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An online mind-body program improves mental health and quality of life in primary biliary cholangitis: A randomized controlled trial

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Abstract

Background and Aims: People with primary biliary cholangitis (PBC) experience high rates of mental distress and fatigue despite standard of care therapy. We aimed to assess the impact of an online mind-body intervention on these symptoms.

Methods: This 12-week RCT used sequential mixed-methods evaluation. Alongside standard of care, participants with primary biliary cholangitis were randomized to receive weekly countdown emails, or the intervention consisting of (i) a weekly 20–30 minute-mind-body follow-along video, (ii) weekly 5–10-minute psychology-based "managing chronic disease skills videos," and (iii) 10-minute telephone check-ins. The primary outcome was a change in the Hospital Anxiety and Depression Scale (HADS). Secondary outcomes evaluated changes in fatigue, perceived stress, resilience, and health-related quality of life. ANCOVA determined between-group differences.

Results: Of the 87 randomized patients (control group: n = 44, intervention group: n = 43), the between-group HADS total score improved by 20.0% (95% CI 4.7, 35.2, $p = 0.011$). Significant improvements were seen in depression (25.8%), perceived stress (15.2%), and 2 primary biliary cholangitis-40 domains [emotional symptoms (16.3%) and social symptoms (11.8%)] with a mean satisfaction of 82/100. This corresponded with end-of-study qualitative findings. Although no improvements were observed in fatigue in the main analysis, a significant benefit was observed

Abbreviations: CEGEP, Collège d'enseignement gènèral et professionnel; COM-B, capability, opportunity, motivation model of behavior; HADS, Hospital Anxiety and Depression Scale; MFIS, Modified Fatigue Impact Scale; PBC, primary biliary cholangitis; PSS, Perceived Stress Scale; UDCA, ursodeoxycholic acid.

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in the subgroup of intervention participants (20/36;56%) who completed the mind-body video routine at least 3 times per week.

Conclusion: This intervention improved measures of mental wellness and quality of life with high satisfaction and reasonable adherence. Future studies could explore strategies to optimize adherence and target fatigue.

INTRODUCTION

Primary biliary cholangitis (PBC) is female predominant, chronic, autoimmune liver disease initiated by immune-mediated damage to the small intrahepatic bile ducts.[1] North America has the highest prevalence of PBC in the world (21.8 per 100,000), with rising incidence and prevalence rates.[2] Ursodeoxycholic acid, the first-line therapy for PBC, is associated with transplant-free survival[1,3] but does not target the debilitating physical and emotional symptoms of PBC, which include chronic fatigue, itch, impaired HRQOL, and mental health comorbidities (anxiety, depression, and stress).[1,4,5] These symptoms predict poor prognosis and increased mortality.[5–8]

Clinical experts and people living with PBC have identified the need for self-management tools that can be provided alongside pharmacological therapy to reduce symptom burden.[5] Mind-body interventions (including movement, breathwork, meditation, and psychology-based practices) improve fatigue, HRQOL, and mental health in other chronic disease populations.[9–13] However, no randomized trials have observed the impact of these interventions in PBC. We conducted a pilot study of an online mind-body wellness intervention in PBC that demonstrated high feasibility and acceptability.[14] Participants in the pilot study highlighted areas for refinement, including a revised chronic disease skills program, more options for mindful movement, and gamification elements.

After making these refinements, the purpose of the current study was to use a mixed-methods approach consisting of a RCT and qualitative interviews to assess the effects of the revised 12-week, online intervention on the primary outcome (change in the Hospital Anxiety and Depression Scale [HADS])[15] and secondary outcomes (fatigue, perceived stress, resilience, and HRQOL). We were also interested in assessing program outcomes, including adherence, retention, and acceptability. We hypothesized that the program would positively affect primary and secondary outcome measures compared to the control group and that the intervention would be associated with high adherence, retention, and acceptability. The specific aims of the qualitative portion of the study were to (a) explore participant experiences with the program and (b) explore perceptions of novel program components, including the chronic disease skills program and gamification.

METHODS

Study design

This mixed-methods study contained a 2-arm RCT and post-program qualitative interviews. Ethics approval was received from the Health Research Ethics Board (Pro00112622). The study was conducted in accordance with both the Declarations of Helsinki and Istanbul. It was registered at www.clinicaltrials.gov (NCT05374200), and written informed consent was obtained from each participant. Remuneration was not provided to study participants.

Setting, participants, and randomization scheme

Participants were recruited through the Canadian PBC Society's email list until the target sample size of eligible participants was reached (July 2021 and September 2021). Inclusion criteria were (1) age ≥ 18 years, and (2) a self-identified diagnosis of PBC. Exclusion criteria were (1) a HADS depression subcomponent score $>$ 10 (at risk for severe depression) and (2) the inability to provide informed consent in English. Patients with (HADS) scores $>$ 10 were referred to resources for psychiatric follow-up. Individuals who met eligibility criteria were invited to complete baseline assessments before randomization. The study statistician generated and validated the allocation tables to be uploaded to the Research Electronic Data Capture data management platform.[16] These lists were concealed from participants, study staff, and team members. Research Electronic Data Capture was used to allocate participants to a treatment group based on the allocation sequence. A parallel design with an equal allocation ratio (1:1) was used, whereby participants were randomized to either the intervention or the control group. Control group participants were offered the option to take part in the intervention after their 12-week control period.

Study arms

Control arm

Participants assigned to the control arm continued to receive standard of care treatment for PBC from their treating hepatologist. They also received weekly emails containing an inspirational quote and a countdown to the end of their control period. An example of these emails is outlined in Appendix A, http://links.lww.com/HC9/A635.

Intervention arm

Participants in the intervention arm received access to the 12-week intervention in addition to the standard of care. The program content varied from week to week and was distributed in a gated fashion, with new content being "unlocked" each week. Gamification elements included a leaderboard, which used pseudonyms and compared points and badge achievements across participants. Each week of the intervention consisted of 3 components for which more details are provided in Appendix B, http://links.lww.com/HC9/A636:

1. Weekly video routines. A 20–30-minute video consisting of guided meditation, breathwork, and mindful movement (patient choice of yoga, tai chi, or chair movement). Participants were encouraged to complete the video routine a minimum of 3 times per week.
2. Additional video content. Additional content included were (1) a 3–5-minute chronic disease skills video and activity, informed by acceptance and commitment therapy,[17] and (2) a 3–5-minute "PBC tip" video from a PBC physician.
3. Weekly check-ins. Participants received weekly, 10-minute phone calls from a program facilitator. In order to offer a natural flow of conversation, these check-ins did not follow a standardized script, but facilitators were given 3 main topic areas to review with participants: answering questions from the week prior, reviewing progress, and facilitating goal setting.

During the program, participants in the intervention group were given the option to attend monthly group zoom sessions hosted by the Canadian PBC Society. These sessions included live sessions from program experts and time for participants to discuss the program in breakout rooms.

Data collection and outcome measures

Quantitative data collection

Quantitative data was collected through Research Electronic Data Capture.[16] Demographic and disease information was collected from patient self-report at baseline. Primary and secondary outcome measures were collected at baseline (October 2021) and after the study period (12 wk post-baseline) (January 2021). Our primary outcome was changes in the HADS, a 14-item scale that differentiates anxiety symptoms from depressive symptoms and provides severity scores in each dimension in addition to an overall score.[15] The HADS was selected as the primary outcome measure upon consultation with our patient partners, who identified anxiety and depression as priorities. Moreover, the HADS has been validated for use in patients with chronic liver disease, and minimal clinically important differences have been defined.[18,19] Our secondary outcome measures were changes in the: Perceived Stress Scale-10—a 10-item scale to assess the degree to which life has been experienced as unpredictable, uncontrollable, and overloaded[20]; Connor-Davidson Resilience Scale—a 25-item resilience scale[21]; Modified Fatigue Impact Scale (MFIS)—a 21-item scale to assess the extent to which fatigue has impacted life[22]; and PBC-40—a 40-item disease HRQOL scale.[23]

Adherence to the weekly video routine was assessed using an end-of-program survey, administered 12 weeks post-baseline, and confirmed through weekly check-ins. To help understand adherence, patients were asked to complete questionnaires at baseline and at the end of the study that assessed capability, opportunity, and motivation to take part in the video routine at least 3 times per week.[23] This survey was informed by the capability, opportunity, motivation model of behavior (COM-B) model of behavior, which outlines that for a behavior to occur, an individual must have the capability, opportunity, and motivation to perform the behavior.[24] Satisfaction was assessed through a survey at the end of the program. Participants were sent follow-up questionnaires 8 weeks after completing the intervention to assess continued engagement with program practices.

To assess the impact of adherence, we explored changes in the primary outcome (anxiety and depression through the HADS) and selected secondary outcomes (fatigue through the MFIS and the PBC-40 fatigue domain) in the subgroup of participants who met the adherence target of completing the video routine at least 3 times a week.

Qualitative data generation

Purposeful maximum variation sampling[25] was employed to understand a range of adherence and satisfaction experiences. Semi-structured interviews were conducted with selected participants by means of telephone from February to March 2022 using a qualitative descriptive approach.[26] The interview guide was informed by the COM-B model of behavior[24] (Appendix D, http://links.lww.com/HC9/A638). All interviews were recorded and transcribed verbatim.

Data analysis

Sample size and statistical analysis

The sample size calculation was based on the primary outcome, anxiety and depression (HADS total score) results from an RCT of a similar intervention in inflammatory bowel disease[27] and pilot data in PBC.[14] With a 0.05 alpha and 80% power and accounting for a 15% dropout rate, 40 participants per group (80 participants in total) were deemed adequate to show a statistically significant difference by independent *t*-test ($d = 0.71$ effect size).

Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 21.0.[28] Demographic measures and program outcomes are presented using descriptive statistics[mean ± SD for continuous variables, frequency (%) for nominal variables]. The normality of continuous variables was examined using histograms and Q-Q plots. ANCOVA was used to analyze the impact of the intervention on the HADS. The absolute impact of the intervention was derived from a linear regression model predicting change in HADS adjusted for baseline HADS. The relative impact was defined as the percentage change in the HADS total score at the end of the study compared to the baseline. The same ANCOVA procedures were used to test secondary outcomes. Within-group differences were analyzed using paired-sample *t*-tests. Statistical significance was established at a 2-tailed *p*-value of < 0.05. The intention-to-treat analyses imputed missing values with the last observation carried forward method. A per-protocol analysis was used as a secondary method of analyzing the data. Finally, ANCOVA was used to evaluate the impact of adherence in the subgroup of patients who met the adherence target.

Qualitative data analysis

Data generation and analysis occurred iteratively to enable the refinement of the interview guide and exploration of emerging themes. Interviews were analyzed using a theoretical thematic approach, whereby data were analyzed inductively, with transcripts coded, then grouped into larger categories, then themes.[29,30] Analysis was completed by 2 members of the study team who developed a coding framework, with disagreements resolved through consensus. NVivo was used for data management.[31]

RESULTS

A total of 123 patients were screened for the RCT portion of the study, 22 declined to participate and 14 were excluded (HADS depression subcomponent score > 10). Eighty-seven patients were randomized to the intervention ($n = 43$) and the control ($n = 44$) group. After the 12-week intervention, the overall retention was 89.7% ($n = 6$ unable to begin the intervention during the specified period, $n = 1$ lost due to follow-up in the intervention arm, and $n = 2$ lost due to follow-up in the control arm) with 78 patients remaining at the end of study (Figure 1).

All participants were invited to engage in the qualitative portion of the study. Twenty-five participants consented to an interview, with 11 eventually interviewed.

Patient baseline characteristics

The mean age of participants in the RCT was 59.8 ± 10.6 y and 98% were female. The intervention

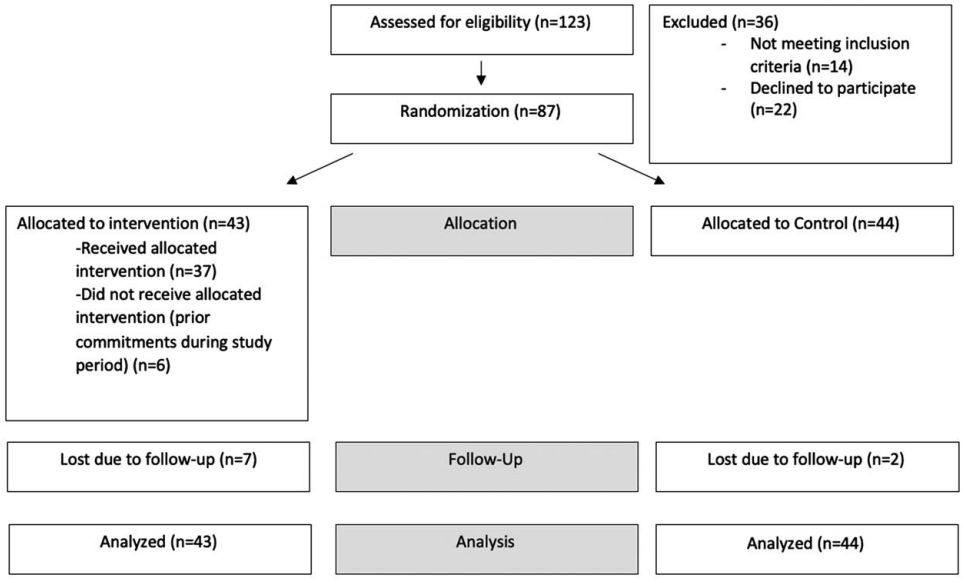

FIGURE 1 Patient recruitment and flow through the study.

group included a greater proportion of patients who were not on any medication for PBC [(4 (9.3%) vs. 0), $p = 0.04$]. Further demographic characteristics are reported in Table 1. The baseline characteristics of the 7 participants in the intervention group with missing post-assessment data were similar to those of participants who completed end-of-study assessments.

Of the 11 individuals who participated in the end-of-study qualitative interviews, 91% were female, with ages ranging from 32 to 82 years (61.1 ± 13.0 y). These characteristics were similar to participants in the main study and are reported in full in Appendix E, http://links.lww.com/HC9/A639.

Primary outcomes

After adjusting for the HADS total at baseline, a significant change was observed in the HADS total and HADS depression scores between baseline and end of study in the intervention arm compared to the control arm. This translated to an absolute improvement of 2.66 (95% CI, 0.628–4.69) and a relative improvement of 20.0% (95% CI 4.72, 35.2 $p = 0.01$) for the HADS total score, and an absolute improvement of 1.44 (95% CI, 0.266–2.61) and a relative improvement of 25.8% (95% CI, 4.77–46.8 $p = 0.02$) for the HADS depression score. No significant differences existed between study groups in HADS anxiety (Table 2).

Secondary outcomes

Data on secondary outcomes are presented in Table 2. There was a significant absolute improvement in the Perceived Stress Scale (2.76; 95% CI: 0.231–5.28, $p = 0.03$), PBC-40 emotional domain (1.36; 95% CI: 0.306–2.42, $p = 0.01$), and PBC-40 social domain (3.08; 95% CI: 0.045–6.17, $p = 0.047$). Relative scores are presented in Table 2. No significant differences existed between study groups in the Connor-Davidson Resilience Scale, MFIS, PBC-40 itch, fatigue, cognitive, or general symptom domains (Table 2). In the per-protocol analysis, there was additionally a significant improvement in the PBC-40 itch domain (Appendix F, http://links.lww.com/HC9/A640).

Program outcomes

Adherence

Of the 36 participants who completed the intervention, 20 (56%) achieved the pre-specified adherence goal of completing the video routine at least 3 times per week: 3 times (n = 10), 4 times (n = 3), 5 times (n = 2), 6 times (n = 3), or 7 times (n = 2) per week. The remaining 16 participants completed the program < 1 time (n = 3), 1 time (n = 7) and 2 times (n = 6) per week. All patients who completed the video routine at least once per week also reported watching the additional video content. Monthly attendance of the optional group sessions ranged from 21% to 51% of participants.

There was a significant absolute decrease in COM-B domains, including physical opportunity (1.24; 95% CI: 0.470–2.01), social opportunity (1.25; 95% CI: 0.220–2.29), automatic motivation (2.03; 95% CI: 1.06–3.00), physical capability (1.26; 95% CI: 0.357–2.16), and psychological capability (1.23; 95% CI: 0.370–2.08) (Table 2). In the per-protocol analysis, there was additionally a significant improvement in reflective motivation (Appendix F, http://links.lww.com/HC9/A640).

Satisfaction

Rated from 0 to 100 (“not satisfied” to “extremely satisfied”), the mean satisfaction score was 81.5% (SD 15.7%). Participant satisfaction with different program elements is illustrated in Figure 2. Thirty-three (91.7%) participants ranked the amount of information as just right, with 2 (5.6%) indicating too little information and 1 (2.8%) indicating too much information. Twenty-eight (77.8%) participants ranked the time commitment of the programming as just right, with 8 (22.2%) indicating the time commitment was too much.

Continuation

After completing the intervention, participants’ mean perceived likelihood of continuing any element of the program (rated from 0 “not likely” to 100 “extremely likely”) was 82.1 (SD 16.4). Eight-week follow-up data was available for 24/36 of the participants who completed the intervention. Of these participants, 15 (62.5%) indicated that they had accessed the program following study completion.

Subgroup adherence analysis

Among the subgroup of patients who met adherence targets compared to the controls, absolute improvements were noted in the HADS total (4.32; 95% CI: 1.70–6.95), anxiety (1.73:95% CI: 0.021–3.43) and depression subdomains (2.56; 95% CI: 1.35–3.77), as well as the MFIS total (6.89; 95% CI: 2.52–11.25), physical (3.95; 95% CI: 1.58–6.32), and psychosocial subdomains (0.888; 95% CI: 0.077–1.70), and the PBC-40 fatigue domain (3.60; 95% CI: 1.18–6.03) (Table 3).

TABLE 1 Patient baseline characteristics

	Total (n = 87)	Control group (n = 44)	Intervention group (n = 43)
Age (y)	59.8 ± 10.6	59.4 ± 9.9	60.2 ± 11.4
Sex, n (%)			
Male	2 (2.3)	1 (2.3)	1 (2.3)
Female	85 (97.7)	43 (97.7)	42 (97.7)
Other	0 (0)	0 (0)	0 (0)
Relationship status, n (%)			
Married	55 (63.2)	30 (68.2)	25 (58.1)
Living common-law	7 (8.0)	3 (6.8)	4 (9.3)
Divorced/separated	14 (16.1)	6 (13.6)	8 (18.6)
Widowed	4 (4.6)	2 (4.5)	2 (4.7)
Single/never married	5 (5.7)	1 (2.3)	4 (9.3)
Prefer not to answer	2 (2.3)	2 (4.5)	0 (0)
Employment status, n (%)			
Employed	40 (46.0)	19 (43.2)	21 (48.8)
Unemployed	34 (39.1)	16 (36.4)	18 (41.9)
Prefer not to answer	13 (14.9)	9 (20.5)	4 (9.3)
Highest education achieved, n (%)			
No post-secondary degree, certificate, or diploma	21 (24.1)	12 (27.3)	9 (20.9)
Trade certificate or diploma from a vocational school of apprenticeship training	4 (4.6)	3 (6.8)	1 (2.3)
Non-university certificate or diploma from a community college, CEGEP, school of nursing, etc.	22 (25.3)	15 (34.1)	7 (16.3)
University certificate below bachelor's level	3 (3.4)	1 (2.3)	2 (4.7)
Bachelor's degree	16 (18.4)	7 (15.9)	9 (20.9)
University degree or certificate above bachelor's degree	18 (20.7)	5 (11.0)	13 (30.2)
Unknown	3 (3.4)	1 (2.3)	2 (4.7)
Years since diagnosis	9.6 ± 8.4	9.7 ± 7.9	9.6 ± 8.9
Cirrhosis status, n (%)			
No cirrhosis	50 (57.5)	26 (59.1)	24 (55.8)
Cirrhosis	20 (23.0)	11 (25.0)	9 (20.9)
Unsure	17 (19.5)	7 (15.9)	10 (23.3)
Current PBC medications, n (%)			
None	4 (4.6)	0 (0)	4 (9.3)
UDCA	75 (86.2)	38 (86.4)	37 (86.0)
Obeticholic acid	15 (17.2)	11 (25.0)	4 (9.3)
Fenofibrate	3 (3.4)	2 (4.5)	1 (2.3)
Bezafibrate	6 (6.9)	3 (6.8)	3 (7.0)
Colchicine	0 (0)	0 (0)	0 (0)
Other	12 (13.8)	9 (20.5)	3 (7.0)
Meditation in past 6 mo, n (%)			
Yes	36 (41.4)	20 (45.5)	16 (37.2)
Yoga in past 6 mo, n (%)			
Yes	36 (41.4)	20 (45.5)	16 (37.2)
Tai Chi in past 6 mo, n (%)			
Yes	7 (8.0)	5 (11.4)	2 (4.7)

Abbreviations: CEGEP, Collège d'enseignement général et professionnel; PBC, primary biliary cholangitis; UDCA, ursodeoxycholic acid.

TABLE 2 Anxiety, depression, stress, resilience, fatigue, quality of life, and behavioral outcomes

	Control group (n = 44)		Intervention group (n = 43)				
	Baseline	End of study	Baseline	End of study	Between group absolute improvement (95% CI)	Between group relative improvement (95% CI)	ANCOVA *p*- value Between groups
HADS total	11.6 ± 5.30	13.0 ± 5.56	12.7 ± 5.67	11.0 ± 5.79	2.66 (0.628, 4.69)	20.0 (4.72, 35.2)	0.01[a]
HADS anxiety	6.89 ± 3.42	7.59 ± 3.37	7.37 ± 3.63	6.60 ± 3.61	1.30 (−0.045, 2.65)	16.8 (−0.581, 34.2)	0.06
HADS depression	4.73 ± 2.80	5.41 ± 2.88	5.28 ± 3.07	4.30 ± 3.46	1.44 (0.266, 2.61)	25.8 (4.77, 46.8)	0.02[a]
Connor-Davidson Resilience Scale	26.1 ± 6.27	26.2 ± 5.63	27.7 ± 6.55	28.3 ± 6.62	2.54 (−0.016, 5.09)	9.78 (−0.062, 19.6)	0.05
PSS	17.7 ± 6.54	17.9 ± 6.52	17.5 ± 6.12	15.7 ± 6.13	2.76 (0.231, 5.28)	15.2 (1.28, 29.2)	0.03[a]
MFIS total	59.0 ± 16.3	59.8 ± 15.5	59.1 ± 15.9	56.4 ± 16.5	5.07 (−0.908, 11.0)	8.37 (−1.50, 18.2)	0.10
MFIS physical	27.4 ± 8.42	27.7 ± 7.64	27.4 ± 7.92	25.7 ± 7.45	2.63 (−0.348, 5.60)	9.40 (−1.24, 20.0)	0.08
MFIS cognitive	26.1 ± 8.28	26.4 ± 8.46	26.4 ± 7.88	25.4 ± 8.35	1.85 (−1.362, 5.06)	6.91 (−5.09, 18.9)	0.26
MFIS psychosocial	5.43 ± 1.93	5.73 ± 1.87	5.33 ± 2.02	5.30 ± 2.27	0.595 (−0.222, 1.41)	10.2 (−3.82, 24.3)	0.15
PBC-40 itch	4.36 ± 3.16	4.55 ± 3.00	3.84 ± 3.15	3.40 ± 2.66	1.11 (−0.121, 2.35)	23.6 (−2.57, 50.0)	0.08
PBC-40 fatigue	31.1 ± 8.63	31.1 ± 8.78	31.8 ± 9.13	30.4 ± 9.03	1.38 (−2.25, 5.01	4.39 (−7.16, 15.9)	0.45
PBC-40 cognitive	14.5 ± 4.85	14.4 ± 5.04	14.8 ± 5.56	13.7 ± 5.81	1.14 (−1.11, 3.40)	7.86 (−7.66, 23.4)	0.32
PBC-40 emotional	8.16 ± 2.32	8.25 ± 2.63	8.09 ± 2.72	7.19 ± 2.72	1.36 (0.306, 2.42)	16.3 (3.66, 29.0)	0.01[a]
PBC-40 social	25.8 ± 7.09	25.7 ± 7.47	24.9 ± 8.98	23.2 ± 8.34	3.08 (0.045, 6.17)	11.8 (0.173, 23.7)	0.047[a]
PBC-40 symptom	16.6 ± 4.17	16.7 ± 4.66	16.4 ± 4.01	15.9 ± 4.66	1.10 (−0.854, 3.05)	6.55 (−5.08, 18.2)	0.27
COM-B physical Opportunity	8.59 ± 1.48	8.59 ± 1.45	8.45 ± 1.63	7.38 ± 2.08	1.24 (0.470, 2.01)	14.5 (5.48, 23.4)	0.002[a]
COM-B social Opportunity	8.05 ± 2.34	8.20 ± 2.11	7.62 ± 2.80	6.93 ± 2.74	1.25 (0.220, 2.29)	15.3 (2.70, 28.1)	0.02[a]
COM-B reflective motivation	9.18 ± 1.15	9.02 ± 1.27	9.36 ± 0.958	8.38 ± 1.83	0.676 (−0.008, 1.36)	7.49 (−0.089, 15.1)	0.05
COM-B automatic motivation	7.61 ± 2.15	7.68 ± 1.97	7.12 ± 2.51	5.62 ± 2.76	2.03 (1.06, 3.00)	26.7 (13.9, 39.4)	< 0.001[a]
COM-B physical capability	8.34 ± 1.68	8.30 ± 1.61	8.19 ± 1.92	7.05 ± 2.53	1.26 (0.357, 2.16)	15.3 (4.34, 26.3)	0.007[a]
COM-B psychological capability	8.68 ± 1.44	8.77 ± 1.31	8.83 ± 7.55	1.51 ± 2.52	1.23 (0.370, 2.08)	14.1 (4.23, 23.8)	< 0.001[a]

[a]Statistical significance was established at a 2-tailed p-value of < 0.05.

Abbreviations: COM-B, capability, opportunity, motivation model of behavior; HADS, Hospital Anxiety and Depression Scale; MFIS, Modified Fatigue Impact Scale; PBC, primary biliary cholangitis; PSS, Perceived Stress Scale.

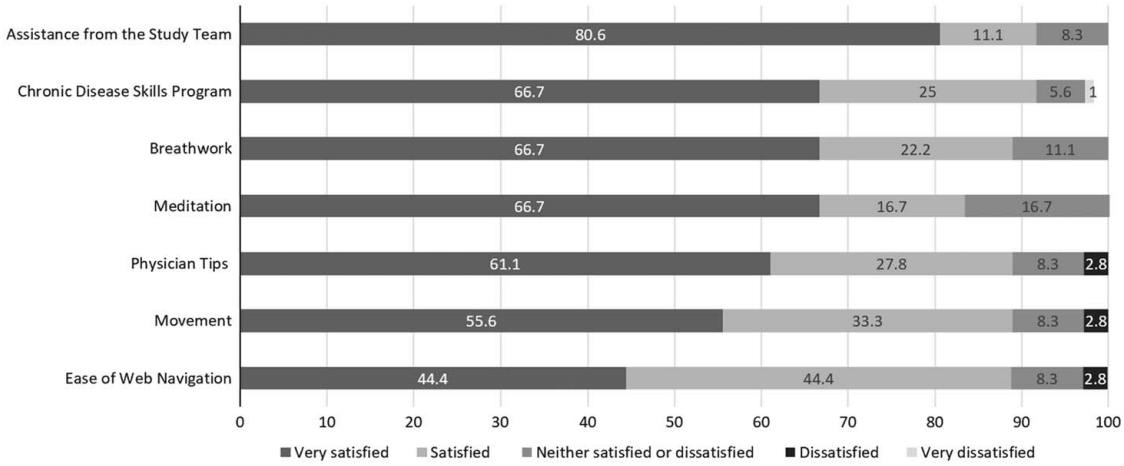

FIGURE 2 Participant satisfaction with core and optional elements of the Peace Power Pack program, scored using a 5-point Likert Scale from very satisfied to very dissatisfied.

Qualitative findings

Three main themes emerged as follows: (i) Understanding the impact of program components on disease management; (ii) Mixed reception: exploring experiences with gamification; and (iii) Bridging the transition: long-term adoption of program practices.

Theme # 1: Understanding the impact of program components on disease management

Participants experienced fatigue that limited their ability to work, interact with family, and perform daily tasks. Many highlighted the unpredictable nature of this fatigue: "It's kind of like from Forrest Gump, life is like a box of chocolates. I never know what my energy is going to be like when I wake up" (57). Some participants recognized that they tended to "overdo it on good days" which resulted in "crashing and needing days to recover." Participants described how learning about pacing through the chronic disease skills program helped them combat this "boom and bust cycle." One participant talked further about this: "We learned about holding yourself back and doing the same amount of stuff on days where you feel normal. And that was a profound thing (135)." Participants clarified that while the "fatigue was still there," pacing allowed them to "manage energy better."

They also spoke of the "underlying stress and anxiety" that came from wondering if their disease would progress, which they felt was "every bit as debilitating if not more than the disease itself" (57). One participant said the following about how the breathwork techniques they learned in the program helped them cope during stressful times:

> *I sometimes just do the breathwork if I feel myself getting stressed during the day. The stuff I heard on social media is just crazy and the news is horrible right now and I just unconsciously find myself just doing a little bit of breathwork to escape (42).*

Theme # 2: Mixed reception: exploring experiences with gamification

After gaining experience with the leaderboard, some felt that their "competitive nature responded well," and seeing others who were "way ahead" motivated them to participate more. One participant reflected on this:

> *The leaderboard obviously motivated me. Ironically, when I first started, I thought: 'I probably won't use [the leaderboard] because I motivate myself.' But I was watching people accumulate points and I thought: 'I want those points' (111).*

One the other hand, many participants felt that the leaderboard "stopped being motivating" as they "fell behind." One participant described this saying:

> *I thought at the beginning the leaderboard would be fun. After about the first week or two I said: 'This feels like a competition where you can never catch up.' If you missed a few days, and somebody else is way ahead, it's sort of like, why am I doing this?' (196).*

Some participants felt that gamification elements that allowed them to form "more in-depth connections" with study peers would "offer more encouragement".

TABLE 3 Subgroup analysis - baseline and end of study measurements comparing the subgroup of patients who met the pre-specified adherence target (n = 20) versus control (n = 44)

	Control group (n = 44)		Intervention group adhered to video routine at least 3× per week (n = 20)		Between group absolute improvement (95% CI)	Between group relative improvement % (95% CI)	ANCOVA *p*-value Between groups
	Baseline	End of study	Baseline	End of study			
HADS total	11.6 ± 5.30	13.0 ± 5.56	13.6 ± 6.43	9.80 ± 6.28	4.32 (1.70, 6.95)	32.4 (12.7, 52.1)	0.002[a]
HADS anxiety	6.89 ± 3.42	7.59 ± 3.37	8.10 ± 3.88	6.50 ± 4.12	1.73 (0.021, 3.43)	22.2 (0.270, 44.0)	0.047[a]
HADS depression	4.73 ± 2.80	5.41 ± 2.88	5.45 ± 2.95	3.30 ± 2.72	2.56 (1.35, 3.77)	46.1 (24.3, 67.9)	< 0.001[a]
MFIS total	59.0 ± 16.3	59.8 ± 15.5	60.6 ± 15.9	54.3 ± 15.9	6.89 (2.52, 11.25)	11.4 (4.18, 18.7)	0.002[a]
MFIS physical	27.4 ± 8.42	27.7 ± 7.64	29.4 ± 7.96	25.2 ± 6.75	3.95 (1.58, 6.32)	14.0 (5.61, 24.0)	< 0.001[a]
MFIS cognitive	26.1 ± 8.28	26.4 ± 8.46	25.8 ± 8.01	24.3 ± 8.70	1.81 (−0.574, 4.20)	6.89 (−2.18, 16.0)	0.134
MFIS psychosocial	5.43 ± 1.93	5.73 ± 1.87	5.45 ± 1.91	4.85 ± 1.90	0.888 (0.077, 1.70)	15.5 (1.34, 29.7)	0.032[a]
PBC-40 fatigue	31.1 ± 8.63	31.1 ± 8.78	33.3 ± 9.30	29.5 ± 9.12	3.60 (1.18, 6.03)	11.3 (3.72, 19.0)	0.004[a]

[a]Statistical significance was established at a 2-tailed p-value of < 0.05.
Abbreviations: HADS, Hospital Anxiety and Depression Scale; MFIS, Modified Fatigue Impact Scale; PBC, primary biliary cholangitis.

Theme # 3: Bridging the transition: long-term adoption of program practices

While reflecting on their use of the program practices after the study period, a few participants shared that they return to the practices as an "automatic response" when "things get tough." One participant said the following about this automaticity:

> *I went through a very stressful moment in my workplace and the first thing that went through my mind was: 'I will run to my car and start that meditation.' (61).*

Others described that while the practices were "not a habit quite yet," they had used strategies such as returning to the program website and tracking their activity to help them "keep up the momentum".

Contrastingly, many participants shared that despite having the intention to "maintain the benefits of the program," they had not stayed consistent after the study period. Some spoke about the "hard adjustment" of losing the "input and support" that was available during the program. Others described how they "got off track" and found it "hard to get back in it" after the program ended. One participant said the following about how finishing the program around Christmas disrupted her routine:

> *I found the structure of the program helpful because I thought: 'This is something so great [that] I'm going to continue with every day.' And then Christmas happened, and then the cold weather happened, and I have to confess I'm not doing it every day (45).*

DISCUSSION

This is the first mixed-methods study and the first study including an RCT to evaluate the impact of a multicomponent mind-body wellness intervention in individuals with PBC. Significant between-group differences occurred in the primary outcome of depression (HADS total and depression domains), and the secondary outcomes of stress (Perceived Stress Scale), and quality of life (PBC-40 emotional symptoms and social symptoms domains). Although no significant improvements were observed in fatigue overall, a significant reduction in fatigue was seen in the 20/36 (55.6%) of participants who adhered to the goal of completing the video routine at least 3 times per week. Moreover, interviews revealed improved ability to cope with fatigue. The findings of this study provide lessons that can be grouped into 3 main categories.

Impact on mental health and quality of Life

Participants experienced statistically significant improvements in measures of mental health and quality of life. The clinical significance of changes in mental health can be understood through the HADS total, with past literature identifying a change of 1.5–2 as a clinically important difference.[18,19] When all participants were considered, the mean improvement absolute in HADS was 2.66, 95% CI: 1.70-6.95 (previously 12.7-52.1), increasing to 4.32, 95% CI: 12.7–52.1 in those participants who met adherence targets. In the qualitative portion, participants described these improvements in mental health, speaking about how the program gave them tools to cope with their disease and manage daily stressors. This echoed the findings from our pilot study.[14] The current study adds to the existing literature as the first RCT in PBC to assess mind-body practices as a way to help patients manage mental health comorbidities and improve quality of life, and one of the few studies to use mixed methods. By capturing the breadth of a participant's experience beyond what can be captured through quantitative surveys alone, mixed methods enrich our understanding of the intervention's impact and potential mechanisms.

Impact on fatigue

Despite the significant impact on mental health and HRQOL, when all participants were considered, there was no impact on fatigue, a symptom that patients have highlighted as a research priority.[25] Interestingly, RCTs in people with cancer-related fatigue and chronic fatigue syndrome have reported significant improvements in fatigue after participation in exercise, yoga, and qigong.[9,32,33] The absence of an effect in our study may be attributable to the relatively low dose of the mindful-movement part of the mind-body intervention (total of 45 min per week if done 3 times per week). Notably, the subgroup analysis of participants who met the adherence target did demonstrate significant changes in fatigue through the MFIS total, physical, and psychosocial domains, as well as the PBC-40 fatigue domain, supporting a benefit if an adequate dose is provided. This finding is relevant as it can help to guide the duration and adherence recommendations for future programming. In the qualitative portion of our study, participants highlighted that while they still experienced fatigue, learning to pace through the program improved how they coped with their fatigue. Adaptive pacing therapy has been used in a variety of other chronic disease populations to help patients achieve prioritized activities.[34]

Engagement with the practices during and after the intervention

At 55.6%, our study demonstrated relatively high target adherence in comparison with other studies that have assessed online mind-body interventions for patients with chronic liver disease (rates ranging from 14% to 55%).[35,36] This is notable, as low adherence has been widely recognized as a challenge to delivering online wellness interventions.[37] One way that past studies have attempted to increase engagement with online wellness interventions is through implementing behavior change techniques (BCTs),[38,39] such as providing feedback on behavior, rewards, and social comparison,[38] some of which can be implemented through gamified program elements such as leaderboards, points, and badges.[39] Past literature has echoed the results of our study, reporting varying perceptions of gamification in wellness interventions.[40,41] A qualitative study of gamification in older adults echoed some of the qualitative portion of our study, reporting that older adults did not see value in points, badges, and leaderboards and were instead motivated by social connection and collaboration.[40] Despite the high adherence observed in this study, there were significant between-group reductions in aspects of capability, opportunity, and motivation. We hypothesize that, as observed in past studies,[42] this decrease in the COM-B domains was a result of participants over-estimating their capability, opportunity, and motivation for engaging in relatively novel behaviors at baseline and then encountering unanticipated barriers to participation. In future studies, it may be more relevant to administer the baseline COM-B survey after 1–2 weeks of programming to allow participants to become familiar with the intervention and more realistically estimate their capability, opportunity, and motivation.

Lastly, our study offers unique insights about continued engagement with wellness practices after the intervention period, which is of interest given that changes in behavior during an intervention do not translate to long-term behavior change.[43] Participants continued to have access to the web-based programming after the intervention. Of the 24 intervention participants who completed the 8-week post-intervention surveys, a considerable number (62.5%) indicated that they had accessed the program in the post-intervention period. Our qualitative data added to this and was consistent with the published literature highlighting habit formation as a factor that promoted continuation.[44–46]

Limitations

We acknowledge the following limitations to our study. First, as a fully online study with enrollment through the Canadian PBC Society, open to inclusion regardless of geographic location, we were unable to review medical

charts. Thus, the diagnosis of PBC was self-reported, and we were unable to confirm whether patients were being followed by a hepatologist, and engagement with psychotherapy or the use of medications to treat psychiatric conditions was also not confirmed. While a potential limitation, this strategy used for enrollment is also seen as a strength in that it represents a pragmatic approach that resulted in enrollment from 4 countries. Second, we did not include a lower-level threshold of the HADS for inclusion as recruitment through a patient partner organization made it challenging to turn away individuals who had low HADS scores but felt they may still experience benefit from the programming. Third, 98% of the participants were female, making results less generalizable to male patients. This is not unexpected, given that the female: male ratio of patients with PBC is estimated to be as high as 10:1,[47] and other studies evaluating mind-body interventions have reported a higher prevalence of female participants.[48,49] Fourth, with recruitment through the Canadian PBC Society, we acknowledge that the patients who expressed interest in this study may be more engaged than the general PBC population. Fifth, while adherence was self-reported, it was evaluated at check-ins and at the end of the study. Sixth, 6 patients who were randomized to the intervention arm dropped out before the study period due to prior commitments and an unclear understanding that they would be unable to choose their start date after randomization. This represented a considerable proportion of patients who were counted as having no change using an intention-to-treat design, causing potential underestimation of intervention effects. Seventh, while the sample size was powered for the HADS, it was not powered to detect changes in the secondary outcomes, such as the PBC-40. Finally, 8-week follow-up data were only available in 67% of participants who completed the intervention, potentially contributing to an overestimation of the percentage of participants who continued with the practices after the study period.

To our knowledge, this is the first RCT to evaluate the impact of a multicomponent mind-body intervention alongside standard of care therapy in people with PBC. Our findings offer insight into the efficacy of online mind-body interventions to help people with PBC manage their mental health, quality of life, and symptom burden. Future studies could explore strategies to optimize adherence, including group support and making gamification more appealing. Increases in adherence, as well as the intensity of the physical activity intervention, may also be shown to result in a greater impact on fatigue.

AUTHOR CONTRIBUTIONS

Puneeta Tandon, Makayla Watt, Gail M. Wright, Shauna Vander Well: Conceptualization and funding information. Makayla Watt, Emily Johnson, and Ashley Hyde: Data curation. Makayla Watt, Puneeta Tandon, and Ashley Hyde: Formal analysis and writing. Makayla Watt and Puneeta Tandon: Investigation. Puneeta Tandon, Ashley Hyde, Makayla Watt, and John C. Spence: Methodology. Makayla Watt, Puneeta Tandon, Emily Johnson, Chikku Sadasivan, Dayna Lee-Baggley, Hin Hin Ko, and Edward Tam: Project Administration. All authors: Writing—review and editing.

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CONFLICTS OF INTEREST

Dayna Lee-Baggley consults, advises and is on the speaker's bureau for Novo Nordisk and Bausch. She is employed, owns stock in, and holds intellectual property rights with ImpactMe Workplace Solutions. She is employed and holds intellectual property rights with Harbinger Press. Andrew Mason advises and received grants from Intercept. He consults for GlaxoSmithKline and Ipsen. He received grants from Merck. Hin Hin Ko consults, advises, is on the speakers' bureau and received grants from Intercept. She consults, advises and is on the speakers' bureau for Sanofi and AbbVie. She consults and advises Ipsen and Lupin. She is on the speakers' bureau and received grants from Gilead and Falk. She received grants from Celgene. Edward Tam consults, advises, and is on the speakers' bureau for AbbVie, Gilead, Merck, Advanz, and Intercept. The remaining authors have no conflicts to report.

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REFERENCES

1. CADTH Common Drug Reviews. Clinical Review Report: Obeticholic Acid (Ocaliva): (Intercept Pharmaceuticals Canada, Inc): Indication: For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health Copyright © 2017 Canadian Agency for Drugs and Technologies in Health; 2017.
2. Trivedi PJ, Hirschfield GM. Recent advances in clinical practice: Epidemiology of autoimmune liver diseases. Gut. 2021;70: 1989–2003.
3. Schattenberg JM, Pares A, Kowdley KV, Heneghan MA, Caldwell S, Pratt D, et al. A randomized placebo-controlled trial of elafibranor in patients with primary biliary cholangitis and incomplete response to UDCA. J Hepatol. 2021;74:1344–54.
4. Mells GF, Pells G, Newton JL, Bathgate AJ, Burroughs AK, Heneghan MA, et al. Impact of primary biliary cirrhosis on perceived quality of life: The UK-PBC national study. Hepatology. 2013;58:273–83.
5. Sivakumar T, Kowdley KV. Anxiety and depression in patients with primary biliary cholangitis: Current insights and impact on quality of life. Hepat Med. 2021;13:83–92.
6. Huang X, Liu X, Yu Y. Depression and chronic liver diseases: Are there shared underlying mechanisms? Front Mol Neurosci. 2017; 10:134.
7. Björnsson E, Kalaitzakis E, Neuhauser M, Enders F, Maetzel H, Chapman RW, et al. Fatigue measurements in patients with primary biliary cirrhosis and the risk of mortality during follow-up. Liver Int. 2010;30:251–8.
8. Jones DE, Al-Rifai A, Frith J, Patanwala I, Newton JL. The independent effects of fatigue and UDCA therapy on mortality in primary biliary cirrhosis: results of a 9 year follow-up. J Hepatol. 2010;53:911–7.
9. Hilfiker R, Meichtry A, Eicher M, Nilsson Balfe L, Knols RH Verra ML, et al. Exercise and other non-pharmaceutical interventions for cancer-related fatigue in patients during or after cancer treatment: A systematic review incorporating an indirect-comparisons meta-analysis. Br J Sports Med. 2018;52:651–8.
10. Yudhawati R, Rasjid HsM. Effect of yoga on FEV1, 6-minute walk distance (6-MWD) and quality of life in patients with COPD group B. Adv Respir Med. 2019;87:261–8.
11. Li Z, Liu S, Wang L, Smith L. Mind-body exercise for anxiety and depression in COPD patients: A systematic review and meta-analysis. Int J Environ Res Public Health. 2019;17:22.
12. Jayawardena R, Ranasinghe P, Ranawaka H, Gamage N, Dissanayake d, misra a. Exploring the therapeutic benefits of pranayama (yogic breathing): A systematic review. Int J Yoga. 2020;13:99–110.
13. Williams H, Simmons LA, Tanabe P. Mindfulness-based stress reduction in advanced nursing practice: A nonpharmacologic approach to health promotion, chronic disease management, and symptom control. J Holist Nurs. 2015;33:247–59.
14. Watt M, Hyde A, Spence JC, Wright GM, Vander Well S, Johnson E, et al. The feasibility and acceptability of an online mind-body wellness program for patients with primary biliary cholangitis. Can Liver J. 2023. doi: 10.3138/canlivj-2022-0045
15. Spinhoven P, Ormel J, Sloekers PP, Kempen GI, Speckens AE, Van Hemert AM, et al. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. Psychol Med. 1997;27:363–70.
16. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: Building an international community of software platform partners. J Biomed Inform. 2019;95:103208.
17. Hayes SC, Strosahl KD, Wilson KG. Acceptance and commitment therapy: The process and practice of mindful change. Guilford press; 2011.
18. Vaganian L, Bussmann S, Gerlach AL, Kusch M, Labouvie H, Cwik JC. Critical consideration of assessment methods for clinically significant changes of mental distress after psycho-oncological interventions. Int J Methods Psychiatr Res. 2020;29:e1821.
19. Lemay KR, Tulloch HE, Pipe AL, Reed JL. Establishing the Minimal clinically important difference for the Hospital Anxiety and Depression Scale in patients with cardiovascular disease. J Cardiopulm Rehabil Prev. 2019;39:E6–11.
20. Lee EH. Review of the psychometric evidence of the perceived stress scale. Asian Nurs Res (Korean Soc. Nurs Sci). 2012;6:121–7.
21. Connor KM, Davidson JR. Development of a new resilience scale: The Connor-Davidson Resilience Scale (CD-RISC). Depress Anxiety. 2003;18:76–82.
22. Larson RD. Psychometric properties of the modified fatigue impact scale. Int J MS Care. 2013;15:15–20.
23. Jacoby A, Rannard A, Buck D, Bhala N, Newton JL, James OF, et al. Development, validation, and evaluation of the PBC-40, a disease specific health related quality of life measure for primary biliary cirrhosis. Gut. 2005;54:1622–9.
24. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42.
25. Mayan M.J. Essentials of qualitative inquiry (Second edition). Routledge. 2023.
26. Bradshaw C, Atkinson S, Doody O. Employing a qualitative description approach in health care research. Glob Qual Nurs Res. 2017;4:2333393617742282.
27. Peerani F, Watt M, Ismond K, Whitlock R, Ambrosio L, Hotte N, et al, (in press). A Randomized Controlled Trial of a Multi-component Online Stress Reduction Intervention in Inflammatory Bowel Disease. Therapeutic Adv Gastroentero. 2022;15: 175628482211272
28. Inc. S. IBM SPSS Statistics for Windows, Version 160. Chicago: SPSS Inc.; 2007. Released.
29. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. Nurs Health Sci. 2013;15:398–405.
30. Braun V, Clarke V. Using thematic analysis in psychology. Qualit Res Psychol. 2006;3:77–101.
31. International Q. NVivo Qualitative Data Analysis Software [Software]. (1999). https://qsrinternational.com/nvivo/nvivo-products/
32. Oka T, Tanahashi T, Chijiwa T, Lkhagvasuren B, Sudo N, Oka K. Isometric yoga improves the fatigue and pain of patients with chronic fatigue syndrome who are resistant to conventional therapy: a randomized, controlled trial. Biopsychosoc Med. 2014;8:27.
33. Chan JS, Ho RT, Chung KF, Wang CW, Yao TJ, Ng SM, et al. Qigong exercise alleviates fatigue, anxiety, and depressive symptoms, improves sleep quality, and shortens sleep latency in persons with chronic fatigue syndrome-like illness. Evid Based Complement Alternat Med. 2014;2014:106048.
34. White PD, Goldsmith KA, Johnson AL, Potts L, Walwyn R, DeCesare JC, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): A randomised trial. Lancet. 2011;377:823–36.
35. Lai JC, Dodge JL, Kappus MR, Wong R, Mohamad Y, Segev DL, et al. A multicenter pilot randomized clinical trial of a home-based exercise program for patients with cirrhosis: The Strength Training Intervention (STRIVE). Am J Gastroenterol. 2021;116:717–22.

36. Kruger C, McNeely ML, Bailey RJ, Yavari M, Abraldes JG, Carbonneau M, et al. Home exercise training improves exercise capacity in cirrhosis patients: Role of exercise adherence. Sci Rep. 2018;8:99.
37. Eysenbach G. The law of attrition. J Med Internet Res. 2005;7:e11.
38. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013;46:81–95.
39. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiyagarajan A, et al. Gamification for health promotion: Systematic review of behaviour change techniques in smartphone apps. BMJ Open. 2016;6:e012447.
40. Altmeyer M, Lessel P, Krüger A. Investigating gamification for seniors aged 75+. Proceedings of the 2018 Designing Interactive Systems Conference; 2018.
41. Arigo D, Brown MM, Pasko K, Suls J. Social comparison features in physical activity promotion apps: Scoping meta-review. J Med Internet Res. 2020;22:e15642.
42. Spence JC, Burgess J, Rodgers W, Murray T. Effect of pretesting on intentions and behaviour: A pedometer and walking intervention. Psychol Health. 2009;24:777–89.
43. Rothman AJ. Toward a theory-based analysis of behavioral maintenance. Health Psychol. 2000;19(1s):64–9.
44. Gardner B, Lally P, Wardle J. Making health habitual: the psychology of 'habit-formation' and general practice. Br J Gen Pract. 2012;62:664–6.
45. Lally P, Wardle J, Gardner B. Experiences of habit formation: A qualitative study. Psychol Health Med. 2011;16:484–9.
46. Rothman AJ, Sheeran P, Wood W. Reflective and automatic processes in the initiation and maintenance of dietary change. Ann Behav Med. 2009;38(Suppl 1):S4–17.
47. Lleo A, Jepsen P, Morenghi E, Carbone M, Moroni L, Battezzati PM, et al. Evolving trends in female to male incidence and male mortality of primary biliary cholangitis. Sci Rep. 2016;6:25906.
48. Cramer H, Ward L, Steel A, Lauche R, Dobos G, Zhang Y. Prevalence, patterns, and predictors of yoga use: Results of a U.S. nationally representative survey. Am J Prev Med. 2016;50:230–5.
49. Upchurch DM, Johnson PJ. Gender differences in prevalence, patterns, purposes, and perceived benefits of meditation practices in the United States. J Womens Health (Larchmt). 2019;28:135–42.

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