



**SDI Review Form 1.6**

**PART 1:**

|                          |                                                                                                                       |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Journal Name:            | <b><u>British Journal of Medicine and Medical Research</u></b>                                                        |
| Manuscript Number:       | <b>2013_BJMMR_4571</b>                                                                                                |
| Title of the Manuscript: | <b>EFFECT OF THE SAMPURNA HRIDAY SHUDDHIKARAN (SHS) MODEL IN HEART FAILURE PATIENTS IN INDIA: A PROSPECTIVE STUDY</b> |
| Type of the Article      | <b>Research paper</b>                                                                                                 |

**General guideline for Peer Review process is available in this link:**

**(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)**

- This form has total 7 parts. Kindly note that you should use all the parts of this review form.



## SDI Review Form 1.6

### **PART 2: Review Comments**

|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Author's comment</b> (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b><u>Compulsory</u></b> REVISION comments | An open label, non-randomized, modest sized study that is very open to bias.<br>There is no clear evidence that the echo-cardiographers were blinded to the sequence of the paired ECHO's and therefore substantial bias may occur. Similar bias would be present for the 6MWT's.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Though present study has limitation lack of control group but expert person doing 2 D echo & conducting 6MWT were blinded.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b><u>Minor</u></b> REVISION comments      | Abstract: There are many areas that would require correction of the English language as well as basic scientific protocols such as providing +/- se or sd for reporting scientific data in the abstract. "Heart" failure is used in the Title but "cardiac" failure is used in the abstract. The number of patients is not given in the abstract. It is an overstatement to say that "At present there is no economical treatment available for cardiac failure" as the first sentence in the Abstract, though this could be the case in India.<br>Main Manuscript:<br>Some of the wording throughout is more educationally orientated rather than scientifically sound.<br>In the Background and Objectives, in the first few sentences, the population is Indian yet the incidence of HF used is from N American data that may not reflect India. Similarly, NA data are used in the same opening paragraph without clear indication that the data are from NA and may or may not reflect their population. It is OK to refer to some NA data but I think it needs to be put into better perspective for India. Nonetheless, the burden of CV disease in India is a major current and future burden. | Number of patients is included in abstract.<br><br>Term heart failure is mentioned in abstract (as per title)<br><br>Correction of statements like no economical treatment is available for heart failure is removed.<br><br>Unnecessary data which may not reflect India is removed.<br><br>NYHA –I patients are excluded from trial.<br><br>6 MWT was done to assess the effort tolerance capacity of symptomatic heart failure patients which is measured as distance covered in meters. This test was done on day 1 <sup>st</sup> (on admission) & day 6 <sup>th</sup> (on discharge) in all patients irrespective of their symptoms & signs.<br><br>Patients were recruited as inpatients in single centre. |



**SDI Review Form 1.6**

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>“At present there is no economical treatment available for cardiac failure. However Ayurvedic may provide promising &amp; beneficial treatment for cardiac failure.” The authors need to clarify and substantiate that diuretics, digoxin and nitrates are <u>not</u> economical for HF in India. Ayurvedic needs to be defined. Similarly, SHS also needs referenced. Also, references to support that claim for Ayurvedic in HF (or at least a resonable/compelling logic) should be provided.</p> <p>In the Methods, first papragraph, it is said that “Symptomatic patients (age 33 – 80 yrs) with CHF (Grade 1-3 of NYHA classification)” will be studied, but NHYA Class 1 is an ‘asymptomatic’ patient. If the patient is asymptomatic, it seems unlikely that there will be an improvement in exercise tolerance that is their primary outcome.</p> <p>The trial design is a prospective observational study. It is not blinded, so any positive results may be spurious. Are there any references to support SHS interventions as laid out in the Table (line 112)?</p> <p>In the Methods, it is noted “Patients were recruited as outpatients by a single centre.” Also, “A baseline 6MWT was performed within 24 h of hospital admission or once symptoms at rest had subsided and fluid retention had resolved, and a second test was performed at discharge.” The reason for the in-hospital 6MWT’s is not clearly defined.</p> <p>In an open label study with no randomized design, it is very difficult to ascribe any increase in a 6MWT to the use of SHS as opposed to a placebo effect. Also, the authors do not report as to whether the order of the ECHO analyses were blinded to the interpreters (ie was the first paired ECHO also analyzed first).</p> | <p>Order of the echo analysis were blinded to the interpreters.</p> <p>References of few studies gives beneficial effect of snehan, swedan in heart failure</p> <p>1)The Journal of Tehran University Heart Center149 TEHRAN HEART CENTER</p> <p>2)Thermal therapy for congestive heart failure: estimation by TEI index.</p> <p>First Department of Internal Medicine, Faculty of Medicine, Kagoshima University, Sakuragaoka 8-35-1, Kagoshima, Kagoshima 890-8520, Japan.</p> <p>3) A Meta-Analysis of Massage Therapy Research Psychological Bulletin Copyright 2004 by the American Psychological Association, Inc. 2004, Vol. 130, No. 1, 3-18<br/>Christopher A. Moyer, James Rounds, and James W. Hannu. University of Illinois at Urbana-Champaign.</p> |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



**SDI Review Form 1.6**

|                                         |                                                                             |  |
|-----------------------------------------|-----------------------------------------------------------------------------|--|
|                                         |                                                                             |  |
| <b><u>Optional/General</u></b> comments | It may be “unethical” to publish a study that has significant risks of bias |  |