

SLCTR/2008/019 - Effect of a mind development program on the clinical profile and primary mental health status of patients with rheumatoid arthritis (RA)

Progress report 2 – submitted date: 10th December 2009.

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| Registration No. : SLCTR/2008/019 | Date of Registration : 17/10/2008 |
| Principal Investigator: Dr. M.W. Gunathunga | Ethical Review Committee Reference No : EC/08/061 |
| Address: Department of Community Medicine, Faculty of Medicine, University of Colombo. | |
| Funded by: Ministry of Health, Education Training Research Unit - 2008 August - 2009 July C,A ₂ IRQUE - 2009 August 1 st - 2010 July 31 st | |
| Study title: "Effect of a mind development program on the clinical profile and primary mental health status of patients with rheumatoid arthritis (RA)" | |

Enrollment: This study is -

Ongoing (i.e. subjects continue to get enrolled) or

Enrollment is closed and subjects are being seen for follow-up assessments only

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| No. of subjects enrolled for experimental meditation group: | 799 |
| No. of meditation group patients interviewed after 6 months: | 46 |
| No. of subjects enrolled for comparison group: | 171 |
| No. of comparison group subjects interviewed after 6 months : | 30 |

Drop outs: Number of drop outs difficult to determine as there is a variability in taking up meditation among study subjects.

Changes in Research:

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| Have there been any protocol amendments since the time this study was initially approved? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| If "Yes", were these reported to the Ethics committee? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Have there been any IB amendments since the time this study was initially approved? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| If "Yes", were these reported to the Ethics committee? (NA) | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Summary of SAEs: No SAEs have occurred

| Subject No. | Subject Initials | SAE | Outcome of SAE |
|-------------|------------------|-----|----------------|
| NA | NA | NA | NA |