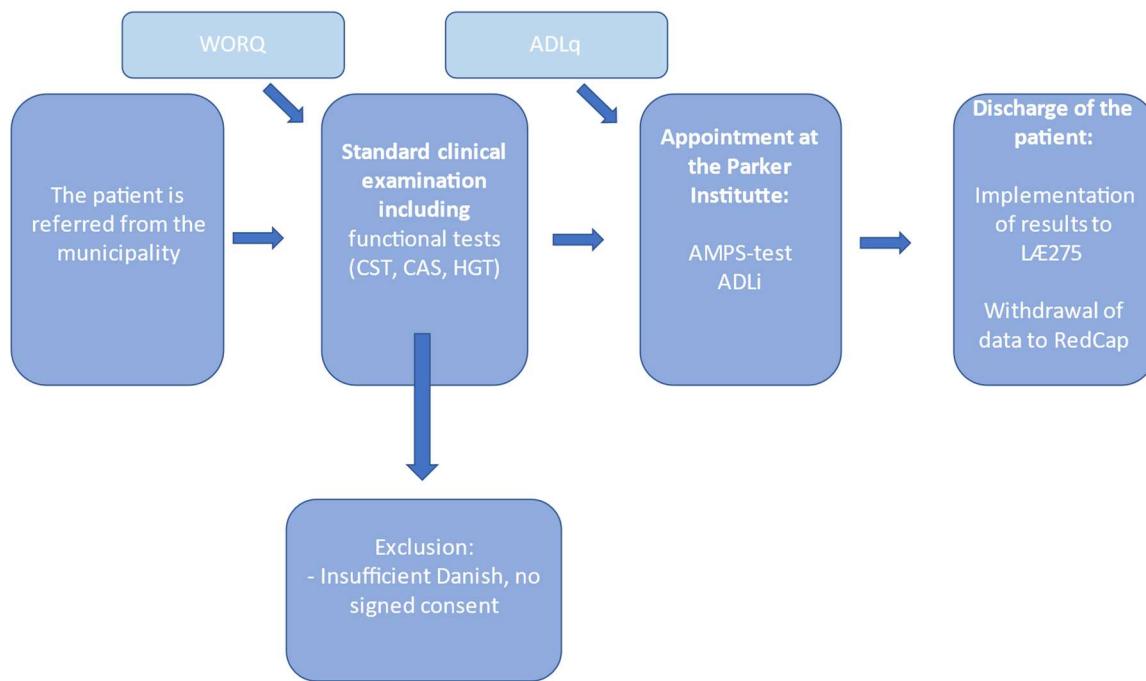
Based on the COSMIN guidelines<sup>21</sup> the study will continue until 100 patients have performed an AMPS-test. Based on the current number of patients referred to the department and an estimation of 50% percent of the patients consenting to participate the duration is estimated to 5-6 months. The study was initiated in October 2023.

### Participants

All patients referred by a municipality to the Department of Social Medicine at Bispebjerg for a clinical assessment (Klinisk Funktion) who consent to participate. Patients are excluded if they are unable to complete questionnaires and receive instructions in Danish without the use of an interpreter.

### Procedures

All patients included in the study will, in addition to standard procedure, be asked to answer two additional questionnaires (ADL-Q and ADL-I), and present for an AMPS-test. performed by an occupational therapist on an additional outpatient day at the Parker institute at Frederiksberg Hospital.



*Figure 1: Work-flow of the elements included in each assessment. CST: 30 seconds chair stand test, CAS: Cumulated ambulation score, HGS: Handgrip strength, AMPS: Assessment of motor and process skills, ADL-I: Activities of daily living interview, ADL-Q: Activities of daily living questionnaire, LÆ275: Documentation and conclusion send to the municipality.*

**WORQ:** As standard procedure WORQ is sent to all patient, who have a personal, digital mailbox (eboks) approximately 10 days prior to the scheduled appointment. One week prior to the scheduled appointment a nurse routinely calls all patients and remind them to respond to the questionnaire. If patients included in the study have not returned the questionnaire electronically a paper print-out is given at the first visit. The patient is asked to complete the questionnaire at home and return at the day of the AMPS-test.

**CAS, 30sCST and HGS:** As standard procedure CAS, 30sCST and HGS are performed during the first visit at the clinic by the principal doctor. Specifically for patients participating in the study, the test will be performed by a trained healthcare professional during the day of the AMPS-test, if not performed at the first visit. Prior to study start all physicians will be re-instructed in the test battery at an assembly. New physicians arriving at the department during the study period will receive individual instructions on the test battery. Furthermore, all physicians will have access to videos demonstrating the test battery and test manual <sup>22</sup>. Test results are noted in the electronic medical system. The physician is immediately informed whether the patient, according to their sex and age, is performing normal, reduced, or strongly reduced according to the reference values.

**ADL-Q:** is responded in a printout version handed to the patient when presenting for the AMPS-test. A secretary checks the answers to ensure all questions are completed. ADLQ is always responded prior to the ADL-I or else omitted.

**ADL-I:** Is performed by a trained occupational therapist prior to the AMPS-test.

**AMPS:** The AMPS-test is performed by an occupational therapist in accordance with

Results in the AMPS-test will be available to the medical doctor after the last consultation and before writing of the conclusion. If considered relevant by the medical doctor, the results will be implemented in

the conclusion sent to the municipality upon of the patient.

All patients will receive standard care.

## Instrumentation

### **Physical performance tests**

A battery of physical performance tests including the 30 seconds chair stand test (30sCST), hand grip strength test, and CAS-score have been implemented for all hospitalized patients seen by a therapist for the evaluation of physical function at Frederiksberg and Bispebjerg Hospital. The tests together demonstrate ability to perform basal activities associated with ADL. Furthermore, they excel by their ability to describe physical performance in different age decades and levels of physical performance.<sup>23</sup> Reference values have been established based on several large Danish cohort studies for the 30sCST and hand grip strength test<sup>24,25</sup> and former studies and consensus for the CAS-score<sup>23</sup>. In the current study, the physical performance tests are performed standardized in accordance with the implemented procedures at Bispebjerg and Frederiksberg hospital.<sup>22</sup> These physical performance tests were implemented at the Department of Social Medicine as part of a quality project in the latter part of 2022. HGS and 30sCST has previously been found to describe both body functions and the ability to engage in activities and participate.<sup>26</sup>

**Thirty Seconds-Chair Stand Test** has been found to describe lower muscle power<sup>27</sup> and an association with general performance has been found<sup>28</sup>. 30SsST is performed using the same chair as hand grip strength with a seat height of approximately 45 cm. The patient is instructed to rise to a full stand and sit as many times as possible in 30 seconds. Arms are crossed at the wrist and held against the body. One-two trial stands are permitted for practice before testing. The final stand is counted only if the patient is more than half erected. 30sCST has previously been used to describe both body functions and activities/participation according to the ICF-model.<sup>26</sup>

**Hand Grip Strength Test** is used as a proxy of general muscle strength<sup>29</sup> and has also been found associated with general performance<sup>30</sup>. The hand grip strength test is performed with the patient placed in a chair with armrests, the dominant arm on the armrest, elbow apart from the body, and wrist in neutral position using a hand dynamometer (Baseline BIMS™ Digitalt hånddynamometer (model 12-0072). The patient is instructed to squeeze the dynamometer as hard as possible for approximately 5 seconds. Three attempts are made and further two if the last attempt is the best. The best result is referred in kilograms. HGS has previously been found to describe body function according to the ICF-model.<sup>26</sup>

**Cumulated ambulation score (CAS-score)** is used as an indicator of basic mobility<sup>31</sup>. The CAS-score is calculated based on the performance of the following three daily activities: getting from lying position on an examination bed to standing position and back, getting from sitting position in a chair with armrests to standing and back, and walking within the facility. The patient is instructed to perform each of the three activities. A cumulated score is calculated based on the ability to perform each task unassisted (2 points), physical or verbally guided (1 point) or not at all (0 points), providing a one-day score of 0-6 points. The use of walking aids does not inflict the results.

### **Questionnaires**

**The Work Rehabilitation Questionnaire (WORQ)** is a validated questionnaire based on the ICF-model developed to evaluate and document functioning in vocational rehabilitation<sup>5</sup>. It has been constructed to describe both body functions and the ability to engage in activities and participate according to the ICF-model.<sup>5</sup>

**ADL-Q and ADL-I** are both based on self-reported evaluation of ADL ability. The ADL-Q is a questionnaire whereas the ADL -I is interview-based. They have identical items and consist of 47 ADL tasks which are each rated using 7 response categories ranging from competent to unable. Subsequently data is analyzed, and the responses are converted to an overall ADL ability measure expressed in logits (log-odds units), based on Rasch Measurement Methods. The ADL-I/ADL-Q measures express self-reported ADL-ability<sup>32,33</sup>. It has previously been found that patients report a better ADL ability using questionnaires compared to the

interview-based method<sup>33</sup>. In aspect of the ICF-model ADL-Q and ADL-I describe ability to engage in activities and participate<sup>34,35</sup>.

The patient receives the ADL-Q in paper form before seeing an occupational therapist at the day of the AMPS-test.

#### **Assessment of Motor and Process Skills (AMPS)**

AMPS is a well-known test measuring ADL motor and ADL process ability<sup>9</sup>. The test will be performed by a trained occupational therapist at the Parker institute at Frederiksberg Hospital. The test consists of more than 120 standardized PADL and IADL tasks of which the patient is asked to perform two tasks. The tasks chosen must be relevant for the patient in daily life and of appropriate challenge. The quality of 16 ADL motor and 20 ADL process actions are evaluated based on the observations during performance of the tasks. Each individual motor- and process ADL skill is evaluated based on the ease, efficiency, safety and independence observed and categorized into one of four categories (1=markedly deficient, 2=ineffective, 3=questionable, 4=competent). The occupational therapist enters the raw ordinal ADL scores in a many-faceted Rasch-based AMPS computer-scoring software which converts the scores into two overall ADL ability measures adjusted for ADL task difficulty and rater severity expressed in logistically transformed probability units, logits. The test has been found to evaluate the ability to engage in activities and participate according to the ICF-model.<sup>20</sup>

#### **Implementation of results in clinical practice**

Upon completion of the AMPS-test and ADL-I the results will be assessed by an occupational therapist at the Parker Institute. Results will be summarized and documented in the electronic medical records in a standardized report. The structure of the report will be developed in collaboration between the two departments prior to study start to assure uniform and clinically relevant data. The report will include a summarization, the two overall ability measures values (ADL motor and ADL process skills) including reference values, and a graphical report demonstrating the results in relation to age-adjusted reference values. The results will be available in the electronic medical records before writing of the conclusion after the last consultation.

#### **Analysis**

Correlation-analysis will be performed to investigate the correlation between each single implemented

## **STATISTICS**

As the study is explorative no fulfilling or conclusive statistical analyses can be made to decide an accurate number of involved participants. Furthermore, no “gold standards” exists to investigate validity of patient-reported outcome measures and expected relationships with other outcome measures and/or differences between relevant groups<sup>21</sup>. To assure an adequate number of participants we have consulted the “COSMIN Study Design checklist for Patient-reported outcome measurement instruments”<sup>21</sup>. For a study design to be adequate to conclude on comparison with other outcome measurement instruments and comparison between subgroups 50-99 patients is advised and >100 is considered very good.

A statistical analysis plan will be available before commencing analyzation.

## DATA OBTAINED FROM THE MEDICAL RECORDS

### **Data obtained before informed consent:**

To be able to inform and include patients following data will be forwarded to a healthcare professional involved in the study (primary investigator, sponsor, or a representative) before informed consent: name, CPR-number and date and time of first appointment at the clinic. To include 100 patients, we estimate the need of information from between 150-200. When 100 patients have performed an AMPS-test, we will stop inclusion and thus the need of information from more patients.

### **Data obtained with informed consent:**

To be able to perform the study, relevant data will be collected from the electronical medical records. Data will be withdrawn by a healthcare professional involved in the study (primary investigator, sponsor, or a representative). Only written records obtained at the Department of Social Medicine will be revised in the collection of data. Following data will be collected:

*Baseline:* Sex, date of birth, municipality of residence, height, weight, marital status, number of children, ethnicity, length of residence in Denmark.

*Health:* diagnoses, medications, substance abuse (alcohol, drugs, smoking).

Employment and education: years since last employment, current social benefit, current social welfare programme (ressourceforløb etc.), years of employment, education, completed elementary school, own perspective on ability to obtain employment.

*Functioning:* Self-reported daily activity, functioning assessed by the medical doctor, results from the AMPS-test, results from the ADL-I/ADL-Q, number of stands in 30sCST, strength in HGS, score in CAS, results in WORQ.

*Data from assessment during the visit at the Department of Social Medicine:* intern referral to psychiatrist, psychologist, social worker or rheumatologist, conclusion on functioning, conclusion on the ability to participate in employment.

## RISK, ADVERSE EVENTS, AND DISADVANTAGES (SHORT AND LONG TERM)

The primary disadvantage is the necessity of the patient to present on an additional day at Frederiksberg Hospital. As we only ask patients to perform tasks associated with daily living we cannot think of any risk for the participants. Based on the study setup we consider the risk of any unforeseen disadvantages or risk very low although it cannot be completely excluded.

## PROCESSING OF PERSONAL DATA

Relevant data for the included patients is retrieved from SocMed (a national RedCap database) on patients examined at the Departments of Social Medicine. Data-withdrawal is pseudonymized. For analysis pseudonymized data is stored in a secured folder on the L-disk drive and deleted immediately upon termination of the analysis. The study meets the requirements in the General Data Protection Regulation and General Data Protection Regulation. The study has been approved and registered by the data committee of the capital region (Forskningsjura i Region Hovedstaden, P-2023-277).

## ECONOMY

The project is initiated and funded by the Department of Social Medicine (Frederiksberg Hospital). The department of Social Medicine guarantee sufficient funding to complete the project. Funding from Danish funds will be sought to cover expenses of salary, conferences etc. In the case of external funding, the local ethics committee and all patients included will be informed on name of the sponsor/fund and amount.

## RECRUITMENT OF PARTICIPANTS AND INFORMED CONSENT

Information regarding the study will be sent (electronically or by letter) to all patients together with the details of their first appointment at the department. The information contains details on the right to bring a family member, friend or other. Upon presentation for the first scheduled appointment, the patient receives oral information from either their principal doctor or a health professional associated with the study. In the case of delegation of oral information and consent, a written agreement is available at the site. To ensure a suitable environment the information will be given in the examination room.

The patient can decide to consent directly upon receiving the information on which occasion, the physical tests will be performed on the same day. If the patient needs further time for consideration a health professional associated with the study will call on the following day and written consent and the physical performance tests will be performed on the same day as the AMPS-test.

## INSURANCE

All patients included will be covered by the Danish Patient Compensation (Patienterstatningen).

## DISSEMINATION OF RESULTS

All results from the study, both positive, negative, and inconclusive findings, will be publicized in relevant international journals. Furthermore, study results will be publicized on the webpage of the department.

## ETHICAL CONSIDERATIONS

We consider the risk and disadvantages of the study very low. The physical performance test and the AMPS test are well known and considered with no risk of harm. The advantage of the study is a more thorough examination of each patient. Furthermore, as the tests are performed as part of a study, we assure that only the best and most reliable tests will be permanently introduced assuring an improved and evidence-based assessment of functioning in the future. The study will be approved by the local ethics committee before initiation (H-23030964). Written informed consent will be signed by all patients prior to participation.

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