Efficacy and safety of Bufei Huoxue capsules in treating convalescent patients with COVID-19: A multicentre, double-blind, and randomized controlled trial

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March 07, 2024

Abstract

Background and Purpose As of 5 March 2021, coronavirus disease 2019 (COVID-19) has infected more than 116 million people worldwide, with over 91 million convalescent patients. A decrease in function of multiple organs has been reported in recovering patients. In China, traditional Chinese medicine (TCM) is recommended to treat patients in the rehabilitation period; however, its efficacy and safety still need to be confirmed. Experimental Approach We conducted a multicentre, double-blind, randomised controlled trial that recruited patients with COVID-19 during the rehabilitation period. In total, 131 patients were randomly divided into two groups: 66 in the Bufei Huoxue capsules (BFHX)-treated group and 65 in the control group. BFHX was administered orally three times a day (1.4g/dose) for 90 days, and the control group was administered placebo for 90 days. The primary endpoint was to evaluate improvements in fatigue symptoms and exercise tolerance. Key Results After three months of treatment, the six-minute walk distance (6MWD) of the BFHX-treated group was significantly longer than that of the control group, compared to baseline. The Fatigue Assessment Inventory (FAI) was lower in the BFHX-treated group than in the control group. Adverse event rates were higher in the BFHX-treated group, but there was no statistical difference between groups. Conclusions and Implications BFHX may have strong rehabilitative effects on patients recovering from COVID-19 in terms of improvements in physiological activities, such as fatigue symptoms and exercise tolerance. The drug has proven to have favourable safety and effectiveness profiles.

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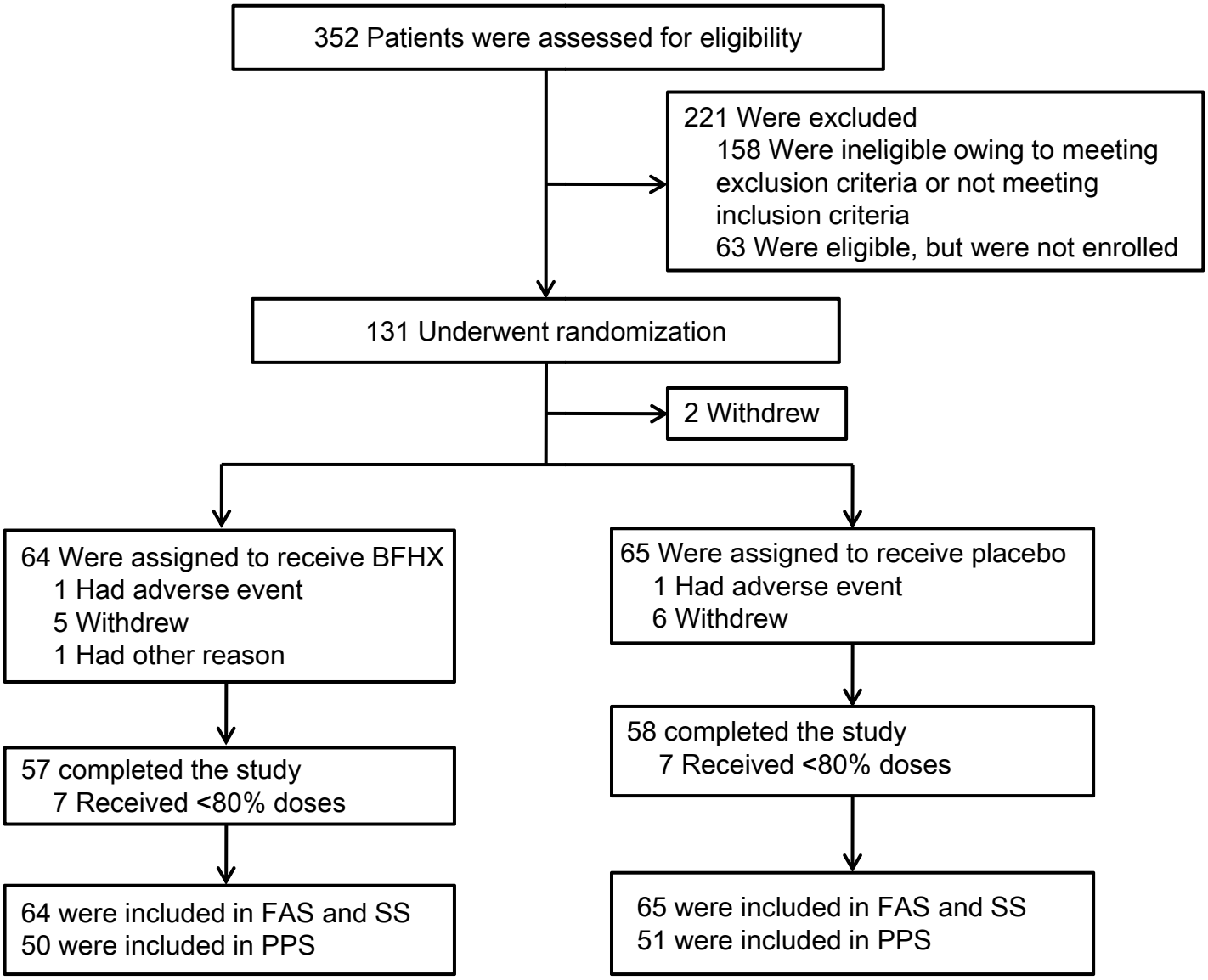
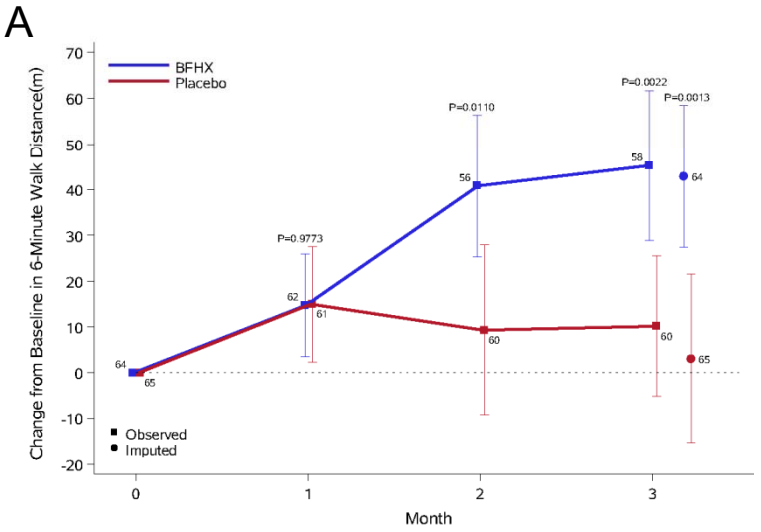
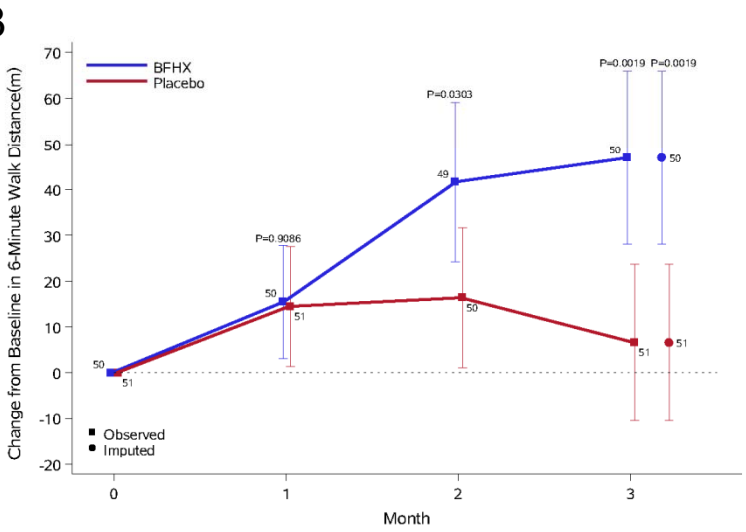
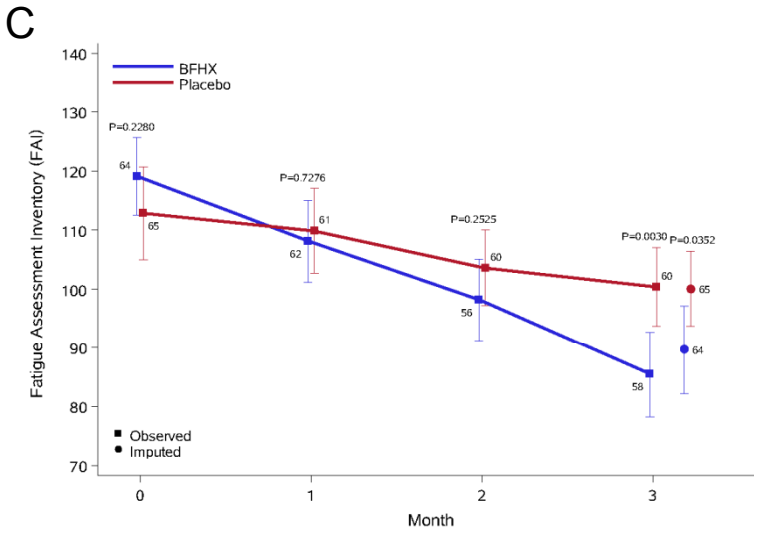
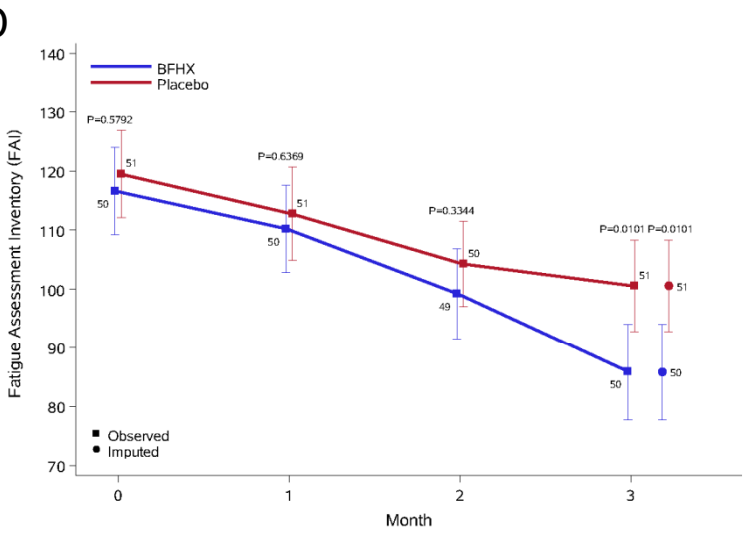


Fig. 1. Study flow chart.
BFHX : Bufei Huoxue Capsule; FAS: full analysis set; PPS: per protocol set; SS:safety set.


A
BFHX
Placebo
Change from Baseline in 6-Minute Walk Distance(m)
P=0.9773
P=0.0110
P=0.0022
P=0.0013
Observed
Imputed
Month


B
BFHX
Placebo
Change from Baseline in 6-Minute Walk Distance(m)
P=0.9086
P=0.0303
P=0.0019
P=0.0019
Observed
Imputed
Month


C
BFHX
Placebo
Fatigue Assessment Inventory (FAI)
P=0.2280
P=0.7276
P=0.2525
P=0.0030
P=0.0352
Observed
Imputed
Month


D
BFHX
Placebo
Fatigue Assessment Inventory (FAI)
P=0.5792
P=0.6369
P=0.3344
P=0.0101
P=0.0101
Observed
Imputed
Month