

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

This paper was submitted to the JECH but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Effectiveness of Cognitive behavioral therapy Augmentation in Major depression treatment (ECAM study): study protocol for a randomised clinical trial
<b>AUTHORS</b>	Nakagawa, Atsuo; Sado, Mitsuhiro; Mitsuda, Dai; Fujisawa, Daisuke; Kikuchi, Toshiaki; Abe, Takayuki; Sato, Yuji; Iwashita, Satoru; Mimura, Masaru; Ono, Yutaka

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Jong-Woo Paik Department of Psychiatry / Kyung Hee University college of medicine
<b>REVIEW RETURNED</b>	05-Sep-2014

<b>GENERAL COMMENTS</b>	<p>Study examines a topic that is important but not studied a lot. This is a well written study protocol. and It would be more valuable because the evidence of CBT is poorly examined in asia-pacific region.</p> <p>I suggest that a description of Current state of CBT in Japan would help the readers to understand aspects of the manuscript. and in inclusion criteria,</p> <p>It is nor clear they exclude admission patients at baseline.</p> <p>I suggest they describe assessors(Psychiatrist or Psychologist? Trained?) and assessor-blind method. It is most important part of study protocol</p>
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## VERSION 1 – AUTHOR RESPONSE

Response to reviewer:

Thank you for your review and valuable comments.  
We have addressed to your comments as following:

1) I suggest that a description of Current state of CBT in Japan would help the readers to understand aspects of the manuscript.

--We have added some description in the Introduction section (3rd paragraph) about the current status of CBT in Japan as following:

Based on the mounting evidence as above, CBT has been drawing considerable attention in Japan as an efficacious treatment for depression not only among clinicians and academics but also the general public. The Japanese Ministry of Health, Labour and Welfare has been encouraging training for, and practical implementation of CBT, as exemplified by the coverage of CBT for mood disorders by the Japanese national health insurance scheme since 2010.

2) And in inclusion criteria, it is not clear they exclude admission patients at baseline.

--We have specified the treatment setting by indicating that eligible patients are outpatients with a diagnosis of MDD in the Inclusion criteria (inclusion criteria (1)).

(1) outpatients with a diagnosis of Major Depressive Disorder,

3) I suggest they describe assessors (Psychiatrist or Psychologist? Trained?). And assessor-blind method. It is most important part of study protocol.

--- We have specified the assessor's profession and elaborated the assessor-blind method in the Outcome measure section (Outcome measure -1.Primary outcome) as following:

All the assessors (psychiatrists and licensed clinical psychologists) have received extensive GRID-HAMD training and achieved excellent inter-rater reliability (ICC=0.98). The GRID-HAMD will be conducted by an assessor blind to treatment randomisation. Due to the nature of the intervention, neither the patients, nor the treating psychiatrists, nor the study therapists can be completely blinded to randomisation, but are strongly instructed not to disclose the randomisation status of the patient at periodical assessments. Further, the assessors will not be present during the treatment administration.