Randomized Controlled Trial of Motivational Interviewing to Improve Medication Adherence of Heart Failure Patients in Mainland China

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Background

➢ Heart failure (HF) is characterized with high incidence and high hospitalization.

➢ Currently, medication is the most common therapy for HF. While, medication adherence is reported poor among HF patients.


➢ In order to improve adherence, motivational interviewing (MI) come into attention, because of its focus on motivation and confidence.
Method

Study design and setting

- This was a randomized controlled study

- The study was conducted in a public hospital specialized in treatment, prevention and research in cardiovascular diseases, Fu Wai Hospital, which is also the National Center for Cardiovascular Diseases in China.
Method - participants enrollment

**Inclusion criteria**

- (1) aged 18 years and older
- (2) diagnosis of HF
- (3) Verbal fluency and ability to read in Chinese.

**Exclusion criteria**

- (1) referred for cardiac surgery or heart transplantation
- (2) cognitive impairment,
- (3) physically impairment
- (4) recruited in other relevant interventions before
- (5) complicated with other severe and uncured diseases, such as malignant tumor
Sampling

Participants were recruited from the heart failure care unit at Fu Wai Hospital. All potential eligible patients were screened by a nurse with Morisky questionnaire. Those with medication non-adherence and written informed agreement were in the study.

Sample size

\[ n = 2 \left( U_\alpha + U_\beta \right)^2 P \left( 1 - P \right) / \left( P_1 - P_0 \right)^2 \]

According to literature, medication adherence is 40%, based on the systematic review conducted by Haynes, adherence rate can be improved by 25% through MI, then 60 participants per group, 120 in total.
Separate randomization schedules were developed from a computerized random-number generator.
Based on usual care, patients randomized this group underwent behavioral counseling about medication adherence using motivational interviewing techniques. All session were conducted with the aid of an adapted version of a standardized structured adherence counseling script, which was specifically developed for use in medication adherence studies of schizophrenia by Grey.

usual care in the Heart failure care unit, and a handbook for heart failure care
Patients in this group underwent behavioral counseling about medication adherence using motivational interviewing techniques.

All session were conducted with the aid of an adapted version of a standardized structured adherence counseling script, which was specifically developed for use in medication adherence studies of schizophrenia by Grey.

It contain 2-3 times, and 30-40 mins each time.
Screening for nonadherence

- Morisky questionnaire: Last month,
  1. Have you ever stop medication when you feel worse?
  2. Have you ever missed taking your medicine?
  3. Have you careless about your medicine?
  4. Have you ever stop medication when you feel better?
Methods - measures

Primary outcome
- medication adherence

Secondary outcome
- Beliefs about medication
- Motivation of adherence
- Confidence of adherence
# Method - data collection

## In hospital

<table>
<thead>
<tr>
<th>Data</th>
<th>Measure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication adherence</td>
<td>2-3 days after admission</td>
</tr>
<tr>
<td>Belief and confidence of medication</td>
<td>2-3 days after admission</td>
</tr>
<tr>
<td>adherence</td>
<td></td>
</tr>
</tbody>
</table>

## Follow up

<table>
<thead>
<tr>
<th>Data</th>
<th>Measure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication adherence</td>
<td>1 month and 3 months after</td>
</tr>
<tr>
<td>Belief and confidence of medication</td>
<td>discharge</td>
</tr>
<tr>
<td>adherence</td>
<td></td>
</tr>
</tbody>
</table>
Participants flow

Assessed for eligibility (n=300)

Randomized (n=120)

Excluded (n=180)
Refused participation (n=20)
Did not meet inclusion criteria (n=160)

Intervention group (Motivational interviewing) n=60

Usual care group n=60

1-month flow up (n=49)
attrition (n=11)

1-month flow up (n=51)
attrition (n=9)
death = 1
rehospitalized = 3

1-month follow up n=48
Withdrawal n=2

1-month follow up n=49
Hospitalization n=1

Figure 1. Participants flow of the study.
## Baseline assessment

<table>
<thead>
<tr>
<th>indicator</th>
<th>subjects (N=97)</th>
<th>Control group (n=49)</th>
<th>Intervention group (n=48)</th>
<th>t/x²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization times</td>
<td>2.9 ± 2.1</td>
<td>0.20</td>
<td>0.84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1</td>
<td>74 (76.3)</td>
<td>39 (79.6)</td>
<td>35 (72.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary disease</td>
<td></td>
<td></td>
<td></td>
<td>4.84</td>
<td>0.31</td>
</tr>
<tr>
<td>CHD</td>
<td>31 (32.0)</td>
<td>13 (26.5)</td>
<td>18 (37.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTN</td>
<td>5 (5.2)</td>
<td>3 (6.1)</td>
<td>2 (4.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVD</td>
<td>22 (22.7)</td>
<td>9 (18.4)</td>
<td>13 (27.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>myocardosis</td>
<td>36 (37.1)</td>
<td>23 (46.9)</td>
<td>13 (27.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>others</td>
<td>3 (3.0)</td>
<td>1 (2.1)</td>
<td>2 (4.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BNP</td>
<td>619.1 ± 100.6</td>
<td>704.6 ± 125.4</td>
<td>531.8 ± 135.4</td>
<td>0.88</td>
<td>0.38</td>
</tr>
<tr>
<td>age （岁）</td>
<td>57.2 ± 13.2</td>
<td>56.7 ± 13.1</td>
<td>57.7 ± 13.1</td>
<td>0.35</td>
<td>0.73</td>
</tr>
</tbody>
</table>
Baseline assessment (con’t)

Chart 2 medication adherence, beliefs, confidence, etc

<table>
<thead>
<tr>
<th>data</th>
<th>participants (N=97) (mean±SD)</th>
<th>Control group (n=49) (mean±SD)</th>
<th>Intervention group (n=48) (mean±SD)</th>
<th>t/Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication adherence</td>
<td>17.47 ± 8.15</td>
<td>16.39 ± 8.21</td>
<td>18.53 ± 8.05</td>
<td>1.29</td>
<td>0.20</td>
</tr>
<tr>
<td>beliefs</td>
<td>39.11 ± 5.09</td>
<td>38.35 ± 5.32</td>
<td>39.89 ± 4.16</td>
<td>1.51</td>
<td>0.14</td>
</tr>
<tr>
<td>motivation</td>
<td>7.21 ± 1.96</td>
<td>7.22 ± 2.08</td>
<td>7.19 ± 1.84</td>
<td>0.09</td>
<td>0.93</td>
</tr>
<tr>
<td>confidence</td>
<td>7.80 ± 1.96</td>
<td>7.43 ± 1.80</td>
<td>8.19 ± 2.04</td>
<td>1.94</td>
<td>0.06</td>
</tr>
</tbody>
</table>
Result and discussion

Intervention group

Figure 2 medication adherence comparison between and within groups
Result and discussion

Beliefs about medication comparison between and within groups

A = admission day; D = discharge day

Figure 3 beliefs about medication comparison between and within groups
### Result and discussion

Chart 3 comparison of motivation and confidence of adherence within group

<table>
<thead>
<tr>
<th>measures</th>
<th>time</th>
<th>control (n=49) (mean±SD)</th>
<th>intervention (n=48) (mean±SD)</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>motivation</td>
<td>admission</td>
<td>7.15 ± 1.88</td>
<td>8.03 ± 1.93</td>
<td>0.531</td>
<td>0.595</td>
</tr>
<tr>
<td></td>
<td>discharge</td>
<td>7.88 ± 2.42</td>
<td>9.50 ± 1.52</td>
<td>3.972</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>1 month</td>
<td>7.43 ± 2.53</td>
<td>9.85 ± 0.41</td>
<td>5.789</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>3 month</td>
<td>6.76 ± 2.52</td>
<td>9.90 ± 0.42</td>
<td>7.228</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>admission</td>
<td>7.37 ± 2.09</td>
<td>7.88 ± 2.19</td>
<td>0.92</td>
<td>0.07</td>
</tr>
<tr>
<td></td>
<td>discharge</td>
<td>8.00 ± 1.98</td>
<td>9.35 ± 1.58</td>
<td>4.032</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>1 month</td>
<td>7.78 ± 2.201</td>
<td>9.71 ± 0.683</td>
<td>5.298</td>
<td>0.000*</td>
</tr>
<tr>
<td></td>
<td>3 month</td>
<td>7.45 ± 2.40</td>
<td>9.75 ± 0.60</td>
<td>5.729</td>
<td>0.000*</td>
</tr>
</tbody>
</table>
Figure 4, 5 comparison of motivation and confidence of adherence between groups

**Result and discussion**

Adherence motivation

1 month 3 month

A= admission day ; D=discharge day

Adherence confidence

1 month 3 month
Limit and suggestion

- Generalizability to HF population is limited because study inclusion was limited to a small proportion of the general HF population and the study siting is the best HF care unit in China, thus the condition there may be more complicated.

- Medication adherence is a continuous and dynamic process. In this study, follow up days were limited to 3 months after discharge, which may not indicate the further change of medication adherence in the long term.

- Repeating of the study and large sample size is suggested and to test further effect of MI, 6 months or 1 year follow up should be researched in future studies.
Conclusion

- Medication adherence of HF patients presents a downturn after 1 month after discharge.

- MI is effective in improving patients' medication adherence and adherence motivation and confidence.

- MI could be used in clinical practice to improve medication adherence.