Obsessive-Compulsive Disorder and quality of life outcomes: protocol for a systematic review and meta-analysis of cross-sectional case-control studies

Anna Coluccia(1), Andrea Fagiolini(2), Fabio Ferretti(1), Andrea Pozza(1), Arianna Goracci(2)

ABSTRACT

BACKGROUND: Obsessive-compulsive disorder (OCD) is a chronic disabling psychological condition, which can severely affect quality of life (QoL). Growing interest has been dedicated to assessing which domains of QoL are more severely affected in patients with OCD but the findings have not been unanimous. Research on QoL in OCD could suggest the domains in which intervention could be improved.

METHODS: Here we propose a systematic review of cross-sectional case-control studies according to PRISMA guidelines, comparing QoL outcomes of patients with a primary OCD diagnosis with healthy controls. Primary objectives will be to examine differences in QoL outcomes between patients with OCD and healthy controls, and to assess which QoL domains are more severely impaired in patients than controls, particularly subjective well-being, social and interpersonal functioning, work functioning and family functioning. The study will then investigate potential moderators of QoL in OCD, including participant characteristics (age, gender, presence of comorbid personality disorders, OCD symptom severity, severity of concurrent depressive symptoms, duration of OCD symptoms and generational cohort) and study characteristics (date of publication and methodological quality of studies). Online databases will be searched (PsycINFO, PubMed, Science Direct, Cinahl, Biological Abstracts, Psyclit, Embase, The Cochrane Central Register of Controlled Trials, and Google Scholar). To locate unpublished records, conference abstracts, doctoral dissertations and theses will be handsearched, and experts will be contacted. Statistical analysis will be performed by random effect model meta-analysis. Risk of bias assessments will be conducted using the instrument Methodological Index for Non-Randomized Studies.

Key words: quality of life, compulsive disorder, systematic review, protocol

(1) Department of Medical Sciences, Surgery and Neurosciences, Santa Maria alle Scotte University Hospital, Siena, Italy.
(2) Department of Molecular Medicine, Santa Maria alle Scotte University Hospital, Siena, Italy.

CORRESPONDING AUTHOR: Fabio Ferretti - Santa Maria alle Scotte University Hospital - Viale Bracci 16, 53100 Siena, Italy - Email: ferrefa@unisi.it - Phone: +39 0577 586409 Fax: +39 0577 233222

The study was not supported by any institutional grant. The authors declare that they have no conflict of interest. The authors have no competing interests to declare.

DOI: 10.2427/10037
Accepted on January 19, 2015
BACKGROUND

Quality of life in Obsessive-Compulsive Disorder

Obsessive-Compulsive Disorder (OCD) is a chronic psychological condition with a lifetime prevalence of 2% in the general population [1-3]. OCD is characterized by intrusive thoughts, impulses or mental images and repetitive behaviours or mental compulsions, which can strongly affect quality of life (QOL) of the individual [4]. The World Health Organization (WHO) has ranked OCD as the 10th leading cause of disability of all health conditions in the industrialized world [5].

Increasing evidence suggested that patients with OCD have worse QOL than healthy individuals [6]. For example, in a cross-sectional case-control study, Huppert et al. [7] found that a group of 66 patients with primary OCD had significantly lower QOL outcomes than a group of 36 controls without any lifetime psychiatric diagnosis.

Growing interest has been dedicated by researchers and clinicians to assessing which domains of QOL are more severely affected in patients with OCD. However, research to date has yielded conflicting findings. Some studies report that OCD is associated with impairment in all domains of QOL [8]. For example, Fontenelle et al. [9] reported that a group of patients with a primary OCD diagnosis had significantly lower scores than controls on all scales of the Medical Outcomes Survey Short Form-36 [10], but not on the scale measuring physical pain. In other studies [11], OCD has been associated with impairment in the specific domain of social functioning. Indeed, lengthy pervasive rituals, and the chronic course of the disorder itself, can break down the social networks of the patient and his/her family [12]. In other studies [13], OCD was significantly associated with impairment only in the family functioning domain but not in other QOL domains. OCD can negatively affect the family functioning of patients, since rituals may often involve informal caregivers [14-15]. Impaired family functioning caused by the expression of compulsions in the home environment, tends to be associated with stronger expressed emotions and hypercriticism by caregivers [16].

Rationale for the current study

Given the inconsistency of findings from available studies, a quantitative summary of current evidence on the QOL domains more severely impaired in OCD would be useful for research and clinical practice. No systematic review and meta-analysis specifically addressing this topic has yet been conducted. In the literature, Olatunji, Cisler and Tolin [17] conducted a meta-analysis of 23 cross-sectional case-control studies examining QOL in patients with anxiety disorders, including OCD, and healthy controls. The findings suggested that, although patients with anxiety disorders had lower QOL than healthy controls, the difference was not statistically significant [17]. It could, however, be argued that impairment was stronger in specific domains of QOL for certain anxiety disorders [17], and, importantly, the meta-analysis did not specifically assess QOL in patients with primary OCD, due to the limited number of studies that could be included.

Assessment of QOL in OCD could have major implications for practice by suggesting integrated treatment strategies, pharmacological and psychotherapeutic, aimed at improving prognosis [18]. Although some evidence implies that pharmacological [19] and psychological treatments [20] can enhance sustained change on OCD symptom outcomes, scores on QOL outcomes after trials tend to remain lower than those of the general population [21]. Low QOL can also be a predictor of negative response to pharmacological treatment and psychotherapy [22]. In addition, poor QOL can increase the risk of early drop out from treatment [23] or the probability of relapse after a successful treatment course. Research on QOL in OCD could suggest the domains in which intervention could be improved.

The current report presents the protocol of a systematic review and meta-analysis of cross-sectional case-control studies on QOL in OCD. Aims of the study are:

1. To examine differences in total QOL outcomes scores between patients with primary OCD and healthy controls (screened without any current or lifetime psychiatric disorder, individuals recruited from the general population, and undergraduates);

2. To determine which QOL domains are more severely impaired in patients with primary OCD compared to healthy controls; differences between patients with OCD and healthy controls will be examined for the following QOL domains: subjective well-being, social and interpersonal functioning, work functioning and family functioning;
To investigate potential moderators of QOL in OCD, specifically: participants characteristics (age, gender, comorbid personality disorders, OCD symptom severity, severity of concurrent depressive symptoms, duration of OCD symptom, and generational cohort, coded as a categorical variable: child/adolescent versus adult samples, and study characteristics (date of publication and methodological quality)

METHODS

Eligibility criteria

Following a modified version of the PICOS approach for observational cross-sectional case-control studies, defined in the PRISMA guidelines [24], the criteria considered for inclusion of studies will be: (a) participants; (b) outcomes; (c) comparators and; (d) design characteristics:

Participant Characteristics. Studies will be included if they were conducted on patients with a primary diagnosis of OCD, provided the diagnosis was made through a semi-structured interview based on standardized diagnostic criteria, such as the Structured Clinical Interview for DSM-IV [25]. Studies will only be included if they involved patients with a current primary diagnosis of OCD. Thus, studies on patients with a lifetime diagnosis of OCD and studies using participants with subclinical OCD symptoms will be excluded. Studies where patients were assessed only through psychometric self-report measures will be excluded. Studies will be included if they used either adult or adolescent/chiln samples. Studies on primary compulsive hoarding will be excluded, as the treatment for hoarding differs from CBT for OCD, and hoarding is a separate diagnosis in DSM-5 [4], albeit included in the OCD-related disorders chapter. Studies where all patients had OCD and a specific comorbid psychological or medical disorder will be excluded. However, studies where some of the patients had comorbid disorders will be included. Studies conducted on mixed samples, consisting of patients with primary OCD and patients with other primary conditions (e.g. mood or anxiety disorders) will be excluded. Concurrent psychological or pharmacological treatments, will not be considered as an exclusion criterion.

Outcome Characteristics. Studies will be included if they used outcome measures of QOL with known psychometric properties, either self-report questionnaires or interviews, such as the SF-36.

Comparator characteristics. Studies will be included if they used healthy control groups consisting of screened participants who did not report any psychiatric disorder during a clinical interview. Such participants may be matched with patients with OCD on socio-demographic variables. Undergraduates or individuals recruited from the general population (i.e. community participants) are also acceptable.

Design characteristics. Studies will be included if they used observational cross-sectional case-controlled design, comparing QOL outcomes between groups of patients with primary OCD diagnosis and healthy control groups.

Information sources and search procedure

The following search strategies will be used to identify studies eligible for inclusion.

Electronic search. Studies will be retrieved by online systematic literature searches, in which key words related to OCD (“obsessive compulsive disorder”, “obsessions”, “compulsions”, “rituals”) will be combined by the boolean operator “AND” with key words and text words indicative of the QOL construct (“quality of life”, “psychological well-being”, “satisfaction with life”, “global functioning”, “social functioning”, “family functioning”, “subjective well-being”) and of QOL measures (“Medical Outcome Survey Short Form-36”, “Quality of Life Inventory”, “Satisfaction with Life Scale”, “WHOQOL-100”, “WHOQOL-BREF”). The following online databases will be searched: PsycINFO, PubMed, Science Direct, Cinahl, Biological Abstracts, Psyclit, Embase, The Cochrane Central Register of Controlled Trial, and Google Scholar. No date restriction will be applied.

Corresponding authors. To request any further papers, published or unpublished, all corresponding authors of studies to be included in the meta-analysis will be contacted.

Handsearch Conference proceedings and doctoral dissertations will be handsearched for abstract books of the following international associations relevant to the issue of QOL in OCD: European Health Psychology Society, International Society for Quality of Life Research, American Psychiatry Association, American
Reference lists. Reference lists of the studies included in the meta-analysis will be examined. In addition, references will be examined for the following peer-reviewed journals relevant to this topic: Anxiety, Stress and Coping, Applied Research in Quality of Life, Behaviour Research and Therapy, British Journal of Health Psychology, Comprehensive Psychiatry, Depression and Anxiety, European Psychiatry, Health Psychology, Health Psychology Review, Journal of Clinical Psychiatry, Journal of Psychiatric Research, Psychotherapy and Psychosomatics, Quality of Life Research.

Study selection

Studies will be assessed on eligibility criteria by two independent reviewers (FF, AC) in three stages. During the first and second stages, studies will be examined with regard to inclusion criteria after reading the title and abstract, respectively. Studies for which reviewers are not unanimous about inclusion will be retained and assessed for eligibility after reading the full-text. After each stage, the reviewers will discuss their reasons for inclusion and discrepancy will be addressed during meetings with two other independent reviewers (AF, AG) in order to obtain a shared pool of included studies for the meta-analysis. Between-reviewer agreement on eligibility will be calculated by Cohen’s Kappa index [26].

Assessment of methodological quality and risk of bias

Methodological quality and risk of bias for the studies included in the meta-analysis will be assessed by the two independent reviewers (FF, AC) using the Methodological Index for Non-Randomized Studies [MINORS; 27]. Between-reviewer agreement on methodological quality scores will be calculated by Cohen’s Kappa index [26]. Quality of studies and data reporting will be assessed according to Strengthening the Reporting of Observational Studies in Epidemiology guidelines [STROBE; 28].

Moderators coding

If inconsistency analyses indicates significant heterogeneity of effect sizes, the role of moderators will be investigated. Two independent reviewers (FF and AC) will code the moderators, extract the data from primary studies and enter it in an excel worksheet. Subsequently, the two reviewers will meet to check worksheet data entry for accuracy, and any discrepancy will be discussed and resolved. The following variables will be coded as moderators: Participants characteristics: (1) mean age of sample; (2) gender of sample (coded as percentage of female participants); (3) co-occurrence of comorbid personality disorders (percentage of participants with comorbid personality disorders in sample); (4) OCD symptom severity (coded as a continuous variable based on Y-BOCS scores); (5) severity of concurrent depressive symptoms (coded as a continuous variable based on BDI-II scores); (6) duration of OCD symptoms (coded as number of years from first diagnosis of OCD made by a mental health professional or as patient self-reported age of onset; (7) generational cohort (categorical variable: child/adolescent versus adult samples).

Study characteristics: (1) date of publication; (2) methodological quality (as continuous variable based on MINORS scores).

Statistical analysis

Power calculations

An a priori power analysis will be performed to investigate the number of studies requested to achieve a statistically powerful analysis for detecting a medium effect size, as defined by Lipsey [29]. Power analysis will be conducted according to the guidelines provided by Borenstein and colleagues [30] using Power and Precision software version 4.00.

Data extraction and summary measures

Before calculating the effect sizes, outlier studies will be identified by the sample-adjusted meta-analytic deviance method [SAMD; 31]. As we expect heterogeneity across the studies included, effect sizes will be calculated using a random effects model. Random effects models assume that the studies included are
drawn from populations of studies that differ systematically from each other. According to these models, the effect sizes derived from included studies differ not only because of random error within studies (as in the fixed effects model) but also because of true variation in effect sizes from one study to another [30].

Data required to calculate effect sizes will be extracted independently by two meta-analysts (FF and AP) using formula [32]:

\[ ES = \frac{M_{OCD} - M_{CONTROL}}{SD_{POOLED}} \]

where \( M_{OCD} \) is the mean of the groups of patients with OCD, \( M_{CONTROL} \) is the mean of the healthy controls and \( SD_{POOLED} \) is the pooled standard deviation.

The effect size for each study will be weighted by application of correction formula (b):

\[ W_{zr} = \frac{1}{SE^2_{zr}} \]

where \( SE_{zr} \) is the standard error of the effect size computed for each study. This formula will be further corrected with formula (c) for sampling error:

\[ W' = W_{zr} (\alpha_{QOL}) (\alpha_{DOC}) \]

where \( \alpha_{QOL} \) is the Cronbach reliability coefficient [33] as internal consistency for QOL measures and \( \alpha_{DOC} \) is the coefficient for OCD symptom measures.

Effect sizes will be estimated using a 95% confidence interval and interpreted according to criteria suggested by Cohen [32]. Thus, effect sizes of 0.80 or more will be assumed to be large, 0.50 moderate, and 0.20 small [32]. The Hedges’ correction for small sample bias will be applied to all effect sizes [34]. A global effect size will be calculated as mean effect size by combining effect sizes related to different QOL measures. For studies using QOL measures related to different QOL domains (e.g. social functioning and subjective well-being), a mean effect size will be calculated for each study. Subsequently, effect sizes will be calculated separately for specific domains related to QOL. Mean effect sizes will be computed for the following domains: subjective well-being, social and interpersonal functioning, work functioning and family functioning.

Inconsistency analysis

In order to assess between-study heterogeneity, two complementary indices will be used, the \( I^2 \) index [35] and the \( Q \) statistic [36]. The \( I^2 \) index determines percentage of heterogeneity of effect sizes of included studies [35]. A value approaching zero suggests homogeneity, whereas values of 25-50%, 50-75% and 75-100% represent low, medium and high heterogeneity, respectively [35].

Analysis of moderators

If inconsistency analysis suggests high heterogeneity, the above-mentioned moderators will be analyzed by mixed model ANOVA and weighted least squares meta-regression.

Publication bias

To investigate the likelihood that effect sizes are subject to publication bias, Orwin’s fail-safe N method [37] and visual inspection of the funnel plot will be used.

The meta-analysis will be performed using Comprehensive Meta-analysis software, version 2.00.

DISCUSSION

The systematic review will examine QOL outcomes in OCD and particularly which QOL domains are more severely affected in this psychological condition. Although no meta-analysis has ever been conducted on this topic, some limitations should be considered. The inclusion of different observational designs prevents any conclusions about causal connection between OCD and QOL. Another source of heterogeneity could come from aggregating different types of QOL measures to calculate a global QOL outcome. A further potential source of bias could arise from using different types of control sample as comparators (e.g. screened participants, individuals from the general population, undergraduates).

In conclusion, by highlighting which
domains of QOL to target for treatment and which patient characteristics could be associated with poorer QOL, the results will be useful for clinical practice. The study could also be a starting point for future research on predictors of poor QOL in OCD.

References


