Reviewer's report

**Title:** Motivational Interviewing and Fitness Tests used to increase Physical Fitness in Patients with Type 2 Diabetes in General Practice: an 18-month intervention study

**Version:** 1 **Date:** 18 February 2010

**Reviewer:** Paul Poirier

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**TITLE**
Motivational Interviewing and Fitness Tests used to increase Physical Fitness in Patients with Type 2 Diabetes in General Practice: an 18-month intervention study.

**AIM OF THE STUDY**
To investigate whether the introduction of motivational interviewing combined with fitness tests in the type 2 diabetes care program resulted in a change in cardio-respiratory fitness expressed by VO2max, muscle strength of upper and lower extremities, HbA1c and HDL-cholesterol.

**FINDING**
The authors concluded that fitness consultations combined with motivational interviewing resulted in increased muscle strength and VO2max, and the lipid profile improved.

**GENERAL COMMENTS**
The purpose of this study is relevant but we have identified major errors in the methodology. The study aims to look whether the intervention (motivational interviewing and fitness tests) resulted in a change in VO2max, muscle strength of upper and lower extremities, HbA1c and HDL-cholesterol but the research design does not include a control group. Medical practice could not be influenced by the results of this study because we don’t know if changes were related to the experimental intervention or other factors. The use of the term “motivational interviewing” (MI) is not appropriate. I suggest reviewing the structure of the manuscript. Furthermore, I would like to address some issues to the authors.

**SPECIFIC COMMENTS**

Abstract section:
1. Could the authors define GP?
2. Could the authors add the p-value for the increments in VO2max. among patients without pain from function limitation?

Background section:
3. I suggest rewriting the first sentence of this section because the literature cited
(Wei & al., Hu & al., Church & al. and Blair & al.) did not demonstrate the association between increment of cardiovascular fitness and decrement of mortality but demonstrates the association between level (low, moderate or high) of cardiovascular fitness and mortality.

4. The primary outcome of this study is change in VO2max, muscle strength, HbA1c and HDL-cholesterol. Could the authors add references regarding the association between those variables and physical activity (PA) behavior? Indeed, the aim of the intervention is to motivate people to increase and maintain their muscle strength and cardio-respiratory fitness by self-managed PA, but the authors did not present the scientific evidence that PA behavior is associated with improvement of the study’s variables (VO2max, muscle strength, HbA1c and HDL-cholesterol) among people with type 2 diabetes.

5. The authors justify the utilization of MI based on one study that concluded that positive attitude toward exercise and sense of control over it was associated with adherence to the exercise regimen. However, this explanation is not sufficient to justify the use of MI. Indeed, MI is based on a variety of theories and concepts such as the Transtheoric Model of Prochaska and Diclemente (1982), the Protection Motivation Theory of Rogers (1975), the Decisional Balance of Jamis and Man (1977), the Reactance Theory of Brehm (1981), the Self-Perception Theory of Bem (1967), the readiness to change (Rollnick, Mason and Butler, 1999) and the ambivalence exploration (Miller and Rollnick, 1991). Those theories and concepts contain much more behavioral determinants than “positive attitude toward the behavior” and “sense of control”. Initially, showing that other behavioral determinants used in MI are present within the study population would be necessary in order to explain the relevance of this technique. Furthermore, the literature possesses a range of researches regarding behavioral determinants conducted among people with type 2 diabetes. It would be more appropriate to refer to those studies.

6. References are required for the sentence beginning by “These patients have many co morbidities...” and for the sentence beginning by “There are many laboratory studies with supervised exercise...” Furthermore, could the authors add information regarding the cardiovascular mortality among persons with type 2 diabetes?

7. The sentence: “Feedback was given in fitness consultations every three months with simple measurements of muscle strength and cardio-respiratory fitness followed by motivational interview” seems to be more relevant in method section since this sentence explains the experimental intervention.

8. The hypothesis proposed by authors is not related with dependents variables (eg. VO2max, muscle strength, HbA1c and HDL-cholesterol). Indeed, authors’ hypothesis is that patient’s knowledge of their own muscle strength and cardio-respiratory fitness (...) may induce behavioral changes. However, they did not evaluate patient’s knowledge of their own muscle strength and cardio-respiratory fitness neither the relation between their knowledge and behavioral changes.

9. The last sentence of the background section could be written as: “The aim of
this study was to evaluate the impact of the motivational interviewing and fitness tests in a change in…”

Methods section:

10. Uncontrolled study was used to evaluate the impact of the motivational interviewing and fitness tests in a change in VO2max, muscle strength, HbA1c and HDL-cholesterol. However, this study design is not appropriate to achieve the aim of this study since the absence of a control group does not allow knowing if the changes were related to the intervention or to other factors. Could the authors justify why they chose this study design?

11. Could the authors add information regarding the inclusion and exclusion criteria, the recruitment and the consent? Two inclusion criteria are listed in table 1, but not in the text.

12. The first paragraph in methods section presents the sample size and the characteristics at baseline. The description of sample’s characteristics seems to be more relevant in the results section.

13. The paragraph beginning by “The six GPs involved were …” and the section entitled “The fitness consultation” could be gathered.

14. The skills to use MI required a specific training; could the authors give more details about the 3-hour session followed by the GPs?

15. (4th page, 2nd paragraph) Could the authors review the section about the use of the principles of MI? I suggest describing how the GPs applied the 4 principles of MI during their consultations: the expression of empathy, the divergence development, working with resistance and increasing self-efficacy. They could also add the 6 essential ingredients to brief interventions according to Miller and Rollnick (1991). The presence of those principles within the interventions is necessary in order to be sure that GPs effectively carried out a MI and did not only listen and encourage the participants.

16. Could the authors include the information about validity and reliability of the tests (fitness and muscle strength) in the subsection entitled “Tests of fitness and muscle strength”?

17. Could the authors add information about the validation of the protocol used to measure the cardio-respiratory fitness?

18. Could the authors explain why they chose HDL-C as a primary outcome when LDL-C is a primary goal regarding dyslipidemia/lipid management for persons with type 2 diabetes (see: Diabetes Care, 2010, 33 (suppl. 1), s11-s61). Furthermore, no specific targets for HDL-C level have been determined in clinical trials (Can J Cardiol, 2009, 25 (10): 567-579).

19. Why blood samples were drawn after 8-hour fast only while the standard procedure to lipid profile is 12-hour fast without consumption of alcohol within 72-hour? If those recommendations were not respected, the results of the lipid profile could be biased.

20. (Page 6, line 3). Authors used function limitation and cardiovascular fitness to identify barriers to increased fitness. However, I think that the term “identify” is
not properly used since “to identify barriers to increased fitness” they should select those variables that have a significant negative impact on fitness. To do that, they should consider all variables in a multivariable model and select those significantly associated with the outcomes. Furthermore, could authors justify why they chose only function limitation and cardiovascular fitness to identify barriers to increased fitness?

Statistical analysis:

21. Authors should present a power calculation to be sure that the non significant differences observed in this study are not due to a lack of power.

22. What are the beta and alpha errors?

23. (Page 6, line 17). The sentence beginning by “Thirteen patients had atypical courses due to severe disease…” could be placed in the results section with description of the sample.

24. Could the authors add references regarding the procedure used to evaluate clinical variables (eg. Waist circumference, blood pressure)

Results section:

25. Seven (7) participants were withdraw during the first 9 months follow-up because they had severe disease and those subjects were not included in the analysis at 9 and 18 months follow-up. How those withdrawals influenced the results? Why the authors kept those subjects in the baseline analysis? (Figure 2: the greater improvements of muscle strength and VO2max were in first 9 months).

26. How many subjects were, or begun, insulino-dependants? Does this condition influence the results?

27. Regarding the change of the HDL-C, why the authors did not compare the group of patients without change of lipid-lowering medication (n=116) with patients who started treatment with simvastatin during the study (n=10) rather than the whole group? Furthermore, could the authors explain what is about one subject who did not change of lipid-lowering medication and did not start treatment with simvastatin?

28. (Page 7). In subgroup analyses section, I suggest to rewrite the sentence beginning by “The development of VO2max…” since it was observed a “change” in this variable instead of a “development”.

29. The authors present secondary outcomes but they did not introduce those outcomes in the introduction or in the study’s question.

30. (Page 8). Why the authors include information regarding the course of the intervention in the results section?

31. Authors did not observe significant differences regarding HbA1c, gender and age between respondents and non respondents at baseline. However, it would be relevant to compare other characteristics that could influence the outcomes. For example, it would be interesting to compare co morbidities and fitness at baseline. If non respondents had more co morbidities and worse fitness than respondents, exclusion of such individuals could have overestimated the impact
of the intervention on the outcomes.

Discussion

32. Authors should start this section by comparing the results with the scientific literature; strengths and limitations of the study should be placed at the end of the discussion section.

33. The explanation regarding the impact of the absence of control group is not sufficient.

34. (Page 9, 2nd paragraph). The references about the validity of the arm curl test and the chair stand test are more relevant in the method section.

35. The authors write that one third of the type 2 diabetic patients were unable to do the fitness test because of contraindications and co morbidity. However, this information was not presented in the results section. Furthermore, the authors did not discuss how this observation may have influenced the results.

36. The authors report a significant increase in VO2max (+0.46 ml/kg/min or 2.5%). This increase is statistically significant (p=0.032). However, could they discuss about the clinical implication of this increase?

37. According to the authors, the increase in HDL-c may be the result of increased muscle strength and increased VO2max. Indeed, those changes may improve metabolic profile and increase HDL-c but, could the authors explain why waist circumference and triglycerides did not change and the blood pressure increased slightly?

38. 227/354 patients (~66%) not responding to the invitation to participate at this study. Could the authors discuss how this result influences their study’s results?

Tables and figures

39. In table 1, could the authors add samples characteristics regarding LDL-C and triglycerides?

40. In table 2, could the authors add standard deviation (SD)?

41. In table 2, the values of the arm curl test and chair stand test could not have a decimal because this is the number of flexions or number of stand ups.

42. In table 2, could the authors round off to one decimal the values of HbA1c an HDL-C to be in accordance with the clinical guidelines?

43. In table 2, could the authors use the same terms that in Table 1 (eg. Antihypertensive medicine vs. Antihypertensive treatment). Furthermore, could the authors add results for subgroups using or not the lipid-lowering agents?

44. In table 3, could the authors add standard deviation (SD) for the difference (#) values?

Level of interest: An article whose findings are important to those with closely related research interests

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'