Study protocol for
The Social-HD Study: A Cross-Sectional Observational Study of Social Cognition in Early Huntington Disease

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Background

Huntington disease (HD) is a fatal neurodegenerative disorder without any disease-modifying therapies available. It affects 1 in 10.000 individuals with around 1000 people affected in Sweden (Furby et al., 2023). It is caused by an expanded CAG repeat in the huntingtin (*HTT*) gene which is inherited in an autosomal dominant fashion with full penetrance. It typically manifests at 30-50 years of age. Clinical diagnosis is based on overt movement disorder with chorea and a genetic test. The disease then progresses leading to premature death around 15 years after onset (Furby et al., 2023). HD is further characterized by cognitive deficits and psychiatric symptoms, which frequently emerge many years before any observable signs of motor dysfunction (Epping et al., 2016; Stout et al, 2011). The cognitive symptoms include executive dysfunction, reduced attention and reduced psychomotor speed, and eventually leads to a state of dementia (Peavy et al., 2010). Commonly reported psychiatric symptoms include depression, apathy, and irritability (Clark et al., 2023; Karagas, Rocha & Stimming, 2020). These non-motor symptoms are assumed to be a significant contributor to patient and informal caregiver burden (Dawson, Kristjanson, Toye & Flett, 2004; Eddy & Rickards, 2022; Mason et al., 2024).

Families with HD often describe a personality change and social functioning to be the first noticeable change in a person with HD. These changes may partly be related to the movement disorder, psychiatric symptoms, and general cognitive impairment. In the past few decades however, there has been an increasing awareness of how specific deficits in social cognition affects persons with HD (Bora, Velakoulis & Walterfang, 2016; Considine et al., 2024; Escudero-Cabarcas et al., 2024), possibly caused by the effects of mutant *HTT gene*. Social cognition is a multidimensional construct which is usually taken to include social perception, emotion recognition, theory of mind (the ability to attribute mental states such as feelings, thoughts, or intentions of others) and social behavior (Christidi et al., 2018). Being able to recognize, process, interpret and appropriately react to social signals is essential for humans when forming and navigating social relationships across the lifespan. Consequently, deficits in social cognition may have substantial negative effects on the persons' well-being, beyond psychiatric symptoms and general cognitive decline, due to altered relationships and difficulties at work. Despite increased awareness of the impact that social cognition may have on patients' quality of life, neuropsychological evaluation in routine clinical practice typically does not include socio-cognitive tests (McDonald, Wearne & Kelly, 2023; Quesque et al., 2024; Rabin, Paolillo & Barr, 2016).

Study rationale

Increased interest in tests that reliably measure social cognitive deficits in HD has led researchers to investigate the several different tests; and among these, ***Reading the Mind in the Eyes Test (RMET)*** (Baron-Cohen et al., 2001) is the most widely used measure of social cognition in HD according to a recent literature review (Escudero-Cabarcas et al., 2024). A related example is ***The Emotion Hexagon Test (EHT)*** (Sprengelmeyer et al., 1996), which has been validated in a HD population (Larsen et al., 2016). RMET and EHT share similar features, since both are relatively brief in administration time; and both require the examinee to evaluate the emotional states based on still pictures of human faces. One assumed weakness of this type of

test, however, is the limited ability of inferring socio-cognitive deficits based on test performance from static images alone (Henry, Cowan, Lee, & Sachdev, 2015).

To counter the above limitation, the development and usage of naturalistic and multi-modal tests that assess socio-cognitive functioning has increasingly been advocated in recent scientific literature (Msika, Despres, Piolino & Narme, 2024; Osborne-Crowley, 2020), including video-based or even interactive tasks. In this context, ***The Movie for the Assessment of Social Cognition (MASC)***, aims to sensitively capture the multidimensionality of the construct to a greater degree (Dziobek et al., 2006). It is a promising candidate for several reasons, not least due to its video-based format. The test has been utilized in addressing deficits in social cognition in several patient groups, including high-functioning autism, schizophrenia, bipolar disorder borderline personality disorder, and multiple sclerosis (Dziobek et al., 2006; Montag et al., 2010a; Montag et al., 2010b; Preißler et al., 2010; Pöttgen et al., 2013). In a recent review of tests of social cognition in a neuropsychology setting, Msika et al. (2024) suggests MASC as a relevant task for assessing theory of mind (ToM) in clinical practice, mainly because of its psychometric properties, ecological validity, and the availability of norms. However, to the best of our knowledge, no research has yet been conducted to determine its usefulness in the case of HD patients.

The central aim of the present study is to explore clinical utility of MASC (or rather, its Swedish translation, DMASC-MC) in a population of HD patients, with the purpose of developing a more comprehensive socio-cognitive test battery in the context of clinical practice. Our assumption is that a broader assortment of measures for social cognition would allow the neuropsychologist to tailor the assessment more flexibly and in turn provide in-depth analysis of socio-cognitive functions. We further assume that this would ultimately benefit both patients and their social relations, for mainly two reasons. Firstly, after including tests of social cognition in the evaluation, a feedback-session with the patient and close relatives has the potential for therapeutic gains due to increased insight of any identified problems (cf. Waldron-Perrine, Rai & Chao, 2021). Secondly, there is a growing literature on treatment approaches aiming at remediation of socio-cognitive deficits (McDonald, Wearne & Kelly, 2023); and by appropriately assessing for such impairments, clinicians set the stage for informed recommendations on how to best alleviate or cope with them.

Potential risks and benefits

Partaking in neuropsychological evaluation is generally assumed to be of value for the examinees and their close ones, since it allows for greater insight and understanding of personal cognitive strengths and weaknesses. For people who suffer from a disease such as HD, this insight alone might in turn lead to a decrease in symptom burden as well as increased quality of life. At the same time, engaging in cognitive testing is typically mentally taxing, which for some people could be experienced as stressful or frustrating. Furthermore, test results indicating deficits could also be cause for emotional distress and further questions regarding how the disease or other factors may have impacted that examinee as a person. To alleviate the above risks, all subjects of the present study will be given the chance to reflect on any distressing thoughts or feelings during a feedback session with a psychologist during a clinical visit or via telephone. The feedback session will be

tailored specifically to each subject's needs and includes the possibility to ask further questions and seek advice or emotional support. An additional feedback session with further support and guidance will be offered if deemed necessary either by the psychologist or the test subject.

Beyond benefits for the individual study participants, the goal of the present study is to further the general understanding of socio-cognitive assessment as well as socio-cognitive deficits in HD. This in turn is taken to increase the potential for optimal care of patients that suffer from impairments in this domain. Since the evaluations are administered during working hours, each study participant will have to consider the possible drawbacks of refraining from work or other personal matters.

Patient and public involvement
In the preparation for the Social-HD study, we invited patient organizations (Riksförbundet för Huntingtons sjukdom; https://huntington.se and YTAN- digital stöd för unga anhöriga; https://ytanforunga.se) and through them, persons in families with HD for patient and public involvement in designing the study. This was done during two separate meetings totaling approximately two hours that were held on the 7th of April and the 14th of May in 2025. During the meetings, the participants were given a presentation of the study background and purpose, as well as an overview of the study design and procedures. The participants were asked to give their spontaneous reactions and asks questions after the initial presentation. Further, we asked them questions prepared by us in advance, regarding the purpose of the study; inclusion and exclusion criteria; the time schedule for the study; and the proposed procedure for feedback to research participants. The feed-back from these sessions has been instrumental in the design of the study.

Study design/ Schedule of assessments
The study will take place at one center, i.e. the HD clinic at the Neurology clinic at Skane University hospital in Lund, Sweden. The study will begin in 2025 and the recruitment period will last into 2026. The assessments in this study are clinician-reported outcome (ClinRO) and performance outcome (PerfO) instruments.

Assessments (in the order they will be used):

Montreal Cognitive Assessment (MOCA) (PerfO)
The Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005) is a cognitive screening tool that can detect cognitive impairment in HD (Videnovic et al., 2010; Ringkøbing et al., 2020). It contains a series of basic assessments, including attention and visuospatial tasks. The total score ranges from 0 to 30, where lower scores indicate greater impairment. It takes approximately 10 minutes to administer.

Total Functional Capacity Scale (TFC) (ClinRO)
The Total Functional Capacity Scale (TFC) is a validated measure of global patient function in HD (Huntington Study Group, 1996). The TFC represents the Investigator's assessment of the participant's capacity to perform a range of activities of basic daily living, including working, chores, managing finances, eating, dressing, and bathing. The five-item assessment is based on a brief interview with the participant. The TFC score ranges from 0 to 13, with a higher score representing better functioning. The TFC takes approximately 10 minutes to administer.

Total motor score (TMS) (ClinRO)
The UHDRS Motor Assessment contains the total motor score (TMS) which is a measure of motor function in HD (Huntington Study Group, 1996). The TMS score is the sum of the individual motor ratings obtained from administration of the 31-item motor assessment portion of the UHDRS by the Investigator. The score ranges from 0 to 124, with a higher score representing more severe impairment. It takes approximately 15 minutes to administer.

Montgomery-Åsberg Depression Rating Scale (MADRS) (ClinRO)
MADRS (Montgomery & Åsberg, 1979) is a widely used rating-scale designed to assess depressive symptoms. It exists both as a clinician rated version, and as a self-report measure, MADRS-S (Svanborg & Åsberg, 1994). The clinician version alone will be used for the present study; it comprises 10 items rated on a 7-point Likert scale (0-6), which are added for a total score (range 0-60).

Apathy Evaluation Scale (AES) (ClinRO/(PerfO)
The Apathy Evaluation Scale (AES) (Marin, Biedrzycki & Firinciogullari (1991) is a wide-spread measure designed to capture symptoms of apathy due to brain-related pathology. It exists both as a self-report measure (AES-S) and informant questionnaire (AES-I), with 18 items covering cognitive, affective, and behavioral aspects of apathy, as experienced by the informants for the past four weeks. It has been shown that self-rated and companion-rated apathy is highly correlated in HD (Mason and Barker, 2015). A clinician version (AES-C) also exists, wherein a health professional rates the same items based on the patient's behavior and information given during an interview. During administration, the rater is asked to answer each statement on a 4-point scale (0-3). Total score can vary between 0 and 72 points; for the Swedish translation (Johansson et al, 2017) a score of >36,5 has been suggested as a preliminary cut-off for apathy. For the present study, AES-S and AES-C will be administered. AES takes approximately 10-20 minutes to administer.

Symbol digit modalities test (SDMT) (PerfO)
The SDMT is used to assess attention, visuoperceptual processing, working memory, and psychomotor speed. It has been shown to have strong reliability and validity (Smith, 1982). The participant pairs abstract symbols with specific numbers according to a translation key. The test measures the number of items correctly paired (maximum of 110 correct pairs) in 90 seconds. The oral form of the test (used in the current study) allows for valid assessment of processing speed with minimal impact of motor deficits. It takes around 5 minutes to administer.

D-KEFS Color Word Interference Test (CWIT) (PerfO)
The CWIT is part of the Delis-Kaplan Executive function system (Delis, Kaplan & Kramer, 2001), based on the Stroop (1935) procedure. CWIT consists of four separate subtests, which include measures of speed of verbal output, verbal inhibition, and cognitive flexibility. The first two conditions serve as baseline measures and simply require the examinee to name colors or words (i.e. "RED", "BLUE", "GREEN") on a printed page. For the third condition, words are printed in dissonant ink, and requires the examinee to inhibit an overlearned verbal response by naming the color of the print (rather than reading the words). The fourth condition introduces a measure of cognitive flexibility by asking the examinee to switch

between naming the dissonant ink colors and reading the words. The score is calculated from the amount of time taken for the examinee to finish each of the four tasks. The test takes approximately 15 minutes to administer.

D-KEFS Verbal Fluency Test (VFT) (PerfO)
The VFT is part of the Delis-Kaplan Executive function system and is based on other similar and often used measures of verbal fluency (Delis, Kaplan & Kramer, 2001). The test includes three similar conditions, all of which were designed to measure spontaneous word-production according to a certain set of rules. The conditions used in the present study (Phonemic fluency and Category switching) requires the examinee to orally produce as many words as possible for one minute. Further, these words must either begin with certain specified letters (phonemic fluency) or alternate between specific categories (category switching). The score is calculated from the amount the words that the examinee can produce; as well as his/her ability to conform to a few specified rules. The test takes approximately 5 minutes to administer.

The Movie for the Assessment of Social Cognition (MASC) (PerfO)
MASC (translated and published as in Sweden DMASC-MC) is a video-based test for the evaluation social cognition and “mentalization” (a construct that is closely related, or even synonymous, to ToM) (Dziobek et al., 2006; Bölte, Fleck & Dziobek, 2014). The test presents the examinee with a 15-minute film which portrays four individuals, played by professional actors, during a dinner-party. The film pauses at 45 different instances, whereupon the examinee is prompted to answer multiple-choice questions about the thoughts and feelings of these individuals. The result is calculated as a total score and can be further analyzed using different subscales. It takes approximately 45 minutes to administer.

Reading the Mind in the Eyes Test (RMET) (PerfO)
RMET is used to measure socio-cognitive function in terms of ToM (Baron-Cohen et al., 2001). The test presents examinees with photographs of the eye-region of 36 different individuals. For each photograph, the examinee is asked to choose which mental state best describes that of the person pictured (i.e. what he or she might be thinking or feeling). Each item provides a set of four possible answers (multiple-choice), and the examinee is allowed to refer to a vocabulary list where the literal meanings of these answers are defined. The result of the test is the total amount of correct responses, excluding one practice item. It takes approximately 15 minutes to administer.

Emotion Hexagon (EHT) (PerfO)
The EHT, originally developed by Sprengelmeyer et al. (1996) includes 30 images of the same man, with morphed facial expressions along a spectrum of different basic emotions, is a measure emotion recognition. For the present study, an adapted Danish-language paper version (Vogel, Jørgensen & Larsen, 2020) consisting of printed cards was translated to Swedish with the permission from the original developers. The examinee is asked to choose which of six basic emotions (a wordlist is provided) best corresponds to each photograph. The test can be given in two separate ways: either as a quick screening, or a more in-depth administration. The result is calculated by adding up the total amount of correct answers, excluding the first practice item. Administration of the screening takes approximately 15 minutes.

Tests to evaluate HD stage

The following tests have been chosen as they have shown to measure disease stage and progression in clinical trials: TFC, TMS, SDMT, CWIT (Boareto et al., 2025; Tabrizi et al., 2022). In HD it is thought that both onset and progression are driven by cumulative exposure to the effects of mutant (or CAG expanded) huntingtin (mHTT). The CAG-Age-Product (CAP) score (i.e., the product of excess CAG length and age) is a commonly used measure of this cumulative exposure and will be used in this project (Warner et al., 2022).

Study objectives
The primary objective and corresponding endpoint are provided in Table 1.

Table 1. Primary objective and corresponding endpoint

Objective	Endpoint
To investigate if persons with HD have a significantly lower score than a control group in the test “The Movie for the Assessment of Social Cognition” (MASC)	Significant difference in mean value of MASC total score between HD and controls

The secondary objectives and corresponding endpoints are provided in Table 2.

Table 2. Secondary objectives and corresponding endpoints

Objective	Endpoint
To investigate if persons with HD have a significantly lower score than a control group in the Reading the Mind in the Eyes Test (RMET) test.	Significant difference in mean value of RMET total score between HD and controls
To evaluate if persons with HD have a significantly lower score than a control group in the Emotional Hexagon (EH).	Significant difference in mean value of EH total score between HD and controls
To investigate if there is a correlation between social cognitive test scores and MOCA scores (= cognitive scores).	Significant correlation between social cognitive test scores and MOCA scores
To investigate if there is a correlation between social cognitive test scores and TFC scores (=scores for everyday life function in HD).	Significant correlation between social cognitive test scores and TFC scores
To investigate if there is a correlation between social cognitive test scores and CAP scores (=scores for disease burden).	Significant correlation between social cognitive test scores and CAP scores
To investigate if there is a correlation between social cognitive test scores and TMS scores (= motor scores).	Significant correlation between social cognitive test scores and TMS scores
To investigate if there is a correlation between social cognitive test scores and MADRS scores (= depression scores).	Significant correlation between social cognitive test scores and MADRS scores

To investigate if there is a correlation between social cognitive test scores and AES scores (= apathy scores).	Significant correlation between social cognitive test scores and apathy scores
To investigate if there is a correlation between social cognitive test scores and SDMT/CWIT/VFT scores (= cognitive scores).	Significant correlation between social cognitive test scores and cognitive scores
To investigate the proportion of both HD subjects and control subjects with impaired results on each of the social cognitive tests, compared to norms.	Percentage of subjects within the HD group performing below 1,5 SD compared to norm data on DMASC-MC, RMET and EHT, compared to prior norm data. Percentage of subjects within the control group performing below 1,5 SD compared to norm data on DMASC-MC, RMET and EHT.

Overview of the research plan

	Consent/Screening	Research: 1	Research: 2	Follow-up	Presentation of results
Visit 1	**MD (A+B)**				
Visit 2		**MD (C1)**	**Psychologist (C2)**		
Visit 3 or Phone				**Psychologist (D)**	
Meeting					**MD, Psychologist (E)**

A.Information about the research project including inclusions/exclusion criteria orally and written, informed consent

B. Screening:
MOCA test
Checklist of inclusion/exclusion criteria

C. Research visit
1. Psychiatrist, duration 1,5 h
1.1: Information:
Age:
Sex:
Education:
CAG repeat:
Age of diagnosis:
Medication:

1.2:Tests:
TFC: General function
TMS: Motor symptoms
MADRS: Depression
AES: Symptoms of apathy (patient + clinician: AES-S + AES-C)

1 h break

2. Psychologist, duration 2h
2.1. Short cognitive battery similar to the global observational study Enroll-HD: SDMT, CWIT, VFT

2.2. DMASC-MC

2.3 EHT and RMET

D. Follow-up visit or phone call by psychologist within 3 weeks

E. Information evening about the results for all participants and the HD community

Study population

Inclusion criteria
Participants are eligible to be included in the study if all the inclusion criteria are met:

Inclusion criteria for persons with HD
1. Clinical diagnosis of HD
2. CAG repeat: 39 and more
3. Age:18-75 years

Inclusion criteria for control group
1. No heritage of HD or negative pre-symptomatic HD gene test
2. Age:18-75 years

Exclusion criteria
Participants in both groups are excluded from the study if any of the following criteria apply:
1. Dementia or MOCA<19, MMSE <19
2. Other neurological disorders
3. Ongoing psychosis
4. Ongoing alcohol/drug addiction
5. Other native language than Swedish
6. Severe problems with vision and hearing

Withdrawal
The participant can withdraw from the study at any time-point.

Screen failures
Screen failures are defined as participants who consent to participate in the study but then do not meet inclusion criteria or where exclusion criteria apply. The primary investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure.

Recruitment Procedures
Recruitment of participants will be made at the HD clinic in Lund, Sweden and through ethical review board-approved advertisment material posted at social media platforms and websites hosted by the Huntingtoncenter at Lund and the Swedish patient organization Riksförbundet för Huntingtons sjukdom (RHS) as well as YTAN.

Statistical analysis plan
All statistical analyses will be performed using SPSS. The primary outcome measure, DMASC-MC total score, of the patient group will be compared to that of the control group using independent samples t-test. Assuming a difference of group means of at least one standard deviation (1 SD), we calculated the number of participants needed for 80% power to be 20 per group (40 in total), based on a 5% significance level.

For secondary outcome measures, RMET total score and EHT total score, of the patient group will be compared to those of the control group using independent samples t-test. Additionally, we plan to assess correlations using Spearman testing between the above measures and the following measures: TFC score (everyday life

function); CAP scores (disease burden); TMS scores (motor scores); MADRS and AES scores (psychiatric symptoms); and MOCA/SDMT/CWIT/VFT scores (= cognitive scores). For calculating the proportion of impaired results on social cognitive tests for both HD and control subjects, norm data based on healthy subjects will be used from Bölte, Fleck & Dziobek (2014) (DMASC-MC); Söderstrand & Almkvist (2012) (RMET); and Vogel, Jørgensen & Larsen (2020) (EHT).

If the underlying assumptions for t-test are violated the groups will be compared using Mann-Whitney U-test.

Data handling and monitoring
Data will be pseudonymized and source data will be stored in folders in fire safe lockers that only investigators in the study will have access to. Data entry in files will be made by the investigators and monitored by a research nurse. Data will be securely stored in password-protected folders in the computer system at Region Skåne.

Ethical and regulatory considerations
Research will be conducted in accordance with the declaration of Helsinki and GDPR regulations. Investigators are trained in GCP, MOCA and TMS.
The study has approval from the Swedish Ethics Review Board (Dnr 2025-04424-01)

Presentation and publication of the results
The data will be published in peer-reviewed scientific journals and at scientific conferences for HD and related disorders, as well as at meetings for the HD community.

Investigators at Region Skåne
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Co-PI: Psychologist Isak Halling, Region Skåne
Co-PI: Associate Professor Håkan Widner, MD PhD, Senior Consultant in Neurology, Region Skåne
Nurses: Camilla Svensson (Neurology) and Susann Schrey (Psychiatry), Region Skåne.

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