Reviewer’s report

Title: Study protocol: Brief Intervention for Medication Overuse Headache - A double-blinded cluster randomised parallel controlled trial in primary care

Version: 1 Date: 13 February 2012

Reviewer: Paolo Rossi

Reviewer’s report:

Main issues
1. Will the study design adequately test the hypothesis?
Yes, it is but I have few criticisms regarding the patients’ selection and the use of SDS (see comments)

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
The authors provided sufficient details to allow replication of the work and comparison with related analysis

3. Does the manuscript adhere to the relevant standards for reporting and data deposition: if not, in what ways?
Yes the manuscripts adhere to the relevant standards

4. Is the writing acceptable?
The writing is acceptable, the study is well introduced, methods are sound and clearly expressed and the discussion is almost complete

COMMENTS
• Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

The authors should include the guidelines for treatment of MOH of the EFNS panel (Eur J Neurol 2011)

background: To support the sentence “Headache is mostly self-managed” the authors used a paper of 1992 that is too old, whereas they have recently published a paper on the management of chronic headache in primary. Please upgrade the reference

It would be interesting to know if the authors had problems to collect funds for this study. MOH is essentially a iatrogenic disorders and there is an interest to avoid the diffusion of the message “too many drugs worsen the headache"

• Minor Essential Revisions (such as missing labels on figures, or the wrong use
Outcome measures paragraph should be placed before the statistics

- Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

BACKGROUND

The authors use two US studies to support the notion that “most patients use OTC drugs”; they should include data from other countries because US drug market is too different from that of many European countries.

Page 6. In introducing MOH the authors report data suggesting that it is an addictive behavior. This is only a part of the history and essentially based on data from clinical populations of patients. MOH is a largely heterogeneous disorders including patients with very low medical needs and complicated difficult- to- treat patients. The heterogeneity of MOH does not emerge from this study. The authors seem to favour the hypothesis of an addictive component underlying MOH to support the use of SDS. Indeed, several authors have worked on the identification of clinical subgroups of MOH in order to identify those patients necessitating intensive withdrawal and multi-specialty approach, and those patients that may be treated with a brief educational intervention (i.e simple and complicated MOH). The experience of the authors in one of their previous papers (Grande 2011) seems to go in this direction because an impressive proportion of the MOH patients screened in the general population have reduced their intake of painkillers after a short information that is unlike to happen in addicted patients. Please consider these aspects (heterogeneity of MOH, dependence or pseudodependence ? effectiveness of educational intervention on dependency of the severity of clinical picture) in the background that should be written in a more balanced way.

METHODS

The authors are requested to specify if there is the possibility that the GPs selected for the study had received in the past any specific training about MOH management. If so, this information should be considered in the findings or used to exclude these physician from the study

The authors have explained in the discussion the reason for choosing an age range of 18-50 years, but they did not mention that accordingly with epidemiological studies on MOH the prevalence of this disease is higher in the age-classes 40-49 and 50-65 and that the mean age of MOH at the diagnosis is often older than 50 years. I think that including the patient in the age class 50-60 years would represent a significant improvement to the protocol.

USE of the SDS questionnaire. The large experience of the authors with this questionnaire indicate that it may be useful to identify MOH patients and dependency-like behavior and to predict the prognosis after educational intervention (a paper from Lundqvist et al published in 2012 should be added to
the references). The advantage in the identification of MOH is questionable because MOH may be suspected and diagnosed with ICHD-IIR criteria with few questions. The SDS appears very useful for therapeutic purpose. Anyway the authors relies on the SDS for diagnostic purposes (diagnosis of MOH in screened patients is made by GPs by using this tool). In this way they risk to include in the study only MOH patients with dependency-behaviour.

Furthermore it is not clear which is the destiny of those patients positive to the screening questions but presenting a SDS score lower than the cut-off level. They may have MOH as well and may represent another control group (MOH with low dependency receiving advice but not BI) Please clarify these points.

Headache classification. It is not clear who will make (and when) the ICHD-II diagnosis. At the moment of the follow-up by the first author? Please specify this point

Two weeks recording of the headache diary is a very short period (for instance menstrual attacks or migrainous state may be responsible for false positives). I have participated in the validation of a basic headache diary in a large multicentre study (Jensen et al 2011, please add to the references) and we did not find any problem with the compliance with 1-month period of recording. I suggest to the authors to ask for a completion of the diary for 1-month period

Ethics. The authors wrote that participating patients and GPs will give informed, written consent. What kind of informations they will receive? Are the authors able to exclude at this level info about medication overuse and the advantage to withdraw the overused drug?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
'I declare that I have no competing interests'