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ORIGINAL ARTICLE

Changing cancer mindsets: A randomized controlled feasibility and efficacy trial

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Abstract

Objective: A cancer diagnosis and subsequent treatment can disrupt the full spectrum of physical, social, emotional, and functional quality of life. But existing psychological treatments are focused primarily on specific psychological symptoms as opposed to improving the overall patient experience. We studied the feasibility and efficacy of a novel digital intervention targeting patient mindsets—core assumptions about the nature and meaning of illness—designed to improve overall health-related quality of life (HRQoL) in newly diagnosed cancer patients undergoing treatment with curative intent.

Methods: Recently diagnosed (≤150 days) adult patients with non-metastatic cancers undergoing systemic treatment ($N = 361$) were recruited from across the United States to participate in this decentralized clinical trial. Patients were randomized 1:1 to receive the Cancer Mindset Intervention (CMI) or Treatment as Usual (TAU). Participants in the CMI group completed seven online modules over 10 weeks (2.5 h total) targeting mindsets about cancer and the body. The primary outcome was overall HRQoL, and secondary outcomes were coping behaviors and symptom distress.

Results: Patients in the CMI group reported significant ($p < 0.001$) improvements in adaptive mindsets about cancer and the body over time. Compared with the TAU condition, the CMI group reported significant improvements in overall HRQoL ($B = 0.60$; 95% CI 0.34–0.85; $p < 0.001$), increased engagement in adaptive coping behaviors ($B = 0.03$; 95% CI 0.02–0.04; $p < 0.001$), and reduced distress from physical symptoms ($B = -0.29$; 95% CI −0.44 to −0.14; $p < 0.01$). Effect sizes of these changes ranged from $d = 0.42$–$d = 0.54$.

Conclusion: A brief mindset-focused digital intervention was effective at improving physical, social, emotional, and functional HRQoL. increasing adaptive coping behaviors, and reducing physical symptom distress in newly diagnosed cancer patients.

KEYWORDS
cancer, digital intervention, health related quality of life (HRQoL), mindsets, oncology, psychologically wise intervention, supportive care

1 | INTRODUCTION

Mindsets are assumptions we make that help us to understand our experiences.[1] The impact of mindsets about intelligence, stress, diet, and exercise on performance, health, and wellbeing outcomes of non-clinical populations is well-documented.[2–4] For patients with cancer, mindsets about the meaning of cancer and the role of the body may be similarly impactful.[5,6] By shaping a patient's cognitive, emotional, and physiological responses to both the illness and the subsequent treatment, these mindsets may influence multiple aspects of overall quality of life.[2] For example, adopting the mindset that cancer is "manageable" or even an "opportunity to grow" may engender a sense of hope, meaning and proactive engagement with treatment, while adopting the mindset that cancer is a "catastrophe" may lead to despair and disengagement, making an already difficult time even more challenging.

Precisely targeting and changing specific mindsets that are central to guiding our meaning-making processes can yield large and long-lasting benefits.[7] A 1-h digital intervention aimed at inspiring growth mindsets—the belief that intelligence can grow and be developed—led to improvements in academic achievement for lower-achieving adolescents transitioning to high-school.[8] Mindset interventions can also impact health outcomes and physiology. Adopting a more adaptive mindset about stress (e.g., that stress is enhancing rather than debilitating) is associated with a more moderate cortisol response, higher DHEA-S levels, and better health and wellbeing as long as 2 years later.[2] Similar effects have also been demonstrated in clinical populations. An intervention aimed at altering patients' mindsets about side effects during oral immunotherapy led to a reduction in the number life-threating symptoms reported and an increase in peanut specific immunoglobulin G antibodies over the course of the study.[9]

Interventions that target mindsets work because they "focus on the meanings and inferences people make about themselves and the situation they are in and use precise, theory-and research-based techniques to alter these meanings".[7] In doing so they evoke changes in emotion, attention, motivation, and physiology in ways that can lead to positive self-fulfilling outcomes.[10] For cancer patients, even subtle changes in mindsets (e.g., from viewing cancer as a catastrophe to viewing it as manageable) could be transformative. While current evidence-based psychological interventions are usually offered to patients with a specific psychiatric diagnosis, like anxiety or depression,[11] brief mindset-focused interventions can be offered to all cancer patients in order to inspire positive psychological health and can lead to enhanced quality of life, better coping, and better functioning.

We used theoretically grounded methods and extensive piloting with patients and oncologists to identify the mindsets most central to patients undergoing cancer. We then developed a brief digital mindset-focused intervention aimed at helping newly diagnosed cancer patients adopt more adaptive mindsets about the nature of cancer (e.g., 'cancer is manageable') and about the role of the body (e.g., 'my body is capable'). In this clinical trial, we test the efficacy of this intervention in improving health related quality of life (HRQoL) in a cohort of patients who were recently diagnosed with non-metastatic cancers.

2 | METHODS

This study was approved by the Stanford University Institutional Review Board (IRB Protocol #43605) to ensure the protection of the rights and welfare of human research participants in accordance with the Declaration of Helsinki. The merit of the research was reviewed and approved by the Stanford Cancer Center Scientific Review Committee (SRC #VAR0174) and the trial was registered on Clinicaltrials.gov. Additionally, the hypotheses (including the directionality of the effects) and full statistical and analytic plan were pre-registered on open science framework (osf.io/5et9g) prior to accessing the data.

2.1 | Study design

A two-arm, parallel group, non-blinded, randomized controlled trial was conducted to compare the efficacy of the Cancer Mindset Intervention (CMI) versus treatment-as-usual (TAU) in supporting the HRQoL of recently diagnosed patients with non-metastatic cancer. Participant flow from recruitment through follow-up is outlined in Figure 1.

2.2 | Recruitment, eligibility, & enrollment

We aimed to recruit $N = 350$ participants, which yielded 80% power to detect a small-to-moderate effect size of $d = 0.33$ This corresponds to a mean difference across conditions of 5 points on the Functional Assessment of Cancer Therapy - General (FACT-G) total score, assuming a pooled standard deviation of 15. The literature suggests a change between 5–8 points on the FACT-G represents the minimum clinically meaningful change in quality of life.[12,13] Therefore, a sample of $N = 350$ would provide sufficient power to detect at least the smallest clinically meaningful difference. This effect size range is also in line with existing supportive care interventions reporting FACT-G Total Score as their primary outcome.[14,15]

Given the constraints of the COVID-19 pandemic, which prevented traditional in-person recruitment, we shifted to a decentralized clinical trial model that allowed us to recruit and enroll interested patients from across the country. Advertisements, similar to those commonly used for in-person studies, were adapted for an online format, and were posted on social media between November 2020 and January 2021. This style of advertising and recruitment, which is common for decentralized clinical trials, often generates a wide funnel of potential participants that quickly narrows to those who are actually interested and eligible. Clicking on an advertisement led to an online screening and eligibility survey. Adults (≥18 years)

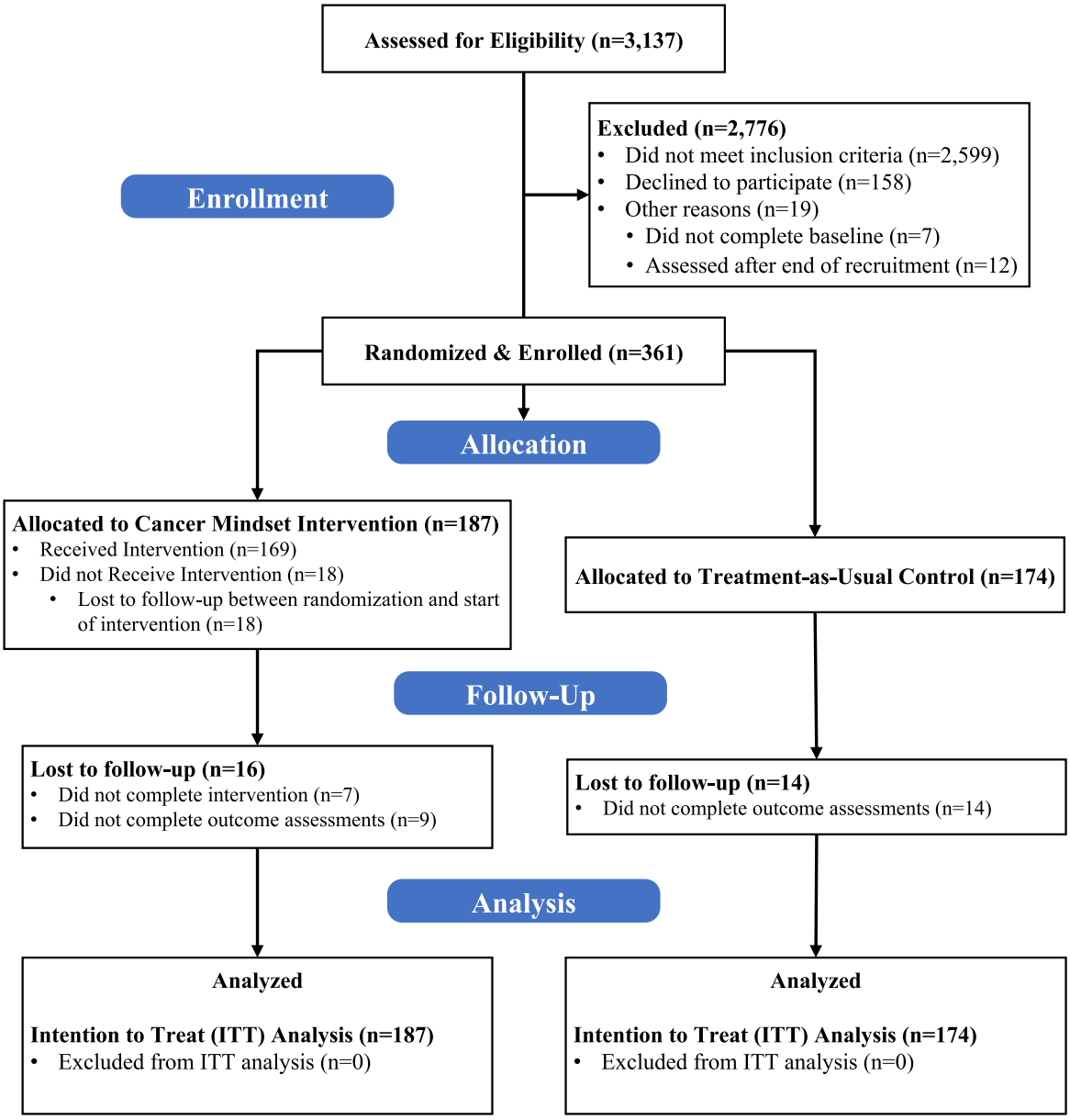

FIGURE 1 CONSORT diagram outlining participant flow from screening to follow-up.

with an initial (i.e., non-recurrent) diagnosis of a non-metastatic (stage I-III) or hematological malignancy in the past 150 days who were undergoing or about to begin a course of treatment were eligible to participate in the study. Patients who failed to meet these inclusion criteria or self-indicated certain psychiatric comorbidities (e.g., severe depression, severe anxiety, bipolar disorder, post-traumatic stress disorder, or schizophrenia) that were not well controlled with treatment were excluded.

Eligible participants were provided with an overview of the study and were told they would be randomly assigned to one of two groups, that both groups were equally important to the study, and that both groups would be compensated equally. The CMI condition was described as the "Modules & Questionnaire Group", which involved watching short videos, completing written activities, and filling out questionnaires. The TAU Control condition was described as a "Health & Wellbeing Measurement Group", which involved completing questionnaires every few weeks over the course of the study. Participants received a $25 gift card for completing each survey plus a bonus $100 gift card for completing the entire study.

Informed consent was obtained for all participants prior to enrollment using RedCap's eConsent Framework. Participants were randomized 1:1 via a stratified block randomization design (block size of 10) across strata of cancer type, cancer stage, and biological sex to either the CMI or TAU condition. Randomization patterns were set before the initiation of the study using RedCap's randomization module.

2.3 | The cancer mindset intervention

The design of this intervention was guided by a large and growing body of research on similar 'psychologically wise' mindset interventions.[7,10] The intervention took the form of an online toolkit with seven modules. Each module included a brief film followed by reflection questions that required approximately 15–25 min to complete. Films featured interviews with cancer survivors describing their experience with diagnosis, treatment, and recovery, and the importance of their mindsets during their experience. The films also featured Stanford faculty with expertise in oncology, psychiatry, and psychology, who offered a scientific framework for the importance of mindsets during cancer treatment and provided examples from their clinical practices. The reflection exercises that followed the films were designed to help patients craft a personalized strategy (a) for changing maladaptive mindsets and maintaining adaptive ones and (b) for translating ideas from the film into actionable behaviors. The content and timing of the models was designed to align with critical moments during the cancer journey: post diagnosis (3 modules), mid-treatment (2 modules), and post-treatment transition to survivorship (2 modules). Modules were extensively piloted in focus groups of cancer patients and survivors to ensure relevance, clarity, and appeal. See Table 1.

2.4 | Measures

2.4.1 | Intervention target: Mindsets

Cancer mindsets were measured using the cancer version of the Illness Mindset Inventory (IMI), a 9-item measure of mindsets about illness, which was developed by experts in mindset research (including

TABLE 1 Cancer mindset intervention: Description and timing of intervention modules.

Module 1: *A Critical Moment* (12-min film | 9 reflection question | administered week 1)
Targets mindsets about cancer (e.g., that 'cancer is a catastrophe'). Film: Cancer survivors describe their own mindsets, their impact, and how they changed from diagnosis through treatment and into survivorship. Experts in oncology and psychology provide a scientific framework for these examples and suggest more useful ways of thinking about a cancer diagnosis and treatment (e.g., that 'cancer is manageable'). Reflection questions guide patients to consider their own mindsets, their impact, and how their experience would be different if they had more (or less) useful mindsets.
Module 2: *My Body Is Capable* (8-min film | 4 reflection questions | administered week 1)
Targets mindsets about the body and guides patients reconsider their implicit narratives about the body's role in the context of cancer. The film introduces patients to common but unhelpful mindsets patients may have about their own bodies (e.g., that their body is incapable or even an adversary) and offers alternative ways of thinking about the capability of the body. Reflection questions prompt patients to consider ways in which their bodies have been capable in the past and encourage health promoting behaviors (e.g., exercise) to help reinforce adaptive mindsets about the body.
Module 3: *How to Change Your Mindset* (4-min film | 6 reflection questions | administered week 1)
Targets mindset-change strategies. Experts provide clear strategies to help patients shift from an unhelpful mindset toward more adaptive ones. Reflection questions guide patients through exercises to practice the strategies presented in the film. Patients are also provided with a handbook of FAQs about what mindset is, how it works, and how to shift from unhelpful mindsets to more adaptive ones.
Module 4: *Opportunities Emerge* (11-min film | 4 reflection questions | administered week 3)
Targets the mindset that 'cancer can be an opportunity' and inspires new meaning through active reflection. Cancer survivors describe how the experience of cancer can be a catalyst for a greater appreciation for life, personal growth, stronger relationships, new possibilities, or a refined sense of purpose. 4 reflection questions prompt patients to consider the opportunities they have already experienced and choose those they want to seek out next.
Module 5: *Managing Challenges* (12-min film | 11 reflection questions | administered week 3)
Targets how to maintain adaptive mindsets about cancer (e.g., that cancer is manageable or even an opportunity) and the body (e.g., that the body is capable and responsive) in the midst of challenges and setbacks. Cancer survivors describe some of the setbacks and challenges they faced during their cancer treatment and how they managed these challenges and maintained useful mindsets during difficult times. Reflection questions guided through strategies to help them maintain adaptive mindsets and manage current/future cancer related challenges.
Module 6: *A New Normal* (12-min film | 5 reflection questions | administered week 9)
Targets mindsets about cancer and mindsets about the body in the context of the transition to cancer survivorship. Cancer survivors describe their experiences with finishing treatment, their mindsets about the transition to a new normal after cancer, and how they managed challenges with this adjustment. Experts provide strategies for maintaining useful mindsets after treatment ends. Reflection questions encourage patients to reflect on their cancer journey so far, consider the opportunities they want to seize after treatment ends, and develop a strategy for cultivating and maintaining useful mindsets in the future.
Module 7: *Share Your Journey* (review of previous responses | 1 writing activity | administered week 9)
Uses a 'saying-is-believing' style prompt to help patients connect to, personalize, and take ownership of the ideas learned throughout the previous 6 modules. Patients are guided through a series of excerpts from their responses to reflection questions in previous modules. They are asked to reflect upon how their responses may be different now and how their mindsets have changed over the last few months and are asked to write a letter to a recently diagnosed cancer patient to share their own wisdom from their experience including the role of their own mindsets.

authors Zion, Dweck and Crum).[5] The cancer version of the IMI consists of 3 subscales: cancer as a catastrophe, cancer as manageable, and cancer as an opportunity. Each item is rated on a 6-point Likert scale ranging from strongly disagree (1) to strongly agree (6). The scale has strong internal consistency ($\alpha = 0.85–0.90$).[5] Body mindsets were measured using The Body Mindset Scale (BMS), a 10-item measure of mindsets about an individual's body in the context of a chronic illness. The BMS consists of 3 subscales: the body as an adversary, the body as capable, and the body as responsive. Each item is rated on a 6-point Likert scale ranging from strongly disagree (1) to strongly agree (6). The scale has strong internal consistency ($\alpha = 0.84–0.95$).[5]

2.4.2 | Primary outcome

Our primary outcome measure was HRQoL as measured by the total score of the FACT-G. The FACT-G consists of 27 questions answered on a 5-point Likert scale ranging from 0 (not at all) to 4 (very much). Higher scores (calculated by summing the items) on the FACT-G indicate better wellbeing. Questions fall into four subscales measuring physical (7 questions), social/family (7 questions), emotional (6 questions), and functional (7-questions) wellbeing.[16] The total score is a sum of these four subscales.

2.4.3 | Secondary outcomes

Coping was measured using the short version of the Cancer Behavior Inventory (CBI), a 12-item measure of self-efficacy for coping with cancer. Items are rated on a 5-point Likert scale indicating confidence in a range of coping skills. The CBI yields a single summary score representing overall confidence in engaging in adaptive coping behaviors. The CBI demonstrates good internal consistency ($\alpha = 0.94$).[17]

Symptom distress was measured using the physical symptom distress subscale of the Rotterdam Symptom Checklist (RSCL). All items are rated on a 4-point Likert scale ranging from (1) not at all to (4) very much. Higher scores (calculated by taking the sum of the items) are indicative of greater distress or impairment. The RSCL demonstrates good internal consistency ($\alpha = 0.72–0.88$).[18]

2.5 | Statistical analyses

All analyses were conducted in R[19] using an intention to treat (ITT) procedure that included all randomized participants. Missingness was addressed by using mixed effects models with repeated measures (MMRM) that account for missing data using a maximum likelihood estimation procedure. In analyses that did not employ MMRM, multiple imputation with predictive mean matching (50 iterations) was used.

The effects of the intervention on mindsets, primary outcomes, and secondary outcomes were analyzed using MMRMs that included fixed effects for time (in weeks) and condition and a random intercept for slope. We further quantify the magnitude of these effects by reporting effect sizes (measured by Cohen's *d*), which were calculated using mean change between baseline (week 0) and post-intervention (week 10) and pooled standard deviations. See Table S5 in the Supplemental materials for additional details on change scores between pre- and post-intervention. Exploratory moderation, mediation, and durability analyses at follow-up (week 14) are reported in the Supplemental Materials.

3 | RESULTS

3.1 | Participant demographics & clinical characteristics

Participants in the ITT sample ($N = 361$) were 82.3% female, 84.8% white, and 65.1% indicated educational attainment of at least a 4-year college degree. The mean (SD) age was 52.39 (12.85) years. In terms of clinical characteristics, slightly more than half (58.4%) of patients indicated a diagnosis of breast cancer, however patients with colon/rectal cancer (10.8%), prostate cancer (5.3%), lymphoma (3.9%), leukemia (3.6%), endometrial cancer (3.3%), lung cancer (1.7%), ovarian cancer (1.4%), pancreatic cancer (1.1%), thyroid cancer (0.8%), and melanoma (0.6%) enrolled in the study. Slightly more than one third (37.4%) of patients reported a stage I diagnosis, 30.2% reported stage II, 18.8% reported stage III, and 13.6% indicated their cancer stage was unknown or not staged. The mean (SD) time since diagnosis was 72.65 (42.10) days. Demographic and clinical details were assessed using self-report measures at baseline. Clinical details were assessed a second time at follow-up to safeguard for potential inaccuracies; inconsistencies in these reported were infrequent and are noted in Figure 1. Equivalence testing using *t*-tests, ANOVA, and/or chi-square tests (depending on the variable type) found no significant differences across conditions at the $p \leq 0.05$ level in biological sex, race, educational attainment, age, cancer type, cancer stage, or times since diagnosis. See Table S1 in the Supplementary Materials for additional information.

3.2 | Acceptability

3.2.1 | Retention

We observed minimal loss to follow-up and no participants requested to be withdrawn from the study. Only 10% of enrolled patients were lost to follow-up over the course of the 10-week study. Loss to follow-up did not differ across conditions (CMI: $N = 16$; TAU: $N = 14$). Comparably, trials of psychosocial interventions in cancer patients and survivors report attrition rates of between 15% and 20%,[20,21] while other digital interventions for patients with chronic health conditions often show rates upwards of 40%.[22]

3.2.2 | Engagement

Engagement with the intervention was also strong, which provides additional support for the acceptability of the digital mindset intervention. On average, patients viewed 84.6% of the short films that accompanied the first six intervention modules. As a component of the seventh and final module, patients were given the option to write a brief letter to a recently diagnosed cancer patient reflecting on their journey and the role of their mindsets. The instructions invited participants to write as much or as little as they preferred. Patients who completed the prompt (59.6%) wrote an average of 179.2 words. Qualitatively, these letters were genuine and insightful.

3.3 | Feasibility

Changing recently diagnosed cancer patients' mindsets was feasible using a brief 2.5-h digital intervention administered over 10 weeks. Significant differences between conditions over time were observed for all three cancer mindsets (catastrophe, manageable, opportunity;) and all three body mindsets (responsive, capable, adversary). Compared with participants in the TAU condition, those in the CMI condition reported significant reductions in their endorsement of the cancer-as-catastrophe ($B = -0.07$; 95% CI −0.09 to −0.05; $p < 0.001$) and body-as- adversary ($B = -0.05$; 95% CI −0.06 to −0.03; $p < 0.001$) mindsets, and significant increases in their agreement with the cancer-as-manageable ($B = 0.04$; 95% CI 0.03–0.06; $p < 0.001$), cancer-as-opportunity ($B = 0.04$; 95% CI 0.03–0.05; $p < 0.001$), body-as-capable ($B = 0.05$; 95% CI 0.04–0.07; $p < 0.001$), and body-as-responsive ($B = 0.04$; 95% CI 0.03–0.06; $p < 0.001$) mindsets compared with participants in the TAU condition, as indicated by significant condition-by-time interactions effects. The effect size for the difference in mean changes between baseline and post-intervention across conditions ranged from $d = 0.54$–0.77. See Figure S1 and Table S2 in the Supplementary Materials for additional details.

3.4 | Efficacy

3.4.1 | Change in primary outcome–health related quality of life (FACT-G)

Significant differences in the trajectory of overall HRQoL as measured by FACT-G total score, were observed across conditions ($B = 0.60$; 95% CI 0.34–0.85; $p < 0.001$) (Figure 2A). This corresponded to a mean change between baseline and post-intervention of 5.55 (SD = 12.05) in the CMI condition compared to a mean change of −1.01 (SD = 13.36) in the TAU condition over the same length of time, a significant effect ($t = -4.88$; $p < 0.001$) with a moderate effect size of $d = 0.52$ [95% CI: $d = 0.30$–0.73]. Analyses by subscale indicated significant differences between conditions in physical ($B = 0.12$; 95% CI 0.01–0.23; $p = 0.036$), social ($B = 0.12$; 95% CI 0.05–0.19; $p < 0.001$), emotional ($B = 0.14$; 95% CI 0.06–0.21; $p < 0.001$), and functional ($B = 0.22$; 95% CI 0.13–0.31; $p < 0.001$) wellbeing (Figure 2B). Effect sizes for the FACT-G subscales ranged from $d = 0.23$–0.51.

3.4.2 | Change in secondary outcomes: Coping & symptom distress

Significant differences in coping behaviors ($B = 0.03$; 95% CI 0.02–0.04; $p < 0.001$) and physical symptom distress ($B = -0.29$; 95% CI −0.44 to −0.14; $p < 0.001$) were observed over time across conditions (Figure 3). The effect size for the difference in mean changes between baseline and post-intervention for coping behaviors and physical symptom were $d = 0.54$ and $d = 0.42$, respectively.

3.4.3 | Exploratory subgroup, mediation, and follow-up analyses

To determine if the effects of the intervention on HRQoL over time remained consistent across levels of demographic and clinical variables, we conducted a series of moderation analyses within the subsample of participants randomized to the CMI condition. We found no significant differences at the $p \leq 0.05$ level in the improvement in HRQoL across any of the demographic variables (age, race, gender, educational attainment) or, importantly, any of the clinical variables (cancer type, cancer stage, days since diagnosis). Similarly, controlling for these variables in a covariate-adjusted sensitivity analysis did not affect our findings. See Table S6 in the Supplemental Materials for additional details.

We also conducted mediation analyses that explored the causal relationship between changes in mindsets and subsequent changes in HRQoL. We found that adaptive changes in both illness and body mindsets mediated the relationship between condition (CMI vs TAU) and post-intervention HRQoL. See Figure S2 in the Supplemental Materials for more information.

Finally, we explored the durability of the effects in the 1 month following completion of the post-intervention outcome measures at week 14. These analyses suggest the effects on mindsets and HRQoL persist for at least 5 weeks after the completion of the last intervention module. See Figures S3-S4 in the Supplemental Materials for additional information.

4 | DISCUSSION

In this randomized clinical trial that evaluated feasibility, acceptability, and efficacy we found that a brief intervention designed to help patients with non-metastatic cancers adopt more adaptive mindsets about their illness and their bodies led to statistically significant and clinically meaningful changes in multiple domains of HRQoL, increased the use of effective coping strategies, and reduced

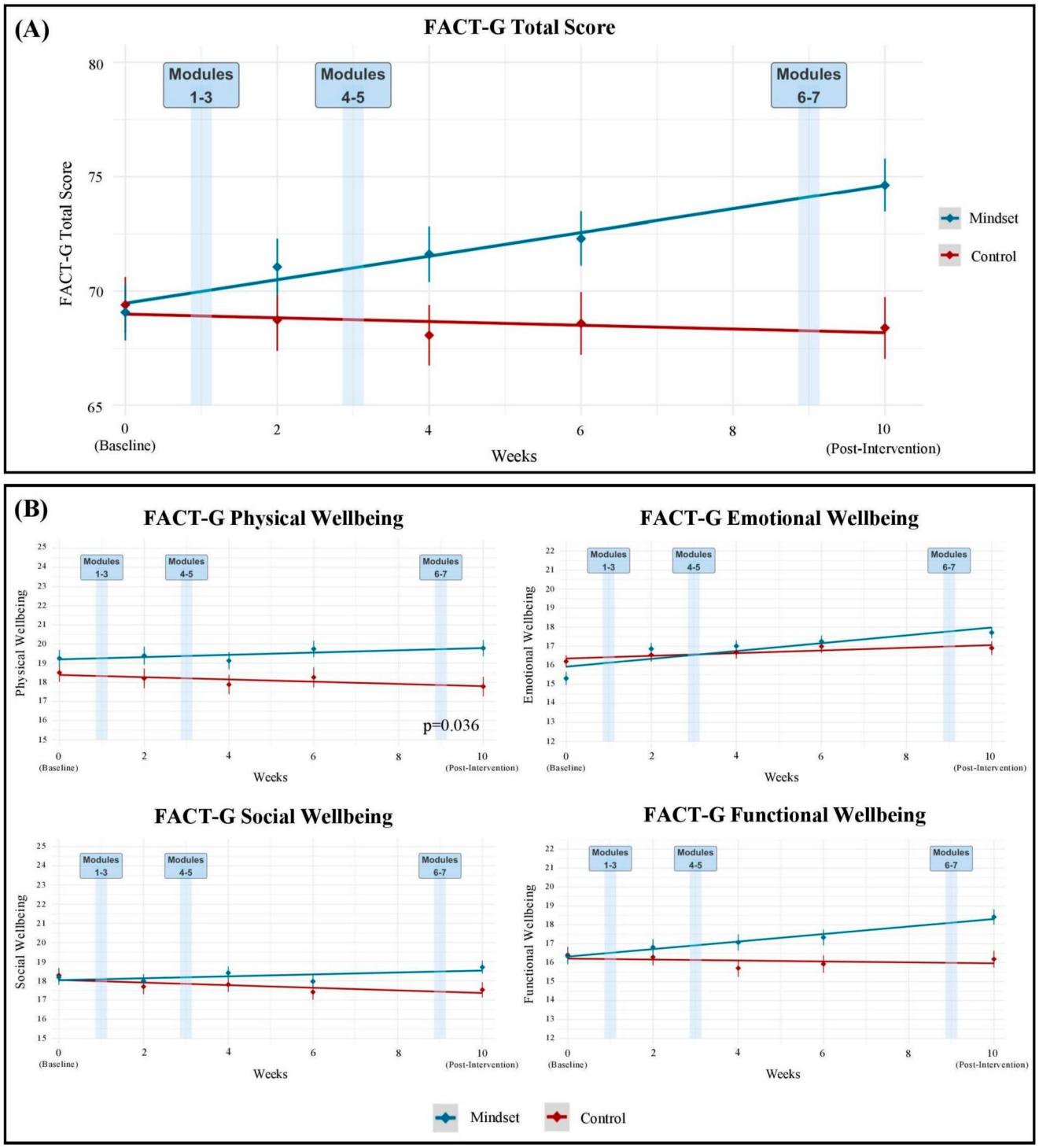

FIGURE 2 Change in wellbeing, measured by the general version of the Functional Assessment of Cancer Therapy - General (FACT-G), over time across conditions. FACT-G Total Score (A) and the four sub-scales (B) are shown. The timing the intervention modules at weeks 1, 3, and 9 are indicated in addition to the outcome measurement timepoints at weeks 0 (baseline), 2, 4, 6, and 10 (post-intervention). Error bars indicate standard errors. Change over time across conditions is significant at the $p < 0.001$ level unless otherwise indicated.

distress related to the physical symptoms of cancer, compared to a TAU control condition. The observed changes were both statistically significant and clinically meaningful, as a five-point difference on the FACT-G total (or between 0.30 and 0.50 standard deviations) has been accepted as rough approximations of a clinically meaningful differences in terms of clinical and subjective indicators.[23,24] In this study, patients in the CMI condition showed an increase of 5.55 points on their FACT-G total score, while those in the TAU condition moved in the opposite direction, reporting a decrease of −1.01 points, on average, over the same period of time.

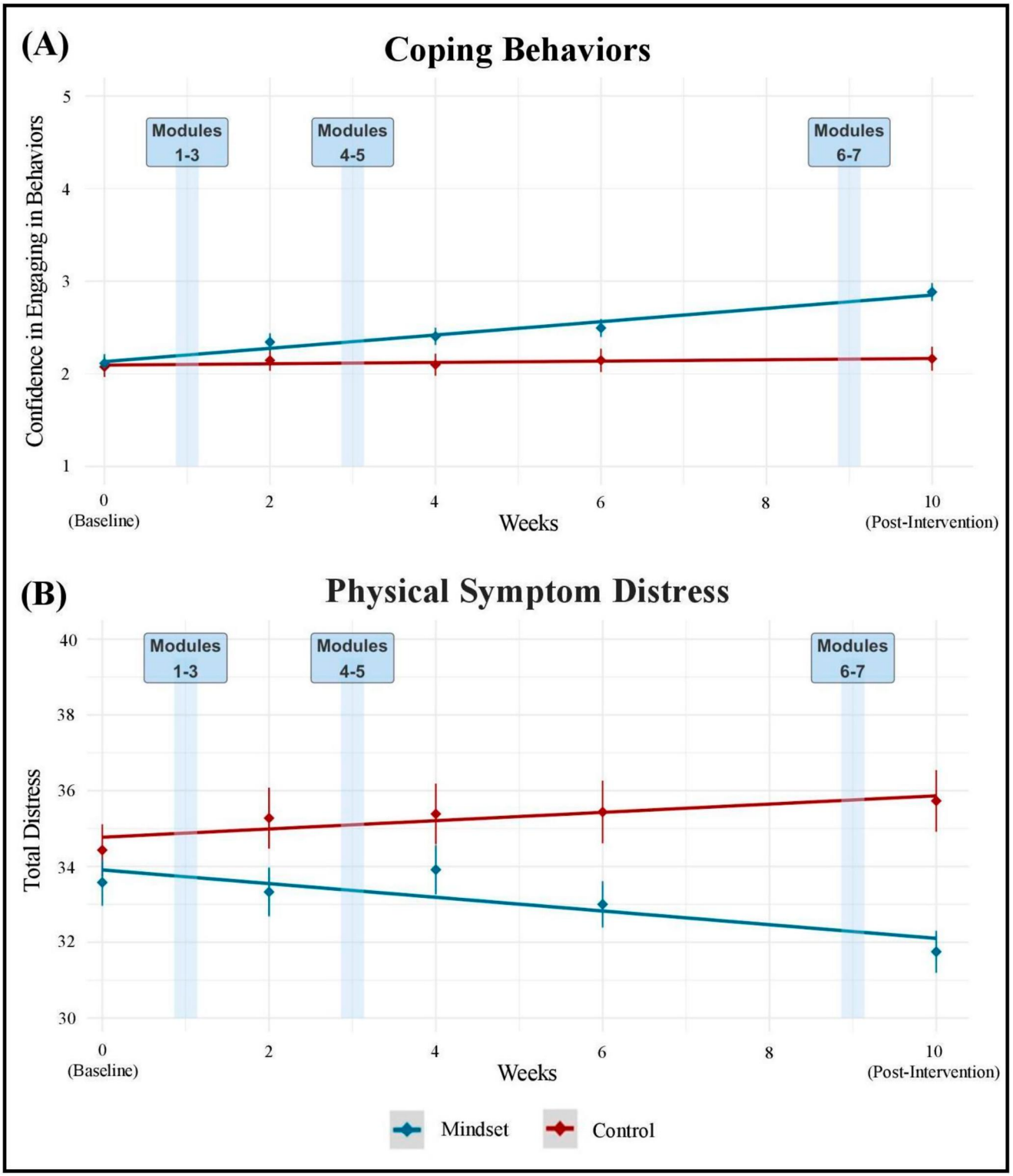

FIGURE 3 Changes in coping behaviors (A) and physical symptom distress (B) over time across conditions. Coping behaviors were measured by the short version of the Cancer Behavior Inventory (CBI) and physical symptom distress was measured by an abridged version of the Rotterdam Symptom Checklist (RSCL). The timing the intervention modules at weeks 1, 3, and 9 are indicated in addition to the outcome measurement timepoints at weeks 0 (baseline), 2, 4, 6, and 10 (post-intervention). Error bars indicate standard errors. Change over time across conditions is significant at the $p < 0.001$ level unless otherwise indicated.

4.1 | Limitations

This study has several limitations. As this study was designed as an initial test of a novel target (i.e., cancer and body mindsets) and format (i.e., digital administration) a treatment-as-usual control group was selected as the basis of comparison. While the time patients spent completing questionnaires and interaction with study staff were held constant across conditions, the CMI condition was more involved, and the time spent completing the intervention was not controlled for. Future studies may benefit from use of an attention matched control condition to further isolate the beneficial effects of the intervention.

A second limitation is the composition of the sample, specifically the disproportionately high representation of female and white participants compared with male and non-white participants. Race, ethnicity, and level of education may all impact variables like health literacy, stigma related to mental health, and willingness to participate in research. Therefore, future research should aim to recruit more representative populations, especially with respect to gender, race/ethnicity, and educational attainment. However, in the present research, we were able to enroll a clinically diverse sample of patients with a variety of types and stages of non-metastatic cancers, which contributes to the generalizability of these findings across disease-specific variables.

Third, this study took place during the COVID-19 pandemic. While the results may have been impacted by the global stress experienced during the pandemic, pandemic-related stressors should have been represented equally in both groups due to randomization. Furthermore, we believe the benefits of the intervention may be all the more promising given that the treatment showed clear effects even under these additional pandemic-related burdens.

Finally, the use of self-report measures to assess clinical characteristics presents a limitation due to the potential for inaccuracies in self-reported cancer type, stage, and length of diagnosis. Future work could improve upon this through the collection of medical records for verification of clinical details.

4.2 | Clinical implications

We interpret the magnitude of the observed effect as proof of concept and attribute the effects to our success in changing a new psychological target: patient mindsets. While novel, this work draws on a rich history of research on how people understand and respond to health-related challenges. This includes research on more general, trait-like factors including optimism, self-efficacy, and locus of control, as well as more specific situationally bound appraisals and perceptions of illness.[5] It also draws on research on more traditional psycho-oncology interventions such as cognitive behavioral therapy (CBT) or mindfulness based stress reduction (MBSR) however, the difference between mindset interventions like this one and CBT or mindfulness-based therapies is comparable to using drugs with different mechanisms of action.[7] Whereas most therapies teach skills aimed at reducing or managing symptoms such as stress or anxiety, mindsets represent a more specific and upstream psychological target: how one construes the meaning of their diagnoses and their body's ability to handle treatment. When done well, targeting mindsets can take considerably less time (2.5 h total vs. 16 h in CBT or MBSR) and yet still have meaningful downstream benefits on functioning, wellbeing, and potentially even physiology.[2]

The diagnosis of any chronic disease, including cancer, can dramatically disrupt an individual's quality of life, including their physical, social, emotional, and functional wellbeing. For many, it can be challenging to maintain the use of adaptive coping behaviors and effectively manage the distress of symptoms and side effects. Helping patients adopt more useful mindsets appears to be one way to improve these critical outcomes. Patients with more adaptive mindsets may be coping more effectively with their illness, feeling less distress from their symptoms, and experiencing a higher quality of life across multiple domains. This is important because these outcomes, especially quality of life, can reduce clinical outcomes and even affect survival rates.[25] However, implementing effective programs that evoke these sorts of improvements can be logistically challenging and financially impractical. This intervention presents a uniquely favorable cost to benefit ratio. It can be delivered efficiently (<2.5 h) alongside ongoing treatment, and its digital format allows for quick, low-cost, and widely accessible implementation and dissemination.

4.3 | Future directions

In the future, comparative efficacy studies in which the CMI is compared with existing in-person or digital interventions (e.g., CBT, MBSR, etc.) may be useful for understanding the relative efficacy of this style of intervention compared with other evidence-based therapeutics that are aimed specifically at symptom reduction. Future research is also needed to refine the intervention itself and define the proper dosing and schedule, as well as the possible value of combining CMI with other established techniques that have been shown to be effective in treating cancer related distress and anxiety. As efficacy and effectiveness of this intervention continue to be documented, implementation research should also consider various strategies for this digital intervention to be incorporated into routine healthcare, such as whether it can be billed or and reimbursed by insurance. Future implementation efforts should also consider ways to synergize patient focused interventions with trainings focused on providing care teams with a framework and skillset to uncover patient mindsets and support constructive mindset change in their practice. Finally, given the accumulating evidence that changes in mindsets may also improve stress and immune responses[9] and even enhance treatment outcomes,[26] future research should examine the degree to which mindset interventions may improve physiological outcomes.

5 | CONCLUSIONS

Improving the HRQoL of recently diagnosed cancer patients has become increasingly recognized as a core component of comprehensive patient centered care in oncology. This study provides an encouraging demonstration that a brief, but targeted digital intervention can improve multiple domains of HRQoL. As such, it helps set the stage for a variety of important questions to follow, including understanding the range and benefit of digital interventions as well as how best to incorporate these interventions into routine clinical care.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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