A multi-center, multi-country, cross-sectional study on the prevalence of ADHD in non-psychotic adult psychiatric care (ADPSYC)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON38985

Source
ToetsingOnline

Brief title
Observational Study Protocol B4Z-EW-B020

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD - hyperactivity

Research involving
Human

Sponsors and support

Primary sponsor: Eli Lilly

Source(s) of monetary or material Support: bedrijf: Eli-lilly and company

Intervention

Keyword: ADHD, non-psychotic adults, outpatients, prevalence

Outcome measures

Primary outcome

The primary objective of this study is to estimate the prevalence of ADHD in non-psychotic adults in psychiatric outpatient care as assessed by the Diagnostic Interview for ADHD in Adults (DIVA) instrument according to DSM-IV criteria.

Secondary outcome

The secondary objectives of the study are as follows:

- to characterize the Adult ADHD population as diagnosed by DIVA in terms of symptoms, functioning, quality of life, work status and resource use prior to study entry and also the population of patients without ADHD diagnosis in psychiatric outpatient care

- to estimate the prevalence of ADHD in adults in non-psychotic psychiatric outpatient care in different settings and countries or groups of countries with similar mental health organization/health care systems

- to estimate the prevalence of ADHD in non-psychotic adults in psychiatric outpatient care based on meeting for example only either 5 or 4 DSM-IV criteria from the attention or hyperactivity/impulsivity symptoms list and with and

without the 7- year age limit for childhood onset of symptoms as per DSM-IV, foreseeing the upcoming changes in the next generation of diagnostic criteria

- to explore properties of Adult ADHD Self-Report Scale Symptom Checklist ;(ASRS) and/or the ADHD questions of the Provisional Diagnostic Instrument-4 (PDI-4) as derived from ASRS by examining the DIVA item results of patients with various scores on the screening instruments

- to estimate the prevalence of other non-psychotic mental disorders in psychiatric care (depression/dysthymia, bipolar disorder, obsessive-compulsive disorder, anxiety disorders, eating disorders, substance/alcohol abuse or dependence, antisocial or borderline personality disorders, autism spectrum disorder) and to estimate their comorbidity with adult ADHD

- to provide additional data to support validation of the DIVA.

Study description

Background summary

For Europe very few community-based estimates of the total care of attention deficit hyperactivity disorder (ADHD) in adults are available and data of the prevalence of adult ADHD in outpatient psychiatric clinics are sparse. In this study, the prevalence of ADHD in nonpsychotic adult outpatient psychiatric care in several European countries will be estimated and patients who screen positive for ADHD will further be examined. Also prevalence of comorbidities in patients with ADHD, as well as the prevalence of comorbid ADHD in patients diagnosed with other psychiatric disorders will be estimated. Resource utilization and subjective well-being will be assessed for the entire sample. Thus, this study will contribute to a better understanding of the presence and

implications of ADHD in adult mental health care. This knowledge can be the basis for a better allocation of appropriate diagnostic and treatment resources, a reduction of primary and secondary costs, and a better outcome for patients with ADHD.

Study objective

The goal of the study is to estimate the prevalence of patients with ADHD in adult outpatient care. About 2300 patients in 8 European countries will participate to this trial. This data will improve the knowledge about the presence and the importance of ADHD in adults in the mental health care.

Study design

Study B4Z-EW-B020 is a multi-center, multi-country, cross-sectional, observational study
to estimate the prevalence of ADHD in non-psychotic adults in psychiatric outpatient care as assessed by the DIVA instrument.

At each study site, all eligible patients known, as well as new patients, regardless of their existing diagnosis (including ADHD), will be invited to participate in the study. Before the start of the study, a predefined maximum number of patients that the site will manage to enter per week will be agreed upon. The sites will be asked to approach all patients during their normal clinic days during pre-specified periods and varying times of the day until their predefined maximum number of entered patients per week is reached.

Patients will be screened for ADHD using the ASRS Symptom Checklist (Part A and the ADHD questions of the PDI-4 as derived from ASRS). All patients screened positive on one of these tools and those with a previous or suspected diagnosis of ADHD will be assessed by the DIVA.
Moreover,in all patients other psychiatric diagnoses will be recorded according to the clinical judgment of the investigator as guided by DSM or International Classification of Disease(s) (ICD) criteria. Clinical status parameters, information on the patients* functioning, quality of life, and resource utilization will be collected by the use of several instruments as well as questions to the patients.

In case the patient and/or physician are not able to perform all needed procedures on the same day, additional sessions can be agreed on during naturally occurring visits. Procedures should be started ideally within 2 weeks, and completed within a maximum of 6 weeks.

Study burden and risks

There will not be any specific study visits: the investigator will collect the

study data during the normal consultations: after signing the informed consent, the procedures will be done, if possible, on the same day. If not possible, one or multiple sessions can be agreed upon, during the normal patient consults. There is only data that will be collected, there will not be any physical examination, blood sampling, etc.

The following patient information is collected:
1/ Age and gender, weight, height, chronic medical non-psychiatric comorbidities

2/ Presence of an ADHD diagnosis (before entering the study); age of diagnosis; specific ADHD treatment (medication and/or psychotherapy) in childhood, adolescence, and/or adulthood

3/ The ASRS (Kessler et al. 2005) will be used to screen for ADHD.

4/ Exploratory screening question for presence of ADHD symptoms since childhood
Have you always had these problems?

5/ The CGI-S (Clinical Global Impressions of Severity) scale (Guy 1976) will be used to rate the severity of overall mental illness and illnesses at the time of study entry. The score ranges from 1 (normal, not at all ill) to 7 (among the most extremely ill patients).

6/Clinical status parameters and medical history will be collected by the use of questions to the patient that will be documented by check boxes
- Tobacco consumption
- Presence of clinical relevant neurological symptoms/diagnoses by clinicaljudgment and patient history.
- Assessment of the patients* family history

7/Information on functioning will be collected by the use of several instruments as well as questions to the patient that will be documented by check boxes:
- The SDS (Sheehan Disability Scale) (Sheehan 1983) is used to assess changes in the patients* personal work schedule, social life/leisure activities, and family life/home responsibilities.
- Education and degrees
- Actual work status and the frequency (or how often) the patient changed his/her employment in the last 3 years
- Parenthood
- Living arrangement
- Possession of a driving license, if it has been revoked (if applicable), the number of times and if the patient has received a traffic fine in the last 3 years
- How frequently does the patient go overdrawn on his/her banking account or debts with family/friends
- Contacts with justice system: has the patient been prosecuted since

adulthood?

8/ Information on the patients* quality of life (QoL) and resource utilization will be collected by the use of several screening instruments as well as questions to the patient that will be assessed by simple check boxes:
- The EQ-5D (EuroQol - 5 Dimensions) questionnaire is a brief, self-administered questionnaire that assesses a patient*s current, perceived, health-related quality of life
- Psychiatric medication in the last 6 months
- Information about if the patient has had any visit in the last 6 months to the following:Primary health care. Number of visits; Psychiatrist. Number of visits; Psychologist/psychotherapist. Number of visits; Other mental health worker (including nurses). Number of visits; Other specialist
- Has the patient had any visits to the emergency room in the last 6 months? Number of visits due to accidents/injuries?; Number of visits due to mental health?
- Number of hospital admissions in the last 6 months for other than psychiatric reason. Total length of stay
- Number of hospital admissions in the last 6 months relating to mental health. Total length of stay

Short overview of the questionnaires used in this trial:
- The ASRS (Kessler et al. 2005) will be used for the ADHD screening (patient to complete this himself)
- CGI-S scale
- SDS (Sheehan Disability Scale) (patient to complete this himself)
- EQ-5D (patient to complete this himself)
-DIVA (in case of ADHD diagnosis)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male or female outpatients aged between 18 and 65 years attending psychiatric outpatient care
- having signed an informed consent to release information prior to any procedure

Exclusion criteria

- Mental disability or disease state to an extent that prevents patients from understanding the nature of the study or that prevents patients from reliably following procedures
- Psychotic disorder at presentation or from patient*s history (schizophrenia,schizo-affective, schizophreniform, delusional disorder). Treatment with antipsychotics ,for other indications is not an exclusion criterion.
- Have previously been approached or screened for the study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2013
Enrollment:	240
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-04-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL43230.072.13