Reviewer’s report

Title: Home Based Telemedicine Intervention for patients with uncontrolled hypertension: a non-randomized study

Version: 1 Date: 18 March 2014

Reviewer: Eric Eisenstein

Reviewer’s report:

Major Compulsory Revisions

1. Methods appropriate:
   a. Population: The authors state that patients were screened between September 2009 and September 2011. Figure 2 shows 2155 patients were screened and 210 were identified who met this study’s inclusion / exclusion criteria and had an in-home analog phone line. Who were these patients and how were they screened in this study? Were they consecutive outpatients receiving cardiovascular check-ups in a specific GP practice at Fondazione Maugeri, Lumezzane medical center?
   b. Allocation: Figure 2 shows 173 eligible individuals, with 76 assigned to treatment and 97 assigned to control. However, the method for allocating patients to treatment and control groups is not described. This information is needed so that the reader can assess whether the treatment selection method may have served to bias this study’s findings. As an example, if the control patients are those who refused the intervention, this would be problematic as patients refusing new treatments could be assumed to be less interested in their treatments and potentially less adherent.
   c. Study duration: The method for determining study duration needs further justification. The average study duration in the present study was 80 days for intervention and 82 days for control patients. However, the text states that duration of home follow-up for intervention patients varied from 40 to 120 days and was related to the time required for reaching and sustaining target BP values. This method for determining the follow-up period appears to be designed to achieve the best BP measurements for intervention patients and ignores the possibility of a rebound effect when treatment is discontinued. What happened when intervention patients did not reach target BP values? Was their study duration automatically terminated at 120 days? If the length of follow-up was based upon the achievement of treatment goals, how was the follow-up period determined for control patients whose BP was not monitored during follow-up?
   d. BP change: Please verify that BP measurements used in this study’s primary endpoint were measured at T0 and T1 using the same oscillometric device. What is the purpose of ABPM? ABPM results are not presented in this paper.

2. Data sound
   a. Primary endpoint: The authors need to report a combined study result. If the
primary endpoint is SBP change, the authors should report the average difference in SPB for patients in the intervention and control groups. Since this is a non-randomized study, statistical adjustment will be required to account for differences between treatment and control group subjects. While propensity matching is the preferred approach, this study likely does not have sufficient subjects to use this technique. At a minimum, a regression model is needed to perform the required adjustments.

3. Standards adherence

a. Figure 2 should be redrafted to comply with CONSORT statement guidance.

Discretionary Revisions

1. Research question:

a. The study aim, evaluate effectiveness, is incomplete. The authors should state how they propose to evaluate effectiveness (primary endpoint). They also should introduce their research question with a sentence stating the knowledge gap their study addresses. The rationale for the present study is not clear from the background material.

2. Methods appropriate:

a. Primary outcome: This study enrolled patients with uncontrolled hypertension. The authors should consider changing their primary outcome to the percent of patients with uncontrolled hypertension. This is the outcome of most interest to health policy makers. Changes in SBP and DBP could be secondary outcomes.

b. BP measurements: What prompted variation in the frequency of intervention group BP measurements? Did subjects receive instructions as to their desired frequency?

3. Data sound:

a. Adherence: Since medication regimen compliance is a primary factor contributing to uncontrolled hypertension, it would be good to report some measure of anti-hypertension medication adherence in this study’s results. This would get at the issue of why BP management improved in the treatment group.

b. Medical costs: The cost comparison should be assessed by treatment strategy. The authors only present costs for their intervention. No attempt is made to determine whether other medical costs (e.g., medication costs) differed between the two groups.

4. Discussion and conclusions supported:

a. The discussion states that this study seems, “to confirm the importance of a much higher level of compliance.” Compliance results should be reported.

b. The conclusion is weak. The authors could be more explicit and say their intervention will decrease the percent of uncontrolled hypertension patients or give the absolute BP improvement (treatment – control).

5. Limitations: Limitations should include a statement that this is a single site study and its results may not be transferred easily to other settings.
6. Acknowledge previous work: Previous work is acknowledged.
7. Title and abstract accurate: Title and abstract are accurate.
8. Writing acceptable: Writing is clear.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.