RESEARCH PROTOCOL

(February 2022)

PROTOCOL TITLE 'Implementation and Validation of the Dutch Translation of the TAPS-tool: a Screener for Tobacco, Alcohol, Prescription Medication and Other Substances for Patients With Severe Mental Illness With and Without Intellectual Disabilities'

Protocol ID	**ECSW-2021-052**
Short title	**Implementation and Validation of the Dutch Translation of the TAPS-tool**
Date	**22.02.2022**
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TABLE OF CONTENTS

SUMMARY

Rationale: Substance use problems (misuse and addiction) are common among patients with Severe Mental Illness (SMI). Substance use problems are often not recognized and therefore not incorporated in the treatment for patients with SMI which leads to more admissions, behavioural problems, aggregation of psychiatric and addiction problems and poorer treatment outcome. Therefore, early detection by screening and assessment is important but this is often omitted in psychiatric departments because there is no suitable instrument (short but informative). NIDA (National Institute on Drug and Addiction) developed the TAPS (Tobacco, Alcohol, Prescription medication and other Substances)-tool for this purpose.

Objective: The aim of the study is to investigate the reliability and validity of the Dutch version of the TAPS-tool. This will be investigated in 2 groups: patients without intellectual disabilities treated in FACT (Flexible Assertive Community Treatment) teams and patients with intellectual disabilities. For the latter group, an adjusted version of the TAPS-tool will be developed. For both groups the TAPS outcome will be compared to a golden standard.

Study design: observational study

Study population: adult people with SMI, with or without intellectual disabilities.

Main study parameters/endpoints: We investigate the suitability of the TAPS-tool to detect substance use problems in a quick and accurate way and evaluate the validity.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden of this research are additional questions about addictive behaviour (about 15 – 20 minutes) by patients who get several tests and questionnaires for their standard treatment. There are no risks associated with participation. By having a suitable instrument to detect substance use problems, these problems will be detected more in clinical practice. This leads to a better treatment.

1. INTRODUCTION AND RATIONALE

20 to 60% of patients treated within mental health care have dual diagnosis problems; a combination and interaction of a psychiatric disorder and substance use. The more severe the psychiatric condition, the higher the risk of comorbid addiction problems. A mild intellectual disability (LVB) also increases the risk of addiction problems (triple problem). Within the target group of patients with severe psychiatric disorders, a significant proportion appears to function at the level of a mild intellectual disability (Seelen-de Lang et al., 2019). Both serious psychiatric disorders and addiction problems lead to social problems, high social (care) costs, poorer treatment results and a poorer prognosis.
Addiction problems are often overlooked in patients with a serious psychiatric disorder, whether or not in combination with MID (Ananth, 1990; Shaner, 1993; Nagel, 2018). Incomplete and/or inadequate diagnosis can lead to incomplete and/or inadequate treatment, which leads to poorer treatment outcomes such as increased risk of relapse, (re)admissions, homelessness, violence, somatic disorders, and higher psychological burden and economic costs (Drake, 1998; Caton, 1994; Lindqvist & Allebeck, 1989; Bartels, 1993; Safer, 1987; Shaner, 1995).
The NIDA (National Institute for Drugs and Additiction, USA) developed the TAPS questionnaire in 2016 that provides a screener to address these issues (McNeely et al., 2016; Gryczynski et al., 2017). Including screening for drug addiction in the TAPS is of added value for the GGZ target group. A Dutch translation is now available in collaboration with the NIDA (DeJong et al., 2019). However, due to the complicated language, this translation is unsuitable for patients with MID. The NIDA has also not developed a version for this target group. By implementing the TAPS as a standard screener within mental health care, more insight can be gained into problematic alcohol and substance use, so that treatment can be adapted accordingly. However, it is important that the validity of the Dutch version is still being established.
The SumID-Q, a structured interview used to investigate addiction problems in patients with MID, has a duration of 45-60 minutes. Because of this time investment, the instrument is only used if there is already a suspicion of highly problematic substance use. As a result, not everyone is screened, which leads to underdiagnosis and undertreatment. We want to be able to trace precisely the group of patients who are not immediately suspected of use, but who may do so anyway, in order to optimize the treatment. In addition, the SumID-Q only asks about alcohol, tobacco, cannabis and “other drugs”. Incorrect medication use is not included. The addition of this extra category, together with a greatly shortened administration time of the TAPS-LVB, ensures that the group of triple problem patients can be better mapped.

2. OBJECTIVES

There are two objectives:

1. Validating and implementing the TAPS in patients with a severe mental disorder and problematic substance use.
2. Developing, validating and implementing the TAPS-ID in patients with a mental disorder, intellectual disability (ID) and problematic substance use.

3. STUDY DESIGN

This is a descriptive study based on routinely collected data. The FACT teams that participate in the study work according to a care program in which screening and assessment are part of the standard care. This implies that since 2016, screening has been carried out at the start of treatment for: PTSD, a mild intellectual disability, addiction problems. The current screening for addiction problems is too limited and lacks a follow-up step in the form of structured assessment. In addition, at the start of treatment and annually in preparation of the treatment plan, the level of complaints is assessed by the care provider involved and the phase of recovery and the patient's quality of life are assessed. We want to use this data from patients in whom there is no suspicion of mild intellectual disability in anonymised form. In the research into the validity of the TAPS, we want to measure whether there is a relationship between the existence of problem substance use and a poorer treatment outcome (less decrease in complaints), and a reduced quality of life.
The TAPS has already been included as a replacement for the previously used screener for addiction problems by the various substantive advisory bodies that deal with the content and improvement of the care of the GGZ Oost Brabant.
In order to investigate the concurrent validity of the TAPS, a group of at least 40 patients will be asked permission to administer some parts of the MATE in addition to the TAPS.

The TAPS is too difficult for patients with intellectual disabilities. We therefore made adjustments to the translated TAPS (see below). The adjusted version for patients with ID is called the TAPS-ID. The validity of the TAPS-ID is examined by the comparison of the TAPS-ID and the SumID-Q (an instrument specially developed to map addiction problems in patients with MID). This will be carried out in a special department within secondary healthcare for patients with a combination of a severe mental disorder and intellectual disability (LVB-P) and in a healthcare setting for people with intellectual disabilities with minimal or light mental disorders (ORO). The SumID-Q is part of standard care for both departments. Trained employees who administer the SumID-Q also take the TAPS-ID.

We would like to analyze the results of these measurements retrospectively over a period of at least 6 months by placing them anonymously and not traceable to individual persons in an SPSS database. We would also like to add some very global background data to this, namely: sex, age in years and the main psychiatric diagnosis. This data will be added to the database without name or other personally identifiable information by a secretary who is affiliated with the research line and who has access to this data in that regard. For this

reason, this secretary also has temporary access to the secured data from the electronic patient file.

4. STUDY POPULATION

4.1 Population (base)

4.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
All patients treated in the participating FACT teams and for patients treated at the LVB-P department of the GGZ Oost Brabant or the ORO foundation.

4.3 Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
If patients do not have sufficient command of the Dutch language or cannot concentrate for 20 minutes, the instruments are not taken.

4.4 Sample size calculation

The number of new registrations for FACT teams is between 30 and 40 per year. With a minimum of three participating FACT teams, there are approximately 100 new patients per year. In the 2.5 years of the planned data collection, there will be 250 new patients. Based on the information that approximately 40% of FACT patients function at the level of mild intellectual disability, we can include at least 150 patients. A very substantial part could refuse to participate in order to obtain the required 40 patients for the validity study.

The SumID-Q is administered at least 20 times a year within the various parts of the LVB-P department (ambulatory, part-time, clinic). Most administrations take place at the clinic, where SumID-Q administration is standard of care at the start of clinical admission. ORO also uses the SumID-Q more than ten times a year. The required 40 patients seems achievable within the period of data collection.

For both groups, we stop data collection at 100 participating patients.

5. TREATMENT OF SUBJECTS

N.a. because this is an observational study.

METHODS

5.1 Study parameters/endpoints

5.1.1 Main study parameter/endpoint

Problematic substance use

5.1.2 Secondary study parameters/endpoints (if applicable)

Quality of Life
Mental complaints

5.2 Randomisation, blinding and treatment allocation

n.a.

5.3 Study procedures

Objective 1:
The validation study of the TAPS was incorporated in a broader comprehensive screening and assessment procedure that is standard care in FACT teams in this mental healthcare institute.

All new patients were screened on intellectual disabilities , trauma-related symptoms and substance use problems. Actual psychiatric symptoms, quality of life, phase of recovery and the burden of care for relatives of the patient were also mapped. This screening and assessment consisted of one test, four self-report questionnaires for the patient, one questionnaire for relatives and one questionnaire for the caregiver. The TAPS-tool was used for screening and brief assessment of substance use problems. Only when a patient was incapable of concentrating for more than 15 minutes, when the Dutch language was a problem or when there was almost no cooperation for the FACT treatment at all, the screening and assessment was omitted .
Psychologists or case managers were the assessors. They invite the patient for an appointment to take the test and fill out the questionnaires together at home or at the office. The screening on possible intellectual disabilities was done first. There was no fixed order for the other parts.

For the validation of the TAPS two elements were added to the standard procedure: First, the assessor also took the parts of the MATE necessary to investigate the severity of the addiction (module 1, 4, and Q1; see description of the MATE above). Second, after completing the TAPS and the MATE, but before the scoring of it, the assessor also rated the severity of the substance use problems on a five-point Likert

scale by answering the following question: “I rate the addiction problem of the client as…”. Possible answers were: absent, mild, moderate, severe, very severe .

Participants were invited by telephone for the regular appointment that was scheduled at least one day later. During this telephone conversation, information was given about the validation study of the TAPS and patients were asked if they want to think about voluntarily participation. During the appointment, the information about the validation study was reviewed again, any additional questions from the patients were answered and when the patient agreed for participation, informed consent was signed. Patients signed informed consent to use the answers of the TAPS and MATE and background information (age, gender, diagnosis, medication, level of education) anonymously for this scientific purpose.

To investigate research objective 1, the following measuring instruments are used:

TAPS:
Tobacco, Alcohol, Prescription medication and other Substances-tool.
The TAPS-tool is a 2-phase screening instrument to detect substance use problems which can be used as an interview or as a self-administered questionnaire. According to McNeely et al., the diagnostic characteristics of both ways are similar (McNeely et al., 2016).
The TAPS-1 (screener) pretends to detect unhealthy substance use in the past year quickly and is based on NIDA’s quickscreen. It contains of four multiple choice questions where the patient answers how often they used tobacco, alcohol, other drugs, and prescription medication in te past year on a five point Likert-scale. Possible answers are: never, less than monthly, monthly, weekly, daily or almost daily. For tobacco and drugs, a positive score is given when there is any use in the past year. For alcohol a positive score is given when someone drinks more than 4 (women) or 5 (men) drinks containing alcohol a day. For medication, a positive score is obtained when someone uses prescription medication in a higher dose, or uses medication from someone else or medication without prescription. If there is a positive score on any of the sections, the TAPS-2 is assessed (see below). Dus de TAPS-1 levert geen scores op zichzelf op, maar de scores dienen ertoe om te beslissen of je doorgaat met de TAPS 2 of niet? For the TAPS-1, the optimal cut-off points for the detection of a possible substance use disorder (SUD) are: For tobacco and alcohol a frequency of monthly use was a predictor for SUD (sensitivity = 0.92 and 0.71, specificity = 0.80 and 0.85, AUC = 0.86 and 0.78, respectively) and for illicit drugs and prescription medication misuse any reported use was suspect for SUD (sensitivity = 0.93 and 0.89, specificity = 0.85 and 0.91, AUC = 0.89 and 0.90, respectively). (Gryczynski et al., 2017)
TAPS-2 (brief risk assessment) is based on the ASSIST-lite (Alcohol, Smoking and Substance Involvement Screening Test) which is developed by the World Health Organization (Ali, Meena, Eastwood, Richards, & Marsden, 2013). The ASSIST has a

good test-retest reliability: substance risk scores from two administrations within 1-4 weeks has excellent concordance (90–98%) and a high correlation (ICC 0.90–0.97) for tobacco, alcohol, and drugs (McNeely et al., 2014). The ASSIST-Lite (a shortened version of the ASSIST) has a single factor structure on which all substances loaded (eigenvalue range, 2.42–3.81). It also has a consistent pattern of positive loadings on this factor (all ≥0.303) (Ali et al., 2013). For the TAPS-2, only ADHD medication and questions about the failure to reduce or stop the use of marihuana, amphetamines and anxiolytics have been added to the ASSIST-Lite. There are nine categories on the TAPS-2: tobacco, alcohol, marihuana, stimulant drugs, opiates, anxiolytic medication, ADHD medication and 'other substances'. Only the elements with a positive score on the TAPS-1 are further assessed. For every category, the assessment with the TAPS-2 contains the usage for the last 3 months and two or three additional questions which can detect unhealthy use. For scoring both the use for the last 3 months and an affirmative answer on each of the additional questions lead to one point. A total score is calculated for each of the categories separately by adding the positive answers together. A total score of +2 per category induces a risk of a substance use disorder and indicates more assessment. Investigation of the TAPS-2 has been done by a comparison with the Composite International Diagnostic Interview (CIDI). Problematic use (with a cut off score of +1) for tobacco has a sensitivity of 0.93 and specificity of 0.87. Alcohol has a sensitivity of 0.74 and specificity of 0.79. For problematic use of illicit and prescription drugs, sensitivity ranges from 0.82 for marijuana to 0.63 for sedatives, and specificity is 0.93 or higher. For identifying any SUD, sensitivity was lower, but a cut off score of +2 greatly increases the likelihood of having a SUD as measured by the CIDI (McNeely et al., 2016).

HoNOS:
The course of the complaints is mapped out annually using the HoNOS (Health of the Nation Scale). This is an observation list that is completed by the practitioner. The outcome of the HoNOS reflects the mental and social functioning of a client in mental health care at a given moment. The HoNOS can be completed at several moments before, during or after a treatment, so that the change in complaints is mapped out. The aim of the HoNOS is therefore to evaluate the treatment or supervision. The score for the 12 items that make up the instrument always ranges from 0 (no problem) to 4 (very serious problem). These are issues that have occurred in the past two weeks. Psychometric properties of the HoNOS are satisfactory to good (Mulder et al., 2004).

MANSA:
The quality of life, as experienced by the patient, is mapped with the MANSA: the Manchester abbreviated quality of life measure (Van Nieuwenhuizen, Schene & Koeter, 2000), the 16 item version. The MANSA is a multidimensional questionnaire

designed to assess quality of life. The closed questions refer to job satisfaction, housing, general health and social relationships.

MATE:
MATE is the Dutch abbreviation of “Measurement of Addiction for Triage and Evaluation”. It is an instrument, developed in Europe to determine patient characteristics for the indication of care for people with addiction problems on a valid and reliable way. The MATE has ten modules (eight interview modules and two self-report questionnaires) which take about one hour to assess totally. These modules are: 1. substance use, 2. substance abuse and dependence, 3. craving, 4. depression, anxiety and stress, 5. psychotic symptoms, suicidality and current psychiatric treatment, 6. personality disorders, 7. physical complaints and symptoms 8. personal and societal functioning, 9. environmental factors influencing recovery, and 10. history of substance abuse treatment. The MATE comprises a set of existing, well-developed and widely accepted instruments to investigate the ten module-themes: for example the CIDI (Composite International Diagnostic Interview) to investigate ICD criteria, the DASS (Depression Anxiety Stress Scales) to investigate depression and anxiety, and the SAPA (Standard Assessment of Personality Abbreviated scale) to investigate personality disorders.
The modular design of the MATE can be used in a flexible way which gives service delivery institutions the freedom to select their intake and evaluation tools individually from the MATE modules. The original Dutch version is translated into English, German and Spanish.
The factor structure of the ICF-related modules has revealed a three-factor model with an acceptable fit. Inter-rater reliability ranges between 0.75 and 0.92 which is satisfactory, but interviewer reliability only ranges between 0.34 and 0.73, indicating that some of subscales need to be improved. Concurrent validity is indicated by significant correlations (>0.50) between the ICF-related modules and the WHO Disability Assessment Schedule II (WHODAS II) and WHO Quality of Life brief version (WHOQOL-BREF) (Schippers, Broekman, Buchholz, Koeter, & Van Den Brink, 2010). A combination of the ten MATE modules can be used in an algorithm to determine the severity of the addiction, severity of other psychopathology, social disintegration and treatment history.
The modules to be used in the present study are:
Module 1 is an interview about substance use of the last month and the total years of regular use during life. The number of days the past month and the amount of use on an average day are asked about for alcohol, nicotine, cannabis, opiates, cocaine, stimulant drugs, XTC, other drugs, sedative medicines and gambling. For the rest of the interview, it is decided with the patient which is the main problem area. For every substance, excessive use can be calculated by specific criteria (e.g. more than 240 units of alcohol for the last month or more than one year of regular use and actual use of 28 out of 30 days for marihuana).

Module 4 contains of 11 binary questions (yes/no) about dependency and misuse of the problem area. Every 'yes' on question 2 to 9 and 11 (so without question 1 and 10) gets one point. The scoring range is 0 to 9. A score of 8 or more indicates a high severity.
Module Q1 contains of five questions about desire, based on a five point Likert-scale (score 0-4). The score of the five questions is added for the total score of this module (range 0-20). A score of 12 or more is an indication for a high severity.
A high severity of the addiction is a binary variable which is computed by following the algorithm below:
1) excessive use of three out of five substances in the last year (alcohol, nicotine, cannabis, opiates, cocaine / stimulant drugs) or,
2) A score of 8 or 9 out of 9 questions about dependency / misuse, or
3) A total score of 12 or more (range 0-20) on questions about desire

Objective 2:

SumID-Q is part of standard care for both departments (LVB-P and ORO). For the purpose of the validation of the TAPS-ID, patients are asked if the are voluntary willing to participate on the study by adding the TAPS-ID to the SumID-Q. Second, after completing the TAPS-ID and the SumID-Q, but before the scoring it, the assessor also rated the severity of the substance use problems on a five-point Likert scale by answering the following question: "I rate the addiction problem of the client as…". Possible answers were: absent, mild, moderate, severe, very severe.

Psychologists or psychiatric nurses are the assessors. They invite the patient for an appointment to take the SumID-Q. Participants were invited by telephone for the regular appointment that was scheduled at least one day later. During this telephone conversation, information was given about the validation study of the TAPS and patients were asked if they want to think about voluntarily participation. During the appointment, the information about the validation study was reviewed again, any additional questions from the patients were answered and when the patient agreed for participation, informed consent was signed. Patients signed informed consent to use the answers of the TAPS-ID and SumID-Q and background information (age, gender, diagnosis, medication) anonymously for this scientific purpose.

The answers from the TAPS-ID and SumID-Q are recorded on paper. Papers are stored in a locked closet at the department of care (GGZ or ORO).

To investigate research objective 2, the following measuring instruments are used:

SumID-Q:
The SumID-Q maps out what the client knows about psychoactive substances, what he/she knows, thinks about them, what is used in his/her environment, what he/she

may use and what the consequences of use and motivation are. to change. The structure of the interview makes it possible to discuss use in an open and pleasant way. It thus lays a foundation for any further diagnostics, interviews, interventions and preventive measures. The SumID-Q is designed to be administered to adults with a Slight Intellectual Disability, but also appears to be suitable for young people or people with a slightly lower or higher level. The SumID-Q can be administered by counselors and behavioral experts who have undergone training in the SumID-Q (Van der Nagel, Kiewik, De Jong, Van Dijk, Didden, 2011).

TAPS-ID:
The TAPS will be adapted for the target group of patients with MID. For this, pictures are added to the TAPS, questions are divided into sub-questions, and difficult words are replaced by a simpler alternative. We test the first version on several patients with ID and with various assessors. On basis of their recommendations, we make de definitive TAPS-ID.

This procedure was approved by the institutional scientific board named CWOI of the mental health care institute (GGZ Oost Brabant) and the Ethics Committee of Social Sciences of the Radboud University Nijmegen (number of approval: ECSW-2021-051).

5.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

5.5 Premature termination of the study

The only reason to end the study prematurely is because we can't get enough participants. If this is the case, we will use the gathered data for a brief report.

6. SAFETY REPORTING

6.1 Temporary halt for reasons of subject safety

This is not applicable because it is a retrospective observational study with one moment of data collection.

6.2 AEs, SAEs and SUSARs

This is not applicable because it is a retrospective observational study with one moment of data collection.

6.3 Annual safety report

N.a.

6.4 Follow-up of adverse events

N.a.

6.5 [Data Safety Monitoring Board (DSMB) / Safety Committee]

The data were gathered in routine treatment procedures. For the purpose of the study, after merging several sources in full database case numbers were anonymized in a way no cases could be traced back. Fully anonymized and corrected data were handed over to the research team. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. The Ethical Commission of the Radboud University, Social Sciences, the Netherlands, reviewed the procedure used in this study and decided that, because no actions or behaviours are imposed on the participants, there was no need for further ethical review.

STATISTICAL ANALYSIS

This study will not test any intervention. It will focus on the level of agreement between patients responses on the newly used instrument for screening and brief assessment of addiction problems (TAPS/TAPS-ID) and the golden standard (MATE / SumID-Q).

Research goal 1:
- With regard to the reliability of the TAPS, the internal consistency is determined (Cronbach's alpha and item-total correlation). To determine the convergent validity, first the correlation is determined between the outcome of the TAPS (indications of problematic use) and the outcome of the severity of the addiction on the MATE (degree of severity).
- To investigate the influence of addiction problems on treatment outcomes and quality of life, the correlation with the outcomes of the Honos and Mansa is calculated. The hypothesis is that a higher score on the TAPS correlates with a higher score on the Honos and a lower score on the Mansa.
- The optimal cut-off point of the TAPS is determined by means of ROC analyses.

Research goal 2:
- For the development of the TAPS-ID, the feasibility (by the interviewers) and feasibility (with the target group) will first be estimated on the basis of a few interviews with the interviewers involved.
- With regard to the reliability of the TAPS, the internal consistency is determined (Cronbach's alpha and item-total correlation). To determine the convergent validity, the correlation is determined between the outcome of the TAPS and the outcome of the SumID-Q.

6.6 Primary study parameter(s)

Statistical analysis will examine agreement between different measures of substance use (sensitivity, specificity and AUC value) to evaluate the level of classification accuracy for each items or candidate combination of items.
This study will not include follow up assessments. We expect a number of patients who don’t want the assessment at all or don’t want to sign informed consent. The extent of missing data will be analyzed and explore differences in missing data by age, gender, and diagnosis.

On objective 1 the primary study parameters are TAPS and MATE outcomes. The total TAPS-score is used as

6.7 Secondary study parameter(s)

The analysis of size and content of addiction problems will be done by an overview of descriptive statistics of the whole patient population, sorted by different substances being used.
For objective 1 the correlation with quality of life (MANSA) and amount of mental complains and social functioning (HoNOS) is also calculated for the divergent validity.

6.8 Other study parameters

6.9 Interim analysis (if applicable)

Na.

7. ETHICAL CONSIDERATIONS

7.1 Regulation statement

This study will be conducted in compliance with the appropriate protocol, current Good Clinical Practice (GCP), the principles of the Declaration of Helsinki 2008 and all other applicable regulatory requirements.

7.2 Recruitment and consent

See above (procedure)

7.3 Objection by minors or incapacitated subjects (if applicable)

Not applicable

7.4 Benefits and risks assessment, group relatedness

<*Please give a justification of the proposed study.*>

7.5 Compensation for injury

The sponsor/investigator has a liability insurance which is in accordance with article 7 of the WMO.

The sponsor (also) has an insurance which is in accordance with the legal requirements in the Netherlands (Article 7 WMO). This insurance provides cover for damage to research subjects through injury or death caused by the study.
The insurance applies to the damage that becomes apparent during the study or within 4 years after the end of the study.

7.6 Incentives (if applicable)

N.a.

8. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

8.1 Handling and storage of data and documents

The anonymous data will be saved on an SPSS-file which is placed in a file where only the investigators and research assistant from the specific research area of FACT patients within the GGZ Oost Brabant have access to.

8.2 Monitoring and Quality Assurance

This research is part of a PhD study. The progress of this research is monitored every 6 weeks by professors involved in the PhD project. In addition to that, the progress is yearly monitored by the commission for scientific research (CWO) at the GGZ Oost Brabant. The main researcher (B.S.) yearly gives the CWO an update and progression will be tested.

8.3 Amendments

All amendments will be notified to the ECSW that gave a favourable opinion.

8.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the CWO of GGZ Oost Brabant once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

8.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the CWO and ECSW of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the CWO and ECSW immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the sponsor will notify the CWO and ECSW within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study,

to the CWO and ECSW.

8.6 Public disclosure and publication policy

The outcome data of this two objectives are sent to a scientific journal.

9. STRUCTURED RISK ANALYSIS

N.a. (No product of risk is used)

10. REFERENCES

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