Reviewer's report

Title: What are the basic self-monitoring components for cardiovascular risk management?

Version: 1 Date: 30 March 2010

Reviewer: Ingrid Mühlhauser

Reviewer's report:

1. Is the question posed by the authors well defined?

The authors want to better understand the variability of effectiveness of self-monitoring in clinical trials (abstract).

It has been repeatedly reported that there is insufficient space for and information on many complex interventions such as self-monitoring in publications of clinical trials.

2. Are the methods appropriate and well described?

Self-monitoring is part of complex interventions. Design and evaluation of complex interventions should follow a stepped or multimodal approach including various levels of evaluation. This includes definition of underlying theories, identification and justification of single components of the complex intervention, followed by pilot testing including qualitative and quantitative research methods, and finally (randomized) controlled trials and implementation studies. The whole package of publications on a specific complex intervention may be difficult or even impossible to identify by applying usual search strategies and using available databases. Authors of studies of the various design and evaluation levels may be different, publications may be in languages other than English, and the evaluation from theory planning to implementation may take more than 20 years (e.g. Mühlhauser I, Berger M; Diabetologia 2002; Lenz M et al. Meta-analysis does not allow appraisal of complex interventions in diabetes and hypertension self-management: a methodological review. Diabetologia 2007).

In order to meet the study objective of the present project it would be necessary to identify all associated manuscripts related to a specific intervention of self-monitoring. This also means that restricting the literature search to systematic reviews of RCTs and RCTs will probably miss important information for many interventions.

As the authors state (discussion) relevant and detailed information on the selection process, rational and characteristics of the various components of complex interventions is usually not provided in the core randomized-controlled trial due to space limitation. However, often the authors refer to previous publications on the theory base or other details of the intervention. These studies should also be traced and acknowledged.
In a second part of the study the authors propose a set of criteria that should be used in further research on self-monitoring. Validation of the instrument is not reported.

3. Are the data sound?

As long as the complete information is not used for assessment of specific self-monitoring interventions valid conclusions are not possible.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

Presentation of results is descriptive. As the study is a (systematic?) review recommendations for the reporting of (systematic) reviews should be followed. This includes mentioning of the study design in the title, a flow chart of manuscript tracing and selection, systematic description, evaluation, and presentation of results of individual studies in tables, description of the method to evaluate and synthesize the results.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

The conclusions are not supported by the present data as methodology is not appropriate.

The set of criteria is a basis for further studies. However, recommendation on general implementation would need validation of this instrument.

6. Are limitations of the work clearly stated?

Only partly stated – see above.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?

Flow chart on literature search and selection should be included.

8. Do the title and abstract accurately convey what has been found?

The title should be adapted – see above.

9. Is the writing acceptable? Yes – Oxford Type

Recommendations

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

1) Publications associated to the individual RCTs on the various self-monitoring interventions should be identified and included in the analyses – see above. Otherwise, this study would not add sufficiently new information to what is known
already.

2) A systematic approach to the analyses and presentation of the study results should be included in the manuscript - see above.

3) The lack of validation of the assessment instrument has to be addressed and recommendations have to be adapted.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

See above remaining comments should be addressed.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

I have been involved on research on this topic myself (self monitoring and evaluation of complex interventions). The authors have referred to one of these publications.