

“Tackling Trauma to Overcome OCD Resistance” (*The TTOOR Florence trial*) Efficacy of EMDR plus CBT versus CBT Alone for Inpatients with Resistant Obsessive Compulsive Disorder. Protocol for a Randomized Comparative Outcome Trial

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Abstract Researchers and clinicians have recently highlighted the usefulness of integrating additional therapeutic approaches into standard intensive cognitive behavioural treatments (CBT) with the aim to improve clinical outcomes for patients with severe resistant OCD. To date, there is still a limited amount of knowledge on the effectiveness of third-wave CBT techniques for OCD, despite such techniques seemed to be effective for a wide range of mental disorders. The Eyes Movement Desensitization Reprocessing (EMDR) is a treatment approach, based on the Adaptive Information Processing model, which conceptualizes psychological disorders as manifestations of unresolved traumatic or distressing memories. EMDR has been conceived as an integrative approach, aimed at facilitating resolution of memories, desensitizing stimuli that trigger present distress as a consequence of second-order conditioning, and incorporating adaptive attitudes and behaviours for better functioning. The present paper describes a research protocol for a randomized comparative outcome trial on inpatients with treatment-resistant OCD in a tertiary inpatient clinic in Italy. The study will aim to: (a) examine the effectiveness of EMDR with intensive brief CBT (EMDR+CBT) compared to intensive brief CBT alone on primary outcomes (OCD symptoms, obsessive beliefs, depression, and anxiety) at immediate post-treatment, one-, six-month-, and one-year-follow-up; (b) compare feasibility and acceptability of EMDR+CBT protocol versus intensive brief CBT alone (in terms of attrition and treatment satisfaction); (c) examine the effectiveness of EMDR+CBT versus intensive brief CBT alone on secondary outcomes (disgust propensity and sensitivity, emotion dysregulation, and dissociative experiences and symptoms). Inclusion/exclusion criteria of participants, outcomes, time scheduling, rationale, and therapeutic components of the treatments will be presented.

Keywords: *Obsessive Compulsive Disorder, Eyes Movement Desensitization Reprocessing, cognitive behavioural therapy, inpatients, randomized controlled trial*

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1. Introduction

1.1. Challenging Non-response to Treatment of OCD

Exposure with response prevention (ERP) is recommended as the first-line treatment of choice for obsessive-compulsive disorder (OCD) [1]. Consistent research data have indicated that CBT for OCD produces statistically significant improvement in approximately 75% of patients [2]. However, when the reliable change criterion is used,

only 25% of cases do achieve a full recovery status [2]. Moreover, ERP is associated with a 25% refusal rate, even in clinical trials in which treatment is offered at no cost [3], presumably due to the apprehension about the time, effort, or perceived distress associated with the treatment. Some evidence also highlighted the importance of tailored treatment approaches with the aim to target frequent relapses in OCD patients [3].

Relatively few treatment approaches have been developed for OCD patients who show resistance to evidence-based treatments. Some data suggested that intensive treatments based on CBT techniques could be a tailored therapeutic strategy to overcome resistance of severe cases with OCD. For example, in a pilot study with 11 patients [4] Pollard reported promising data on the effectiveness of intensive outpatient CBT combined with pharmacotherapy for resistant OCD. The program involved 2-hour daily therapist-assisted ERP combined with weekly individual sessions devoted to cognitive restructuring. In a study conducted in an inpatient setting [5], intensive treatment was found to be effective for inpatients with severe OCD, who had not responded to outpatient CBT. The program involved daily and prolonged CBT combined with medications for two months of average hospitalization. However, approaches exclusively based on ERP therapy may be experienced strongly stressful by the patients, since they have been found to be associated to high drop out rates, loss of motivation, and high risk for long-term relapses [6,7,8].

Therefore, researchers and clinicians have recently highlighted the usefulness of integrating additional therapeutic approaches with the aim to improve outcome for resistant OCD [7]. Some preliminary research has been developed to evaluate alternative therapeutic approaches incorporating third-wave CBT components. For example, in two small samples of patients with resistant OCD Sookman and Pinard [9] and Sookman and colleagues [10] evaluated a long-term schema-based CBT delivered through individual weekly sessions. Sample sizes were 7 and 32 respectively and the treatment mean duration was 10 months. Results showed that about 80% of the patients achieved clinically significant improvement.

1.2. Eyes Movement Desensitization Reprocessing (EMDR)

The Eyes Movement Desensitization Reprocessing (EMDR) is a treatment approach, based on the Adaptive Information Processing (AIP) model [11], which conceptualizes psychological disorders as manifestations of unresolved traumatic or distressing memories. EMDR has been conceived as an integrative treatment approach, aimed at (a) facilitating resolution of memories (eg, elicitation of insight, cognitive reorganization, adaptive affects, and physiological responses), (b) desensitizing stimuli that trigger present distress as a consequence of second-order conditioning, and (c) incorporating adaptive attitudes, skills, and behaviours for enhanced functioning [11]. These comprehensive treatment goals are attained through EMDR's standardized procedures [12], which integrate components of different theoretical orientations. These include psychodynamic [13], cognitive-behavioral [14], experiential and interactional therapies [15].

Originally, EMDR was applied to anxiety related to traumatic memories [16], and to date EMDR is recognized as a well-established therapy for posttraumatic stress disorder (PTSD). In effect, some meta-analyses [17] have reported that EMDR is equivalent or superior to CBT consisting of exposure therapy and cognitive restructuring in treating PTSD. Subsequently, EMDR has been effectively adopted to target a variety of experientially-based disorders [18].

1.3. The Contribution of EMDR to Target Resistance to Change of OCD

Despite the growing interest on the application of EMDR therapy for psychological problems, there is still a limited body of research investigating the efficacy of EMDR techniques for patients with OCD, and current evidence appear unclear. Preliminary research has suggested that EMDR may be an effective treatment strategy for long-standing and severe cases with OCD [19]. Marr [19] adapted an EMDR protocol for four severe OCD patients using two different strategies: one strategy delaying the cognitive installation phase, and the other one using mental video playback in the desensitization of triggers. Patients received 14–16 one-hour sessions, without homework assignment. Scores at post-treatment were in the subclinical/mild range for all participants on the Y-BOCS. Follow-up assessments were conducted at 4–6 months, showing maintenance of treatment effects. Symptom decrease was 70.4% at post-treatment and 76.1% at follow-up for the Adapted EMDR Phobia Protocol and 81.4% at post-treatment and at follow-up for the Adapted EMDR Phobia Protocol with Video Playback, respectively.

Bae, Kim, and Ahn [20] reported two clinical cases with OCD. Patients were two men, diagnosed with chronic OCD, who had shown no response to pharmacological or psychotherapeutic interventions. Bae et al. provided Parnell's [21] modified EMDR protocol with both patients, identifying and resolving feeder memories, consistent with Shapiro's [16] AIP theory that addressing etiological events with EMDR will decrease the client's symptoms. However, OCD symptoms did not appear to change by treatment.

Böhm and Voderholzer [22] investigated the effects of the combination of ERP and EMDR for three adult patients diagnosed with OCD while receiving 8–12 weeks of inpatient treatment. The first two patients received a course of either EMDR or ERP and then a course of the alternative treatment. This design allowed for the evaluation of the incremental effects of each treatment. The Y-BOCS [23] was administered at pre-treatment, after completion of the first course of treatment, and at post-treatment. The first participant was a 34-year-old man with checking compulsions. He received 6 weeks of EMDR, addressing traumatic experiences of abandonment during childhood, but apparently without addressing current triggers or future action with EMDR. There was a reduction in his Y-BOCS score from 36 to 32. This was followed by administration of ERP, with a reduction in his Y-BOCS score from 32 to 9. Effects were maintained at follow-up, and he reported that the benefit of EMDR was increased insight into his OCD symptoms, with resultant ability to tolerate the exposure therapy. The second

participant was a 24-year-old woman with aggressive and sexual obsessions. She first engaged in 7 weeks of ERP, with a reduction in the Y-BOCS (obsessive thinking only) score from 16 to 12. This was followed by administration of 4 weeks of EMDR, focusing first on a traumatic fall in childhood, and then on an obsessive image. After EMDR, the Y-BOCS (obsessive) score had dropped from 12 to 8. Although at follow-up, the Y-BOCS score had increased to 11, she described much improved function. The third participant was a 27-year-old man with ordering and checking compulsions, with a fear of losing some possessions. He received 10 weeks of alternate sessions of EMDR and ERP. He reported no traumatic events in his history. His EMDR sessions did not follow standard procedures. Instead, a strategy that the authors called “the EMDR absorption technique (resource building)” [22], p. 180] was applied, in which he engaged in eye movements while simultaneously imagining successfully resisting the compulsive behaviors. His Y-BOCS score decreased from 35 at pre-treatment to 16 at post-treatment, with effects maintained at follow-up. Böhm and Voderholzer [22] recommended the use of EMDR as an augmentation method with ERP to assist clients in emotional mastery.

Only one randomized controlled trial has been conducted to assess EMDR for OCD. Nazari et al. [24] randomly assigned 90 OCD patients to receive EMDR or medication by Citalopram for 12 weeks. Patients were assessed with the Y-BOCS at post-treatment by diagnosticians blind to treatment assignment. Results showed that improvement on OCD symptoms was significantly greater for patients assigned to EMDR arm than those to medication [24]. However, this study did not assess maintenance of treatment gains at follow-up associated to EMDR, and, importantly, did not compare EMDR with traditional CBT techniques.

1.4. Rationale for the Current Study

Despite the growing interest on the use of EMDR techniques for the treatment of patients with OCD, to date there is still a limited amount knowledge on the effectiveness of EMDR for OCD and on the maintenance at follow-up of therapeutic gains produced by this treatment approach. There is a lack of research assessing the capacity of EMDR to address vulnerability and maintenance factors specific to OCD, such as obsessive beliefs, or investigating which OCD dimensions could be specifically targeted by this approach. EMDR techniques could be an effective treatment strategy adjuvant to CBT for complex cases, resistant to prior treatments, since EMDR active ingredients have been indicated as potentially suitable to target processes associated to resistance to change in OCD, such as disgust and emotion dysregulation [2].

1.5. Objectives

1.5.1. Primary Objectives

Starting from the promising clinical advantages of EMDR, the current study aims to assess the effectiveness of an EMDR treatment protocol as an adjuvant strategy to improve treatment response, adherence, and acceptability of inpatients with severe and resistant OCD. Specifically, the primary aims will be to:

- a). examine the effectiveness of a protocol combining EMDR with intensive brief CBT (EMDR+CBT) compared to intensive brief CBT alone on primary outcomes (OCD symptoms, obsessive beliefs, depression, and anxiety) at immediate post-treatment, one-, six-month-, and one-year-follow-up.
- b). compare feasibility and acceptability of EMDR+CBT protocol versus intensive brief CBT alone (in terms of attrition and treatment satisfaction).

1.5.2. Secondary Objective

Secondary objective will be to:

- c). examine the effectiveness of EMDR+CBT versus intensive brief CBT alone on secondary outcomes (disgust propensity and sensitivity, emotion dysregulation, and dissociative experiences and symptoms) at immediate post-treatment, one-, six-month-, and one-year-follow-up. Disgust propensity and sensitivity will be used as a secondary outcome, since an increasing body of research has suggested that disgust propensity and sensitivity is strongly associated to OCD symptoms [25], and it plays as a vulnerability and maintenance factor specific to contamination-based OCD [26-28]. Specifically, preliminary prospective investigations showed that changes in disgust sensitivity or propensity mediated changes on contamination-based symptoms [27]. In addition, during exposure disgust reactions appear to decrease more slowly and to a less extent in patients with contamination-based OCD compared to patients with other OCD symptoms [29].

Emotion dysregulation will be used as a secondary outcome, since some recent work suggested that emotion dysregulation and intolerance for negative emotions in OCD is associated to greater functional impairment and symptom severity [30]. In addition, some authors have suggested that stronger emotion dysregulation could be a predictor of negative treatment response or greater risk for relapses in OCD [7].

Dissociative experiences will be used as a secondary outcome, as early traumatic events and dissociative symptoms seem to be relatively frequent among patients with resistant OCD [31-32]. OCD associated to dissociative experiences tends to present with more severe clinical correlates, including more impairing OCD symptoms, earlier onset of compulsions, poorer insight, and comorbid personality and eating disorders [33]. In effect, concurrent dissociative experiences in OCD have been found to be a prognostic factor for poorer outcome after CBT [34].

2. Method

The current study will be conducted according to the The Standard Protocol Items: Recommendations for Interventional Trials [SPIRIT 2013; [35]].

2.1. Study Context and Setting

The study will be conducted at the Unit for Treatment of Resistant OCD of the Poggio Sereno Clinic, a CBT specialist inpatient clinic in Fiesole, Florence (Italy).

2.2. Inclusion Criteria of Participants

Inpatients with treatment-resistant OCD will participate to the study. According to Rasmussen and Eisen [36], treatment-resistant OCD is defined by no change or worsening symptoms after an adequate trial of well-established therapies [20 to 30 hours of ERP or 10 to 12 continuous weeks of serotonin reuptake inhibitor medication (SRIs)]. No change or worsening symptoms after an adequate trial is defined according to the following criteria: a) OCD symptoms on gold-standard self-report measures are not resolved to within normal limits (post-treatment Y-BOCS scores are still above the cut-off); b) the patient continues to meet diagnostic criteria for OCD; c) the patient experiences little or no symptom improvement.

Inclusion criteria are: a) a primary diagnosis of OCD according to the DSM-5 [37]; diagnoses will be determined through clinical interviews performed by clinical psychologists and psychiatrists experienced and trained in the assessment of OCD; b) a score ≥ 16 on the Y-BOCS; c) an age range between 18 and 65 years. All the inpatients will be receiving concomitant pharmacotherapy by SRIs or antipsychotic drugs, that will be kept on a stable dosage for the whole treatment duration.

2.3. Exclusion Criteria

Exclusion criteria include current or past comorbid psychosis, substance-addiction, current active suicide intent, organic mental disorders, and mental retardation. Current psychological treatments for any other Axis I or II disorder also result in exclusion.

2.4. Power Calculations

To estimate the number of participants needed to detect differences between the two treatment groups on outcomes, a priori power calculations were performed. For a medium effect size ($\eta^2 = 0.50$), 80% power, and a significance level set at 0.01, the required total sample size is 68.

2.5. Participants Recruitment Strategies

Eligible participants will be identified and recruited through advertisements on the clinic website, through sheets and e-mail messages sent to mental health professionals. Participants can be referred by mental health professionals working in public or private settings or can self-refer to the clinic.

2.6. Baseline Measures

2.6.1. Axis I Disorders

Axis I disorders will be assessed through The Structured Clinical Interview for DSM-IV-TR Axis I Disorders [SCID-I; [38]; SCID-I Italian version; [39]]. OCD diagnoses will be independently assigned by a clinical psychologist and a psychiatrist. Between-diagnostician agreement will be assessed as inter-rater reliability through the Kappa index [40].

2.6.2. Comorbid Personality Disorders

Comorbid personality disorders (CPDs) will be assigned through the Structured Clinical Interview for

DSM-IV-TR Personality Disorders [SCID-II; [41]]. The SCID-II will be administered by an interviewer before the start of treatment. The interviewer is a clinical psychologist who has done internships and training in conducting the SCID-II.

The SCID-II contains 140 questions to assess the 94 DSM-IV criteria, which are scored on a three-point scale (1= absent, 2= doubtful, 3= present). Each of the ten DSM-IV CPDs is represented by the sums of its raw item scores. Internal consistency of the CPDs scales is adequate, with Alpha coefficients averaging .79. Inter-rater reliability is good [42]. Diagnoses will be assigned through a systematic evaluation of the criteria for each CPD after the examination of all available information (clinical interview, course of past treatments). Although the inter-rater reliability for the CPDs diagnoses will not be examined formally in the current study, each case will be carefully reviewed for accuracy in supervisory daily meetings of the staff and all the diagnoses will be reached by inter-rater consensus.

2.7. Primary Outcomes

Primary and secondary outcome measure will be administered at baseline, immediate post-treatment, three-, six-month, and one-year follow-up. Primary outcomes are OCD symptoms, obsessive beliefs, depression, and anxiety.

2.7.1. OCD Symptoms

The Yale-Brown Obsessive-Compulsive Scale (Y-BOCS; [23]) is a 10-item semi-structured, clinician-administered interview, recognized as the gold standard for the assessment of OCD symptoms severity in outcome studies [2]. Symptoms from the past week are rated on a 5-point Likert scale ranging from 0 to 4, with higher scores corresponding to greater symptom severity. Items regarding obsessions and compulsions are summed to derive the total score. Internal consistency has shown to be moderate to excellent [23].

2.7.2. OCD Symptom Dimensions

The Dimensional Obsessive Compulsive Scale [DOCS; [43]] is a 20-item self-report measure that assesses severity of four empirically validated OCD symptom dimensions: (a) contamination, (b) responsibility for harm and mistakes, (c) symmetry/ordering, and (d) unacceptable thoughts. Within each symptom dimension, five items (rated 0 to 4) assess the following parameters of severity over the past month: (a) time occupied by obsessions and rituals, (b) avoidance behavior, (c) associated distress, (d) functional interference, and (e) difficulty disregarding the obsessions and refraining from the compulsions. The DOCS subscales have excellent reliability in clinical samples (Cronbach's Alpha= .94-.96), and the measure converges well with other measures of OC symptoms (Abramowitz et al., 2010). The Italian version of the DOCS [44] has replicated the 4-factor structure of the original version, showing good internal consistency (Cronbach's Alpha= .80 in all subscales).

2.7.3. Depression

The Beck Depression Inventory-II [BDI-II; [45]] is a 21-item self-reporting inventory rating severity of

depressive symptoms. Items are rated from 0 to 3 and the total score ranges from 0 to 63. The Italian version [46] has excellent internal consistency for both non-clinical and clinical samples (Cronbach's Alpha of .93 and 0.92, respectively).

2.7.4. Anxiety

The Beck Anxiety Inventory [BAI; 47] is a 21-item questionnaire designed to assess anxious symptoms. Items are rated from 0 to 3 scores. The Italian version [48] has good internal consistency (Cronbach's Alpha= .80).

2.7.5. Obsessive Beliefs

The OBQ-44 is a 44-item self-report instrument that measures three subscales of dysfunctional obsessive beliefs hypothesized to underlie OCD symptoms: (a) threat overestimation and responsibility (OBQ-RT), (b) importance and control of thoughts (OBQ-ICT), and (c) perfectionism and need for certainty (OBQ-PC). The instrument has good validity, internal consistency, and test-retest reliability [49]. For the Italian version [50], factor analyses indicated a five-factor solution and 46 out of the 87 original items were retained (differently from the original brief version comprising 44 items). The resulting five subscales are Excessive responsibility for omission, Excessive responsibility for commission, Overimportance of thoughts, Excessive control of thoughts and Perfectionism. The OBQ- 46 has adequate internal consistency for the total score and each of the 5 scales [50].

2.8. Secondary Outcomes

Secondary outcomes consist of Disgust Propensity and Sensitivity, Emotion dysregulation, dissociative symptoms.

2.8.1. Disgust Propensity and Sensitivity

The Disgust Propensity and Sensitivity Scale-Revised [DPSS-R; 51] is a 16-item measure designed to assess the frequency of disgust experiences and the overestimation of the negative impact of experiencing disgust. Previous research has shown that the DPSS-R is an internally consistent and valid measure of disgust [52].

2.8.2. Emotion Dysregulation

The Difficulties in Emotion Regulation Scale [DERS; 53] is a 36-item self-report measure of emotion regulation difficulties. It consists of the following six subscales: (a) Non-Acceptance of emotional responses (Non-Acceptance); (b) Difficulties engaging in goal-directed behavior (Goals); (c) Impulse control difficulties (Impulse) measuring the problems in behavioral control and regulation in time of experiencing (negative) emotions; (d) Lack of emotional awareness (Awareness) subscale assessing the lack of attention to emotional signals considering feelings as unimportant; (e) Limited access to emotional regulation strategies (Strategies); and (f) Lack of emotional clarity (Clarity). Participants are asked to indicate on a 5-point Likert-type scale how often the items apply to themselves, with 1= almost never (0–10%), 2= sometimes (11%–35%), 3= about half the time (36%–65%), 4= most of the time (66%–90%), and 5= almost always (91%–100%). Higher scores indicate greater difficulties in emotion regulation. The Italian version [54]

has shown good internal consistency in non-clinical samples (Cronbach's Alpha ranging from 0.74 to 0.88).

2.8.3. Dissociative Experiences and Symptoms

The Dissociative Experience Scale [DES; 55] will be used as a measure of dissociative experiences. The Italian version of the scale has shown good internal consistency (Cronbach's alpha= .91) [56].

2.8.4. Client Satisfaction for Treatment

A questionnaire measuring patients' satisfaction judgements and experience with regard to treatment will be developed using a Likert-type scale. The questionnaire will measure global satisfaction for treatment. Psychometric properties of the measure will be assessed using item response theory analysis

2.9. Feasibility

Feasibility and acceptability of treatments will be evaluated using attrition rates for each treatment arm. A researcher not involved in the study (eg, not conducting assessments or treatments) will document this indicator using a pre-formatted template form.

2.10. Design

The current study is a single-blinded exploratory parallel-group randomized controlled trial. Eligible participants will be randomly assigned to an EMDR+ERP arm or to an ERP alone arm. Participants in both treatment arms will be on pharmacotherapy with SSRIs or antipsychotic drugs. Flowchart of participant progression over all the study stages is provided in Figure 1 according to The Consolidated Standards for Reporting Trials [CONSORT Statement; 57].

2.11. Randomization

Random sequence will be created by a computerized program. An independent worker, not involved in the study will assign participants to treatment arms. Allocation will be conducted through a 1:1 blocking procedure.

2.12. Allocation Concealment

Random sequence will be concealed by an independent researcher, who will put random numbers into envelopes. Allocation concealment will be ensured, as the researcher will not release the randomization code until the patient has been recruited into the trial, which takes place after all baseline measures have been conducted.

2.13. Single-blinding

A single-blinding procedure will be adopted. Assessment at baseline, post-treatment, and follow-up with both clinical interviews and self-report measures will be conducted by blind independent assessors. Due to difficulties related to blinding of participants in psychotherapy trials, in the current study a double-blinding procedure will not be adopted. Assessors will be instructed to guess to which treatment arm the patient has been assigned in order to control for blinding integrity. Assessor will also gather information on adverse events,

which will occur between sessions and after post-treatment.

2.14. Synthesis of Treatment Arms

Clinical psychologists trained in CBT or in EMDR techniques will deliver psychological treatments. With regard to the CBT arm, an ERP-based residential individual treatment will be delivered to the inpatients intensively for 2 hours in the morning and 2 hours in the afternoon for 5 days a week during a 5-week period overall. During the first weeks, psycho-education will be offered everyday to explain the maintaining factors of OCD, and to provide inpatients with a rationale for the

ERP. An anxiety-eliciting situations hierarchy will be also developed. During the subsequent four weeks, ERP will be delivered, based on a therapy manual for OCD [58]. Inpatients will be gradually and repeatedly exposed to the anxiety-eliciting situations, and will be encouraged to remain in those situations until they experience a significant reduction in their levels of discomfort (at least 50% decline in the Subjective Unit of Discomfort). The response prevention component will consist of the suppression of any safety behaviour alleviating the discomfort produced by the obsessions. A description of therapeutic components of intensive CBT arm is provided in Figure 2.

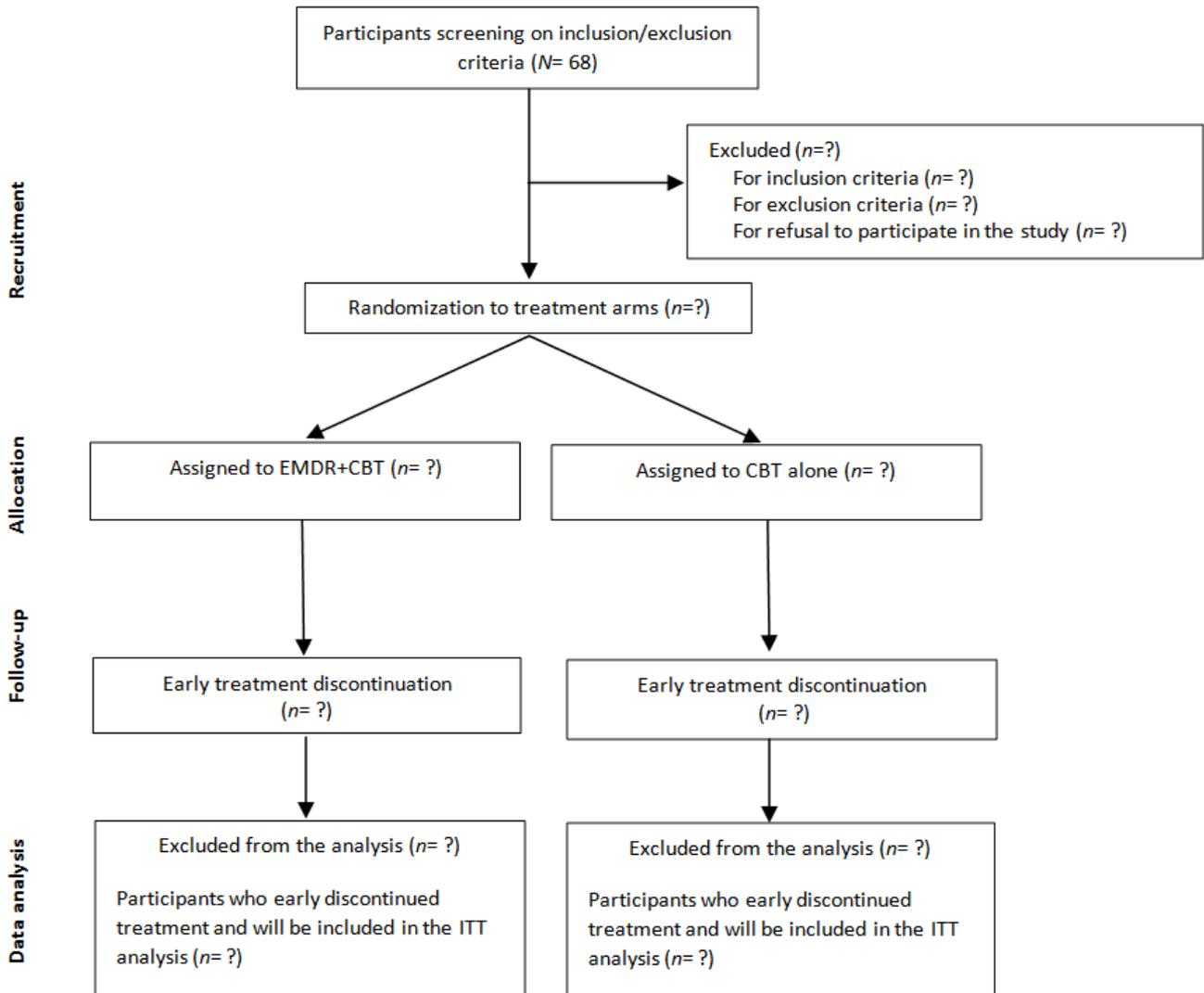


Figure 1. CONSORT flowchart on participants progression over the stages of the study

With regard to the EMDR+CBT arm, the same components of the intensive CBT arm will be used in combination with EMDR. Specifically, an EMDR protocol based on techniques of Shapiro's [11] protocol will be delivered. The therapist and the patient will work in cooperation on traumatic events through the eight phases of the standard EMDR. During the first week, characteristics of the EMDR model and techniques will be introduced, and the patient will be prepared to work on memories and traumatic events. Therapeutic goals based on EMDR model will be set and shared by the therapist

and the patient. During the history taking phase, the patient will be encouraged to identify traumatic events, which could have activated or precipitated the onset of the disorder. Subsequently, the exercise of "A safe place" will be introduced. During the entire second week the patient will be invited to reconstruct early episodes and aetiological memories in which OCD symptoms occurred for the first time. During the entire third week, the "Floatback technique" will be used with the aim to guide the patient to recall earlier events with similar affect or cognitions.

Week number	Treatment components	Details of therapeutic components
I week	Psycho-education	The OCD appraisal model will be provided highlighting the role of faulty appraisals for the persistence of OCD and related distress. The aim of this work will be to normalize the experience of unwanted intrusions.
	Behavioural analysis	Identification of triggers for obsessions will be conducted assigning to the inpatients obsession and compulsions diaries. The objective of this work will be to monitor symptoms and to identify a list of different obsession-provoking situations which the inpatient find distressing in order to construct a tailored fear hierarchy. A list of compulsions and safety behaviours will be developed in collaboration with the inpatient.
	Case-formulation and goal setting	The aim of this work will be to help the inpatient to understand the connection between triggers, obsessions, appraisals and safety behaviours, and how they contribute to OCD maintenance. A further aim will be to provide the inpatient with a rationale for the ERP therapy. A goal setting will be also established to reach shared directions that could help inpatient engaging in ERP.
	Family meetings	Meetings will be scheduled between the entire staff, inpatient and relatives to provide education on how to not accommodate with OCD requests at home.
II-IV weeks	Daily and Prolonged ERP	Daily and prolonged individual ERP sessions will be conducted for 2 hours in the morning and two hours in the afternoon. Inpatients will be gradually and repeatedly exposed to anxiety-provoking situations, and they will be encouraged to remain in those situations until they experience a significantly great decrease in their levels of discomfort (at least 50% decline in the Subjective Unit of Discomfort). Avaried-stimuli exposure training will be adopted, using several variants of situations eliciting obsessional thoughts.
	Homework assignment	Self-directed exposure exercises were assigned after the III week to be performed during the week-end. Exposure was assigned for those steps of the hierarchy that the inpatient had been habituated to.
	Symptom monitoring	Meetings will be scheduled between inpatient and entire staff to review progress on goals made in the therapeutic contract. Staff will provide support and positive feedback on therapeutic gains.
V week	Relapse Prevention	Meetings will be scheduled between inpatient and entire staff to provide residents with education on the difference between relapse and slip. Information on how to identify triggers and relapse signals, to deal with negative emotions was also provided. Information on how to engage in homework for maintaining gains will be provided. A self-help handbook will be offered with bullet points on CBT model and case-examples.

Figure 2. Description of therapeutic components of the intensive CBT arm over treatment course

2.15. Treatment Integrity Checks

Treatments will be delivered by trained psychotherapists. With the aim to enhance internal validity of the study, adherence to treatment protocol will be monitored through meetings between the staff and an independent experienced psychotherapist, not involved in the treatments.

2.16. Time Scheduling

The study has started start in May 2014, and it will last for one year and half. The project consists of four stages: recruitment of participants, allocation to treatment arms,

treatment, and post-treatment/follow-up assessments. With regard to the assessments, four time-points are scheduled: recruitment, baseline, post-treatment, and follow-up (one-, six-month, and one-year follow-up). The SCID-I and the SCID-II will be administered during recruitment. Self-report measures will be administered at baseline, post-treatment, and follow-up. Time interval between recruitment and baseline will not be longer than a week. A schedule of the study with regard to recruitment, treatment, and assessment as a function of time-points is provided in Table 1 according to the SPIRIT 2013 guidelines [35].

Table 1. Schedule of the study according to the SPIRIT 2013 guidelines with regard to recruitment, treatment, and assessment as a function of time-points

TIMEPOINT	DURATION OF THE STUDY					
	Recruitment	Baseline	Post-treatment	Follow-up (1 month)	Follow-up (6 months)	Follow-up (1 year)
	t_0	t_1	t_2	t_3		
RECRUITMENT						
Participants screening on inclusion/exclusion criteria	X					
Informed consent	X					
Assignment to treatment arms		X				
TREATMENT						
EMDR+ERP		X	X			
ERP alone		X	X			
ASSESSMENT						
SCID-I	X					
SCID-II	X					
Y-BOCS		X	X	X	X	X
DOCS		X	X	X	X	X
OBQ-46		X	X	X	X	X
BDI-II		X	X	X	X	X
BAI		X	X	X	X	X
DPSS		X	X	X	X	X
DERS		X	X	X	X	X
DES		X	X	X	X	X

2.17. Ethical Approval

The research protocol has been approved by the Ethics Committee of the Poggio Sereno Clinic.

2.18. Data Analytic Plan

According to guidelines provided by Newell [59], an intention to treat approach will be used with The last observation carry-forward technique.

Within- and between- effect sizes will be computed as unbiased Hedges' *g* indices [60]. The proportion of participants achieving recovery status on OCD symptoms will be assessed following recommendations of Jacobson and Truax [61].

Efficacy of treatments will be assessed conducting repeated measures ANOVAs. For all the analyses statistical significance will be set at a 0.01 *p*-value.

Statistical analyses will be conducted with the Statistical Packages for the Social Sciences software (SPSS, version 21.00).

Conflicts of Interest

The authors have no conflict of interest to declare.

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