Psychiatry Research Review™

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Issue 40 – 2016

In this issue:

Abbreviations used in this issue
BA = behavioural activation
CBT = cognitive behavioural therapy
HR = hazard ratio
IPT = interpersonal therapy
MI = myocardial infarction
OR = odds ratio
SSRI = selective serotonin reuptake inhibitor
TIA = transient ischaemic attack

Welcome to issue 40 of Psychiatry Research Review.

The dose-dependent QTc prolongation identified for the SSRIs citalopram and escitalopram is well established (Castro VM, et al. *BMJ.* 2013;346:f288) and has resulted in widespread warnings and changes in prescribing. As reviewed in this issue, and reassuring for prescribers, a recent, large UK cohort study found no evidence for a link between SSRI use and increased risk of cardiovascular events (myocardial infarction, arrhythmia, stroke or transient ischaemic attack) in people aged between 20 and 64 years diagnosed with depression.

Two other articles provide insights into schizophrenia and its effects in New Zealand Māori, one of them including suggestions as to how the condition can be better managed.

We hope you find this issue useful for your daily practice and we welcome any comments or feedback.

Kind regards,

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Antidepressant use and risk of cardiovascular outcomes in people aged 20 to 64: cohort study using primary care database

Authors: Coupland C et al.

Summary: Using records from the UK QResearch primary care database, this analysis sought to determine potential associations between different antidepressant treatments and rates of myocardial infarction (MI), stroke or transient ischaemic attack (TIA), and arrhythmia, in a cohort of 238,963 patients aged 20–64 years with a first diagnosis of depression. Over 5 years of follow-up, 772 patients had an MI, 1106 had a stroke or TIA, and 1452 developed arrhythmia. There were no significant associations between antidepressant class and MI. In the first year of follow-up, patients treated with SSRIs had a significantly reduced risk of MI (adjusted HR 0.58; 95% CI, 0.42 to 0.79) compared with no use of antidepressants; among individual agents, fluoxetine was associated with a significantly reduced risk (0.44; 0.27 to 0.72) and lofepramine with a significantly increased risk (3.07; 1.50 to 6.26). No significant associations were found between antidepressant class or individual drugs and risk of stroke or TIA. Antidepressant class was not significantly associated with arrhythmia during follow-up, although the risk was significantly increased during the first 28 days of treatment with tricyclic and related antidepressants (adjusted HR 1.99; 95% CI, 1.27 to 3.13). Fluoxetine was associated with a significantly reduced risk of arrhythmia (adjusted HR 0.74; 95% CI, 0.59 to 0.92) over 5 years, but citalopram was not significantly associated with risk of arrhythmia even at high doses (1.11; 0.72 to 1.71 for doses ≥40 mg/day).

Comment (DM): This ambitious and well-powered UK study set out to investigate the effect of antidepressant treatment on cardiovascular outcomes. The results are important and have implications for clinical practice, notably in primary care where the majority of such prescriptions are written. Perhaps most strikingly, SSRIs (notably fluoxetine) approximately halved the risk of MI during the 1st year of treatment. Although the authors don't seem concerned about relevant mechanisms, indeed there is one: SSRIs are inhibitors of platelet aggregation, and are known to prolonged bleeding time, particularly at higher doses. Accordingly, an antiplatelet effect may well account for some or all of the reduced risk of infarction seen during the 1st year. Also of interest is the finding that tricyclic antidepressants are associated with increased risk of arrhythmia during the 1st month of treatment, possibly related to their effects on cardiac conduction. However, this risk was not detectable with longer treatment intervals, suggesting some degree of tolerance to the effect. Finally, citalopram prescription was not associated with arrhythmias at any time point, providing a useful counterpoint (and, for clinicians, a degree of reassurance) with respect to recent warnings regarding this drug's recognised capacity to prolong the QT interval (*BMJ* 2013;346:f288).

Reference: BMJ. 2016;352:i1350
Abstract

Cost and outcome of behavioural activation versus cognitive behavioural therapy for depression (COBRA): a randomised, controlled, non-inferiority trial

Authors: Richards DA et al.

Summary: This non-inferiority and cost-effectiveness study compared the effects and costs of behavioural activation (BA) with those of cognitive behavioural therapy (CBT) for adults (≥18 years) with major depressive disorder from primary care and psychological therapy services in the UK. 221 such patients were randomised to receive BA from junior mental health workers and 219 to CBT from psychological therapists. The primary outcome was depression symptoms according to the Patient Health Questionnaire 9 (PHQ-9) at 12 months. The non-inferiority margin was 1.9 PHQ-9 points. In the modified intention-to-treat population (all those who were randomly allocated and had complete data; 175 BA recipients, 189 CBT recipients), BA was non-inferior to CBT (8.4 PHQ-9 points in each group; p=0.89); corresponding values in the per protocol population (all those who were randomly allocated, had complete data, and received ≥8 treatment sessions; 135 BA recipients, 151 CBT recipients) were 7.8 and 7.9 PHQ-9 points, respectively (p=0.99).

Comment (DM): As has been noted repeatedly in Research Review, a major problem with scaling up, rolling out and implementing evidence-based psychological therapies relates to the costs of recruiting, training and funding skilled therapists. The current UK-based study directly tackles this problem by investigating a much cheaper alternative to CBT, namely behavioural activation (BA). For those unfamiliar with this therapeutic modality, BA involves promoting patients' active engagement in meaningful activities, in the face of depression and other life adversities. BA's key attributes include its adaptability to individual preferences and various cultural settings (enhancing acceptability and reducing stigma), and its suitability for resource poor jurisdictions, given the modest training requirements of therapists. The results of the present trial are encouraging; with minimal exclusions (and apparent generalisability to New Zealand) BA showed effectiveness comparable to CBT in terms of improvements in depression. There remain, of course, many obstacles to the scaling up and rolling out of novel treatments. Based on the present evidence, however, BA should be seriously considered by the cost-conscious NZ health system. It will also be useful to consider how BA may interdigitate with other therapeutic modalities, such as antidepressant pharmacotherapy in patients who are difficult to motivate or activate in the face of severe symptom burden. Finally, the results are consistent with a recent Cochrane review focusing on the personal health benefits of caring for the environment (Husk K, et al. Participation in environmental enhancement and conservation activities for health and well-being in adults: a review of quantitative and qualitative evidence. Cochrane Database of Systematic Reviews. 2016(5)).

Reference: Lancet. 2016;388(10047):871-80
Abstract

Comparative efficacy and tolerability of antidepressants for major depressive disorder in children and adolescents: a network meta-analysis

Authors: Cipriani A et al.

Summary: This network meta-analysis included published and unpublished randomised controlled trials up to 31 May 2015 that assessed the efficacy and safety of antidepressants in the acute treatment of major depressive disorder in children and adolescents. The antidepressants consisted of amitriptyline, citalopram, clomipramine, desipramine, duloxetine, escitalopram, fluoxetine, imipramine, mirtazapine, nefazodone, nortriptyline, paroxetine, sertraline, and venlafaxine. The primary outcomes were efficacy (change in depressive symptoms) and tolerability (discontinuations due to adverse events). Thirty-four trials (5260 patients) were included in the analysis. The quality of evidence was rated as very low in most comparisons. Fluoxetine was the only agent that was statistically significantly more effective than placebo (standardised mean difference –0.51, 95% credible interval [CrI], –0.99 to –0.03) and fluoxetine was also better tolerated than duloxetine (OR 0.31; 0.13 to 0.95) and imipramine (0.23; 0.04 to 0.78). Imipramine, venlafaxine and duloxetine were associated with higher rates of discontinuations due to adverse events as compared with placebo (ORs of 5.49, 3.19 and 2.80, respectively). In terms of heterogeneity, global I^2 values were 33.21% for efficacy and 0% for tolerability.

Comment (DM): Following on from the same authors' landmark study of adult antidepressant trials (Lancet. 2009;373:746-58), this network meta-analysis represents a substantial effort to define the place of antidepressant drugs in the treatment of depressed children and adolescents. After the FDA's Black Box warnings in 2004, there has been widespread controversy about both the efficacy and safety of these drugs in young people, culminating in the publication last year of a reanalysis of the infamous Study 329 (BMJ. 2015;351:h4320). Unfortunately, the methodological quality of most of the trials available for the present meta-analysis was rated as "very low", limiting the robustness of the conclusions. Notwithstanding this drawback, coupled with concern about bias arising from the industry sponsorship of many of the trials, the overall results are disappointing in the sense that antidepressant treatment shows generally little value (in terms of benefit exceeding harm) in this population; only fluoxetine appears to offer a (modest) advantage in this regard, and thus remains the antidepressant of choice when drug treatment is required. Also of note, venlafaxine stood out as particularly dangerous in terms of treatment-emergent suicidality. The authors of the study, and of an accompanying editorial, emphasise that psychological treatments for depression are to be preferred in this demographic, but there remain difficulties in many jurisdictions (including New Zealand) in accessing these interventions, and so antidepressant prescription is likely to continue for many patients who would be better managed with psychosocial interventions. In this regard, the development of behavioural activation (see COBRA study reviewed this page) as a cost-effective alternative to CBT is of particular interest.

Reference: Lancet. 2016;388(10047):881-90
Abstract

Prenatal nicotine exposure and risk of schizophrenia among offspring in a national birth cohort

Authors: Niemelä S et al.

Summary: This study analysed archived data from all live births in Finland from 1983 to 1998 for this investigation into the relationship between prenatal nicotine exposure (cotinine level) in maternal sera and schizophrenia in offspring. Maternal serum cotinine levels were measured by quantitative immunoassay from early- to mid-gestation. Cases of schizophrenia in offspring (n=977) were identified from a national registry and matched 1:1 to controls on date of birth, sex, and residence. A higher maternal cotinine level was associated with an increased odds of schizophrenia (OR 3.41; 95% CI, 1.86 to 6.24). Heavy maternal nicotine exposure was associated with a 38% increased odds of schizophrenia. These findings persisted after adjusting for maternal age, maternal and parental psychiatric disorders, socioeconomic status, and other covariates. There was no clear evidence that weight for gestational age mediated the associations.

Comment (DM): This remarkable and statistically robust report from Finland is characteristic of similar Scandinavian cohort studies, enabled by the meticulous collection of population data in Nordic countries, and careful control of possible confounders. If confirmed in other cohorts, the results will be of major public health significance, in light of the devastating personal, social, and economic costs of schizophrenia. Applicability to New Zealand may be examined by reviewing data from the Dunedin and Christchurch birth cohort studies -- which have, inter alia, already demonstrated links of maternal smoking with offspring conduct disorder and ADHD, e.g. JAMA Psychiatry 2013 September; 70(9). The results also suggest important implications for Māori health, given excess rates of maternal smoking and of schizophrenia, and should provide the New Zealand government with an added impetus to pursue its smoke-free agenda.

Reference: Am J Psychiatry. 2016;173(8):799-806
Abstract

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Time spent reading this publication has been approved for CNE by The College of Nurses Aotearoa (NZ) for RNs and NPs. For more information on how to claim CNE hours please **CLICK HERE**.

Antipsychotic prescribing and its correlates in New Zealand

Authors: Dey S et al.

Summary: This analysis of antipsychotic prescribing included 451 patients discharged from inpatient units in three New Zealand regions with a diagnosis of schizophrenia or a related disorder between July 2009 and December 2011. One-third of patients (33.7%) were prescribed multiple antipsychotics. Clozapine was under-utilised (20%); Māori were prescribed clozapine more frequently than non-Māori (24% vs 13%, respectively). Compulsory treatment was associated with more use of injectable medication and increased length of stay in hospital. Clinician characteristics (including the prescriber's country of postgraduate training and years of postgraduate experience) did not significantly influence prescribing.

Comment (DM): See below.

Reference: Australas Psychiatry. 2016;24(4):360-4
Abstract

Correlates of rehospitalisation in schizophrenia

Authors: Dey S et al.

Summary: Using the same national database and patient cohort described in the previous article, the researchers analysed associations between discharge variables and rehospitalisation rates. Nearly half (44%) of the cohort were rehospitalised within 2 years. Rehospitalisation was less likely in patients aged over 50 years (HR 0.58; 95% CI, 0.35 to 0.97; p=0.04), whereas those whose index admission included compulsory treatment were more likely to be rehospitalised (HR 1.3; 95% CI, 0.98 to 1.71; p=0.06) and to have a longer period of rehospitalisation (p=0.05). Rehospitalisation was less likely for those whose index admission was ≥3 weeks (HR 0.53; 95% CI, 0.39 to 0.72; p=0.001). Antipsychotic types, routes and dosages did not significantly affect rehospitalisation rates, except for those prescribed clozapine (HR 0.61; 95% CI, 0.41 to 0.89; p=0.01).

Comment (DM): These two papers in Australasian Psychiatry can be considered together as part of a Waikato-based PhD thesis investigating antipsychotic drug utilisation and impacts in New Zealand (competing interest declaration: I am one of Dr Dey's PhD supervisors). Many of the results, such as frequent readmission and high rates of antipsychotic polypharmacy overall, and increased use of depot preparations in association with compulsory treatment, are unsurprising. On the other hand, other findings are of note, including the observation that shorter index admissions were associated with higher risk of rehospitalisation. This challenges a key facet of current practice, focused as it is on rapid treatment and discharge from hospital. Finally, the results are clear that only clozapine reduces the risk of readmission compared to alternatives. Other pharmaceutical variables (including the use of depot) were not significantly predictive, suggesting again that our most effective (and arguably most toxic) antipsychotic is under-utilised in New Zealand.

Reference: Australas Psychiatry. 2016;24(4):356-9
Abstract

The Brief Assessment of Cognition in Schizophrenia: reliability, sensitivity, and comparison with a standard neurocognitive battery

Authors: Keefe RS et al.

Summary: The Brief Assessment of Cognition in Schizophrenia (BACS) assesses those aspects of cognition that are most impaired and most strongly correlated with outcome in people with schizophrenia. The tool takes patients a little over half an hour to complete, has a high completion rate, and shows high reliability. Moreover, the BACS is as sensitive to cognitive impairment in people with schizophrenia as a standard battery of tests that requires over 2 h to administer. Compared to healthy controls matched for age and parental education, people with schizophrenia performed 1.49 standard deviations lower on a composite score calculated from the BACS and 1.61 standard deviations lower on a composite score calculated from the standard battery. The BACS composite scores were highly correlated with the standard battery composite scores in the schizophrenia cohort (r=0.76) and healthy controls (r=0.90).

Comment (WM): This article outlines the problems with the available tests for evaluation of cognition in schizophrenia. Three particular areas of concern were noted; the fact that none of the widely used tests was specifically designed with the areas of likely deficit in schizophrenia in mind; the considerable time that the typical battery of tests took to administer and the need for highly specialised administrators; the low completion rates and patient unfriendliness.

The BACS was tailored to measure cognitive impairment on domains clearly impacted in schizophrenia: verbal memory, working memory, motor speed, attention, executive function and verbal fluency. It was as sensitive to the cognitive deficits of schizophrenia as a standard battery of neurological tests that took nearly four times as long to administer. A greater percentage of patients were able to complete the tests in the BACS compared to the standard measures. The study also showed the portability of the test and its ease of administration by a range of mental health workers. The training required for successful administration was minimal. Average completion time was around 30 minutes.

The article gives a full description of the tests used that are deemed relevant to the particular domains of cognitive function.

Reference: Schizophr Res. 2004;68(2-3):283-97
Abstract

Successful evaluation of cognitive function and the nature of cognitive deficits among people with schizophrenia in clinical rehabilitation settings

Authors: John AP et al.

Summary: These researchers describe how they successfully measured cognitive function and the nature of cognitive deficits in people with schizophrenia/schizoaffective disorder admitted during a 5-year period to a public in-patient rehabilitation facility. The analysis used the BACS to evaluate cognitive function in 122 of 135 admissions. The mean composite score on the BACS was 1.8 standard deviations below the norm, and 43% had moderate or severe cognitive deficits. The BACS subtests of list learning and symbol coding revealed more severe deficits.

Comment (WM): This article from Western Australia reminds us why cognition is an important factor in determining return of function after experiencing schizophrenia. The researchers describe an audit of cognitive testing conducted in the setting of a public inpatient rehabilitation unit. The principle tool for that assessment was the BACS {see the preceding review by Keefe et al. in this Research Review}. The testing was conducted by nurses and psychologists who had training in its administration. The patient population was typical for such a setting, mean age 32, predominantly male, predominantly treatment-resistant psychosis. Of the 135 patients admitted over the audit period, 90% completed the BACS; non-completion was because of refusal, felt to be too disorganised or having an insufficient grasp of English. Less than one-third scored in the normal range on composite scores; most impacted areas were speed of processing, verbal memory and working memory.

This report should be very encouraging for clinicians involved in treatment of people with schizophrenia. It confirms what the test designers said about ease of application and acceptability to clinicians and to patients of this test of cognition. It could be more widely used in routine practice.

Reference: Australas Psychiatry. 2016;24(4):342-6
Abstract

Cognitive neuropsychological functioning in New Zealand Māori diagnosed with schizophrenia

Authors: Kake TR et al.

Summary: Cognitive neuropsychological functioning was examined in 54 adult Māori diagnosed with schizophrenia and 56 controls, matched on sociodemographic variables, handedness and premorbid cognitive ability. The study also analysed associations between cognition, medication and symptoms of psychosis in the schizophrenia group. In neuropsychological testing of attention, executive ability, motor, premorbid ability, verbal/non-verbal memory and verbal fluency (English/Māori versions), performance was significantly poorer in the schizophrenia group versus the control group on all tests, except the test of attention. Effect sizes were moderate to large: 0.78 for motor function; 1.3 for executive ability, verbal fluency and visual memory; 1.6 for verbal learning and 1.8 for verbal memory. These differences persisted in analyses that adjusted for multiple comparisons and covariates. A higher dose of antipsychotic medication and a higher anticholinergic load were associated with greater verbal memory impairment (r = –0.38 and r = –0.38, respectively). A longer duration of illness was associated with greater impairment of verbal memory (rho = –0.48), verbal learning (rho = –0.41) and visual memory (rho = –0.44).

Comment (WM): This report describes the first case-control study that was designed to evaluate cognitive function in New Zealand Māori diagnosed with schizophrenia. It is of considerable importance, given that Māori have higher rates of the illness and poorer outcomes and in 2013 Kahn and Keefe described "Schizophrenia as a Cognitive Illness". As well as the primary goal of measuring the cognitive state in comparison to controls, the study has as secondary questions the relationship between cognition and medication dose, duration of untreated illness, substance abuse and positive and negative symptoms.

The study enrolled 54 subjects with schizophrenia and 56 controls. The study population is well described. There are only minor differences between patient and control groups; the latter being slightly older and having less use of cannabis. They are not different on socioeconomic measures, duration of education, Te Reo competency and Iwi affiliation. Data gathered included the neuropsychological profile, PANSS and medication. The article outlines how this was obtained. The analysis of the data is well described.

There are significant performance differences in most of the cognitive areas. These lowered performances are much as reported in the international literature. The largest differences were seen in verbal learning, verbal fluency and executive function. The most relevant finding in secondary analysis was the association of performance deficit with higher antipsychotic dose.

This very well-designed and conducted study does confirm that for New Zealand Māori with schizophrenia, cognitive impairments are significant and likely to be at a level that has serious impact on ability to function. It suggests that the development and regular use of a culturally informed cognitive remediation tool is required to improve the outcomes for New Zealand Māori who have schizophrenia.

Reference: Aust N Z J Psychiatry. 2016;50(6):566-76
Abstract

Independent commentary by Associate Professor David Menkes, an academic psychiatrist with a background in psychology and pharmacology (PhD 1983, Yale). Since completing specialist training in Dunedin (FRANZCP 1989) he has worked as an academic liaison psychiatrist in NZ and the UK. He has a continuing interest in the pharmacology and toxicology of drug treatments in psychiatry, is a member of the Medicines Adverse Reactions Committee (Medsafe), the PTAC Mental Health Subcommittee that advises PHARMAC, www.healthyskepticism.org, and works closely with the International Society of Drug Bulletins (www.isdbweb.org).

Independent commentary by Associate Professor Wayne Miles, a psychiatrist with Waitemata DHB, Clinical Director of Awhina Research and Knowledge, and a Clinical Associate Professor with Auckland University School of Medicine. He has had many roles with the RANZCP including that of President, and has also been involved with NZMA and is currently on that organisation's Board. Wayne has had extensive experience in both the treatment of, and research into schizophrenia. He has conducted sponsored research with, and/or received honoraria for services to Otsuka, Pfizer, Roche, Eli Lilly, Janssen, Amgen, Bristol Myers Squibb and GSK.

Intervention to prevent major depression in primary care: a cluster randomized trial

Authors: Bellón JÁ et al.

Summary: Outcomes are reported from an evaluation of an intervention based on personal predictors of risk for depression implemented by two primary care physicians (PCPs) in over 3000 nondepressed adult patients attending primary care centres in Spain. For each patient, PCPs communicated individual risk for depression and personal predictors of risk and developed a psychosocial programme tailored to prevent depression. Patients were randomised to either usual care (controls) or the intervention. Over an 18-month period, they were assessed every 6 months for major depression. At 18 months, the incidence of major depression was lower in the intervention group compared with the control group (7.39% vs 9.40%; p=0.070).

Comment (WM): This interesting study addresses an important issue for psychiatrists, namely, the capacity of a primary care-based initiative to decrease the prevalence of episodes of major depression. The work emerges from a consortium in Spain with a considerable track record in the area of depression and primary care. The authors have previously developed an instrument to predict an individual's risk for depression (predictD). Based on that tool, they developed an intervention whereby Primary Care Physicians (PCPs) measured the probability of developing depression in people attending their service. They then provided feedback on this risk, a booklet about preventing depression, and a tailored bio-psycho-family-social intervention assembled for each patient.

A multicentre cluster randomised trial was conducted across 7 Spanish cities. Though not possible to have total blinding the authors attempted to reduce bias by having random and independent selection of practices, PCPs and patients. I found it unclear, however, exactly how the recruitment process happened and numbers in the body of the article are different from those available in the supplementary information. I have assumed that the primary randomisation was at the level of the enrolled practice.

The primary outcome was new occurrence of depression during the 18 months. Secondary analyses included development of anxiety and use of antidepressants. The article is light on details that allow one to have confidence in the veracity of the outcome data. The end outcome of the trial is disappointing in that the intervention failed to have a significant impact on depression presentation when compared to controls. There was a modest effect on anxiety.

The authors conclude that there are possible recruitment biases that could influence results and suggest the study results should neither support nor reject the use of and development of the model. For people interested in this area the paper is worth review but it will be important to look at the supplementary information on the journal website as well as the article itself.

Reference: Ann Intern Med. 2016;164(10):656-65
Abstract

Interpersonal psychotherapy for mental health problems: a comprehensive meta-analysis

Authors: Cuijpers P et al.

Summary: A search of the PubMed, PsycInfo, Embase, and Cochrane databases yielded 90 randomised trials (a total of 11,434 participants) that were analysed for the effects of interpersonal psychotherapy (IPT) for any mental health problems.

Comment (WM): This is an article that has to have immediate appeal, doesn't it; it's a comprehensive meta-analysis after all, but then when shouldn't a meta-analysis be comprehensive, you might well ask!

The authors set out to review all randomised trials examining the effects of IPT for any mental health disorder. It updates previously published analyses (2011, 2012, and 2013) and extends those published by looking at conditions other than depression. To be included, a study needed to utilise the method of Klerman and Weismann, be targeted at a mental health condition and be compared with a control condition or an alternative type of therapy. The search utilised the traditional databases; the actual search terms/strategy is not detailed, just that it was for interpersonal psychotherapy with filters for randomised trials. They did not search for the "grey" literature. This limitation to published only might bias to positive results, as those are typically published more than negative ones. The analytic method follows usual practice and is well described in the article and accompanying supplementary data.

Of the 90 studies found, two-thirds were for depression. All these showed a moderate to large effect size on prevention, treatment or relapse. Effect size was less for older people and those with diagnostic criteria for a depressive disorder. There was not a significant difference from other psychotherapies. Pharmacotherapy was slightly better than IPT but the combination of pharmacotherapy and IPT had the largest effect size. There is an association of effect size with number of sessions; 10 or more increases effect size. The authors comment that the evidence might favour the 16-session IPT; a factor for consideration when brief interventions are being considered. For anxiety disorders IPT is as effective as CBT; for eating disorders CBT has a small benefit over IPT. There are promising effect sizes for addictions and distress from general medical conditions. The authors caution, however, that the numbers are small. Overall, the analysis suggests a growing evidence base for the effectiveness of IPT.

Reference: Am J Psychiatry. 2016;173(7):680-7
Abstract