Clinical utility of the AMPD

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25774

Source
NTR

Brief title
TBA

Health condition

Personality disorders

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: De Viersprong

Intervention

Outcome measures

Primary outcome

Clinical utility questionnaire- Patient version
A specific outcome instrument measuring clinical utility for patients has been developed for the purpose of this study. Given the lack of such an instrument, a focus group was organized to collect implicit patient knowledge on clinical utility of PD assessment. The procedure has been described in a submitted paper. Briefly: a group of patients was asked to brainstorm about the concept of clinical utility of assessment; this procedure was repeated with other patient groups until no new information arose. The resulting themes were described and

returned to all participants in a Delphi procedure until sufficient consensus (at least 75%) was reached. Following up on consensus on the definition, specific items were formulated to assess the aspects of clinical utility that had emerged from the focus groups, until sufficient consensus was reached. We found that patients defined clinical utility of assessment as the ability of an assessment procedure to 1) Be destigmatizing, 2) Start a process in which the patient starts to get more insight into patterns and become hopeful and motivated to change, 3) Summarize the core patterns which underly the patients' problems, 4) Collaboratively work with the patient, and 5) Communicate transparently with the patient about the results of the assessment.

Clinical utility questionnaire – Clinician version
Although some very brief 'top-down' constructed measures for clinician clinical utility exist, we deemed these instruments incomplete and insufficient. Similarly as for patients, we used several focus groups and a subsequent Delphi procedure to define clinical utility of PD assessment from a clinician perspective and to formulate items to assess each of these aspects. Clinicians defined clinical utility of assessment as the ability of an assessment procedure to 1) Start a process in which the patient becomes curious about the problems he is facing and gets motivated to change, 2) Summarize the core patterns which underly the patients' problems, 3) Give a balanced view of both vulnerabilities and resilience, 4) Make predictions (prognostic) useful in treatment (i.e. risks, expected treatment success, expected interactional patterns, useful treatment interventions), 5) Use accessible and easy to understand language and paint a vivid picture of the patient, and 6) Communicate transparently with the patient about the results from the assessment.

Secondary outcome

Outcome expectancy
Expectancy for Future Treatment Scale (EFTS; available from project leader): a one-item visual analogue scale for patients to rate their expectancy regarding future treatment ("To what extent do you believe this intervention will benefit your future treatment?").

Satisfaction
For assessing general satisfaction with the assessment procedure we will use questions from the Client Satisfaction Questionnaire (Larsen et al., 1979). The questionnaire consists of 8 items, rated on a 4-point Likert scale. Internal consistency and concurrent validity of the CSQ-8 in a Dutch sample of 262 patients was high, with $\alpha = .92$ (de Wilde & Hendriks, 2005).

Benefits of assessment
The assessment questionnaire (Finn et al., 1994) will be used to assess different aspects of patient's experience of the assessment procedure. The AQ is a 48-item self-report questionnaire, with a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). It has been used in research concerning therapeutic/ collaborative assessment (Holst et al., 2009; Allen et al., 2003). The questionnaire consists of four factors: New self-awareness/understanding, Positive accurate mirroring, Positive relationship with the examiner, Negative Feelings about the assessment.

Motivation

Motivation will be assessed with the motivation for treatment questionnaire (MTQ-8, van Beek & Verheul, 2008), an 8-item self-report questionnaire comprised of two factors: need for help and readiness to change. Internal consistency of the MTQ-8 is fair to good, with α's ranging from .63 to .77.

Clinical utility scale clinicians
Morey (2014) developed a 6-items to assess different aspects of clinical utility in clinicians, which will be used as a secondary outcome to enhance comparability with other international studies.

Study description

Background summary

Rationale:
The traditional section II on Personality Disorder (PD) model has been contested for its limited validity and lack of clinical utility. To counter these shortcomings, DSM-5 has introduced in its section III an Alternative Model for Personality Disorders (AMPD). Previous AMPD studies have focused on separate criteria of the new model, e.g. by designing new instruments to assess sections of the AMPD. No studies have investigated the full AMPD assessment procedure and compared it to the existing, traditional DSM-5 PD assessment. This project will compare both assessment procedures (traditional/categorical (Section II) versus alternative/dimensional (Section III)) with regard to different aspects of clinical utility, from both a patient and clinician perspective.

Objective:
We will compare the AMPD model to the traditional (Section II) PD model with regard to patients' and clinicians' experience of the clinical utility of both models. As the AMPD model was designed to improve clinical utility, we expect that both patients and clinicians will report stronger clinical utility for the AMPD assessment procedure.

Study design:
Randomized Controlled Trial. Patients referred to de Viersprong for assessment and treatment will be randomly assigned to a traditional versus AMPD assessment procedure. Both procedures are comparable in terms of their multi-method approach and length of assessment and both have been manualized and approved by international experts. After having finished the assessment procedure, patients will complete a clinical utility questionnaire as well as questionnaires concerning process variables like satisfaction, motivation, and treatment readiness. Likewise, clinicians who will treat these patients, will assess the assessment report for clinical utility regarding the treatment to come.

Study population:
Patients are treatment seeking adults (18-65) referred to De Viersprong, a mental health care center specialized in the assessment and treatment of personality pathology.

Intervention:
In the traditional assessment procedure patients will have an intake consult with a clinician and the SCID-5-P will be administered (i.e., assessment as usual). In the AMPD admission procedure patients will be interviewed by a clinician and the STiP 5.1 and SCID-AMPD-II will be administered. In both conditions, screening questionnaires will be included after the initial intake consult.

Main study parameters/endpoints:
The primary outcome is clinical utility as assessed by patients and clinicians.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Burden will be minimal. Number of sessions will be the same in both conditions and also similar to the present standard assessment procedure (3 sessions). Patients will be asked to complete questionnaires at the end of the assessment procedure; an additional visit to the site is not necessary. Both groups will receive DSM-5 diagnoses (when applicable), according to the respective model. No impact is to be expected for treatment assignment.

Study objective

Research questions:
1. How do patients experience the clinical utility of the AMPD assessment procedure as compared to the clinical utility of the traditional, categorical (DSM-5 section II) assessment?

Based upon our review of the literature and the stated aim of the AMPD to improve clinical utility, we expect that the AMPD assessment procedure will be superior to the traditional categorical assessment procedure with respect to clinical utility as perceived by patients (primary outcome)

Based upon our expectation that the AMPD assessment procedure will be more clinically useful for patients, we also expect that the AMPD assessment procedure is superior to the traditional categorical Section II assessment with respect to motivation for treatment, outcome expectancy, and client satisfaction with the assessment procedure.

2. How do clinicians who will continue treatment with an assessed patient, experience the clinical utility of an assessment report based upon an AMPD assessment procedure as compared to a traditional, categorical assessment procedure.

Based upon our review of the literature and the stated aim of the AMPD to improve clinical utility, we expect that the AMPD assessment procedure will be superior to the traditional, categorical assessment procedure with regard to the clinical utility as perceived by the assigned therapist based upon the assessment report.

Study design

1 time point, after the assessment.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria (inclusion criteria are similar to the general criteria used in screening referrals at de Viersprong, all patients that are screened and eligible for an admission procedure at de Viersprong will be included):
- (Presumed) personality disordered

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- IQ below 80
- Acute Psychotic disorder

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-10-2021
Enrollment:	128
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-01-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50957
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9191
CCMO	NL75676.018.20
OMON	NL-OMON50957

Study results