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Effects of a mobile health intervention based on a multitheoretical model of health behavior change on anxiety and depression, fear of cancer progression, and quality of life in patients with differentiated thyroid cancer: A randomized controlled trial

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Abstract

Background Despite the high cure rate of differentiated thyroid cancer (DTC), patients endure side effects from treatment and psychological distress, impacting their quality of life. The potential of mobile health (mHealth) interventions to address these issues remains unexplored. The purpose of this study is to develop an mHealth intervention based on the Multi-Theoretical Model of Health Behavior Change (MTM) and evaluate its impact on reducing anxiety, depression, fear of cancer progression, and enhancing quality of life in DTC patients.

Methods A single-blind, single-center, prospective, randomized controlled trial was conducted. One hundred and eleven consecutive DTC patients from Harbin Medical University's Fourth Hospital were enrolled from March 2023 to March 2024. Participants were randomized into a control group and an intervention group that received a 3-month mHealth intervention based on MTM theory. Outcomes were assessed using web-based questionnaires at baseline and conclusion.

Results One hundred four patients with DTC completed the study, with 7 lost to follow-up (6.3%). The intervention group experienced a significant drop in PHQ-4 scores post-MTM-mHealth intervention ($P < .026$), with no change in the control group, demonstrating a significant difference. The intervention group also had significantly lower anxiety ($P < .015$) and depression ($P < .032$) scores compared to controls. All PHQ-4 scores improved in the intervention group except for "Little interest or pleasure in doing things." Anxiety levels were significantly lower in the intervention group ($P < .026$) but remained unchanged in controls. The control group exhibited a significant increase in FCR-4 scores at follow-up, differing from the intervention group ($P < 0.001$). Quality of life scores did not differ at baseline but saw a significant improvement in the intervention group, while the control group experienced no significant change. The intervention group had higher VAS scores ($P < .030$) and greater health education satisfaction across all dimensions ($P < .019$).

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Conclusions The MTM-based mHealth intervention significantly benefits DTC patients by reducing anxiety, fear of cancer recurrence, and improving quality of life, though its effect on depression requires further investigation.

Trial registration China Clinical Trial Registry ChiCTR2200064321.

Keywords Differentiated thyroid cancer, mHealth, MTM, PHQ-4, FCR-4, Anxiety depression, Fear of cancer progression, Quality of life, EQ-5D-5L

Background

Differentiated thyroid cancer (DTC) is the most common type of thyroid cancer and accounts for the majority of all thyroid cancer cases. This type of cancer grows relatively slowly and serious complications are rare. DTC has a higher cure rate than other types of cancer. Despite the relatively good outcome of DTC, patients who receive subsequent iodine-131 radioactive isotope therapy (I-131) and thyrotropin suppression therapy (TST) can experience significant side effects, including hypothyroidism, allergic reactions, and fatigue [1, 2]. Patients often experience psychological problems such as anxiety and depression during diagnosis and treatment, while fear of cancer progression can also negatively affect their quality of life. Therefore, how to effectively alleviate anxiety and depression and fear of cancer progression in DTC patients and improve their quality of life has become a focus of attention for clinicians and researchers.

The development of mobile technology has shifted communication between patients and healthcare professionals from offline to online, and the delivery of health-related interventions via mobile apps, text messaging, or other mobile communication technologies has been shown to be effective in improving the quality of life and psychological status of patients with chronic diseases [3–5]. However, there are no studies that adequately substantiate the impact of mHealth interventions on the mental health of DTC patients. Theoretical models of health behavior play a key role in guiding disease treatment and rehabilitation as well as in enhancing physical and mental health, but no study has yet applied them to improve the postoperative psychological status of patients with direct DTC. The multi-theory model of health behavior change (MTM) is an integrative health behavior theoretical framework designed to explain patient change at the emotional and behavioral levels (Fig. 1). The MTM model promotes health behavior change through two linked components: initiation (i.e., once) and maintenance (i.e., ongoing). The initiation component consists of three elements: participatory dialogue, behavioral confidence, and physical environment change, which involve communication, confidence building, and environment modification, respectively. Participatory dialogue involves two-way communication between the health educator and the participant. Behavioral confidence focuses on the subject's confidence to change health behaviors in the future. Changes in the physical environment emphasized that resources to support health behavior change in the subject's physical environment became more readily available. The maintenance component also consists of three elements: emotional shifts, changing practices, and social environment changes, which focus on emotional adjustment, reflection on action, and support system building, respectively. Emotional transformation focuses on focusing the subject's feelings and emotions on the change in health behavior and directing thoughts to sustain that change. Changing practice focuses on reflective action, during which the subject thinks about his or her health

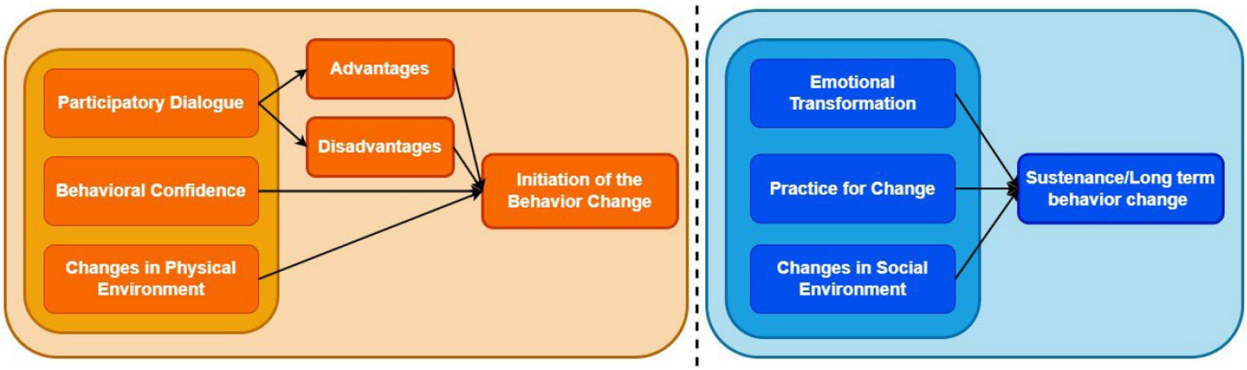

Fig. 1 Multi-theory model of health behavior change (MTM) model map

behavior change. Finally, the concept of "social environment change" involves surrounding oneself with a firm support system that encourages health behavior change. As a fourth-generation theoretical model for health education [6–8], it has been shown to play an important role in health behavior change such as smoking cessation [9], HPV vaccination [10], and physical activity [6, 11]. The application of the MTM in the field of DTC is still in the preliminary stages of research, and there are few practical applications.

In China, the popularization of Internet technology and the ease of online information exchange have provided a broad platform for the dissemination of health information and ensured that healthcare services can transcend the limitations of time and geography. During a pandemic, mHealth interventions show great potential due to their less restrictive nature and a high degree of patient need fulfillment [12]. In addition, mHealth applications have significantly reduced the cost of healthcare services while enhancing the interaction between healthcare providers and patients. WeChat, as an important part of China's digital life, has been shown in related studies that WeChat-based mobile Internet healthcare models not only effectively improve the health status and treatment outcomes of different populations, but also show significant cost-effectiveness [13, 14]. Therefore, this study aimed to develop an MTM-based mHealth intervention model for DTC patients and to assess whether this intervention implemented on the WeChat platform could effectively reduce anxiety and depression levels, alleviate the fear of cancer progression, and significantly improve the overall quality of life of DTC patients.

Methods

Study design

The study protocol has been disclosed in detail [15]. The trial was a single-blind, single-center randomized controlled trial and the study was conducted from March 2023 to March 2024. The study was conducted using quantitative methods of research and the effect assessment protocol used clinical reagent tests as well as internationally recognized scales. This study was conducted at the Fourth Hospital of Harbin Medical University, Harbin, Heilongjiang Province, China, and was approved by the Ethics Committee of the Fourth Hospital of Harbin Medical University (2022-WZYSLLSC-20). Written informed consent was obtained from all participants. Registration (ChiCTR2200064321) was completed with the China Clinical Trial Registry (www.chictr.org.cn) before the start of the trial. This research report complies with the CONSORT-eHEALTH reporting standard (see Additional file 1, Complete CONSORT-eHEALTH Form V 1.6.1 for details).

Study randomization

Given that the patient population was socially dispersed DTC patients and that patients coming to the hospital were far from meeting the trial needs of the minimum study sample size at one time in the short term, we included patients by consecutive enrollment into the group. The researchers recruited patients with a combination of inclusion and exclusion criteria as well as patients who demonstrated a positive attitude and commitment to their treatment plan when they came to the hospital to assess their potentially higher adherence to future treatment. Patients who agreed to participate in the study were randomized to either the MTM-mHealth group or the control group, followed by a baseline assessment. Given that the total number of patients registered at the hospital visit on a daily basis is uncertain, we generated random numbers by means of the function algorithm RANDBETWEEN in the computer software EXCEL to ensure that randomized allocation was fully achieved. For a detailed randomization strategy, please see the disclosure of the previous study protocol [15].

Study participants

We began recruiting patients in March 2023 and ended recruiting patients in March 2024, with patient recruitment occurring after radical surgery and prior to the start of iodine-131 therapy and endocrine therapy. Patients will be required to undergo a minimum of 2 weeks after undergoing radical surgery to ensure that they have recovered from the procedure to a state where randomization assignments can be made. Of note is that according to treatment guidelines [16], after a period of recovery following the completion of radical surgery for thyroid cancer, patients come to the hospital for a review of TSH levels $\geq$ 30.0 mU/L before iodine-131 therapy can be administered. Each patient was enrolled in the trial and signed an informed consent form at the hospital after a face-to-face meeting with the attending physician. (Please see Additional file 4 for informed consent.) Participants in this study were recruited on a consecutive enrollment basis, so not all patients started the intervention at the same time. However, all participants completed the 3-month intervention cycle. Inclusion and exclusion criteria were as follows:

Inclusion criteria:

(1) Patients were $\geq$ 18 years old;
(2) Patients were resident in Heilongjiang province (annual time away from home less than 1 month);

(3) The patients all met the relevant diagnostic criteria for thyroid cancer in the Guidelines for the Diagnosis and Treatment of Thyroid Nodules and Differentiated Thyroid Cancer, and were diagnosed with differentiated thyroid cancer by pathological examination;
(4) Patients were clinically diagnosed with a high risk of DTC recurrence risk stratification;
(5) Radiation iodine-131 therapy and endocrine therapy were given after receiving radical surgery for thyroid cancer;
(6) The patients use smartphones on a daily basis and are familiar with the general function of WeChat;
(7) Patients voluntarily participated in the study and signed an informed consent form.

Exclusion criteria:

(1) The patient has no fixed contact information, no family member is responsible for contact, and it is not convenient to contact by phone or WeChat;
(2) Patients taking any psychotropic drugs;
(3) The patients had psychiatric symptoms such as delirium, slurred speech, and uncooperative;
(4) Patients with a combination of any of the following serious systemic diseases: heart failure (NYHA class III or IV); cirrhosis of the liver in Child–Pugh class B or C; end-stage renal disease requiring dialysis or peritoneal dialysis; severe chronic obstructive pulmonary disease (COPD) with FEV1 < 30% of predicted; organ dysfunction or failure due to endocrine disorders, and severe somatic functional impairment and participation in other clinical trials;
(5) Pregnant or lactating women; and
(6) The patient is not expected to complete the required follow-up or treatment cycles within the next year.

Sample size

The study sample size was estimated based on the primary outcome (change in anxiety and depression levels) using G*Power, version 3.1.9.7 (University of Dusseldorf) [17]. To the best of our knowledge, similar intervention studies using the PHQ-4 to assess similar outcomes do not yet exist, and therefore effect sizes for the primary outcome of anxiety and depression levels, respectively, were considered. The pooled effect sizes for anxiety and depression in previous studies were 0.63 and 0.59, respectively, with 80% efficacy at a 5% two-sided significance level [18]. The sample size required for studies of changes in anxiety levels was approximately 18, while for studies of changes in depression levels, the sample size required was approximately 21. Based on the estimation results, in order to saturate the study sample size, the sample size for this two-group parallel trial would need to be at least 21 participants per group to detect an effect size of at least 0.50 on the post-intervention change score for the primary outcome, which, taking into account a potential attrition rate of 20%, would require a sample size of 54 patients, with 27 patients in each group.

Treatment programs

Two groups of patients received I-131 treatment and TST therapy [19, 20]. Before treatment, thyroid uptake scans were performed to detect whether there was residual or recurrent thyroid cancer [21]. Patients took 50–200 mCi iodine-131 according to individual conditions and were observed in the isolation ward for 3 days to reduce the risk of radiation. On the second day of treatment, levothyroxine sodium tablets were taken orally. The initial dose was usually 50 μg per day, the maximum was not more than 100 μg, and the maintenance dose was 50–200 μg per day. Four weeks later, the thyroid function was reviewed and the dose was adjusted according to the results. During the subsequent maintenance phase [22], the goal of treatment was to maintain TSH levels in the range of 0.3–0.5 mU/L to optimize therapeutic efficacy and reduce adverse effects.

Interventions

This study established a multidisciplinary team composed of a thyroid cancer pharmacist, a nursing expert, a thyroid cancer doctor, and a public health expert. After several rounds of discussion, the team developed a comprehensive intervention strategy. In the control group, patients received standard medical and nursing services, while the intervention group received additional MTM-based mHealth intervention on this basis.

The personalized intervention program for the intervention group included:

- Online health education: Through an intelligent WeChat platform, patients in the intervention group were able to access immediate health education resources. The platform not only supports direct communication between doctors and patients so that patients can get professional answers quickly, but also allows doctors or nurses to provide real-time interventions to patients, such as reminding the time to take medication, and providing popularization of thyroid cancer-related knowledge (please see the multimedia database for materials used in popularization of the science, please refer to the Additional file 2).
- Comprehensive medical care: From the first day of hospitalization, patients in the intervention group

received comprehensive medical care services including WeChat group health education, online health lectures, personalized health education programs, and drug supervision. During the outpatient treatment, the patients continued to receive professional guidance, and after discharge, through mobile health education services, for a period of 3 months of intervention.

- MTM-based intervention content design: The entire intervention process follows the MTM theory to ensure that the content is scientific and relevant.

    1. Participatory dialogue: Physicians distribute educational brochures to encourage patients to improve their health behaviors, and regular communication through WeChat emphasizes positive facing of the disease.
    2. Behavioral confidence: Through health behavior diaries and patient communication, patients' confidence in changing health behaviors is enhanced.
    3. Changes in physical environment: Provide online educational resources to guide patients to change their daily diet and living habits.
    4. Emotional change: guiding patients to focus on health behavior change, reminding them of precautions through WeChat, helping them make long-term plans, and taking different measures depending on their compliance.
    5. Practical change: reflecting and adjusting health behaviors through patients' sharing diaries and exchange salons.
    6. Social environment change: motivate patients to change health behaviors through WeChat communication and psychological support, and encourage or guide patients in time.

The control group received a standard program of care to ensure that they received the basics of thyroid cancer treatment and lifestyle guidance. This included a detailed Health Education for Thyroid Cancer Patients booklet, which covered the basics of thyroid cancer, sensible dietary advice, guidance on medication, and information on possible adverse effects.

At the time of discharge, patients are informed of the anticipated follow-up schedule so that they understand the importance of and expectations for follow-up visits. At the end of the first month after discharge, the first telephone follow-up was carried out to ensure a smooth transition from the patient to the home treatment environment. Each month thereafter, regular follow-up phone calls are made to monitor the patient's health status, treatment compliance, and any potential problems. These follow-up calls provide an opportunity for patients to ask questions, share their experiences, and receive support and guidance from the care team. Through this routine pattern of follow-up visits, patients in the control group were able to maintain contact with their healthcare professionals and receive the necessary help when they encountered difficulties in their daily lives.

The specific flow of the study is shown in Fig. 2, which clearly demonstrates the stages and key aspects of the study, and the complete and detailed intervention program has been disclosed [15].

Outcome measures

This study used Questionstar, a web-based survey instrument, to collect study questionnaires completed by all participants at baseline and follow-up.

Clinical pharmacists were responsible for distributing the questionnaires through Questionnaire Star and providing the necessary standardized instructions to patients during the completion process, while clinical pharmacists were unaware of the grouping of patients. For hospitalized patients, the pharmacist's guidance was provided through face-to-face communication; for post-discharge patients, guidance was provided through telephone communication to ensure that all patients were able to complete the questionnaire successfully. Patient demographic information was collected through the case system and supplemented with self-designed questionnaires to obtain more comprehensive and accurate data. The questionnaire design used in this study followed strict scientific standards to ensure the accuracy and reliability of the data collection process.

Primary outcome

Anxiety and depression levels In this study, symptoms of depression and anxiety were assessed using a simplified version of the Anxiety Depression Scale (PHQ-4). The PHQ-4 scale is a validated brief self-report scale suitable for assessing the frequency of depressive and anxiety symptoms in an individual over the past 2 weeks. The PHQ-4 scale has been designed to be concise, straightforward, easy to administer, and easy to understand, allowing healthcare professionals to quickly screen individuals with symptoms of anxiety and depressive disorders, to and provide an initial assessment. The scale consists of two main dimensions: depression and anxiety, and contains a total of four entries. The first two entries are designed to assess depressed mood, while the last two are used to assess anxiety [23]. Each entry was rated on a four-point scale, i.e., "not at all," "a few days," "more than half the days," and "almost every day," corresponding to scores of 0, 1, 2, and 3, respectively. The total score of the scale ranges from 0 to 12. In a study in China, the

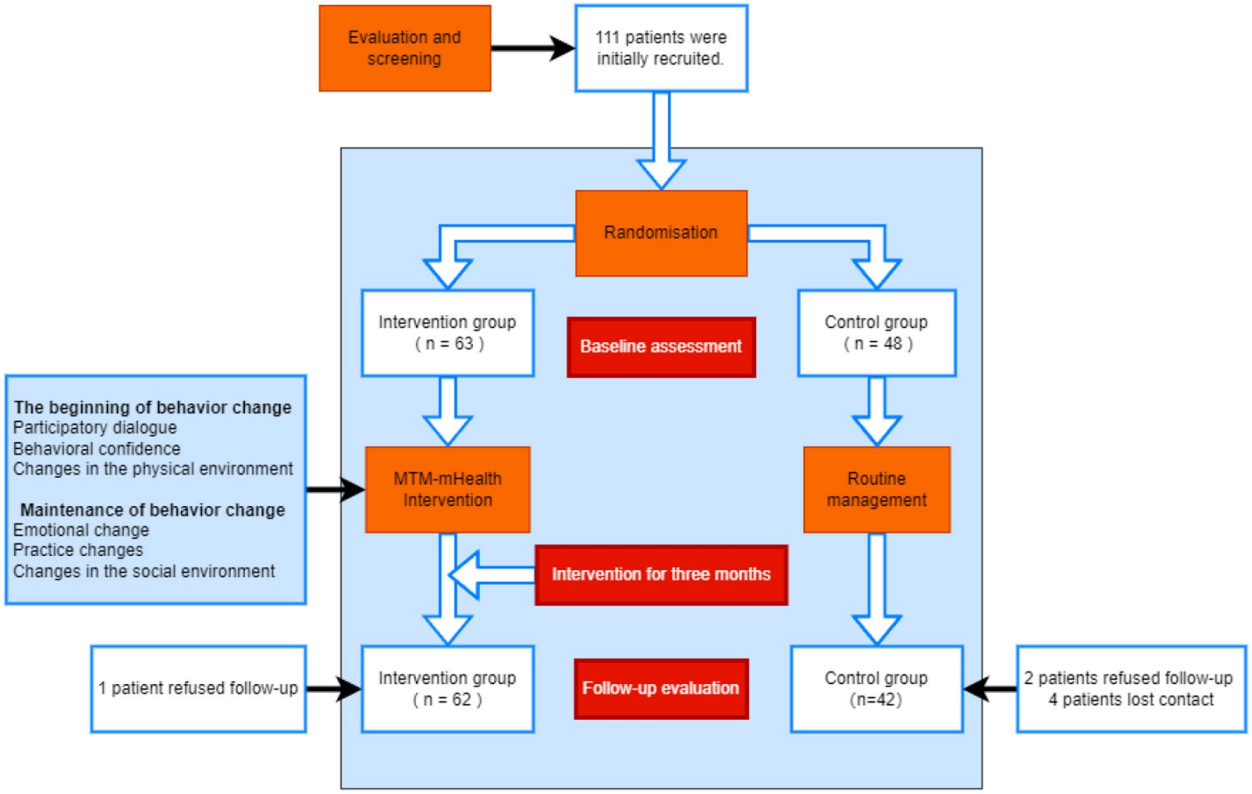

Fig. 2 Flowchart of the study

Cronbach's alpha coefficient of the PHQ-4 scale was 0.833, indicating high internal consistency reliability and validity [24]. Its Cronbach's alpha coefficient in this test was 0.839.

Secondary outcomes

Fear of cancer recurrence In this study, the Fear of Cancer Recurrence Scale (FCR-4) was used to assess the patients' level of concern about cancer recurrence [25]. The FCR-4 scale is based on the simplification of the original "FCR-7" scale, which was developed by Simard and Savard in 2018 and has already shown good reliability in the previous study, with a Cronbach's alpha coefficient of 0.86 [26]. The use of the FCR-4 scale helps healthcare professionals to accurately identify patients' fears of cancer recurrence and provide customized mental health support and resources accordingly. The scale consists of four questions designed to provide insight into cancer patients' fear of cancer recurrence. The questions are rated on a five-point Likert scale ranging from "never" to "always" to quantify the patient's level of fear. The Cronbach's alpha coefficient was 0.885 in this trial.

Quality of life The quality of life was assessed using the EQ-5D-5L scale, which is an updated and improved version of the EQ-5D scale. It adds five different levels based on the five dimensions of the former to provide a more detailed description of health status [27, 28]. These five dimensions are Mobility, Self-care, Usual activities, Pain/Discomfort, and Anxiety/Depression, each of which is subdivided into No Difficulty, Little Difficulty, Moderate Difficulty, Great Difficulty, and Complete Difficulty. Difficulty, Major Difficulty, and Complete Difficulty. The EQ-5D-5L has been shown to have high validity and reliability in seven studies of cancer patients with health utility values ranging from 0.62 to 0.90 [29–35].

Compared to the traditional EQ-5D (EQ-5D-3L), the EQ-5D-5L retains the same dimensional and hierarchical structure, but the number of ratings per dimension has been increased from three to five, which improves the granularity of the assessment. In addition, the EQ-5D-5L includes a visual analog scale (VAS) that allows individuals to rate their current state of health on a scale of 0 to 100 based on how they feel. This score provides a continuous variable to measure an individual's overall quality

of life. Its Cronbach's alpha coefficient in this trial was 0.678.

Satisfaction with health education Patient satisfaction was assessed by the customer satisfaction questionnaire (CSQ-3), and the questionnaire was adapted to better adapt to the purpose of this study. The CSQ-3 is a widely used instrument designed to assess customer satisfaction with a product, service, or experience, and has demonstrated good reliability and validity in a number of domains, with a Cronbach's alpha coefficient of 0.84 [36, 37]. The questionnaire was developed by Roger, D et al. in 1993 and has been widely used in market research, customer relationship management, and corporate decision-making [38, 39]. Its Cronbach's alpha coefficient in this trial was 0.837.

Statistical analysis

The study was statistically analyzed using SPSS Statistics 27.0 software. Count data were presented as frequencies and percentages (%). For continuous data, normality tests were performed to determine the distributional characteristics of the data. Data were described as mean ± standard deviation ($\bar{x} \pm s$) if they conformed to normal distribution, and median and interquartile range (IQR) if they did not. We conducted a series of comparisons to assess specific hypotheses for within- and between-group differences in outcome variables at different time points between the two groups. We used the Mann–Whitney *U* test to compare the change in scores for each scale between the two groups at baseline and endpoint. And for the differences in the scale scores at baseline and endpoint within the two groups, we used the Wilcoxon test for comparison. Since the data did not satisfy the assumption of normal distribution, nonparametric tests were considered appropriate. The effect size *r* (Pearson's correlation coefficient) was calculated by dividing the *Z* value by the square root of the total sample size to quantify the mean difference between the two groups. In addition, the demographic characteristics between the two groups were compared using the chi-square test. All statistical tests were two-sided, and $P < 0.05$ was considered statistically significant.

Results

Characteristics of the patients

A total of 111 patients participated in this study and were divided into an intervention group ($n = 63$) and a control group ($n = 48$) after strict randomization. Throughout the study period, 7 patients were lost to follow-up (1 patient in the intervention group (0.9%) and 6 patients in the control group (5.4%)), giving an overall loss to follow-up rate of 6.3% for the trial. Therefore, 104 patients were finally included for statistical analysis. A total of 82 out of 104 patients were female, which is a high percentage (82/104, 78.8%). All patients were aged 18 years and above, with a mean (SD) age of 42.1 (9.1) years, and the main age group was dominated by 41–50 years old (43/104, 41.3%), with only 4 patients over 60 years old (3.8%). About half of the patients had high school or higher education (50/104, 48.1%). The majority of patients (69/104, 66.3%) had a permanent residence in the city, and only a few patients had a per capita monthly household income of 12,000 or more (3/104, 2.8%). Almost all patients had health insurance (102/104, 98.1%). The demographic-sociologic baseline characteristics of the patients are shown in Table 1. At baseline, baseline characteristics such as age, gender, education level, place of residence, monthly household income, and health insurance were similar between the intervention and control groups, and there were no statistically significant differences.

Primary outcome: Anxiety and depression levels

In terms of PHQ-4 scores, the intervention group showed a significant decrease in total score scores from baseline after the 3-month MTM-mHealth intervention ($P < 0.026$), whereas the control group remained at baseline levels ($P = 0.586$). The total score in the intervention group was significantly lower than the control group ($P < 0.020$) (Fig. 3). Appendix Exhibit 1 shows that there was no significant difference between the intervention and control groups at baseline for all PHQ-4 scores, including total scores on the anxiety as well as depression dimensions.

After the intervention, there was a significant difference between the two groups in each of these PHQ-4 scores except for "Little interest or pleasure in doing things" ($P = 0.062$) (Appendix Exhibit 2). Total scores on the anxiety ($P < 0.015$) as well as depression ($P < 0.032$) dimensions were significantly lower in the intervention group compared to the control group (Appendix Exhibit 1, Exhibit 2). Further refining the analysis of the entries, the intervention group showed a significant reduction in anxiety levels from baseline ($P < 0.026$), whereas none of the controls showed significant changes (Appendix Exhibit 3).

Secondary outcomes

Fear of cancer recurrence

The total FCR-4 score remained at baseline after the intervention group ($P = 0.507$), and there was no significant difference between baseline and endpoint in the control group ($P = 0.250$) (Fig. 4). There was no significant difference between the total score of the two groups at baseline ($P = 0.124$), but there was a

Table 1 Demographic characteristics of the patients

Characteristics	MTM-mHealth group ($n=62$), n (%)	Control group ($n=42$), n (%)	χ^2 (df)	P value
Gender			1.072 (1)	0.301
Female	51 (82.3)	31 (73.8)		
Male	11 (17.7)	11 (26.2)		
Age group (years)			2.288 (4)	0.683
18–30	5 (8.1)	2 (4.8)		
31–40	19 (30.6)	18 (42.9)		
41–50	27 (43.5)	16 (38.1)		
51–60	9 (14.5)	4 (9.5)		
> 60	2 (3.2)	2 (4.8)		
Academic qualifications			1.661 (5)	0.894
No education	3 (4.8)	2 (4.8)		
Less than high school	28 (45.2)	21 (50.0)		
High School	7 (11.3)	5 (11.9)		
Specialized	10 (16.1)	6 (14.3)		
Undergraduate	13 (21.0)	6 (14.3)		
Graduate school and above	1 (1.6)	2 (4.8)		
Permanent residence address			0.230 (1)	0.631
Rural	22 (35.5)	13 (31.0)		
Urban	40 (64.5)	29 (69.0)		
Per capita monthly income (CNY)a			9.122 (6)	0.167
Less than 600	4 (6.5)	9 (21.4)		
600–3000	20 (32.3)	11 (26.2)		
3000–6000	27 (43.5)	15 (35.7)		
6000–9000	8 (12.9)	4 (9.5)		
9000–12,000	1 (1.6)	2 (4.8)		
12,000–15,000	0 (0.0)	1 (2.4)		
≥ 15,000	2 (3.2)	0 (0.0)		
Coverage of medical expenses			5.906 (4)	0.206
Resident medical insurance	13 (21.0)	16 (38.1)		
Employee medical insurance	25 (40.3)	14 (33.3)		
New rural cooperative medical insurance	23 (37.1)	10 (23.8)		
Commercial medical insurance	0 (0.0)	1 (2.4)		
No medical insurance	1 (1.6)	1 (2.4)		

significant difference between the two groups at follow-up after 3 months ($P<0.001$), with a significant increase in the total score of the FCR-4 score in the control group compared to the intervention group (Fig. 4). There was no significant difference in the scores between the two groups at baseline (Table 2), and the two groups showed extremely significant differences in the scores at follow-up, with a significant increase in the scores in the control group compared to the intervention group (Table 3). The intervention group showed a decrease in all scores compared to baseline, with a significant decrease in entry 1 ($P<0.047$), while the control group showed an increase in all scores, with a significant increase in entry 4 ($P<0.027$) (Table 4).

Quality of life

There were no significant differences in quality of life between the two groups for each of the scores as well as the total score of the scores at baseline (Fig. 5 and Table 5) but after the intervention, the scores of the intervention group on the anxiety/depression dimension were significantly lower ($P<0.036$) and significantly lower than the scores of the control group ($P<0.005$). There was no significant change in the pre- and post-intervention

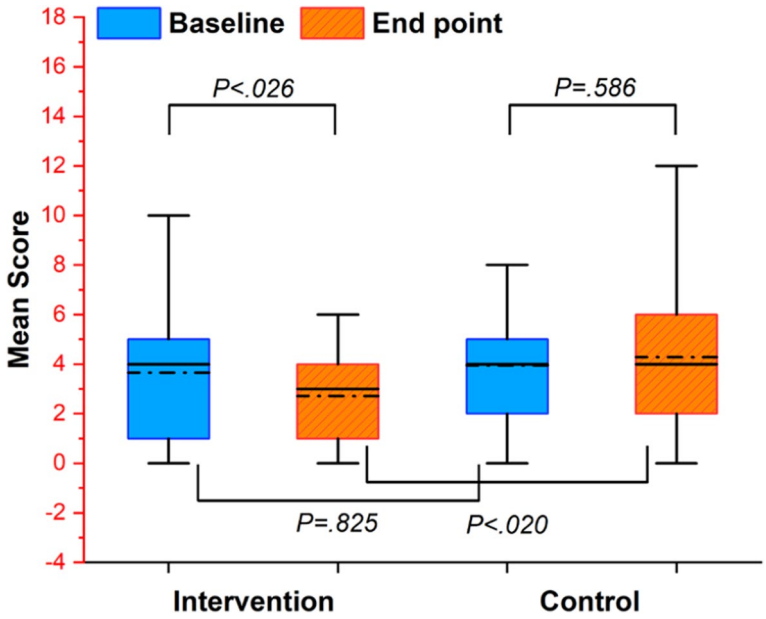

Fig. 3 Mean PHQ-4 scores of the two groups before and after the intervention

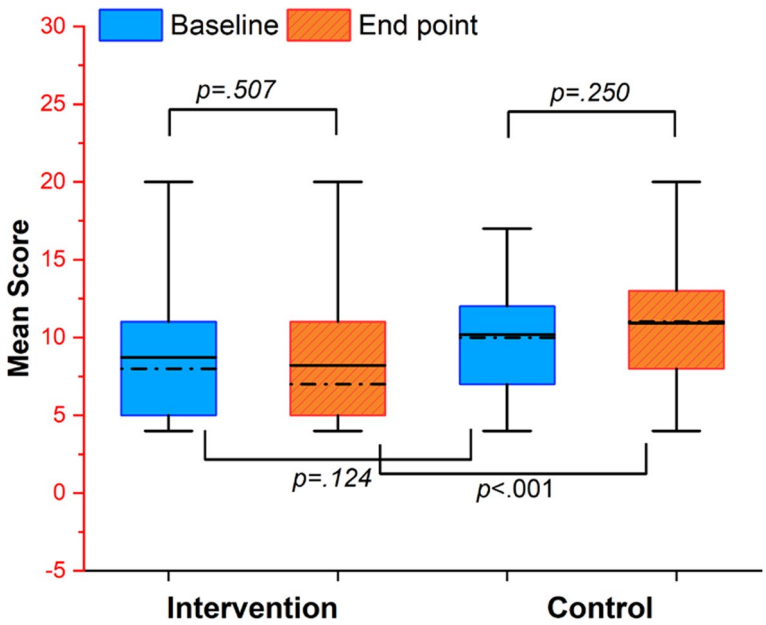

Fig. 4 Mean FCR-4 scores of the two groups before and after the intervention

scores of the control group (Tables 5 and 6). The total quality of life score decreased after the intervention in the intervention group ($P=0.056$), and there was no significant change in the control group compared to baseline ($P=0.640$) (Fig. 5). In addition, the VAS score was significantly higher in the intervention group ($P<0.030$) and significantly higher than the control group ($P<0.030$). There was no significant change in the scores of the control group before and after the intervention (Tables 5 and 6).

Health education satisfaction

Health education satisfaction was assessed in both groups after 3 months using CSQ-3 for the three dimensions

Table 2 Scores of FCR-4 at baseline in the intervention and control groups

FCR-4	MTM-mHealth group		Control group		*Z*	*P* value
	Median (P25–P75)	Mean	Median (P25–P75)	Mean		
F1	3.00 (2.00–3.00)	2.55	3.00 (1.75–3.00)	2.81	1.173	0.241
F2	3.00 (1.00–3.00)	2.50	3.00 (1.75–3.00)	2.79	1.143	0.253
F3	2.00 (1.00–3.00)	2.31	3.00 (2.00–3.00)	2.69	1.567	0.117
F4	2.00 (1.00–2.00)	1.84	2.00 (1.00–2.25)	1.90	0.186	0.853

Table 3 Scores of FCR-4 at the end point of the study in the intervention and control groups

FCR-4	MTM-mHealth group		Control group		*Z*	*P* value
	Median (P25–P75)	Mean	Median (P25–P75)	Mean		
F1	2.00 (1.00–3.00)	2.21	3.00 (2.00–4.00)	2.86	2.885	0.004
F2	2.00 (1.00–3.00)	2.15	3.00 (2.00–4.00)	2.93	3.279	0.001
F3	2.00 (1.00–3.00)	2.06	3.00 (2.00–4.00)	2.83	3.513	< 0.001
F4	1.00 (1.00–2.00)	1.79	2.00 (1.00–3.00)	2.31	2.648	0.008

Table 4 Intragroup comparison results for the FCR-4 (end point–baseline)

FCR-4	MTM-mHealth group			Control group		
	MD	*Z*	*P* value	MD	*Z*	*P* value
F1	−0.34	−1.987	0.047	0.05	0.463	0.643
F2	−0.35	−1.913	0.056	0.14	0.737	0.461
F3	−0.25	−1.452	0.146	0.14	0.973	0.331
F4	−0.05	−0.316	0.752	0.41	2.211	0.027

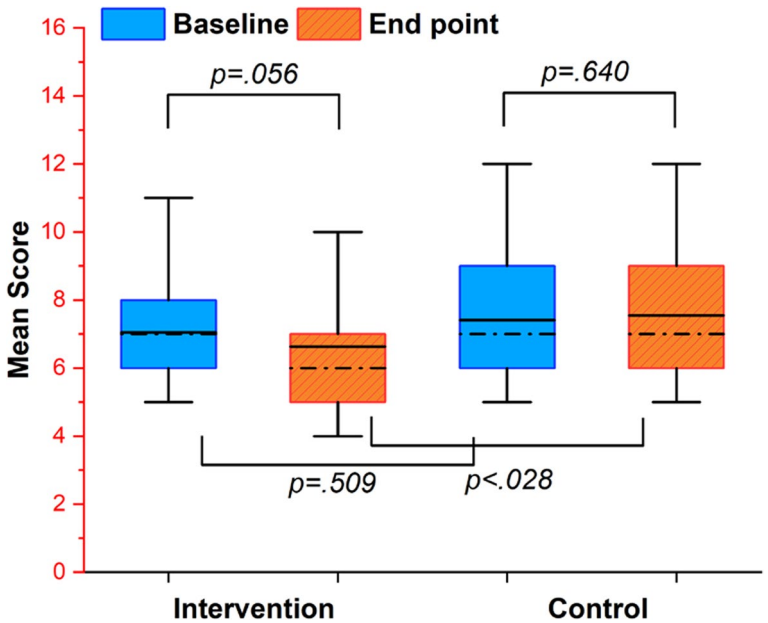

Fig. 5 Mean EQ-5D-5L scores of the two groups before and after the intervention

Table 5 Median scores of EQ-5D-5L for both groups at baseline and end point

EQ-5D-5L	MTM-mHealth group		Control group		*Z*	*P* value
	Median (P25–P75)	Mean	Median (P25–P75)	Mean		
Mobility						
Baseline	1.00 (1.00–2.00)	1.4	1.00 (1.00–1.00)	1.33	−0.46	0.648
End point	1.00 (1.00–2.00)	1.24	1.00 (1.00–1.00)	1.17	−0.85	0.393
Self-care						
Baseline	1.00 (1.00–1.00)	1.08	1.00 (1.00–1.00)	1.15	0.992	0.321
End point	1.00 (1.00–1.00)	1.15	1.00 (1.00–2.00)	1.5	2.539	0.011
Usual activities						
Baseline	1.00 (1.00–1.00)	1.11	1.00 (1.00–1.00)	1.21	0.862	0.389
End point	1.00 (1.00–1.00)	1.13	1.00 (1.00–1.25)	1.33	1.592	0.111
Pain/discomfort						
Baseline	2.00 (1.00–2.00)	1.68	2.00 (1.00–2.00)	1.74	0.342	0.733
End point	2.00 (1.00–2.00)	1.61	2.00 (1.00–2.00)	1.69	0.377	0.706
Anxiety/depression						
Baseline	2.00 (1.00–2.00)	1.77	2.00 (1.00–2.00)	1.9	0.574	0.566
End point	1.00 (1.00–2.00)	1.5	2.00 (1.00–2.00)	1.86	2.793	0.005
Visual analog scale (VAS)						
Baseline	80.00 (63.25–91.00)	75.85	89.00 (75.75–100.00)	72.6	−0.48	0.634
End point	80.00 (60.00–92.75)	83.13	74.00 (60.00–100.00)	73.45	−2.17	0.03

of Demand fulfillment, Quality Evaluation, and Re-acceptance. After the intervention, the scores of all three dimensions were significantly higher in the intervention group than in the control group (Table 7) and the total score of the scores was significantly higher than in the control group ($P < 0.019$).

Discussion

Principal findings

Overview

For patients with DTC, especially those categorized as high-risk in the assessment of risk factors for first postoperative recurrence, active adherence to postoperative medical advice, including TST therapy and self-health management after receiving I-131 treatment, is crucial. Although the mortality rate of DTC is low compared with other types of cancer, patients may experience lax self-management during the prognostic process, especially lax control of iodine-containing foods in their daily diets or intake of foods and beverages that may interfere with the effects of TSH-inhibiting medications, which may adversely affect the outcome of treatment. Adverse effects of postoperative and pharmacological treatments may be exacerbated by patients' poor health behaviors, which may not only cause physical discomfort, but may also further increase psychological stress and reduce quality of life. Therefore, emphasizing strict adherence to medical advice and effective self-health management in postoperative patients is essential to improve treatment outcomes and overall well-being of DTC patients. In the field of oncology, postoperative health management plays a key role in patient recovery and prognosis. Scientific studies have shown that the Multi-Theoretical Model (MTM) provides comprehensive theoretical support for promoting and maintaining healthy behaviors by integrating multiple theories of health behavior change [40]. This is similar to the Integrated Theory of Health Behavior Change (ITHBC) model used in our previous study [41]. The health management model constructed under the guidance of the health theory model helps patients to improve their bad life habits, which in turn improves their quality of life and health status. This study provides DTC patients with a more convenient and scientific approach to postoperative health management of cancer patients by guiding patients to change adverse health behaviors based on a theoretical model of health behavior.

In comparing related studies, a study by Tamminga SJ et al. revealed that e-health interventions were effective in promoting the return to work of cancer patients [5]. However, this study did not incorporate an authoritative theoretical model of health behavior change in terms of study design and interpretation of results. We have therefore improved our study by incorporating a sound theoretical rationale at the design stage, which provides more solid theoretical support and practical evidence for the

Table 6 Intragroup comparison results for EQ-5D-5L (end point–baseline)

Group	Mobility			Self-care			Usual activities			Pain/discomfort			Anxiety/depression			VAS		
	MD	*Z*	*P* value	MD	*Z*	*P* value	MD	*Z*	*P* value	MD	*Z*	*P* value	MD	*Z*	*P* value	MD	*Z*	*P* value
Intervention	−0.16	−1.4	0.162	0.07	0.551	0.582	0.02	0.302	0.763	−0.07	−1	0.605	−0.22	−2.101	0.036	7.28	2.174	0.030
Control	−0.16	1.604	0.109	0.35	1.572	0.116	0.12	1.02	0.308	−0.05	0	0.721	−0.04	−0.185	0.853	0.85	−0.17	0.869

Table 7 Median scores of the degree of satisfaction with health education for both groups at end point

CSQ-3	MTM-mHealth group		Control group		*Z*	*P* value
	Median (P25–P75)	Mean	Median (P25–P75)	Mean		
ALL	11.00 (9.00–12.00)	10.44	9.55 (9.00–12.00)	2.86	−2.34	0.019
Demand fulfillment	3.00 (3.00–4.00)	3.23	3.00 (2.00–4.00)	3.26	−2.16	0.031
Quality Evaluation	4.00 (3.00–4.00)	3.56	3.00 (3.00–4.00)	3.43	−1.91	0.056
Re-acceptance	4.00 (3.00–4.00)	3.65	3.00 (3.50–4.00)	9.55	−2.00	0.045

application of mHealth interventions. Similarly, a study by Wang L. et al. demonstrated that a mHealth application based on the transtheoretical model (TTM) can help women with PCOS to make lifestyle changes [42]. Although the study by Wang L. et al. used the traditional theory of health change, in order to explore the potential of the new generation of theories of health change for application in health intervention research, a more comprehensive multivariate theoretical model (MTM) was chosen as the theoretical framework for this study. Furthermore, despite the growing number of mHealth studies, authoritative health theories have not been widely adopted as a guide for health interventions in the specific population of cancer patients, especially in postoperative health care. This study aims to fill this gap by applying MTM theory to provide a scientific and theoretical mHealth intervention program for postoperative health management in cancer patients.

Primary outcomes

After the MTM-mHealth intervention, the intervention group showed a significant reduction in the PHQ-4 scores compared to baseline, and the total score significantly decreased to a lower level compared to the control group, proving that the MTM-mHealth intervention model has a significant improvement effect on the anxiety and depression levels of the postoperative patient population of DTC. Further analysis of the PHQ-4 entries and dimensions showed that the improvement in anxiety levels was more significant in the intervention group ($P<0.026$), while the improvement in depression levels was not significant. There was no significant improvement in anxiety and depression levels in the control group. Comparative between-group analyses of the entries showed highly significant differences. Related studies have shown that patients suffering from cancer maintain high levels of anxiety throughout the life cycle, and mHealth management support interventions for cancer patient groups, as well as scientific health guidance, can effectively reduce the anxiety level of patients, which is consistent with the results of our study [43]. For the changes in depression levels, it may be related to the specificity of the patient group itself. DTC usually has a better prognosis, but postoperative recurrence and survival remain an important clinical issue. In addition to traditional biomedical factors, psychosocial factors, particularly depressed mood, have been shown to be associated with survival in patients with a wide range of cancers [44]. Patients with DTC have an extremely high postoperative survival rate, and the patients themselves, after initial as well as ongoing learning about the subject, showed relatively nonsignificant post-intervention manifestations of depressed mood compared with anxiety ($P=0.062$), possibly related to the efficacy of the intervention diminishing over time, but a decrease in scores compared to the control group. In the present study, we collected data on the PHQ-4 at baseline and three months after the intervention. By the Wilcoxon test, we found that the depression dimension scores of the intervention group were lower than the baseline after 3 months (MD $=-0.46$, $Z=1.87$, $P=0.062$), indicating that the level of depression improved during this time, but not significantly. However, through the Mann–Whitney *U* test, we found a medium effect significant improvement in the depression dimension scores of the intervention group compared to the control group at 3 months ($Z=2.141$, $P=0.032$, $r=0.210$), and although the reduction in the within-group depression scores of the intervention group did not reach the traditional level of statistical significance ($P<0.050$), this result still suggests a trend toward a possible improvement in depression levels, a trend that may have practical clinical significance.

When discussing the effect sizes of this study, since the data did not conform to a normal distribution, we calculated the corresponding effect sizes based on r, and we found that there was a significant difference between the experimental group and the control group in terms of the levels of anxiety and depression ($Z=2.323$, $P=0.030$, $r=0.228$). This indicates a moderate difference between the two groups. When the PHQ-4 was split into anxiety and depression dimensions for analysis, anxiety levels remained moderately different between the two groups ($Z=2.44$, $P=0.015$, $r=0.239$). Depression levels were also moderately different between the two groups ($Z=2.141$, $P=0.032$, $r=0.210$). This effect size is consistent with previous findings, which supports the validity of the new

health management approach [18]. Considering the limitations of current health management approaches, our findings provide a new perspective on postoperative cancer management.

Secondary outcomes

FCR-4 scores remained at baseline levels in the intervention group after 3 months of intervention ($P=0.507$),while they increased significantly in the control group. The available results seem to be difficult to interpret whether our intervention improved patients' level of fear of cancer recurrence. However, the fact that the level of fear of cancer recurrence did not increase further in the intervention group compared with the control group, which had a significantly higher FCR-4 score ($P<0.001$), may explain the potential intervention improvement efficacy of our intervention model in a sideways manner. Routine nursing care did not provide significant improvement in the control of recurrence fear levels in cancer patients, which is consistent with our findings [45].

Level of fear of cancer recurrence ($Z=3.552$, $P<0.001$, $r=0.3483$) suggests a statistically significant and clinically meaningful greater moderating effect of the intervention on the level of fear of cancer recurrence. For EQ5D-5L, there was a moderate positive difference between the two groups ($Z=2.196$, $P=0.028$, $r=0.215$), which implies that the intervention group had a higher average health status or quality of life than the control group. This may indicate that the treatments or interventions in the intervention group were more effective in improving the health status and quality of life of the patients. There was a moderate negative difference in the VAS visualization scale ($Z=-2.165$, $P=0.030$, $r=-0.212$), which suggests that the intervention group had a lower average intensity of pain or severity of adverse experiences than the control group.

Fear of cancer progression is an important issue associated with reduced quality of life in patients with DTC, and there may be a potential benefit of the MTM-mHealth intervention model on fear of cancer progression, and our study is the first to show that the MTM-mHealth intervention model can improve anxiety and fear of cancer progression.

The MTM-mHealth intervention model showed a borderline significant impact on the quality of life in DTC patients, with a decrease in scores and a clinically significant trend ($P=0.056$). A noteworthy aspect of our study was the impact of the MTM-mHealth intervention on overall quality of life in the absence of significant changes in physical function and physical symptoms ($P<0.028$). This finding is similar to the results of a prostate cancer lifestyle trial, which reported no significant changes in physical functioning in prostate cancer patients after lifestyle interventions (exercise, diet, and stress management) [46, 47]. The slightly significant increase in overall quality of life in our study suggests that the MTM-mHealth intervention may improve cancer-related quality of life more by improving psychological functioning than physical functioning and physical symptoms. This finding implies that the intervention may be particularly valuable for addressing non-physical aspects of cancer survival that are known to have a significant impact on patients' overall health. Further research is needed to confirm these preliminary findings and to elucidate how the intervention specifically contributes to improving the overall quality of life of cancer patients.

Limitations

There are several limitations of this study. First, this study was a single-center, single-blind, randomized controlled trial and included only post-DTC patients, which may limit the generalizability and replication of the findings. Second, the baseline to post-intervention change in FCR-4 in the intervention group was not significant ($P=0.507$), which may be due to the small sample size, which in turn affects the statistical test power, making it possible that the study may have failed to accurately detect an effect that was actually present. Therefore, future studies need to increase the sample size to further validate our findings. Third, the short observation period (3 months) reported in this study does not allow for the assessment of long-term intervention effects. To address this issue, we plan to continue the published study protocol with long-term follow-up studies of 6 and 12 months, focusing on patients' clinical outcomes and improvements in health behaviors. Finally, consecutive enrollment may have resulted in a gradual diminution of the intervention effect over time, which may have reduced the intervention efficacy of this study.

Conclusions

This study demonstrates that an MTM-based mHealth intervention strategy offers an innovative and promising approach to postoperative health management for DTC patients. This strategy showed exploitable potential in the postoperative DTC patients in this study, where it was able to significantly improve patients' anxiety levels, reduce the fear of cancer recurrence, and enhance patients' quality of life. It is worth noting that the study did not show significant improvement in depression status, which needs to be verified in further trials. In addition, this intervention approach may help to enhance patient compliance with postoperative treatment regimens, thereby improving the overall outcome of treatment.

The results of this study provide new perspectives on health management programs for cancer prognosis and rehabilitation and provide further scientific justification for the development of mHealth applications in the field of health management. These findings emphasize the importance of theory-based mobile interventions in promoting patients' physical and mental health and enhancing treatment outcomes, providing guidance for future clinical practice and health policy development.

Appendix

Exhibit 1. Scores of PHQ-4 at baseline in the intervention and control groups.

PHQ-4	MTM-mHealth group		Control group		*Z*	*P* value
	Median (P25–P75)	Mean	Median (P25–P75)	Mean		
Anxiety	2.00 (1.00–3.00)	1.94	2.00 (1.00–3.00)	2.19	0.356	0.722
A1	1.00 (0.00–2.00)	1.06	1.00 (1.00–2.00)	1.19	0.468	0.640
A2	1.00 (0.00–1.00)	0.87	1.00 (0.00–1.00)	1.00	0.474	0.635
Depression	2.00 (0.00–2.00)	1.73	2.00 (0.00–2.00)	1.76	−0.145	0.884
D1	1.00 (0.00–1.00)	0.89	1.00 (0.00–1.00)	0.98	0.181	0.856
D2	1.00 (0.00–1.00)	0.84	1.00 (0.00–1.00)	0.79	−0.500	0.618

Exhibit 2. Scores of PHQ-4 at the end point of the study in the intervention and control groups.

PHQ-4	MTM-mHealth group		Control group		*Z*	*P* value
	Median (P25–P75)	Mean	Median (P25–P75)	Mean		
Anxiety	2.00 (0.75–2.00)	1.44	2.00 (1.00–3.00)	2.29	2.44	0.015
A1	1.00 (0.00–1.00)	0.85	1.00 (0.75–2.00)	1.31	2.073	0.038
A2	1.00 (0.00–1.00)	0.58	1.00 (0.00–2.00)	0.98	2.286	0.022
Depression	1.00 (0.00–2.00)	1.27	2.00 (0.00–3.00)	2	2.141	0.032
D1	0.50 (0.00–1.00)	0.58	1.00 (0.00–1.00)	0.93	2.038	0.042
D2	1.00 (0.00–1.00)	0.69	1.00 (0.00–2.00)	1.07	1.868	0.062

Exhibit 3. Intragroup comparison results for the PHQ-4 (end point–baseline).

PHQ-4	MTM-mHealth group			Control group		
	MD	*Z*	*P* value	MD	*Z*	*P* value
Anxiety	−0.50	−2.22	0.026	0.10	0.253	0.800
A1	−0.21	−1.40	0.162	0.12	0.535	0.592
A2	−0.29	−2.47	0.014	−0.02	−0.16	0.872
Depression	−0.46	−1.87	0.062	0.24	0.981	0.327
D1	−0.31	−2.50	0.012	−0.05	−0.25	0.801
D2	−0.15	−1.05	0.293	0.28	1.731	0.083

Abbreviations

DTC	Differentiated thyroid cancer
MTM	Multi-theory model of health behavior change
TTM	Transtheoretical model
I-131	Iodine-131 radioactive isotope therapy
TST	Thyrotropin suppression therapy
COPD	Chronic obstructive pulmonary disease
ITHBC	Integrated Theory of Health Behavior Change

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12916-024-03652-0.

Additional file 1. CONSORT-eHEALTH

Additional file 2. Differentiated Thyroid Cancer Health Science Push Database

Additional file 3. The content description for the CQS-3

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Authors' contributions

XJS, YBW and YJ conceived and designed thestudy. XJS and YJ drafted the initial protocol. XJS, XMZ, YBW, YJ, JW, SYF, MMJ, XHF and ZA reviewed and revised the manuscript. YBW provided theoretical anmethodological guidance. XJS, YBW, MMJ and XMZ is responsible for the study management. YJ, XHF and XMZ designed the questionnaire. XJS,YJ and XHF are responsible for the study implementation. All authors provided revisions and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the Fourth Affiliated Hospital of Harbin Medical University, Harbin, Heilongjiang Province (2022-WZYS-LLSC-20), and the registration of the study protocol with the China Clinical Trial Registry (ChiCTR2200064321) was completed.

Consent for publication
All authors have read and approved the manuscript for publication.

Competing interests
The authors declare no competing interests.

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