Randomized controlled trial of a cardiac rehabilitation of Thai patients with myocardial infarction

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- Conflict of interest: NO

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Goal and Objectives

**Goal:** increase understanding of the RCT for improving health outcomes in MI patients

**Learner objectives:**

- To learn the significant problems of patients with MI after discharge
- To learn and share how to conduct the randomization and blinding
- To learn and share how to implement the intervention
Background & Significance

- Myocardial infarction (MI) has become a major health problem in developing countries, including Thailand.

- The rate of hospitalized MI patients per population of 100,000 increased from 80.70 in 2009 to 96.68 in 2011.*

*Bureau of Policy and Strategy-Thailand, 2013
Background & Significance

The early recovery period after MI (1st month after discharge)

MI patients return to previous functional status

Return to the ability to perform usual activities of daily living

(Brink et al., 2008; Rancić et al., 2013; Sriprasong et al., 2009)
Most MI patients receiving medical therapy

- Usually perform only light basic ADLs
- Do not perform & spend less time in advance activities.

Functional status

(Brink et al., 2008; Rancic et al., 2013)
Background & Significance

Functional status (FS) is defined as... an individual’s ability to perform activities of daily living designed to meet basic needs, fulfill usual roles, and maintain health and well-being.

(Leidy, 1994a,b; Wang, 2004).

• FS seems to worsen in cardiac recovery, and impacts health and well-being long term.
• *Existing interventions for improving FS cardiac rehabilitation (CR)*

Commonly focus only on physical/medical factors

less attention to psychosocial factors

Effect sizes: small for FS improving

(Clark, et al., 2005).
Background & Significance

A new approach to CR programs

• Multidimensional
• Psychosocial factors

(Brink et al., 2008; Rancic et al., 2013; Sriprasong et al., 2009)
Background & Significance

Self-efficacy


**Personal factors**
- The interaction between the person and the environment involves beliefs and cognitive competencies developed and modified by social influences.

**Behaviour**
- The interaction between the person and their behaviour is influenced by their thoughts and actions.

**Environmental factors**
- The interaction between the environment and their behaviour determines their environment, which in turn, affects their behaviour.

**Family member**
CR programs have shifted to focus more on psychosocial factors.

To date in Thailand, CR programs showed positive effects of CR programs.
Few interventional studies on SE and Family support have focused on the Asian MI population.

limited evidence on the effect of CR involving SE enhancement and collaboration with family of Thai patients.

Gap of knowledge
Purpose of this study

• To determine the effectiveness of the self-efficacy enhancement program for cardiac rehabilitation (SEPCR) on self-efficacy and functional status.
A two-group RCT with pretest/posttest

- Experimental group
  - O1
  - X
  - O2

- Control group
  - O1
  - baseline
  - O2
  - 4 wks

- Random assignment of MI patients
- Generated randomization schedule: Block of four
Randomization and blinding

Blocks of four (Six types of blocks)

Control gr. blinded to usual care
Experimental gr. blinded to SEPCR
Setting & Samples

MI patients in medical wards in Maha Sarakham Hospital, in northeastern part of Thailand

**Inclusion criteria for participants**

- consenting patients diagnosed with either an ST-elevation MI (STEMI) or a non-ST-elevation MI (NSTEMI)
- Receiving only medical therapy
- Classified as low risk pts
- Having a family caregiver
Setting & Samples

MI patients in medical wards in Maha Sarakham Hospital, in northeastern part of Thailand

Inclusion criteria for MI Pts.
- Diagnosed STEMI or NSTEMI
- Receiving only medical therapy
  - Classified as low risk pts
- Having a family caregiver
  - willing to participate
66 participants for recruitment

Allocated to the SEPCR (n=33)

Allocated to the comparison (n=33)

Follow Up

Could not continue intervention (n=1)
Was referred to other tertiary care (n=1)

Readmission (n=2)
Was referred to other tertiary care setting (n=1)

Analysis

Analysed (n=31)

Analysed (n=30)
Measurements

Daily Activity Status Index Thai version (DASI-T)*

- 12-item 4-domain for measuring FS
- A “yes/no” answer: “yes,” a weighted score was assigned, “no” a weighted score = 0
- Range of sum score = 0-58.2
- MET criteria: <4 METs = Low FS; 4-6 METs = moderate; 7-10 METs = good***
- Cronbach’s alpha coefficient was 0.76

The Maintain Function subscale of the Cardiac Self-efficacy Scale (CSES)**

- A 5 item, five-point Likert scale from zero (not at all confident) to four (completely confident).
- Cronbach’s alpha = 0.87.

*Hlatky et al., 1989, **Sullivan, et al., 1998, ***Fleisher et al., 2007
SEPCR: Program implementation

**Process:**
1. Using self-efficacy enhancement (Bandura, 1986, 1997)
   - Mastery experience
   - Vicarious experience
   - Verbal persuasion
   - Physiological feedback
2. Using family support
   **Support from family member** (House, 1981)

**Content:**
- CR (Thai CR guideline 2010) & literature review about CR

**Components**
1. Motivation building activities
2. Skill training
3. Monitoring

4 sessions with 6 different contacts
(3 hospital visits, 3 telephone calls)
## SEPCR: Program implementation

| 1. Motivation-building activities for the walking exercise and ADL performance | - Promote relaxation  
- Promote the sharing of MI pts’ symptom experiences  
- Reinterpretation of symptoms.  
- Individualized patient education  
- Assist with goal setting  
- Identify strategies achieve goals.  
- Approach to role models. |
| Family member | - Encourage to participate in same activities as pts. and give positive verbal reinforcement |

Promote relaxation  
Promote the sharing of MI pts’ symptom experiences  
Reinterpretation of symptoms.  
Individualized patient education  
Assist with goal setting  
Identify strategies achieve goals.  
Approach to role models.
## SEPCR: Program implementation

| 2. Skill training: | - walking exercise demonstration and practice, heart rate checks and assessments of the RPE, and an energy conservation demonstration and practice.  
|                   | - Record and evaluate practice in the diary. |
|                   | Family member |
|                   | - Encourage to participate in same skill training as pts. and give positive verbal reinforcement  
|                   | - Discuss about how to provide support for the MI participant at home  
|                   | - Train about how to validate and provide feedback |
| a) activity prescription. | |
| b) symptom management. | |
| c) self-recording and evaluation | |
| 3. Monitoring the walking exercise and ADL performance | - Provide diary for self-recording and evaluation  
- Telephone F/U once a week x 3 wks |
<table>
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</thead>
<tbody>
<tr>
<td>Family member</td>
<td>- Encourage to give pts. emotional, informational, appraisal, and instrumental support through telephone F/U once a week x 3 wks (same day with pts.)</td>
</tr>
</tbody>
</table>
• Received the usual care
• Received the Booklet before discharge for self-study at home.

The booklet contains information about CR during the first month after discharge.
Data collection period: June-December 2013

- Descriptive and inferential statistics (independent *t*-test *and* chi-square test): to analyze the participants’ baseline demographic and clinical characteristics.

- An independent *t*-test: to determine differences in the SE and FS scores of the experimental and control groups.
## Research results

<table>
<thead>
<tr>
<th>Participants characteristics</th>
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<tbody>
<tr>
<td>Age (Range 40–82 years)</td>
<td>M = 64.08 years (SD = 9.72)</td>
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<tr>
<td>Male</td>
<td>57.58%</td>
</tr>
<tr>
<td>Living with a spouse</td>
<td>80.30%</td>
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<tr>
<td>Diagnosed with non-STMI</td>
<td>80.30%</td>
</tr>
<tr>
<td>Multiple comorbidities</td>
<td>69.70%</td>
</tr>
<tr>
<td>BMI &lt; 25 kg/m²</td>
<td>69.69%</td>
</tr>
<tr>
<td>No exercise</td>
<td>77.27%</td>
</tr>
<tr>
<td>Current smokers</td>
<td>22.73%</td>
</tr>
<tr>
<td>Regularly ate food with high saturated fat and cholesterol</td>
<td>10.61%</td>
</tr>
</tbody>
</table>
Research results

• There were no statistically significant differences in the demographic or clinical characteristics between the groups at baseline.

• No significant differences between the groups were found with regard to either SE \((t = 0.09, P = 0.93)\) or FS \((t = 0.30, P = 0.77)\).
### Table

Comparisons of mean scores of self-efficacy and functional status between the experimental and control groups at four weeks after discharge

<table>
<thead>
<tr>
<th>Self-efficacy</th>
<th>Experimental group (n = 31)</th>
<th>Control group (n = 30)</th>
<th>t-test</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social activity</td>
<td>3.29 ± 0.46</td>
<td>1.67 ± 0.66</td>
<td>11.09</td>
<td>1.33–1.92</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Household task</td>
<td>3.81 ± 0.40</td>
<td>2.13 ± 0.43</td>
<td>15.63</td>
<td>1.46–1.89</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Occupation</td>
<td>3.16 ± 0.37</td>
<td>1.57 ± 0.68</td>
<td>11.31</td>
<td>1.31–1.88</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Sexual activity</td>
<td>0.65 ± 1.25</td>
<td>0.23 ± 0.57</td>
<td>1.66</td>
<td>−0.09–0.91</td>
<td>0.106</td>
</tr>
<tr>
<td>Exercise</td>
<td>3.29 ± 0.46</td>
<td>1.60 ± 0.72</td>
<td>10.84</td>
<td>1.38–2.00</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Total score</td>
<td>13.97 ± 2.14</td>
<td>7.07 ± 1.48</td>
<td>14.61</td>
<td>5.96–7.85</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Functional status (METs)</td>
<td>6.25 ± 0.66</td>
<td>4.40 ± 0.61</td>
<td>11.33</td>
<td>1.53–2.19</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

CI, confidence interval; m, mean; METs, metabolic equivalents; SD, standard deviation.
Limitations and suggestions

• The SE and FS were observed at only one time point (4 weeks).
• The FS was measured through a self-administered questionnaire; therefore, recall bias may have affected the results.
• Given the fairly major exclusion criteria, this trial needs to be repeated with a more heterogeneous group.
Limitations and suggestions

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Conclusions

- The SEPCR based on Bandura’s social cognitive theory appears to be a useful intervention for CR for Thai patients with MI, and would be a useful supplement to medical care.
Thank you for attention
Any questions and suggestions?