Effectiveness of nurse-led program on mental health status and quality of life in patients with chronic heart failure

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Abstract
Current study was to evaluate the effectiveness of nurse-led program in improving mental health status (MHS) and quality of life (QOL) in chronic heart failure (CHF) patients after an acute exacerbation. CHF patients were enrolled after informed consent was obtained and were assigned into the control and treatment group. Patients in the control group received standard care. In the treatment group, patients received standard care plus telehealth intervention including inquiring patients medical condition, providing medical advice, counseling patients, and having positive and emotional talk with patients. At the third and sixth month after discharge, participants were called by registered nurses to assess Mental Health Inventory-5 (MHI-5) and Kansas City Cardiomyopathy Questionnaire (KCCQ) scores. Compared to the treatment group, patients in the control group were less likely to have educational attainment ≥ high school degree and have a married status, but were more likely to have diabetes. No significant differences in MHI-5 (68.5 ± 12.7 vs 66.9 ± 10.4) and KCCQ (70.0 ± 12.2 vs 68.7 ± 10.9) scores at baseline between the control and treatment groups were observed. There were significantly differences in MHI-5 (72.7 ± 15.6 vs 65.2 ± 11.4) and KCCQ score (74.2 ± 14.9 vs 66.4 ± 12.1) at 3 months follow-up between control and treatment groups. Nonetheless, at 6 months follow-up, although MHI-5 and KCCQ scores remained higher in the treatment group, there were no statistically significant differences (MHI-5: 65.4 ± 12.8 vs 61.4 ± 10.0; KCCQ: 65.1 ± 12.3 vs 61.9 ± 10.3). After multivariate regression analysis, not receiving nurse-led program were significantly associated with reduced MHI-5 (odds ratio [OR] 1.25% and 95% confidence interval [CI]: 1.14–1.35) and KCCQ (OR: 1.20% and 95% CI:1.11–1.54) scores. Nurse-led program is helpful to improve MHS and QOL in CHF patients after an acute exacerbation. However, these achievements are attenuated quickly after the nurse-led intervention discontinuation.

Abbreviations: CHF = chronic heart failure, MHS = mental health status, QOL = quality of life, SSRI = selective serotonin receptor inhibitor, NYHA = New York Heart Association, LVEF = left ventricular ejection fraction, eGFR = estimated glomerular filtration rate, MHI-5 = Mental Health Inventory-5, KCCQ = Kansas City Cardiomyopathy Questionnaire.

Keywords: chronic heart failure, mental health status, quality of life

1. Introduction
Chronic heart failure (CHF) is a major cause of morbidity and mortality around the world including in China.\textsuperscript{[1,–4]} The 5-years mortality rate of CHF is up to 50% and the rate of rehospitalization for HF is also extremely high in patients after acute exacerbation, which causes a huge health and economic burden.\textsuperscript{[5–7]} Furthermore, prior studies have shown that mental health status (MHS) and quality of life (QOL) in patients with CHF are significantly worse compared to those without CHF.\textsuperscript{[8–11]} These data together demonstrate that concerted and continuous efforts are needed to improve the overall health status for CHF patients.

Prior studies have reported that a substantial proportion of CHF patients have mental health problem such as depression and anxiety.\textsuperscript{[11–13]} However, results from prior studies have shown that compared to the placebo, the use of anti-depressants (e.g., selective serotonin receptor inhibitor, SSRI) did not improve the cardiovascular outcomes in CHF patients, although the MHS was improved in patients receiving SSRI.\textsuperscript{[14–16]} In recent decade, some studies suggest that the nurse-led program might provide adjuvant benefits for CHF management. For example, Thompson et al reported that compared to the control group, nurse-led program was associated with lower risk of rehospitalization for HF and unplanned admission,\textsuperscript{[17]} which was also observed in another report.\textsuperscript{[18,19]} These data together suggest that nurse-led program may be beneficial for improvement of MHS and QOL in CHF patients.

Given the adverse physical and psychological effects, as well as huge economic and health burden of CHF, continuous efforts are needed to reduce mortality and improve MHS and QOL in patients with CHF. Therefore, the purpose of current research is
to evaluate the effectiveness of nurse-led program in improving MHS and QOL in CHF patients after an acute exacerbation.

2. Methods

2.1. Participants enrollment

The study protocol was approved by the Research Ethic Committee of Hainan Western Central Hospital. The inclusion criteria were as follows: acute exacerbation of CHF during the index hospitalization, New York Heart Association (NYHA) class II-IV, left ventricular ejection fraction (LVEF) was ≤40% as assessed by echocardiography, and participants were hemodynamically stable at discharge. The exclusion criteria were as follows: patients were discharged with hospice status, terminal illness with life expectancy <6 months, advanced stage of malignant disease, significant mental illness such as dementia, cannot provide informed consent, or cannot finish questionnaire for MHS and QOL assessment. Participants who agreed with the nurse-led intervention program were assigned to the treatment group, and those who did not agree with the nurse-led intervention program was assigned to the control group. Informed consent was obtained before enrollment. Baseline characteristics (clinical factors and socioeconomic status) and relevant laboratory data were extracted from electronic medical record by 2 independent investigators. Serum creatinine was used to calculate estimated glomerular filtration rate (eGFR). Study flowchart was presented in Figure 1.

2.2. Nurse-led intervention program

The day before discharge, the Mental Health Inventory-5 (MHI-5) was used to assess baseline MHS, and the Kansans City Cardiomyopathy Questionnaire (KCCQ) was used to evaluate baseline QOL in both treatment and control groups by registered nurses. These performances were supervised by board-certified psychiatrists and cardiologists, respectively. In order to validate the performances of registered nurses, 20% participants were randomly selected and assessed by psychiatrists for MHI-5 and by cardiologists for KCCQ assessment, respectively. The scores evaluated by registered nurses and psychiatrists and cardiologists were consistent, which demonstrated the validation and accuracy of MHS and QOL assessed by registered nurses. Patients in the control group received standard care (e.g., explanation of their diseases conditions, current prescribed medications, low sodium consumption, body weight monitor, etc.). In the treatment group, patients received standard care plus telehealth intervention. In specific, investigators call patients at the first and second month after discharge. During the communications, investigators will inquire patients medical condition, therapeutic regimen, and lifestyle. Thereafter, investigators will provide information on self-care management, persuasive statement regarding medical management, educating and counseling patients. Finally, investigators will have non-medical chitchat including positive talk (e.g., agreement) and emotional talk (e.g., reassurance and empathy) with patients. At the third and sixth month after discharge, participants were called by registered nurses to reassess MHI-5 and KCCQ score.

Figure 1. Study flowchart.
performed using SPSS 23.0 and a two-sided entered into multivariate regression analysis. All analyses were considered as statistical significance.

Association class III-IV (NYHA; 51.3% vs 56.6%). No 230 vs 874

As presented in Figure 2a and 2b, there were no significant differences in MHI-5 (68.5 ± 12.7 vs 66.9 ± 10.4) and KCCQ (70.6 ± 12.2 vs 68.7 ± 10.9) scores at baseline between the control and treatment groups. During follow-up, both MHI-5 and KCCQ scores were gradually decreased in the control group. However, in the treatment group, both MHI-5 and KCCQ score were increased at 3 months follow-up, and then were decreased at the 6 months follow-up. There were significantly differences in MHI-5 (72.7 ± 15.6 vs 65.2 ± 11.4) and KCCQ score (74.2 ± 14.9 vs 66.4 ± 12.1) at 3 months follow-up. Nonetheless, at 6 months follow-up, although MHI-5 and KCCQ scores remained higher in the treatment group, there were no statistically significant differences (MHI-5: 65.4 ± 12.8 vs 61.4 ± 10.0; KCCQ: 65.1 ± 12.3 vs 61.9 ± 10.3).

3.3. Factors associated with reduced MHI-5 and KCCQ scores

As presented in Table 2, after multivariate regression analysis, increased age, female gender, presence of diabetes mellitus, increased serum NT-proBNP level and NYHA classification, decreased LVEF, and not receiving nurse-led program were significantly associated with reduced MHI-5 score. With respect to the factors associated with KCCQ score, after multivariate regression analysis, increased age, female gender, presence of hypertension, diabetes mellitus, coronary heart disease and dilated cardiomyopathy, increased serum NT-proBNP level, decreased LVEF and not receiving nurse-led program were significantly associated with reduced KCCQ score.

4. Discussion

To our knowledge, this is the first few studies to evaluate the impact of nurse-led program on mental health status and quality of life in CHF patients with acute exacerbation in China. Our current analyses have the 3 main findings: first, nurse-led program is beneficial for improving MHS, and QOL in CHF patients after an acute exacerbation; second, these benefits are gradually decreased after discontinuation of nurse-led program; third, many factors such as increasing age and female gender are significantly associated with worsening MHS and QOL, suggesting that these population groups are vulnerable to worsening MHS and QOL after an acute exacerbation of CHF.

Chronic heart failure causes substantial morbidity and mortality around the world including China. CHF patients commonly have poor MHS ad QOL, and the underlying mechanisms are likely multifactorial and needed to be further elucidated.[11,20] Prior studies have shown that lower socioeconomic status, lack of social support, older age, and female gender were associated with poor QOL.[21,22] Similarly, in our current analyses, we also observed that after adjustment for multiple covariates, increased age and female gender were significantly associated with reduced KCCQ score. Notably, KCCQ score has been broadly applied to evaluate the QOL in patients with cardiovascular diseases.[19] Our findings suggest that elderly and female patients are vulnerable populations and nurse-led program might provide greater benefits to these 2 specific groups. It is noted that, as presented in Figure 2b, after 2 consecutive months nurse-led program intervention, KCCQ score was significantly increased in the treatment group. In contrast, KCCQ score was continuously decreased in the control group. Extending findings from prior studies,[17–19] our current analyses also showed that presence of cardiovascular risk factors (e.g., hypertension and diabetes) and comorbidities (e.g., coronary heart disease) were associated with reduced KCCQ score. These findings support the notion that strictly controlling

| Variables                      | Control group (n = 152) | Treatment group (n = 106) |
|-------------------------------|-------------------------|--------------------------|
| Age (years)                   | 53.5 ± 12.8             | 51.7 ± 10.6              |
| Male, n (%)                   | 103 (67.9)              | 69 (65.1)                |
| Education ≥ high school, n (%)| 72 (47.4)               | 60 (56.6)                |
| Married status, n (%)         | 130 (85.5)              | 98 (92.5)                |
| Smoking, n (%)                | 60 (39.5)               | 42 (39.6)                |
| Hypertension, n (%)           | 82 (53.9)               | 57 (53.8)                |
| Diabetes mellitus, n (%)      | 55 (36.2)               | 30 (28.3)                |
| Dyslipidemia, n (%)           | 68 (44.7)               | 50 (47.2)                |
| Coronary heart disease, n (%) | 80 (52.6)               | 58 (54.7)                |
| Dilated cardiomyopathy, n (%) | 28 (18.4)               | 20 (19.0)                |
| Valvular heart disease, n (%) | 34 (22.4)               | 26 (24.5)                |
| Systolic blood pressure, mm Hg| 131 ± 13                | 133 ± 12                 |
| Diastolic blood pressure, mm Hg| 79 ± 10                 | 80 ± 11                  |
| Heart rate, beat per minute   | 96 ± 17                 | 98 ± 16                  |
| Fasting blood glucose, (mmol/L)| 6.2 ± 1.1               | 6.1 ± 1.0                |
| Total cholesterol (mmol/L)    | 5.1 ± 0.9               | 5.1 ± 1.0                |
| Creatinine (μmol/L)           | 71.2 ± 16.8             | 72.3 ± 15.5              |
| eGFR (ml/min/1.73m²)          | 70.4 ± 15.6             | 72.6 ± 16.9              |
| NT-proBNP (pg/ml)             | 855 ± 230               | 874 ± 208                |
| Left ventricular ejection fraction, (%) | 34 ± 5 | 33 ± 5               |
| NYHA class III-IV, n (%)      | 78 (51.3)               | 60 (56.6)                |

*eGFR = estimated glomerular filtration rate, NT-proBNP = N-terminal pro-B type natriuretic peptide, NYHA = New York Heart Association.

2.3. Statistical analysis

Continuous variables were presented as mean and standard deviation (SD) and categorical variables were presented as number and percentage. Continuous variables were assessed by Student t test and categorical variables were assessed by the χ²-test. Linear regression analysis was used to evaluate factors associated with MHI-5 and KCCQ scores changes. In specific, in the univariate regression analysis, factors with P value < .1 were entered into multivariate regression analysis. All analyses were performed using SPSS 23.0 and a two-sided P value < .05 was considered as statistical significance.

3. Results

3.1. Comparisons of baseline characteristics

As presented in Table 1, compared to the treatment group, patients in the control group were less likely to have educational attainment ≥ high school degree (47.4% vs 36.5%) and have a married status (85.5% vs 92.5%). Patients in the control group were more likely to have diabetes (36.2% vs 28.3%), lower eGFR (70.4 ± 15.6 vs 72.6 ± 16.9 ml/minute/1.73m²), lower serum level of N-terminal pro B-type natriuretic peptide (NT-pro BNP; 855 ± 230 vs 874 ± 208 pg/ml), and less likely to have New York Heart Association class III-IV (NYHA; 51.3% vs 36.6%). No significant differences in other baseline characteristics were observed.

3.2. Trends of MHI-5 and KCCQ score

As presented in Figure 2a and 2b, there were no significant differences in MHI-5 (68.5 ± 12.7 vs 66.9 ± 10.4) and KCCQ (70.6 ± 12.2 vs 68.7 ± 10.9) scores at baseline between the control and treatment groups. During follow-up, both MHI-5 and
cardiovascular risk factors and comorbidities can help to improve QOL in CHF patients. Furthermore, our study also implies that serum NT-proBNP level and LVEF value can be used to evaluate and predict the QOL in CHF patients.

Prior studies have shown that SSRI treatment was associated with improvement of MHS in patients with cardiovascular diseases including CHF. However, a substantial proportion of patients cannot adhere to or are intolerant to SSRI treatment. Prior studies have suggested that nurse-led intervention might help to enhance MHS in CHF patients. For example, Scott et al reported that compared to the controlled group, patients in the intervention group had better MHS as reflected by higher MHI-5 score at the third and sixth months follow-up. Similarly, we also observed that after 2 consecutive months intervention, MHI-5 score was significantly higher in the treatment group than control group. Nonetheless, these achievements were reduced after discontinuation of intervention. Compared to prior study, our study has much larger sample size. In addition, we have conducted multivariate regression analysis to evaluate the factors associated with MHI-5 score change. As presented in Table 2, we found that both age and female gender were significantly associated with reduced MHI-5 score, which once again indicated that elderly and female patients should be considered as high risk population groups and intensive nurse-led program might provide additional benefits to these 2 population groups. Increased serum NT-proBNP level, decreased LVEF, and higher NYHA classification were significantly associated with reduced MHI-5 score, suggesting that worsening CHF symptoms might portend a higher risk of poor MHS and these factors might be used to predict the deterioration of MHS in CHF patients.

Finally, it is warranted to address the reasons for short-term of nursing intervention: first, we planned to conduct the short-term preliminary study to evaluate the feasibility of a nurse-led program for CHF patients; second, the short-term study can allow us to evaluate the efficacy and safety of this interventional strategy immediately, which can also provide feedback and foundation for us to develop a long-term study; third, due to the current limited budget and human resources, it was pragmatic to evaluate whether this strategy would be practical. Furthermore,
since selective serotonin receptor inhibitor (SSRI) has been shown to improve mental health status for patients with CHF, and it is considered that a combination of SSRI and nursing-therapy might provide additional benefit for improving MHS and QOL for these patients. However, in current study, we were unable to address this issue. In the future study, it is warranted to investigate this strategy.

Some limitations of our study need to be addressed. First of all, this is an open-label interventional study and findings from current analyses should be interpreted with caution. However, due to the characteristics of nurse-led program, it is hard to conduct a double-blind trial. Second, this is a single center and relatively small sample size study. Future large sample size and multiple center studies should be conducted to corroborate our findings. Third, whether these findings can be extrapolated to HF patients with LVEF > 40% is unknown. Finally, whether continuous of nurse-led program can provide persistence of MHS and QOL improve deserves further evaluation.

5. Conclusion

In conclusion, our current study shows that consecutive nurse-led program is helpful to improve the MHS and QOL in CHF patients after an acute exacerbation. However, these achievements are attenuated quickly after the nurse-led intervention discontinuation. Future studies are needed to evaluate whether continuous nurse-led program can provide consistent benefits to improving MHS and QOL in CHF patients.

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