ISRCTN51527289 https://doi.org/10.1186/ISRCTN51527289

Can incorporating person-centered cultural assessments into psychiatric diagnostic evaluation affect the prevalence of anxiety and depression diagnoses?

Submission date
03/05/2019

Recruitment status
No longer recruiting

Registration date
30/07/2019

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Expectations of help from psychiatric care can be mixed. Poor mental health can also be felt and expressed in many ways. Prior to any psychiatric treatment, an assessment is made of the patient's mental health and, if relevant, a diagnosis is set.
In order to understand the individual patient's experience and understanding of his or her problems, a new interview has been included in DSM-5, a manual for psychiatric diagnosis. This interview is intended for use in psychiatric diagnostics and is called the Cultural Formulation Interview. During the interview patients are asked how they view, and can explain, their problems They are also asked about their expectations of help. The interview also includes questions regarding the significance of the patient's social and cultural environment.
The aim of this study is to assess whether the new Cultural Formulation Interview, as described in DSM-5, can improve the understanding, assessment and treatment of a patient's mental health problems.

Who can participate?
Patients who came into contact with Järvapsykiatrin during the period August 2015 to May 2017, were invited to participate in the study.

What does the study involve?
All those participating in the study were given the standard form of psychiatric assessment and a treatment plan, at the clinic and on the ward. As well as this, half of the participants were questioned using the new Cultural Formulation Interview. Those questioned using this new interview were selected by lottery. The interview took approximately 20 minutes and was carried out during an ordinary appointment at the outpatient clinic.
The study compared the details of psychiatric assessment relating to the group where the new Cultural Formulation Interview was used with the details relating to the group where it was not. The comparisons were made anonymously. Treatment was given according to the usual procedures of the outpatient clinic.

What are the possible benefits and risk of participating?
One advantage of participating in the study was that the questions asked in the new Cultural Formulation Interview may have given the caseworker a better understanding of the patient's problems, needs and wishes. There may have been a risk that the questions asked in the new interview were perceived as difficult to understand or made the interviewee feel uncomfortable. If this was the case, the interview was terminated immediately, and an opportunity given to address this with the staff in charge of treatment.

Where is the study run from?
The principal body for the research was Stockholm County Council, Box 22550, 104 22 Stockholm. The study was conducted in collaboration between Transcultural Centre, Stockholm County Council and Järvapsykiatrin, Praktikertjänst AB.

When is the study starting and how long is it expected to run for?
Data collection was between 1/8/2015 and 31/5/2017

Who is funding the study?
The study was funded by Stockholm County Council with the research grant, PPG PPG-fund, Dnr LS1311-1462

Who is the main contact?
The personal data officer in charge of the details relating to the researchers and participants is Sofie Bäärnhielm, Transcultural Centre, Solnavägen 4, 113 65 Stockholm phone +46 8 123 486 79, mobile +46 70 484 61 62, email sofie.baarnhielm@sll.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Dnr LS 1311-1462

Study information

Scientific Title
Evaluating the Cultural Formulation Interview in DSM-5. A randomized controlled trial.

Study objectives
1. More patients in the Cultural Formulation Interview (CFI) group than in the usual routine group will get a depression diagnosis after the initial diagnostic procedure
2. More patients in the CFI group than in the usual routine group will get an anxiety diagnosis after the initial diagnostic procedure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2015, The Regional Ethical Review Board in Stockholm (Etikprövingsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; + 46 10-475 08 00; registrator@etikprovning.se), ref: 2015/243-31/2.

Study design
Single centre individually randomized controlled parallel trial unblinded

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Psychiatric diagnostic evaluation

Interventions
The intervention group is interviewed with core Cultural Formulation Interview (CFI) in DSM-5 in addition to the standard psychiatric diagnostic procedure, which besides the CFI is the same for both the intervention and control groups.

The assessment for referral inclusion and exclusion criteria is made by a team at the clinic in charge of examining new referrals. The same team perform the individual randomization, to intervention or control arm done by lottery.

The standard psychiatric diagnostic procedure for psychiatric care in Stockholm County was used in both study arms. This includes social and clinical anamneses; the assessment tool MINI (The Mini International Neuropsychiatric Interview); CGI (Clinical Global Impression); and three web-based self-report screening tools, AUDIT-C (Alcohol Use Disorder Identification Scale), PHQ-9 (Patient Health Questionnaire) and ASRS (Adult ADHD Self-Report Scale). The CFI was also used as a part of the diagnostic evaluation in the intervention arm.

The standard psychiatric diagnostic procedure used in psychiatric care in Stockholm County usually takes between one to four, 45-minute clinical appointments.

The CFI used in the intervention arm takes between 20-40 minutes.

Individual randomisation, to intervention or control arm, was carried out by lottery.

Intervention Type
Other

Primary outcome measure
The diagnostic advantage measured using the difference or ratio in the prevalence of the diagnoses of depression (F32.0-F39.0) and anxiety (F41.0-F41.9) after the completion of the diagnostic procedure

Secondary outcome measures
1. The prevalence of depression diagnoses (F32.0-F39.0) and anxiety diagnoses (F41.0-F41.9) after the end of the diagnostic procedure in patients with “Swedish as mother tongue” and those with a “non-Swedish mother tongue”

Overall study start date
01/01/2014

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. New patients who have not been in contact with psychiatric care at Järva Psychiatric clinic for the preceding two years.
2. Aged 18-64.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
150 in each arm.

Total final enrolment
114

Key exclusion criteria
1. Suicidal risk.
2. Inability to take a conscious decision (e.g. impaired cognition or psychosis).
3. Need for acute treatment.

Date of first enrolment
01/08/2015

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Transcultural Center.
Solnavagen 4
Stockholm
Sweden
113 65

Study participating centre
Praktikertjanst, Psykiatri
Salagatan 2
Spanga
Sweden
163 53

Sponsor information

Organisation
Karolinska University Hospital

Sponsor details
FoU
Karolinska University Hospital
Eugeniavägen
Solna
Stockholm
Sweden
171 76
+46 8 517 700 00
registrator.karolinska@sll.se

Sponsor type
Hospital/treatment centre

Website
www.karolinska.se

ROR
https://ror.org/00m8d6786

Funder(s)

Funder type
Government

Funder Name
Mission Mental Health

Funder Name
PPG Industries

Alternative Name(s)
PPG Industries, Inc., Pittsburgh Plate Glass Company, Pittsburgh Plate Glass, PPG

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
The results of the trial are planned to be published in autumn 2020.

Intention to publish date
12/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		29/07/2019	16/08/2019	No	Yes
Results article		01/08/2020	07/09/2021	Yes	No
Results article		25/02/2022	18/08/2023	Yes	No