Development of a Theoretically Informed Web-Based Mind-Body Wellness Intervention for Patients With Primary Biliary Cholangitis: Formative Study

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Abstract

Background: Mind-body interventions have the potential to positively impact the symptom burden associated with primary biliary cholangitis (PBC). Interventions are more likely to be effective if they are informed by a theoretical framework. The Behaviour Change Wheel (BCW) and the behaviour change technique taxonomy version 1 (BCTv1) provide frameworks for intervention development.

Objective: This study describes how theory has guided the development of a 12-week multicomponent mind-body wellness intervention for PBC.

Methods: The steps involved in developing the BCW intervention included specifying the target behavior; explaining barriers and facilitators using the Capability, Opportunity, Motivation, and Behaviour and the theoretical domains framework; identifying intervention functions to target explanatory domains; and selecting relevant behavior change techniques to address intervention functions. Qualitative data from patients with inflammatory bowel disease using an earlier version of the program and feedback from a PBC patient advisory team were used to guide intervention development.

Results: Barriers and facilitators to intervention participation associated with capability, opportunity, and motivation were identified. Intervention functions and behavior change techniques were identified to target each barrier and facilitator.

Conclusions: The Peace Power Pack PBC intervention was developed to help individuals with PBC manage their symptom burden. The theoretical frameworks employed in this intervention provide direction on targeting antecedents of behavior and allow standardized reporting of intervention components.

Trial Registration: ClinicalTrials.gov NCT04791527; https://clinicaltrials.gov/ct2/show/NCT04791527

Introduction

Primary biliary cholangitis (PBC) is a female predominant chronic liver disease estimated to affect between 9000 and 11,000 Canadians [1]. Despite the relatively low prevalence of PBC, global incidence and prevalence rates have been reported to be on the rise [1]. PBC is associated with symptoms including pruritus and fatigue, which can lead to social isolation and emotional dysfunction [1-3]. Fatigue, defined as a persistent state of exhaustion, inability to perform usual routines, and a decreased capacity for physical and mental work, has been reported as the most common and debilitating among these symptoms [4-7]. Individuals with PBC also commonly experience a low health-related quality of life (HRQOL), with 1 study concluding that 35% of individuals with PBC had an...
impaired HRQOL compared to 6% of healthy controls [6]. Current medical therapies are ineffective at improving PBC-related symptoms or impacting quality of life [5,6,8]. Building upon the recognized need for novel interventions [6,9], our team was approached by patients and the Canadian PBC Society to develop self-care tools to manage symptom burden. Although to our knowledge, mind-body wellness interventions have never been trialed in PBC, interventions of this nature have been found to improve fatigue and HRQOL in other chronic diseases [10-12].

The use of a clear theoretical framework during the design of an intervention has been associated with increased adherence rates, and sustained changes to health-related behaviors [13-15]. The Behaviour Change Wheel (BCW), a framework synthesized from 19 individual models of behavior, has been used to guide development of several acceptable and effective theory-based interventions [16-18]. At the core of the BCW is the Capability, Opportunity, Motivation and Behaviour (COM-B) model, which describes the key antecedents to the target behavior. The BCW then outlines intervention functions that can be used to facilitate behavior change [16]. This process is further enhanced by the behavior change technique taxonomy version 1 (BCTv1), which details standardized active intervention ingredients that can be implemented to target intervention functions [19]. Optimally, theory would also extend to the evaluation of behavior change and maintenance.

This paper describes how theory has guided the development of a 12-week multicomponent mind-body wellness intervention for PBC (ClinicalTrials.gov NCT04791527) using several theoretical constructs: BCW guidelines [16], the COM-B model [16], the theoretical domains framework (TDF) [20], and the BCTv1 [19]. Development of the intervention involved the following steps, which were informed by the BCW guidelines: (1) specify the target behavior; (2) explain barriers and facilitators to the target behavior by using the COM-B model and the TDF; (3) identify intervention functions to target explanatory domains; and (4) select relevant behavior change techniques to address intervention functions.

**Methods**

The following sections outline the processes (methods) for each of the 4 steps of intervention development. An outline of the 4 steps of intervention development can be found in Figure 1.

**Step 1: Specify the Target Behavior**

The target behavior was determined through a review of the literature on adherence to behavioral health interventions, and in consultation with the Canadian PBC Society.

**Step 2: Explain Barriers and Facilitators to Behavior Using the COM-B and TDF**

Domains from the COM-B model and the TDF were selected to explain barriers and facilitators to the target behavior. The COM-B model outlines that for a behavior to occur, an individual must have the capability, opportunity, and motivation to perform the behavior. Capability is composed of psychological capability (knowledge), and physical capability (physical skills); opportunity is composed of physical opportunity (environmental resources) and social opportunity (cultural milieu); and motivation includes reflective motivation (evaluations, plans) and automatic motivation (emotions, impulses) [16]. As the COM-B model provides a relatively general understanding of behavior, the TDF, which outlines 14 processes involved in behavior change, is often used to provide further specification of behavioral determinants [20]. To identify barriers and facilitators driving health-related behavior, we conducted qualitative interviews with individuals who had participated in the previous iteration of the intervention carried out in a separate chronic disease group (ie, individuals with inflammatory bowel disease [IBD]) [21]. Similar to PBC, individuals with IBD experience high rates of fatigue and impaired quality of life [22,23]. These interviews were coded and thematically analyzed by 2 independent coders [21]. A COM-B characteristic and a TDF domain were then identified for each barrier and facilitator of behavior mentioned by those participants.

**Step 3: Identify Intervention Functions to Target Explanatory Domains**

Intervention functions were selected to address each barrier and facilitator to behavior. The BCW specifies 9 standardized intervention functions that can be used to address barriers and facilitators to behavior change [16]. The BCW guide then outlines intervention functions that are appropriate for each TDF domain [24]. The web-based nature of the program and characteristics of the target population (ie, chronic fatigue) were considered when selecting intervention functions.

**Step 4: Specify Intervention Content by Selecting Relevant BCTs**

Behavior change techniques were selected to allow standardized implementation of intervention functions. Following the procedure outlined by Jennings et al [13] and Tombor et al [25], BCTs were specified for each of the intervention functions identified in step 3.

![Figure 1. Steps involved in intervention development. BCT: behavior change technique; COM-B: Capability, Opportunity, Motivation and Behaviour; TDF: theoretical domains framework.](https://formative.jmir.org/2021/10/e29064)
Results

Overview

The Peace Power Pack PBC (PPP\textsubscript{PBC}) intervention was co-developed with a patient advisory team from the Canadian PBC society. The web-based intervention is described in Multimedia Appendix 1. The intervention is 12 weeks in duration with each week featuring: (1) a video detailing a core practice of mindful movement (yoga, tai chi, and low-intensity exercise divided into a standing stream and a chair stream), energizing breathwork practices, and guided meditation (increasing in length from 20-30 minutes over the course of the program); (2) an introductory video describing a weekly positive psychology theme (3-5 minutes); and (3) an interactive positive psychology activity related to the theme for the week (3-5 minutes). All programming is hosted on the investigator's website [26]. Throughout the duration of the study, participants will receive standardized weekly motivational emails, weekly 10-minute motivational interviewing check-ins, and will be invited to participate in weekly group sessions with fellow participants. The following section outlines the outcomes (results) for each of the 4 steps of intervention development previously outlined.

Step 1: Specify the Target Behavior

Adherence to the video-based program at least 3 days a week was selected as the primary target behavior, with a gradual increase in the video duration over the course of the 12 weeks. Based on feedback from the Canadian PBC society, this target behavior was chosen with the intent to balance the intervention dose with likelihood of adherence. Available evidence suggests that higher levels of adherence to behavioral health interventions leads to improved outcomes in a dose-dependent manner [27]. High levels of fatigue in individuals with PBC have been associated with a decreased sense of self-efficacy for a particular behavior [28] and inability to adhere to a target could lead to further reductions in self-efficacy. To ensure participants are aware of the anticipated study commitment, the target will be advertised to participants interested in enrollment.

Step 2: Explain Barriers and Facilitators to Behavior Using the COM-B and TDF

A comprehensive list of barriers and facilitators, along with the associated COM-B and TDF domains is provided in Table 1. The most common barriers to program participation described by the individuals with IBD were difficulty fitting the program into daily routine, and finding that the movement portion of the program was not matched with the ability level [21]. Perceived facilitators to program participation included accessible presentation of content on the host website and contact with program facilitators/fellow participants. Of the 14 domains of the TDF, 9 were associated with barriers and facilitators to intervention participation: behavior regulation, physical skills, environmental context and resources, memory attention and decision processes, social influences, goals, beliefs about capabilities, beliefs about consequences, and reinforcement. The most common TDF domains were social influences (check-ins with program facilitators and other participants enhancing accountability), and behavioral regulation (fitting the program into daily routine).
Table 1. Use of behavior change techniques in developing an intervention for people living with primary biliary cholangitis.

| Enabler | Barrier | COM-B/TDF/IF | Behavior change technique | Implementation of a behavior change technique |
|---------|---------|--------------|---------------------------|-----------------------------------------------|
| Interactions with program facilitators enhanced accountability | • COM-B: reflective motivation  
• TDF: goals  
• IF: persuasion | 1.5 Review behavior goal(s)  
1.6 Discrepancy between current behavior and goal  
3.1 Social support (unspecified) | 1.5 Weekly adherence vs target adherence goal were discussed during check in  
1.6 Weekly adherence vs target adherence goal were discussed during check in  
3.1 Weekly check ins employed motivational interviewing techniques to support program adherence |
| Able to integrate in everyday routine | Difficulty integrating program into daily routine | • COM-B: psychological capability  
• TDF: behavioral regulation  
• IF: enablement, persuasion | 1.4 Action planning (Future consideration)  
1.6 Discrepancy between current behavior and goal  
2.2 Feedback on behavior  
15.3 Focus on past success (self-belief) | 1.4 In week 1, participants watched an interactive video prompting them to plan their performance of the target behavior (adherence to the program at or above the set minimum adherence goal). This included committing to a personal adherence goal at or above the set minimum, and writing down (1) potential obstacles to meeting their adherence goal; and (2) actions that could be taken to avoid or overcome these obstacles.  
1.6 The host website recorded weekly participation (indicated by accessed content). At the top of the website, the user’s current weekly participation was presented beside the user’s adherence goal.  
2.2 The host website recorded weekly participation (indicated by accessed content). At the top of the website, the user’s current weekly participation was presented.  
15.3 In week 1, participants watched an interactive video that prompted them to think about instances in which they successfully adhered to a goal. |
| Access to accommodations to physical activity program where needed | Insufficient access to accommodation to physical activity program | • COM-B: physical capability  
• TDF: skills  
• IF: enablement | 4.1 Instruction on how to perform a behavior  
6.1 Demonstration of the behavior | 4.1 Instruction for accommodations were provided  
6.1 Demonstration of accommodations were provided |
| Interaction with others in program associated with increased motivation | • COM-B: social opportunity  
• TDF: social influences  
• IF: persuasion, modeling | 3.1 Social support (unspecified) | 3.1 Participants were invited to weekly live group sessions in which they had the opportunity to participate in program practices with peers |
| Desire to feel better | • COM-B: reflective motivation  
• TDF: goals  
• IF: persuasion | 5.1 Information about health consequences  
5.2 Information about emotional consequences | 5.1 Introductory videos provided information about health consequences associated with participating in the program  
5.2 Introductory videos provided information about health consequences associated with participating in the program |
| Enabler                                      | Barrier                                                                 | COM-B\textsuperscript{a}/TDF\textsuperscript{b}/IF\textsuperscript{c} | Behavior change technique                                                                 | Implementation of a behavior change technique                                                                 |
|----------------------------------------------|-------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Physical movement was too difficult          | - COM-B: physical capability, psychological capability                  | - 4.1 Instruction on how to perform a behavior                         | - 4.1 Within each stream, the mindful movement videos featured description of how to perform each specific posture/exercise |
|                                              | - TDF: physical skills                                                  | - 6.1 Demonstration of the behavior (comparison of a behavior)         | - 6.1 Within each stream, the mindful movement videos featured demonstration of how to perform each specific posture/exercise |
|                                              | - IF: enablement, training, environmental restructuring                | - 12.1 Restructuring of the physical environment                       | - 12.1 Two streams of mindful movement were implemented, which were differentiated by difficulty |
| Physical movement was not difficult enough    | - COM-B: reflective motivation                                          | - 12.1 Restructuring of the physical environment                       | - 12.1 Two streams of mindful movement were implemented, which were differentiated by difficulty |
|                                              | - TDF: beliefs about capabilities                                       |                                                                       |                                                                                            |
|                                              | - IF: environmental restructuring                                       |                                                                       |                                                                                            |
| Feeling better/good after participating in intervention | - COM-B: reflective motivation                                          | - 5.1 Information about health consequences                            | - 5.1 Introductory videos provided information about health consequences associated with participating in the program |
|                                              | - TDF: beliefs about consequences, reinforcement                        | - 5.2 Information about emotional consequences                         | - 5.2 Introductory videos provided information about health consequences associated with participating in the program |
|                                              | - IF: persuasion                                                        | - 9.1 Credible source                                                  | - 9.1 Introductory videos featured health care professionals discussing potential benefits associated with participating in the program |

1.1 Short meditations were provided that could be completed when individuals are not feeling as well.
1.1 All mindful movement was low intensity.
4.1 Individuals received an introduction to the online platform via zoom, in which the research assistant provided instruction on accessing the intervention. Written instructions were also forwarded to all participants in an email.
6.1 Individuals received an introduction to the online platform via zoom in which the research assistant demonstrated accessing the intervention.

The table represents various behavior change techniques and their corresponding implementation strategies. It highlights the use of the COM-B model, TDF, and IF framework to address different barriers and enablers in behavior change interventions.
Step 3: Identify Intervention Functions to Target Explanatory Domains

The intervention functions persuasion, environmental restructuring, and education were used to target theoretical domains relating to motivation. The intervention functions persuasion, enablement, training, and environmental restructuring were selected to target theoretical domains related to capability, and the intervention functions persuasion and modelling were selected to target theoretical domains related to opportunity. See Table 1 for a full outline of the intervention functions selected for each domain.

Step 4: Specify Intervention Content by Selecting Relevant BCTs

The comprehensive list of selected BCTs along with a description of how they were operationalized can be found in Table 1. Examples of how selected BCTs were translated into each of the general intervention components are detailed in the following.

Implementation of BCTs Into Core Practice

To address the behavior barrier “physical movement was too difficult,” the BCTs “including instructions on how to perform a behaviour,” “demonstration of the behaviour,” and “restructuring of the physical environment” were employed. These were operationalized by including short videos to describe and demonstrate each exercise featured in the mindful movement routines, and through restructuring the program to include participant choice between a chair versus a standing stream of mindful movement.

Implementation of BCTs Into Positive Psychology

The BCTs “action planning” and “focus on past successes” were integrated into the positive psychology portion of the program to help address the barrier “integrating the program into daily routine.” Specifically, an interactive positive psychology activity at the beginning of the program was created to prompt participants to set their adherence goal, schedule their behavior, consider potential barriers and facilitators to behavior, and think about past successes with behavior change.

Discussion

Principal Findings

The PPP_PBC intervention was developed to provide individuals with PBC a tool to help better manage their symptom burden. The intervention was designed to optimize participation by enhancing a participant’s physical capability (ie, enable self-regulation), psychological capability (ie, enable self-regulation), automatic motivation (ie, help participants build a routine), reflective motivation (ie, building intention to participate in wellness practices), and social opportunity (ie, connect with peer models). Owing to the web-based nature of this intervention, we were not able to alter the individual’s physical environment and therefore did not target physical opportunity. Capability, opportunity, and motivation were targeted through the intervention functions persuasion, education, modelling, enablement, environmental restructuring (restructuring of intervention platform), and training. Additionally, 13 BCTs from the BCT taxonomy v1 were chosen to deliver the intervention content.
Utility of a Theoretical Framework

Informing behavioral interventions by theory not only provides a means to increase the efficacy of these interventions, but also allows researchers to standardize reporting of the active ingredients of interventions through BCTs. Current guidelines for reporting behavioral interventions are largely focused on reporting intervention delivery rather than intervention content [29,30]. Consequently, few reports detail active components of existing behavioral interventions and often use different language to describe active components. This presents a barrier to evaluating and replicating aspects of interventions that effectively bring about behavioral change. Experts in behavioral medicine have reported a low level of confidence in their ability to replicate effective behavioral interventions, which is likely linked to poor reporting of these interventions [19]. The current intervention is among a small number of multicomponent behavioral interventions to report on theoretically informed intervention development in a standardized manner [30]. In addition, this is the first known mind-body intervention tailored to PBC. This report provides a basis for (1) better consensus to be reached around a standardized approach to employing behavior change theory to inform an intervention and (2) evidence to be synthesized around which BCTs are effective in the context of an intervention. Both of these factors will allow for replication of successful aspects of implementation and successful active components. Importantly, after study rollout is complete, subsequent qualitative and quantitative assessment of behavior change will be necessary to determine successful components of the intervention.

Limitations

This project is not without limitations that should be acknowledged. The qualitative feedback used to inform barriers and facilitators to participating in the intervention was provided by participants with IBD, with no large-scale data collection occurring from individuals with PBC. Given the similarity of the symptom burden experienced with IBD and PBC (e.g., fatigue, depression, anxiety, stress) the barriers and facilitators provided in the interviews were deemed to be applicable to PBC. To further mitigate this limitation, we worked with an advisory team of patients with PBC to better understand how intervention design needed to be tailored to meet the specific needs of this population (e.g., providing a chair stream within the mindful movement to accommodate for potential fatigue and mobility restrictions).

Conclusions

To our knowledge, the PPP_PBC intervention is unique in that it is a mind-body wellness program designed for individuals with PBC, and in that it has taken a structured approach to considering theory in design and evaluation. Development was informed by the BCW [16] and BCTs [19]. Application of these frameworks was guided by feedback from our patient advisory team. Further standardized reporting of complex interventions conducted in different contexts, along with subsequent assessment of behavior change, is necessary to determine how contextual variables influence the effectiveness of different BCTs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Description of the web-based intervention.
[DOCX File, 16 KB-Multimedia Appendix 1]
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Abbreviations

- **BCT**: behavior change technique
- **BCTv1**: behavior change technique taxonomy version 1
- **BCW**: Behaviour Change Wheel
- **COM-B**: Capability, Opportunity, Motivation and Behaviour
- **HRQOL**: health-related quality of life
- **IBD**: inflammatory bowel disease
- **PBC**: primary biliary cholangitis
- **PPP**<sub>PBC</sub>: Peace Power Pack PBC
- **TDF**: theoretical domains framework

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