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ORIGINAL RESEARCH

Construction and Application of Patient-Participated Health Care Guidance Plan for Patients with Decompensated Hepatitis B Cirrhosis

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Objective: The goal of this study was to develop and assess the effectiveness of a patient-engaged healthcare guidance plan for individuals with decompensated hepatitis B cirrhosis.

Methods: This study employed literature review, situational analysis, and expert consultations to create a healthcare guidance plan that includes patient participation for those suffering from decompensated hepatitis B cirrhosis. Between January 2022 and January 2023, 86 patients with this condition admitted to our hospital were selected through convenience sampling and randomly assigned into two groups using a random number table. The control group (n=43) received standard care, while the intervention group (n=43) received the novel patient-engaged healthcare guidance in addition to standard care. We compared both groups in terms of anxiety and depression levels, self-care capability, uncertainty about their illness, and overall quality of life.

Results: Upon discharge, scores for the Self-Rating Anxiety Scale (SAS), Self-Rating Depression Scale (SDS), and Mishel's Uncertainty in Illness Scale (MUIS) decreased in both groups compared to their scores at admission ($P<0.05$), with the intervention group showing more significant improvements than the control group ($P<0.05$). Additionally, scores for the Self-Care Ability Scale (ESCA) and the component threshold scores of the Health Survey Short Form (SF-36) increased for both groups from admission to discharge ($P<0.05$), with the intervention group showing greater improvements than the control group ($P<0.05$).

Conclusion: The patient-engaged healthcare guidance plan developed for individuals with decompensated hepatitis B cirrhosis proved to be highly effective. It significantly reduced patient anxiety and depression, enhanced self-care capabilities, diminished illness uncertainty, and improved overall quality of life.

Keywords: hepatitis B, cirrhosis, decompensation period, patient participation, health care guidance plan

Introduction

China faces a significant health challenge with the high prevalence of hepatitis B, a leading cause of chronic hepatitis B virus infection.[1,2] Hepatitis B cirrhosis represents a critical stage in the disease's progression, often leading to a decompensated state characterized by poor prognosis and high mortality rates.[3] Despite this, specific treatments for decompensated hepatitis B cirrhosis are lacking, underscoring the vital role of patient participation in disease management. Patient participation focuses on empowering individuals to take an active role in their recovery by engaging in self-management practices that promote health.[4] This approach has been successfully implemented across various healthcare settings, including primary care for patients with multiple conditions,[5] chronic disease management,[6] and elderly care,[7] demonstrating improvements in self-care capabilities and overall quality of life. Despite the recognized value of patient involvement in healthcare, standardized protocols for engaging patients with decompensated hepatitis B cirrhosis in their care are absent. This gap in understanding patient needs and participation levels may impede further integration of

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patient-centered practices in managing this condition. Consequently, this study seeks to establish a patient participation guidance protocol for decompensated hepatitis B cirrhosis care and assess its efficacy. The goal is to lay a theoretical groundwork for enhancing patient involvement in the healthcare process for this patient group. The findings are presented below.

Application of Health Care Guidance Program for Patients in Decompensated Phase of Hepatitis B-Related Cirrhosis

Study Subjects

Using convenience sampling, 86 patients with decompensated hepatitis B-related cirrhosis were selected upon their admission to our hospital from January 2022 to January 2023. These patients were randomly allocated into two groups—a control group (n=43) and an intervention group (n=43)—using a random number generator. To minimize potential biases, patients in each group were accommodated in separate wards. Inclusion criteria: (1) Diagnosed with decompensated hepatitis B-related cirrhosis based on the "Viral Hepatitis Prevention and Control Program" criteria,[8] confirmed through imaging and histopathological examinations, with a Child-Pugh score of Grade B or A; (2) Age 18 years or older; (3) First episode of the disease; (4) Undergone antiviral therapy for at least 12 weeks; (5) Provided informed consent. Exclusion criteria: (1) Psychiatric disorders; (2) Impaired consciousness; (3) Severe cardiac or renal dysfunction; (4) Primary liver cancer. The study protocol was approved by the Hospital Ethics Committee.

Methods

Control Group

The control group received standard nursing care, including admission orientation, health education, dietary advice, and medication management.

Study Group

In addition to the standard nursing care, patients in the intervention group received our Healthcare Guidance Program. Upon admission, patients were given the "Healthcare Guidance Program for Patients in the Decompensated Phase of Hepatitis B-Related Cirrhosis" manual and were encouraged to actively engage in their healthcare according to the manual's instructions.

Formation of the Research Team

The research team consisted of one graduate advisor (professor), two senior gastroenterologists, two deputy chief nurses in the gastroenterology department (both nurse managers), four specialized nurses, one rehabilitation therapist, one nutritionist, one psychological counselor, and four graduate students.

Literature Search

Chinese and English databases were searched, including the Wanfang Data Knowledge Service Platform, China National Knowledge Infrastructure (CNKI), VIP Full-text Database, PubMed, Embase, Web of Science, etc.

Chinese search terms: "hepatitis B cirrhosis", "cirrhosis", "decompensated cirrhosis", "cirrhosis after hepatitis", "non-alcoholic cirrhosis", "patient participation", "health caregiving", "self-care".

English search terms: "Hepatitis B cirrhosis", "cirrhosis", "decompensated cirrhosis", "cirrhosis after hepatitis", "non-alcoholic cirrhosis", "patient participation", "health care", "self-care".

Timeframe for the literature search: From database inception to March 2023.

Expert Consultation

Development of Expert Consultation Questionnaire. The questionnaire was designed in three sections. The first section, "Letter to Experts", outlined the research goals, methods, and instructions for completing the questionnaire. The second section, "Expert Consultation Form", detailed the guidance protocol for patient engagement in healthcare for individuals

with decompensated hepatitis B cirrhosis, asking experts to rate the importance of each aspect on a Likert 5-point scale. The third section, "Expert Basic Information Form", gathered demographic information and evaluated the experts' understanding of the consultation material and their judgment criteria.

Selection of Consultation Experts. Criteria for expert selection included: (1) Experience in gastroenterology medical and nursing work. (2) Holding a senior medical professional title or a deputy chief nurse position or higher. (3) At least 10 years of experience related to hepatitis B cirrhosis care. (4) Willingness to voluntarily participate in the study. Ultimately, six experts were selected, with an average age of 42.75±6.11 years. Their qualifications included one bachelor's degree, three master's degrees, and two doctoral degrees, with work experience ranging from 15 to 22 years (average 19.46±1.25 years). The group comprised one chief physician, two associate chief physicians, two chief nurses, and one associate professor.

Implementation of Expert Consultation. Questionnaires were distributed and collected via email, undergoing two rounds of consultation. In the first round, all six distributed questionnaires were returned, yielding a 100% response rate. Feedback led to adjustments in the indicators by the research team. The second round mirrored the first in distribution and collection rates, reaching a consensus among experts.

The expertise of the consultants across both rounds was demonstrated by an academic achievement coefficient of 0.923, judgment criteria coefficient of 0.941, familiarity coefficient of 0.899, and an overall expert consultation authority of 0.911 (>0.7). These figures affirm the experts' comprehensive understanding of the patient participation guidance protocol, their scientifically grounded assessments, and the high reliability of their contributions. The finalized guidance protocol encompasses three primary indicators, 18 secondary indicators, and 43 tertiary indicators, detailed in Table 1.

Observation Indicators

Anxiety and Depression Status

Upon admission and discharge, the anxiety levels of patients in the decompensated phase of hepatitis B-related cirrhosis were assessed using the Self-Rating Anxiety Scale (SAS),[9] and their depression levels were assessed using the Self-Rating Depression Scale (SDS).[9] SAS consists of 20 items, with each rated on a 4-point scale (1–4). The sum of these items' scores is converted to a standard score by multiplying by 1.25 and rounding to the nearest whole number. A SAS standard score ≥ 50 indicates the presence of anxiety, with higher scores reflecting greater anxiety levels. The Cronbach's α coefficient of this scale is 0.777. SDS consists of 20 items. Similarly, the SDS also comprises 20 items rated on a 4-point scale. (1–4). The summed scores are adjusted to a standard score in the same manner. An SDS standard score ≥ 53 indicates the presence of depression, and the standard score is positively correlated with the degree of depression. The SDS demonstrates a Cronbach's α of 0.782.

Self-Care Ability

The exercise of self-care agency scale (ESCA)[10] was used to evaluate the self-care capabilities of patients upon admission and discharge. The ESCA consists of four dimensions and 43 items, including self-care responsibility (8 items), self-concept (9 items), self-care skills (12 items), and level of health knowledge (14 items). Items are scored on a scale from 0 to 4, leading to a maximum total score of 172, where higher scores indicate more robust self-care capabilities. TThe ESCA's reliability, indicated by a Cronbach's α of 0.880, attests to its validity.

Disease Uncertainty

The Mishel's uncertainty in illness scale (MUIS)[11] was used to assess the disease uncertainty of patients in the decompensated phase of hepatitis B-related cirrhosis upon admission and at discharge. MUIS consists of three dimensions and 20 items, including ambiguity (8 items), lack of clarity (7 items), and unpredictability (5 items). Each item is rated on a 5-point scale (1–5), with a total score ranging from 20 to 100. A higher score indicates a stronger sense of disease uncertainty. The Cronbach's α coefficient of this scale is 0.825.

Quality of Life

The Quality of Life for patients in the decompensated phase of hepatitis B-related cirrhosis was evaluated using the 36-Item Short Form Health Survey (SF-36) at both admission and discharge. The SF-36 encompasses two primary components—

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Table 1 Guidance Protocol for Patient Participation in Health Caregiving for Patients with Decompensated Hepatitis B Cirrhosis

Primary Indicator	Secondary Indicator	Tertiary Indicator	
Participation in caregiving	Participation in environmental adaptation	1	Be familiar with the hospital environment, ward environment, and the use of facilities.
		2	Be familiar with the regulations and policies regarding daily routine, visitation, and caregiving during hospitalization.
		3	Be familiar with the safety regulations during hospitalization.
	Participation in doctor-patient communication	4	Proactively understand one's attending physician and responsible nurse.
		5	Provide correct identification information proactively to healthcare providers during treatment/examinations/nursing.
		6	Proactively provide healthcare providers with medical history, allergy history, medication history, family history, etc.
		7	Proactively provide feedback to healthcare providers about personal feelings and physical discomfort during hospitalization.
		8	When having questions about the diagnosis and treatment of the disease, proactively ask and consult healthcare professionals for professional help.
		9	Proactively consult healthcare providers about personal illness and diagnosis and treatment information during hospitalization.
	Participation in medication management	10	Understand the purpose of medication, the names of medications, dosage, administration methods, and timing.
		11	Be aware of medication contraindications and possible adverse reactions during medication use.
		12	Adhere to medical advice and take medication on time, in the correct dosage, and in the proper manner.
	Participation in hospital examinations	13	Be aware of the preparation required for various examinations, including the examination location, time, cooperation instructions, and precautions.
		14	Understand the results of various examinations and their clinical significance.
	Participation in self-care	15	Adjust lifestyle habits according to the advice of healthcare providers.
		16	Proactively seek social support.
		17	Learn and master self-care skills.
		18	Monitor changes in personal health condition.
		19	Proactively learn disease-related knowledge.
	Participation in dietary management	20	Participate in hospital-organized dietary management and health education activities, and participate in the development of therapeutic meal plans.
	Participation in sleep management	21	Maintain a regular daily routine.
	Participation in psychological adjustment	22	Learn meditation, deep breathing, and other psychological adjustment methods to manage mental well-being.
	Participation in complication management	23	Develop a risk awareness mindset and cooperate with healthcare providers in preventing and managing complications.
	Participation in rehabilitation exercises	24	Determine suitable exercise methods and intensity based on guidance from healthcare providers.
		25	Determine suitable exercise methods and intensity based on guidance from healthcare providers.
	Participation in discharge preparation	26	Proactively understand the discharge process.
		27	Participate in the development of a discharge plan.
		28	Be aware of the post-discharge follow-up schedule, content, and frequency.

		29	Proactively learn home-based rehabilitation knowledge and skills.
		30	Understand how to handle unexpected situations after discharge.
Participation in decision-making	Participation in medical decision-making	31	Participate in the selection of hospitals for medical consultations.
		32	Consider hospitalization options when feeling physically unwell.
	Participation in diagnosis and treatment decision-making	33	Proactively participate in the selection of treatment plans and express opinions on treatment options.
	Participation in medication decision-making	34	The attending physician will recommend medication options based on the patient's condition, and the patient can make decisions based on economic status and personal preferences.
	Participation in discharge decision-making	35	Communicate with healthcare providers to develop a discharge plan, among other things.
Participation in supervisory inquiry	Participation in patient safety assurance	36	Pay attention to the safety of the hospital's hospitalization environment and hardware facilities.
		37	Pay attention to the technical competence of healthcare providers.
		38	Cooperate with healthcare providers to assess potential safety risks and take targeted preventive measures.
		39	Cooperate with healthcare providers to assess potential safety risks and take targeted preventive measures.
	Participation in medical demands	40	Pay attention to hand hygiene practices of healthcare providers.
		41	Proactively verify the medications being used.
	Hospital management promotion and suggestion participation	42	Report medical disputes to department leaders and relevant departments.
		43	Provide management suggestions and recommendations to the supervisory department when perceiving unreasonable hospital or department management.

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Physical Health (including physical functioning, role limitations due to physical health, bodily pain, and general health) and Mental Health (encompassing vitality, social functioning, role limitations due to emotional problems, and mental health), across eight dimensions in total. Each dimension is scored on a scale from 0 to 100, where a higher score denotes a better Quality of Life. The reliability of the SF-36, as indicated by a Cronbach's α of 0.869, confirms its validity for this assessment.

Statistical Analysis

Statistical analyses were conducted using SPSS software, version 23.0. Continuous variables, assuming a normal distribution, were described using mean and standard deviation, with differences assessed through *t*-tests. Categorical variables were expressed as frequencies and percentages (n (%)) and examined using chi-square tests. A p-value of less than 0.05 was considered indicative of statistical significance.

Results

Comparison of General Data

There were no statistically significant differences in gender, age, disease duration, and Child-Pugh classification between the two groups (P >0.05), as shown in Table 2.

Comparison of Anxiety and Depression Status

At discharge, the SAS and SDS scores in both groups were lower than those at admission (P <0.05), and the study group had lower scores than the control group (P <0.05), as shown in Table 3.

Comparison of Self-Care Ability

At discharge, the scores of each dimension of the ESCA scale in both groups were higher than those at admission (P<0.05), and the study group had higher scores than the control group (P <0.05), as shown in Table 4.

Comparison of Disease Uncertainty

At discharge, the scores of each dimension of the MUIS scale in both groups were lower than those at admission (P <0.05), and the study group had lower scores than the control group (P <0.05), as shown in Table 5.

Table 2 Comparison of General Characteristics Between the Two Groups

Group	n	Gender n (%)		Age ($\bar{x} \pm s$, Years)	Course of Disease ($\bar{x} \pm s$, Years)	Child-Pugh n (%)	
		Male	Female			Grade A	Grade B
Control group	43	29 (67.44)	14 (32.56)	49.18±5.24	4.82±1.57	32 (74.42)	11 (25.58)
Study group	43	27 (62.79)	16 (37.21)	50.09±4.93	5.23±1.69	29 (67.44)	14 (32.56)
χ^2, t		0.205		0.829	1.166	0.508	
P		0.651		0.409	0.247	0.476	

Table 3 Comparison of Anxiety and Depression Status ($\bar{x} \pm s$, Scores)

Group	n	SAS		SDS	
		On Admission	At Discharge	On Admission	At Discharge
Control group	43	60.08±5.16	50.34±4.89*	62.76±5.63	54.42±4.95*
Study group	43	59.11±5.23	46.48±4.65*	60.98±5.17	50.08±4.69*
t		0.866	3.751	1.527	4.174
P		0.389	<0.001	0.131	<0.001

Note: compared with the same group at admission *P<0.05.

Table 4 Comparison of Self-Care Ability ($\bar{x} \pm s$, Scores)

group	n	Self Care Responsibility		Self-Conception		Self Care Skills		Health Knowledge Level	
		On Admission	At Discharge	On Admission	At Discharge	On Admission	At Discharge	On Admission	At Discharge
Control group	43	16.09±5.33	25.13±5.22*	17.11±5.59	29.86±5.28*	22.94±7.46	35.86±7.13*	25.24±6.32	47.75±4.11*
Study group	43	14.48±4.79	30.42±4.53*	16.25±5.37	34.19±5.04*	20.68±6.85	45.59±6.94*	27.13±6.21	53.42±3.98*
t		1.473	5.019	0.728	3.890	1.463	6.413	1.399	6.499
P		0.144	<0.001	0.469	<0.001	0.147	<0.001	0.166	<0.001

Note: compared with the same group at admission *P<0.05.

Table 5 Comparison of Disease Uncertainty ($\bar{x} \pm s$, Scores)

Group	n	Ambiguity		Lack of Clarity		Unpredictability	
		On Admission	At Discharge	On Admission	At Discharge	On Admission	At Discharge
Control group	43	30.01±4.86	20.34±4.28*	26.48±4.24	18.19±3.96*	20.02±2.47	13.08±2.96*
Study group	43	28.13±5.07	14.26±3.11*	24.97±4.72	13.63±3.27*	18.94±2.92	9.96±2.44*
t		1.755	7.536	1.561	5.822	1.852	5.333
P		0.083	<0.001	0.122	<0.001	0.068	<0.001

Note: compared with the same group at admission *P<0.05.

Comparison of Quality of Life

At discharge, the scores of each component of the SF-36 scale in both groups were higher than those at admission (P <0.05), and the study group had higher scores than the control group (P <0.05), as shown in Table 6.

Discussion

The Health Care Guidance Program for Decompensated Hepatitis B Cirrhosis Patients Developed in This Study

This study sought to create a healthcare guidance program tailored for patients with decompensated hepatitis B cirrhosis. Starting from a preliminary draft and evolving to its final form, the process included an extensive review of both national and international literature, incorporating feedback from experts to enhance the program's scientific validity and practical applicability. Experts selected for consultation were highly qualified medical and nursing professionals in gastroenterology, holding positions of associate professor or higher and possessing over ten years of experience in managing hepatitis B cirrhosis, ensuring the credibility and relevance of their contributions. The second-round expert inquiry yielded a 100% positive response rate, reflecting substantial expert engagement. In China, systematic and patient-inclusive healthcare guidance programs are scarce, and patients with decompensated hepatitis B cirrhosis face considerable physical and psychological challenges. Through active patient involvement in their healthcare, the program aims to

Table 6 Comparison of Quality of Life ($\bar{x} \pm s$, Scores)

Group	n	Mental Health		Physical Health	
		On Admission	At Discharge	On Admission	At Discharge
Control group	43	289.84±49.46	324.61±22.38*	277.81±52.57	311.47±24.19*
Study group	43	293.37±47.82	369.72±14.86*	281.37±49.43	357.94±20.28*
t		0.336	11.011	0.324	9.653
P		0.737	<0.001	0.747	<0.001

Note: compared with the same group at admission *P<0.05.

improve patients' understanding of their condition, foster disease management skills, and build recovery confidence, thereby enhancing health outcomes.

Reducing Anxiety and Depression by Intervention of the Health Care Guidance Program for Decompensated Hepatitis B Cirrhosis Patients

Patients with decompensated hepatitis B cirrhosis often endure significant physical and psychological strain due to lengthy treatment durations and complex medication schedules, potentially leading to anxiety and depression. Without prompt and specific interventions, these psychological states can adversely affect disease prognosis.[12,13] Therefore, in addition to routine liver protection, antiviral treatment, and symptomatic management, psychological counseling deserves attention.[14,15] In this study, the SAS and SDS scores were used to assess anxiety and depression levels in both groups of patients. The results showed that the healthcare guidance program significantly alleviated anxiety and depression among patients. This improvement is likely attributed to the program's emphasis on patient engagement in healthcare, encouraging individuals to take charge of their health promotion.

This approach not only enhances self-awareness and self-care skills but also introduces patients to psychological coping strategies, such as meditation and deep breathing exercises, for better mental health management and overall well-being improvement.

Enhancing Self-Care Abilities Through the Healthcare Guidance Program

Studies have shown that patient participation leads to active health promotion, heightened self-care awareness, and the continuous enhancement of self-care skills.[4,16] In this study, the ESCA scale was used to evaluate the self-care abilities of both groups of patients. Results demonstrate that the Healthcare Guidance Program significantly improved the self-care abilities of patients with decompensated hepatitis B cirrhosis. This enhancement likely stems from the program's design and execution, which honor patient preferences, motivations, knowledge, and skills, empowering them to make informed health decisions and engage in self-management practices actively. Additionally, rational interaction and active communication between healthcare providers and patients encourage patients to actively participate in health care, while targeted guidance is implemented comprehensively, thus greatly improving patients' self-care abilities. For example, decision-making participation such as participation in medical decision-making can enhance the sense of responsibility for self-care of patients with hepatitis B cirrhosis in the decompensated period, nursing participation such as participation in hospital examinations can improve the self-concept of patients with hepatitis B cirrhosis in the decompensated period, nursing participation such as participation in medication management, participation in complication management, and participation in rehabilitation exercise can enhance the self-care skills of patients with hepatitis B cirrhosis in the decompensated period, and nursing participation such as participation in self-care can improve the health knowledge level of patients with hepatitis B cirrhosis in the decompensated period.

Reducing Disease Uncertainty Through the Healthcare Guidance Program

Patients with decompensated hepatitis B cirrhosis often face a grim prognosis and, due to limited disease understanding, experience significant uncertainty about disease progression and outcomes. This uncertainty can foster negative emotions, behavioral issues, treatment discontinuation, and a marked decline in quality of life. In this study, the Mishel Uncertainty in Illness Scale (MUIS) was used to assess disease uncertainty in both patient groups. The results showed that the intervention of the Health Care Guidance Program for Decompensated Hepatitis B Cirrhosis Patients can reduce patients' disease uncertainty. The reason behind this may be that patient participation in health care is a process of acquiring knowledge and skills, reconstructing internal cognition, reinforcing health concepts, and promoting behavioral changes. Through positive doctor-patient communication, patients gradually develop awareness of participation and knowledge of how to participate, leading to a gradual reduction in and effective management of disease uncertainty. For example, improvements in the ambiguity dimension are achieved through caregiving participation in areas such as environmental adaptation; clarity is enhanced through involvement in diagnostic and treatment decisions; and unpredictability is mitigated through patient safety assurance and oversight activities.

Improving Quality of Life by Intervention of the Health Care Guidance Program for Decompensated Hepatitis B Cirrhosis Patients

Patients with decompensated hepatitis B cirrhosis face a significantly reduced quality of life due to high mortality rates and complications like upper gastrointestinal bleeding.[17,18] This study employed the SF-36 questionnaire to evaluate the quality of life in both patient groups. The intervention provided by the Healthcare Guidance Program was found to significantly improve the patients' quality of life. This finding is consistent with the conclusion of Hjorth et al,[19] who believed that empowering patients to take an active role in managing their diet, exercise, and mental well-being can lead to substantial quality of life enhancements. In this study, decompensated hepatitis B cirrhosis patients had an awareness of participating in health care and gradually learned how to effectively participate under the guidance of healthcare professionals. By helping patients better and more effectively participate in health care and setting common goals between healthcare providers and patients, their quality of life can be significantly improved. For example, nursing participation in medication management, complication management and rehabilitation exercise can promote the physiological health of patients with decompensated hepatitis B cirrhosis. Nursing participation, such as participation in environmental adaptation, psychological adjustment and sleep management, contributes to the mental health of patients with decompensated hepatitis B cirrhosis.

Limitations and Prospects

Limitations: (1) The study was limited to patients with decompensated hepatitis B cirrhosis from a single hospital, resulting in a small and possibly non-representative sample.; (2) The intervention utilized only instructional manuals, not incorporating innovative digital interventions; (3) The study was preliminary, with a limited duration and a lack of objective observational measures. Outlook: (1) Future studies will aim to broaden the sample base, increase the sample size, and further refine the healthcare guidance program; (2) The research will extend to additional diseases and departments.; (3) The implementation of the program will increasingly leverage digital technologies to enhance its scientific rigor and practicality, fostering more effective patient participation in healthcare; (4) Objective measures such as nutritional status, liver function tests, and portal vein pressure will be included to assess the program's impact more comprehensively.

Conclusion

The Health Care Guidance Program for Decompensated Hepatitis B Cirrhosis Patients developed in this study has a high level of scientific validity and can alleviate patients' anxiety and depression, enhance their self-care abilities, reduce their disease uncertainty, and improve their quality of life.

Data Sharing Statement

The original contributions presented in the study are included in the article.

Ethics Approval and Consent to Participate

The study involving human participants were reviewed and approved by the Ethics Committee of the The Second Affiliated Hospital, Hengyang Medical School, University of South China (Ethical approval number:20220187) and with the 1964 Helsinki Declaration. Written informed consent to participate in this study was provided by all participants.

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Disclosure

The authors declared no conflicts of interest in this work.

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