Original Paper

Examining the Feasibility, Acceptability, and Preliminary Efficacy of a Health App for Postacute Pandemic Years in Managing Physical and Psychological Distress Symptoms: Pilot Quasi-Experimental Study

Justina Yat Wa Liu[1,2,3], PhD; David Man[4,5], PhD; Frank Ho Yin Lai[5,6], PhD; Rina Wing Yan Wong[1], MBA; Pui Ying Mak[1], BSc; Lin Yang[1], PhD; Daphne Sze Ki Cheung[1,7,8], PhD; Rick Yiu Cho Kwan[9], PhD; Gabriel Ching Hang Fong[10], PhD; Teris Cheung[1,5], PhD; Simon Ching Lam[9], PhD; Vincent To Yee Ng[11], PhD; David Ho Keung Shum[2,5,10], PhD

[1]School of Nursing, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

[2]Research Institute for Smart Ageing, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

[3]Research Center for Assistive Technology, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

[4]President's Office, Tung Wah College, Hong Kong, China (Hong Kong)

[5]Mental Health Research Centre, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

[6]Department of Social Work, Education and Community Wellbeing, Northumbria University, Newcastle, United Kingdom

[7]School of Nursing and Midwifery, Deakin University, Melbourne, Australia

[8]Alfred Health, Melbourne, Australia

[9]School of Nursing, Tung Wah College, Hong Kong, China (Hong Kong)

[10]Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

[11]University Research Facility in Big Data Analytics, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

Corresponding Author:
Simon Ching Lam, PhD
School of Nursing
Tung Wah College
16/F, School of Nursing, Ma Kam Chan Memorial Building
31 Wylie Road, Homantin, Kowloon
Hong Kong, 00000
China (Hong Kong)
Phone: 852 3468 6854
Email: simonlam@twc.edu.hk

Abstract

Background: Physical and psychological distress symptoms can adversely affect daily functioning and quality of life, highlighting the need for accessible self-management support. Although mobile health (mHealth) interventions show promise in supporting physical symptom management, evidence regarding their feasibility and potential effects on psychological distress remains limited.

Objective: This pilot study aimed to evaluate the feasibility, acceptability, and preliminary efficacy of the health app for postacute pandemic years (HAPPY) for managing physical and psychological distress symptoms.

Methods: A 2-arm, single-blind, quasi-experimental trial was conducted from July 2023 to January 2024. Thirty-eight participants experiencing distress symptoms related to COVID-19 were assigned to the experimental group or a waitlist control group. The experimental group received a 24-week mHealth intervention through the HAPPY app, which included an 8-week supervised phase with weekly face-to-face sessions and a 16-week self-management phase. The control group received no active treatment. Feasibility was assessed through recruitment, adherence, and adverse event monitoring, whereas preliminary efficacy was evaluated at 8 weeks (T1) and 24 weeks (T2) and compared with baseline (T0) using quantitative measures of distress, fatigue, sleep quality, pain, emotional regulation, and posttraumatic stress disorder (PTSD).

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Results: The study demonstrated the feasibility of the HAPPY app, with a recruitment rate of 88.37% (38/43), a dropout rate of 10.5% (4/38), and an adherence rate of 93.33% (14/15) for the supervised sessions. No adverse events were reported. Significant within-group improvements were observed for distress (Kessler Psychological Distress Scale [K10]; *P*<.001), fatigue (Brief Fatigue Inventory–Chinese [BFI-C]; *P*<.001), sleep quality (Chinese Pittsburgh Sleep Quality Index [CPSQI]; *P*=.009), and PTSD symptoms (Chinese Impact of Event Scale–Revised [CIES-R]; *P*=.02). However, between-group differences were limited.

Conclusions: The study demonstrated the HAPPY app's feasibility, acceptability, and potential efficacy for managing physical and psychological distress symptoms. High recruitment, retention, and adherence rates, along with measurable improvements in distress, fatigue, sleep quality, and pain, suggest the app's promise as a scalable intervention.

Trial Registration: ClinicalTrials.gov NCT05459896; https://clinicaltrials.gov/study/NCT05459896

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KEYWORDS

long COVID; mHealth intervention; mobile health; distress symptoms; mobile apps; self-management; psychological distress; feasibility studies

Introduction

Persistent physical and psychological distress symptoms can adversely affect daily functioning and quality of life, highlighting the need for accessible self-management support [1]. Mobile health (mHealth) refers to the use of mobile devices and apps to enhance health service delivery and access to health information, including health monitoring, disease management, telemedicine, and patient education [1]. mHealth has become an increasingly important tool for supporting health care delivery and self-management by enabling symptom monitoring, patient-reported data collection, and remote interventions [2,3]. Such support is especially important for individuals with persistent symptoms [4].

The World Health Organization (WHO) announced in 2023 that COVID-19 no longer constituted a Public Health Emergency of International Concern (PHEIC), marking a shift toward managing COVID-19 as an ongoing health concern rather than an extraordinary event [5]. Although this announcement signaled a new phase in the global response, the health and social consequences of the pandemic continue to affect communities [6]. As societies move beyond the acute emergency phase, there remains a need to address the ongoing physical and psychological burden experienced by many individuals in the community [6,7]. In this context, persistent symptoms, including fatigue, pain, insomnia, cognitive difficulties, anxiety, and stress, remain common and may continue to affect daily functioning and quality of life [6-8]. These symptoms may occur in individuals with or without a confirmed diagnosis of long COVID, suggesting that persistent symptoms may affect a broader population, including individuals without a confirmed diagnosis of long COVID [9].

A scoping review of 8 studies identified mHealth interventions as a commonly used approach to the rehabilitation of individuals with post-COVID-19 symptoms. Some included studies reported reductions in breathlessness and fatigue and improvements in daily functioning [10]. Although current evidence suggests potential benefits of mHealth interventions for managing physical symptoms, evidence regarding their efficacy in alleviating psychological challenges, such as distress, remains limited. Additionally, few longitudinal studies have assessed their long-term effects on both physical and psychological outcomes. Most studies have focused on short-term outcomes, leaving a gap in our understanding of the sustained effects of mHealth interventions [10]. Evidence remains limited regarding the feasibility of these interventions and their effects on psychological distress among people experiencing persistent physical and psychological symptoms [11,12].

This study aimed to pilot-test the feasibility, acceptability, and preliminary efficacy of a health app for postacute pandemic years (HAPPY; hereafter referred to as the app) for managing both physical and psychological distress symptoms. The app was designed as a theory-driven, structured intervention informed by the transactional model of stress and coping theory (TMSCT). TMSCT provides a useful framework for understanding how individuals respond to stressors through cognitive appraisal and coping strategies, including problem-focused (targeting the source of stress) and emotion-focused (targeting emotional responses to stress) approaches [13]. Participants in the experimental group used the app for 24 weeks, starting with an 8-week supervised phase supported by well-trained research assistants (RAs), followed by a 16-week self-management phase during which participants continued using the app independently to manage their health concerns. Participants using the app were compared with those in a waitlist control group that received no active treatment. We hypothesized that the app would be feasible, acceptable, and efficacious for self-management of distress syndromes during both the supervised and self-management phases.

Methods

Trial Design

This pilot study was a 2-arm, single-blind, single-center, quasi-experimental trial designed to collect quantitative data alongside qualitative data from focus groups. It was conducted from July 2023 to January 2024. During the pilot, the app was compatible only with Android smartphones. Consequently, participants were allocated to either the experimental or waitlist control groups based on their phone model rather than through random assignment. Despite the lack of randomization, the study followed a clinical trial structure and adhered to the CONSORT (Consolidated Standards of Reporting Trials) 2010

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statement extension for randomized pilot and feasibility trials [14]. The trial was registered at ClinicalTrials.gov (identifier: NCT05459896).

Ethical Considerations

Ethical approval was obtained from the Human Subjects Ethics Review Committee of The Hong Kong Polytechnic University (HSEARS20220318003). Written informed consent was obtained from all participants after they were provided with detailed information about the study's purpose, procedures, risks, and benefits, allowing for an informed decision to participate. Participants were given the opportunity to ask questions about the study procedures. The participants were assured that their identities and collected personal data would be kept confidential. They were also informed that they could opt out from the study whenever they wished. No major risks were anticipated throughout the study period. While the primary risk identified was muscle fatigue during physical activity, participants were closely monitored for adverse effects, and a protocol was in place for addressing any issues that arose. To acknowledge their time and participation, eligible participants received compensation in the form of HKD 100 (US $12.76; HKD 1=US $0.1276 as of July 3, 2023) supermarket coupons after completing each assessment point, with a total of HKD 300 (US $38.28) for the baseline, T1, and T2 follow-up assessments. This compensation aimed to minimize financial barriers to participation while ensuring ethical standards were upheld.

Participants

Setting

Participants were recruited through a community health center in Hong Kong, which plays a crucial role in health promotion by providing education on healthy lifestyles, chronic disease management, and preventive measures. The center also fosters social interaction, essential for mental and emotional well-being [15].

Recruitment

Recruitment posters were displayed at a community health center and emailed to its service users. Interested individuals self-registered for the study by scanning the QR code provided on the poster. Participants were recruited through convenience sampling due to the research team's inability to know the health profile of each eligible participant in the community setting. An RA screened potential participants based on the following eligibility criteria.

Inclusion Criteria

The inclusion criteria were (1) aged 18 years or older; (2) ability to communicate in Cantonese; and (3) ownership of a smartphone with internet access; (4) exhibiting psychosocial distress, indicated by a Kessler Psychological Distress Scale (K10) score of ≥20 [16]; and/or (5) experiencing at least one of the following 3 physical distress symptoms for at least 3 days in the previous week: physical fatigue, indicated by Brief Fatigue Inventory–Chinese (BFI-C) score of ≥4 [17]; decreased sleep quality, measured by a Chinese Pittsburgh Sleep Quality Index (CPSQI) score of >5 [18]; or pain (eg, headaches, upset stomach, and other forms of pain), measured by an 11-point Numeric Rating Scale (NRS) score of >3 [19].

Exclusion Criteria

Participants were excluded if they (1) reported impaired vision that prevented them from viewing texts and graphics on a smartphone; (2) reported hearing impairment that hindered their ability to hear the audio instructions in the app; and/or (3) had a self-reported diagnosis of intellectual disability or cognitive impairment.

Interventions

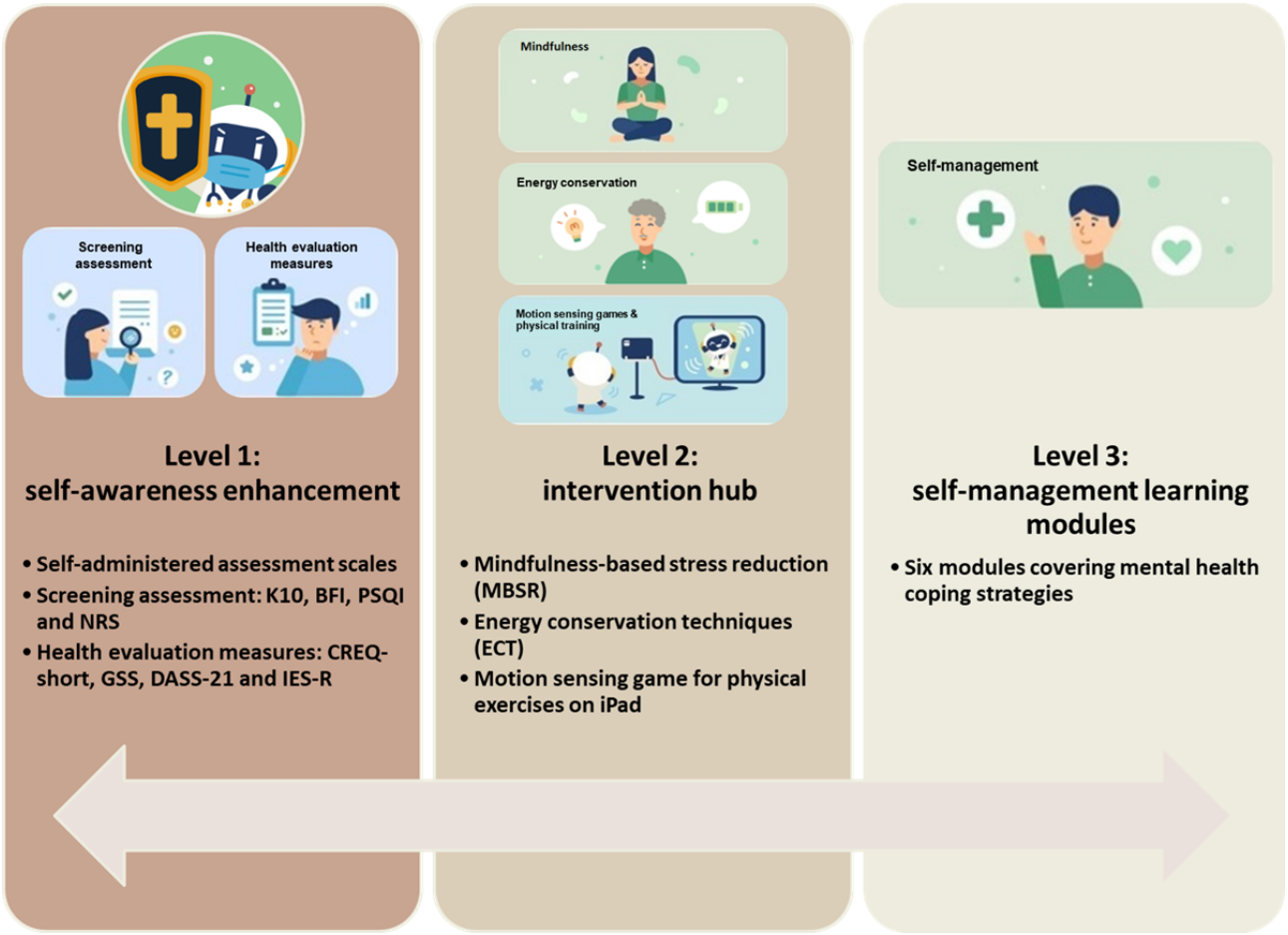
Experimental Group

The intervention included an 8-week supervised phase followed by a 16-week self-management phase. The supervised phase aimed to empower participants to manage their distress during and beyond the study. During the supervised phase, an RA conducted 8 weekly, 1-hour sessions at a health center. In the first session, participants were introduced to the basic features and functions of the app. Sessions 2-7 focused on how mindfulness practices, physical exercise, and energy-saving techniques could reduce symptoms of COVID-19-related distress. Additional guidance was provided on using the app for various embedded interventions aimed at relieving distress, including mindfulness-based intervention, gamified motion-based physical exercises, and energy conservation techniques. Participants could continue accessing this information and training through the app at their convenience. The final session reviewed and summarized the knowledge participants gained throughout the 8-week program. Participants were then encouraged to continue using the app to self-monitor and self-manage their physical and psychological well-being in order to reduce their distress levels.

The app was designed with 3 levels informed by the TMSCT (Figure 1).

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Figure 1. The 3-level design of the app: level 1, enhancement of self-awareness (assessment); level 2, the intervention hub; and level 3, self-management learning modules. BFI: Brief Fatigue Inventory; CERQ-short: Cognitive Emotion Regulation Questionnaire-short form; DASS-21: 21-item Depression Anxiety Stress Scale; GSS: General Self-Efficacy Scale; IES-R: Impact of Event Scale–Revised; K10: Kessler Psychological Distress Scale; NRS: Numeric Rating Scale; PSQI: Pittsburgh Sleep Quality Index.



App Features

Level 1 (Self-Awareness Enhancement)

Self-awareness enhancement involved participants regularly completing self-administered assessment scales to enhance their understanding of their health conditions. These assessment scales also served as outcome measures to evaluate the efficacy of the app, as described in the section on secondary outcomes.

Level 2 (Intervention Hub)

The intervention hub offered various interventions included in the app to alleviate participants' levels of distress. The recommendation was made based on participants' assessment results at Level 1. The interventions were as follows:

1. The mindfulness-based intervention was adapted from the mindfulness-based stress reduction (MBSR) [20,21] and consisted of 10 mindfulness techniques. One technique was unlocked each week during the supervised phase, and participants were encouraged to practice the unlocked mindfulness techniques at least twice a week. The frequency of practice increased during the self-management phase, and participants were asked to engage in the mindfulness practice daily. The intervention materials and training guidelines were validated by a certified mindfulness practitioner.
2. The energy conservative techniques (ECT) included 5 thematic animation videos demonstrating energy conservation principles applicable to various daily activities, such as self-care, household tasks, and activities performed outdoors or in the workplace [22]. Energy conservation was included as a general self-management strategy to support participants experiencing fatigue, low energy, or difficulty balancing daily activities, regardless of whether they had long COVID [23,24]. One video was unlocked weekly during the supervised phase, and participants were encouraged to watch the video multiple times to enhance knowledge and skills. A brief quiz was provided after each video for participants to self-assess their understanding of the techniques. Participants were also advised to practice these techniques in their daily lives. A team of experienced occupational therapists validated the intervention materials and training guidelines.
3. Two gamified, motion-based physical exercises were designed to enhance the participants' engagement. In the motion-based exercises, participants interacted with a virtual sports trainer to complete training tasks, while they followed the preset exercise postures demonstrated by the virtual sports trainer in the resistance exercises. An 11-inch iPad Pro (Apple, Inc) embedded with the light detection and ranging (LiDAR) scanner [25] captures real-time body movements, and an integrated feedback system was used

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to evaluate posture accuracy. The subsequent level was unlocked with cumulative total scores from participants' performances on various exercise tasks, such as posture accuracy. Participants were encouraged to practice both during supervised sessions and throughout the self-management phase using the app. They were also advised to adhere to the weekly aerobic activity guidelines of 150 minutes moderate-intensity or 75 minutes of vigorous-intensity exercise, as recommended by the WHO guidelines [26].

Level 3 (Self-Management Learning Modules)

The self-management learning modules included 6 modules covering mental health coping strategies, such as emotional and cognitive regulation, wellness, and self-care practices. The modules used post-COVID-19 symptoms (such as fatigue, sleep difficulties, and pain) as illustrative examples to demonstrate the application of these self-management strategies in the context of persistent physical and psychological distress. In addition to the 3 aforementioned interventions at Level 2, participants were required to complete one thematic self-management module each week before unlocking the subsequent modules.

Waitlist Control Group

The waitlist control group received the same intervention immediately after the experimental group completed their interventions in week 25. During the waiting period, the control group received materials promoting general physical and psychological health.

Outcomes

Overview

Participants' characteristics, including demographic information, were collected at baseline (T0).

Primary Outcomes

The primary outcome was to assess the feasibility of using the app for alleviating distress symptoms. Assessments included the recruitment rate, dropout rate, response rate, intervention adherence rate, and adverse events. The recruitment rate was defined as the proportion of eligible participants who successfully enrolled in this study. The response rate was the percentage of usable responses obtained from our quantitative data questionnaires, calculated as a proportion of the number of eligible participants. The dropout rate was the proportion of participants who exited this study before its completion. The intervention adherence rate was measured by the number of participants who attended more than 80% of the 8 supervised sessions [27]. The overall rating of participants' satisfaction on the intervention program was defined as the average scores given by participants on a scale of 10, where 0 represented the worst rating and 10 represented the best rating. Participants self-reported adverse events or side effects. Success criteria for this pilot study were established with prespecified thresholds of a 60% recruitment rate and 70% response, adherence, and engagement rates [28].

Secondary Outcomes

Secondary outcomes evaluated the preliminary treatment effect at 8 weeks, immediately following the weekly supervised sessions (T1), and at the 16-week follow-up (T2). The data were collected using the app by an RA. These included participants' psychological distress levels, assessed using the K10, which consists of 10 items [16]. Each item was rated on a 5-point Likert scale. The total score, ranging from 10 to 50, was calculated by adding up the scores of all items. A cutoff score of 20 or above was indicative of psychosocial distress [29]. This scale demonstrated satisfactory internal consistency, with a Cronbach α of 0.80 [16].

The BFI-C, consisting of 9 items, was used to assess participants' fatigue levels [17]. The initial 3 items assessed fatigue severity, and the remaining 6 items evaluated fatigue interference with daily activities, including general activity, mood, ability to walk, regular work (including both working outside home and household chores), interpersonal relationships, and life enjoyment. Each item was scored on an 11-point Likert scale, and the total score, ranging from 0 to 10, was calculated by averaging all item scores. A cutoff score of 4 or higher indicated moderate to severe fatigue [17,30]. The BFI-C demonstrated high convergent validity with correlation coefficients ranging from –0.44 to –0.71 and high reliability with Cronbach α values between 0.90 and 0.92 for the fatigue interference and severity items [17].

The CPSQI was used to evaluate participants' sleep quality [18]. It consisted of 19 items, which were categorized into 7 domains: sleep duration, sleep latency, habitual sleep efficiency, sleep disturbances, subjective sleep quality, use of sleep medications, and daytime dysfunction. Each item was scored on a 4-point Likert scale, with a total score ranging from 0 to 21. A cutoff score greater than 5 indicated poor sleep quality [18]. The CPSQI was found to be a valid and reliable tool for assessing sleep quality, with an acceptable test-retest reliability ranging from 0.77 to 0.85 [18].

The NRS was used to assess the intensity of pain experienced by each participant [31-33]. The NRS is a single-item, 11-point numeric scale in which 0 represents "no pain" and 10 represents "the worst pain imaginable." A cutoff score greater than 3 was indicative of moderate to severe pain [31]. This scale demonstrated a high intraclass correlation of 0.95 and good convergent validity of 0.94 when compared with the Visual Analog Scale (VAS) [19].

The Cognitive Emotion Regulation Questionnaire-short form (CERQ-short), derived from the validated long version of the Chinese Cognitive Emotion Regulation Questionnaire (CERQ-C) [34,35], was used to assess participants' cognitive emotion regulation. This 18-item scale consisted of 9 conceptually different subscales, namely self-blame, other-blame, rumination, catastrophizing, positive refocusing, planning, positive reappraisal, putting into perspective, and acceptance. Each subscale included 2 items, scored on a 5-point Likert scale. The score for each subscale was calculated by adding the related items, resulting in a total score ranging from 2 to 10. Higher scores indicated a more frequent application of a particular cognitive strategy [34]. The long version of the

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CERQ-C was reported to be a reliable and valid instrument, with a moderate internal consistency (Cronbach α=0.83) and an interclass correlation coefficient of 0.79 [35].

The Chinese General Self-Efficacy Scale (CGSS) was used to assess participants' ability to cope with daily challenges and adjust to stressful life events [36]. The CGSS was a 10-item scale scored on a 4-point Likert scale. The total score, ranging from 10 to 40, was calculated by adding all the items scored. High scores indicated greater self-efficacy [36]. The CGSS has been shown to be a reliable and valid instrument across various studies [36,37].

The Chinese version of the 21-item Depression Anxiety Stress Scales (DASS-21) was used to assess symptoms of depression and anxiety [38]. This scale, derived from the DASS-42, consists of 3 subscales, including depression, anxiety, and stress. Each subscale included 7 items, scored on a 4-point Likert scale. The score for each subscale, ranging from 0 to 21, was calculated by adding the related items. Higher scores indicated more severe symptoms in that specific domain [38,39]. For the analyses reported in this study, each subscale sum was multiplied by 2, yielding a score range of 0–42. The DASS-21 was reported to be a reliable and valid instrument, with moderate convergent validity against the Chinese Beck Depression Inventory (r_1=0.51 and r_2=0.64) and the Chinese State-Trait Anxiety Inventory (r=0.41). The Cronbach α values for the 3 domains and the overall DASS-21 scale ranged between 0.80 and 0.92, indicating high reliability [38].

The 22-item Chinese Impact of Event Scale–Revised (CIES-R) was used to evaluate participants' subjective distress due to the pandemic [40-42]. This scale consists of 3 subscales, including intrusion (8 items), avoidance (8 items), and hyperarousal (6 items). Each item was scored on a 5-point Likert scale. The total score, ranging from 0 to 88, was calculated by summing up all 22 items. Higher scores indicated a greater risk of PTSD symptomatology [43]. The external validity of the intrusion (r=0.54), avoidance (r=0.53), and hyperarousal (r=0.64) components with the General Health Questionnaire-20 was found to be moderate [40]. The scale demonstrated an acceptable level of internal consistency, with Cronbach α values ranging from 0.83 to 0.89.

Sample Size

As this was a pilot study, no formal sample size calculation was performed for hypothesis testing. To determine the pilot sample size, we applied the stepped rule of thumb [44]. The sample size was justified by the planned primary outcome of the future definitive trial, psychological distress measured using the K10 at T1, and an anticipated standardized effect size of 0.5. For a future definitive trial targeting 90% power at a 2-sided 5% significance level, the approach recommended 15 evaluable pilot participants per group. After allowing for approximately 20% attrition, we set the recruitment target of 38 participants (19 per group).

Randomization, Concealment, and Blinding

During the pilot study, the app was only compatible with Android smartphones. As a result, participants were assigned to either the experimental or waitlist control groups based on their phone model instead of random assignment. Therefore, randomization and allocation concealment were not performed in this pilot study. Because of the nature of this study, participants and RAs delivering the interventions could not be blinded; however, outcome assessors remained blinded to group allocation.

Procedures

Participants with Android smartphones were assigned to the experimental group. A preset login password was assigned to them before the first supervised session to address privacy concerns. During the first supervised session, participants were instructed and assisted in downloading the HAPPY app and learning its features. A set of devices for motion-sensing exercises at home was provided during the third supervised session, including an 11-inch Apple iPad Pro embedded with a LiDAR scanner with a protective case, a tripod, a type-C-to-HDMI adapter, an HDMI cable, and a set of resistance bands. All equipment was returned after the completion of the T2 assessment.

Data Analytical Methods

Quantitative data were analyzed using IBM SPSS Statistics (version 28.0) [45]. An intention-to-treat principle was applied [46]. Missing data were imputed using multiple imputation, generating 5 completed datasets based on the assumption of missing at random [47]. Participants' characteristics and baseline outcome scores for the experimental and waitlist control groups were examined using the Mann-Whitney *U* test for continuous variables, while the chi-square test or the Fisher exact test were used for categorical variables. Multilevel modeling (MLM) was used to measure the changes of the outcome measures over time, specifically at 8 weeks (T1) and 24 weeks (T2) relative to its baseline (T0), to determine the effectiveness of the intervention. The level of significance was set at 0.05.

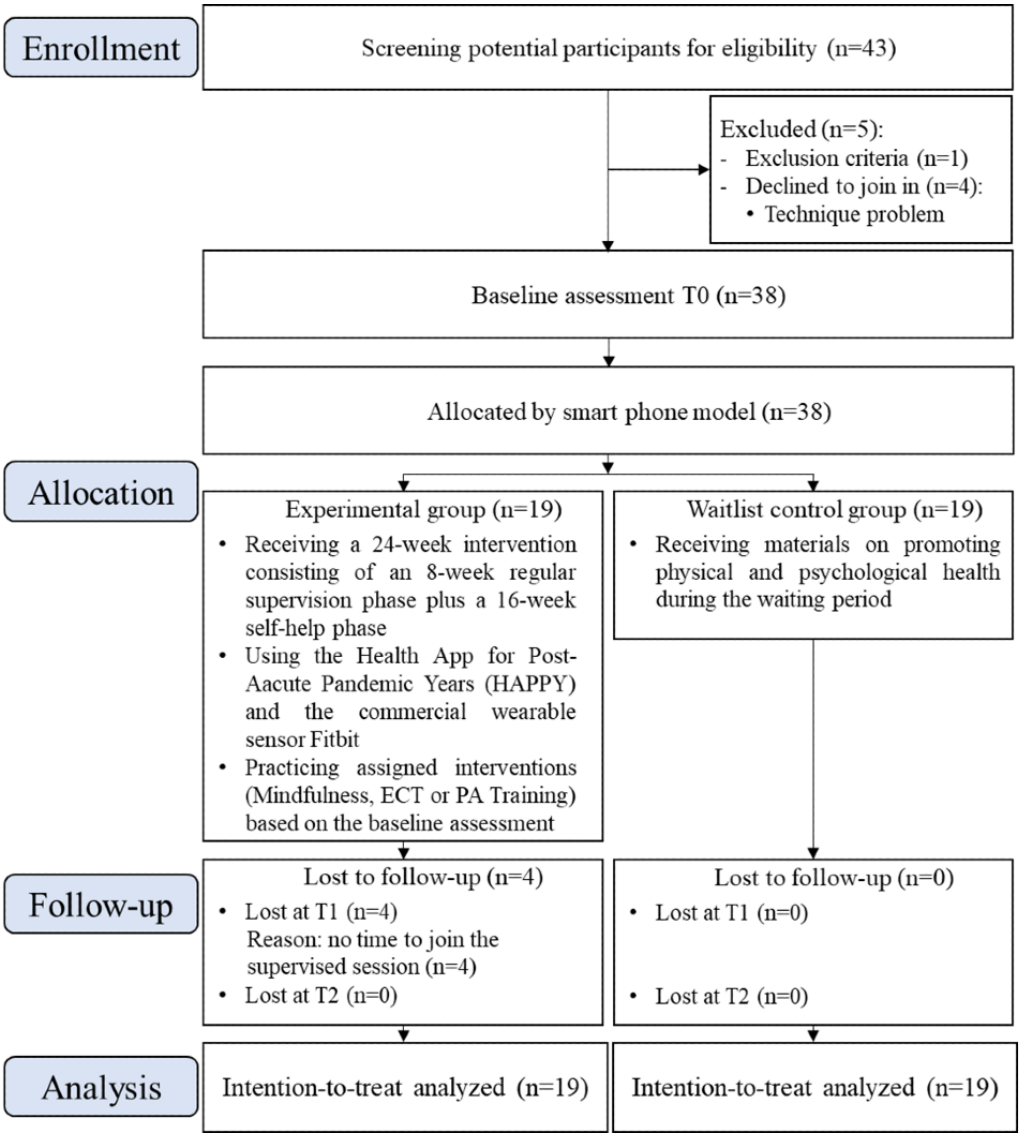
Results

Participants

As shown in Figure 2, 43 participants were screened, of whom 38 were eligible. Five participants were excluded: one for not fulfilling the eligibility criteria and 4 due to technical issues with smartphone models that did not support the app. The 38 participants were allocated to either the experimental (n=19) or control (n=19) groups based on their smartphone models. In the experimental group, only 15 participants completed the intervention, whereas 4 participants declined to attend the supervised sessions because they were unavailable. No withdrawals occurred in the control group. Thirty-four participants completed the outcome assessment at T1 and T2, and the data of all participants were used in the data analysis.

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Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flowchart of participant recruitment. ECT: energy conservative technique; PA: physical activity.



Baseline Characteristics of the Participants

The demographic characteristics of the participants are shown in Table 1. The mean age was 55.1 (SD 16.7) years old, and the average weekly smartphone usage in hours was 28.2 (SD 16). The participants were predominantly female, and most had attained tertiary education or higher, were married, lived in private housing, were retired, and owned their own homes. Additionally, most participants reported having sufficient income to purchase antipandemic materials, and most indicated that COVID-19 had influenced their decision-making. There were no significant differences in demographics among participants. As shown in Table 2, no significant difference was found between the experimental and waitlist control groups in all secondary outcome measures at baseline.

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Table 1. Demographic characteristics of participants at baseline (intent-to-treat).

Demographics	Total (n=38)	Experimental (n=19)	Control (n=19)	$X^2(df)^b$ /z^c	*P* value
Gender, n (%)				0.9 (1)	.32
Male	15 (39.5)	6 (31.6)	9 (47.4)		
Female	23 (60.5)	13 (68.4)	10 (52.6)		
Age (years), mean, (SD)	55.1 (16.7)	59.1 (13.8)	51.0 (18.6)	–1.551[c]	.12
Education level, n (%)				6.2 (5)	.29
Primary or below	2 (5.3)	2 (10.5)	0 (0.0)		
Junior secondary (form 1-3)	3 (7.9)	3 (15.8)	0 (0.0)		
Senior secondary (form 4-7/DSE/Project Yi Jin)	8 (21.1)	4 (21.1)	4 (21.1)		
Tertiary education: sub-degree course (including diploma/certificate/associate degree course)	2 (5.3)	1 (5.3)	1 (5.3)		
Tertiary education: degree course (Bachelor's degree)	12 (31.6)	5 (26.3)	7 (36.8)		
Master's degree or above	11 (28.9)	4 (21.1)	7 (36.8)		
Marital status, n (%)				3.7 (4)	.44
Single	10 (26.3)	4 (21.1)	6 (31.6)		
Married	22 (57.9)	11 (57.9)	11 (57.9)		
Cohabited	1 (2.6)	0 (0.0)	1 (5.3)		
Divorced/separated	3 (7.9)	2 (10.5)	1 (5.3)		
Widowed	2 (5.3)	2 (10.5)	0 (0.0)		
Type of house, n (%)				2.5 (2)	.29
Public housing	6 (15.8)	2 (10.5)	4 (21.1)		
Subsidized home ownership	5 (13.2)	4 (21.1)	1 (5.3)		
Private housing	27 (71.1)	13 (68.4)	14 (73.7)		
Employment status, n (%)				4.3 (5)	.50
Full-time	6 (15.8)	4 (21.1)	2 (10.5)		
Part-time	6 (15.8)	2 (10.5)	4 (21.1)		
Unemployed	1 (2.6)	1 (5.3)	0 (0.0)		
Retired	20 (52.6)	10 (52.6)	10 (52.6)		
Student	4 (10.5)	1 (5.3)	3 (15.8)		
Homemakers/stay-at-home spouses	1 (2.6)	1 (5.3)	0 (0.0)		
House ownership, n (%)				1.3 (1)	.45[a]
Self-owned	29 (76.3)	16 (84.2)	13 (68.4)		
Rented	9 (23.7)	3 (15.8)	6 (31.6)		
A dequacy of income for purchasing antipandemic materials, n (%)				0.4 (1)	≥.99[a]
Enough	35 (92.1)	18 (94.7)	17 (89.5)		
Not enough	3 (7.9)	1 (5.3)	2 (10.5)		
Average weekly smartphone usage in hours, mean (SD)	28.2 (16.0)	28.2 (16.3)	28.2 (16.0)	–0.089[c]	.93
COVID-19 impacts on individual's personal decision-making, n (%)				0.1 (1)	.73
Yes	27 (71.1)	13 (68.4)	14 (73.7)		
No	11 (28.9)	6 (31.6)	5 (26.3)		

[a]Fisher exact test.

[b]Chi-square test.

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[c]Mann-Whitney *U* test.

Table 2. Descriptive statistics of outcome measures at baseline (intent-to-treat).

Outcome measures	Total (n=38)		Intervention (n=19)		Control (n=19)		z[a]	*P* value
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		
K10[b] (range=10-50;↑score =↑distress)	26.3 (7.8)	24.5 (21.0-32.0)	27.4 (8.5)	27.0 (21.0-33.0)	25.2 (7.0)	24.0 (21.0-28.0)	–0.980	.32
BFI-C[c] (range=0-10;↑score =↑fatigue)	5.1 (1.9)	5.2 (3.9-6.2)	5.6 (1.9)	5.9 (4.2-7.1)	4.6 (1.9)	4.2 (3.2-6.0)	–1.797	.07
CPSQI[d] (range=0-21;↑score =↓sleep quality)	10.8 (3.3)	11.0 (9.0-13.0)	11.3 (2.7)	11.0 (10.0-13.0)	10.3 (3.8)	11.0 (6.0-13.0)	–0.867	.39
NRS[e] (range=0-10;↑score =↑pain)	3.3 (2.6)	3.0 (1.0-5.0)	3.9 (2.7)	4.0 (1.0-7.0)	2.7 (2.3)	3.0 (0.0-4.0)	–1.564	.12
CERQ-short[f] (range=18-90;↑score =↑use of cognitive strategy)	58.5 (5.6)	58.5 (54.0-60.0)	58.6 (5.9)	58.0 (55.0-60.0)	58.4 (5.3)	59.0 (54.0-61.0)	–0.059	.95
CGSS[g] (range=10-40;↑score =↑self-efficacy)	22.4 (5.7)	22.5 (18.0-26.0)	21.9 (6.7)	20.0 (16.0-28.0)	22.8 (4.6)	23.0 (21.0-26.0)	–0.938	.35
DASS-D[h] (range=0-42;↑score =↑severity)	10.1 (7.7)	9.0 (4.0-16.0)	10.5 (8.8)	10.0 (2.0-18.0)	9.6 (6.6)	8.0 (4.0-16.0)	–0.073	.94
DASS-A[i] (range=0-42;↑score =↑severity)	9.2 (6.9)	8.0 (4.0-14.0)	9.8 (6.3)	10.0 (6.0-16.0)	8.6 (7.6)	6.0 (4.0-12.0)	–0.954	.34
DASS-S[j] (range=0-42;↑score =↑severity)	17.5 (8.4)	16.0 (12.0-22.0)	16.6 (8.9)	14.0 (12.0-22.0)	18.4 (8.0)	16.0 (12.0-22.0)	–0.572	.57
CIES-R[k] (range=0-88;↑score =↑risk of PTSD[l])	23.6 (14.1)	20.0 (13.0-32.0)	23.7 (13.4)	22.0 (13.0-38.0)	23.5 (15.1)	19.0 (13.0-32.0)	–0.146	.88

[a]Mann-Whitney *U* test.
[b]K10: Kessler Psychological Distress Scale.
[c]BFI-C: Brief Fatigue Inventory–Chinese.
[d]CPSQI: Chinese Pittsburgh Sleep Quality Index.
[e]NRS: Numeric Rating Scale
[f]CERQ-short: Cognitive Emotion Regulation Questionnaire-short form.
[g]CGSS: Chinese General Self-Efficacy Scale.
[h]DASS-D: Depression Anxiety Stress Scales-Depression.
[i]DASS-A: Depression Anxiety Stress Scales-Anxiety.
[j]DASS-S: Depression Anxiety Stress Scales-Stress.
[k]CIES-R: Chinese Impact of Event Scale-Revised.
[l]PTSD: posttraumatic stress disorder.

Primary Outcome: Feasibility of Using the App

The pilot study, from recruitment to completion of follow-up, was performed from July 2023 to January 2024. The recruitment rate was 88.37% (38/43), the dropout rate was 10.5% (4/38), and the retention rate was 79.07% (34/43). The response rate of all the questionnaires at T1 and T2 among the participants who were fully involved in the trial was 100%. The intervention adherence rate of participants in the experimental group who attended the 8-week supervised session at least 6 out of 8 times was 93.33% (14/15; mean 7.13, SD 1.19). The overall rating of the supervised sessions was 8.6 out of 10. No adverse events were reported throughout the study.

Secondary Outcome: Preliminary Effects of the Intervention

As shown in Table 3, the experimental group showed a significant reduction in the score of K10 from baseline to T1 (score-difference=–3.526; $P<.05$) and baseline to T2 (score-difference=–4.520; $P<.005$), while the waitlist control only showed a significant difference between baseline and T2

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(score-difference=–3.906; P<.05). A significant time effect was found for K10 ($F_{2,72}$=11.289; P<.001), BFI-C ($F_{2,72}$=11.984; P<.001), CPSQI ($F_{2,72}$ =5.011; P=.009), and CIES-R ($F_{2,72}$=4.076; P=.02), indicating significant within-group changes over different time points. A significant between-group difference was found for pain scores ($F_{1,36}$=5.120; P=.03). However, no significant group-by-time interactions were observed between the experimental and waitlist control groups for any outcomes measured. As this pilot study was not designed or powered for effectiveness testing, these findings should be interpreted as preliminary and should not be considered evidence of no intervention effect. For the effect size, small but noticeable effects of the intervention were found in K10 (f^2=0.052), BFI-C (f^2=0.108), NRS (f^2=0.071), Depression Anxiety Stress Scales-Depression (DASS-D; f^2=0.024), and Depression Anxiety Stress Scales-Anxiety (DASS-A; f^2=0.020).

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Table 3. Data analysis on study outcomes at baseline and postintervention.

Outcomes	Mean (SE)			Comparison within group[a]			Time effect		Group effect		Group-by-time effect		Effect size (f^2)[b]
	T0[c]	T1[d]	T2[e]	T0 vs T1	T0 vs T2	T1 vs T2	*F* test (*df*)	*P* value	*F* test (*df*)	*P* value	*F* test (*df*)	*P* value	
K10[f] (range=10-50;↑score=↑distress)							11.289 (2, 72)	<.001	0.728 (1, 36)	.40	0.155 (2, 72)	.86	0.052
Experimental group	27.421 (1.567)	23.895 (1.732)	22.901 (1.581)	–3.526[g]	–4.52[h]	–0.994	—[i]						
Control group	25.211 (1.567)	22.737 (1.567)	21.304 (1.571)	–2.474	–3.906[g]	–1.433							
BFI-C[j] (range = 0-10;↑score =↑fatigue)							11.984 (2, 72)	<.001	1.321 (1, 36)	.26	1.458 (2, 72)	.24	0.108
Experimental group	5.649 (0.472)	4.706 (0.619)	3.609 (0.518)	–0.943	–2.041[h]	–1.098							
Control group	4.602 (0.472)	3.737 (0.472)	3.518 (0.473)	–0.865	–1.084	–0.219							
CPSQI[k] (range=0-21;↑score =↓sleep quality)							5.011 (2, 72)	.009	0.506 (1, 36)	.48	0.177 (2, 72)	.84	0.012
Experimental group	11.263 (0.799)	9.642 (0.869)	9.612 (0.808)	–1.621	–1.651	–0.03							
Control group	10.263 (0.799)	9.421 (0.799)	8.95 (0.813)	–0.842	–1.314	–0.472							
NRS[l] (range = 0-10;↑score =↑severe intensity of pain)							0.457 (2, 72)	.64	5.120 (1, 36)	.03	0.166 (2, 72)	.85	0.071
Experimental group	3.947 (0.537)	3.853 (0.619)	3.807 (0.570)	–0.095	–0.14	–0.045							
Control group	2.684 (0.537)	2.421 (0.537)	2.146 (0.556)	–0.263	–0.538	–0.275							
CERQ-short[m] (range=18-90; ↑score =↑use of cognitive strategy)							1.868 (2, 72)	.16	0.064 (1, 36)	.80	0.833 (2, 72)	.44	0.005
Experimental group	58.632 (1.465)	56.537 (2.247)	57.791 (1.471)	–2.095	–0.841	1.254							
Control group	58.368 (1.465)	56.263 (1.465)	59.751 (1.469)	–2.105	1.383	3.488							
CGSS[n](range = 10-40;↑score =↑self-efficacy)							2.975 (2, 72)	.06	0.852 (1, 36)	.36	0.554 (2, 72)	.58	0.007
Experimental group	21.947 (1.389)	22.779 (1.554)	22.963 (1.394)	0.832	1.015	0.184							
Control group	22.789 (1.389)	24.526 (1.389)	25.391 (1.395)	1.737	2.601	0.864							
Depression Scale (DASS-21[o]; range = 0-42;↑score =↑severity)							0.638 (2, 72)	.53	0.160 (1, 36)	.69	0.153 (2, 72)	.86	0.024
Experimental group	10.526 (1.927)	10.547 (2.034)	8.958 (1.955)	0.021	–1.568	–1.589							
Control group	9.579 (1.927)	8.737 (1.927)	8.576 (1.937)	–0.842	–1.003	–0.161							
Anxiety scale (DASS-21; range = 0-42;↑score =↑severity)							0.019 (2, 72)	.98	0.003 (1, 36)	.96	1.398 (2, 72)	.25	0.02
Experimental group	9.789 (1.723)	10.063 (2.296)	8.209 (1.730)	0.274	–1.58	–1.854							
Control group	8.632 (1.723)	8.737 (1.723)	9.886 (1.726)	0.105	1.254	1.149							

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Outcomes	Mean (SE)			Comparison within group[a]			Time effect		Group effect		Group-by-time effect		Effect size (f^2)[b]
	T0[c]	T1[d]	T2[e]	T0 vs T1	T0 vs T2	T1 vs T2	*F* test (*df*)	*P* value	*F* test (*df*)	*P* value	*F* test (*df*)	*P* value	
Stress scale (DASS-21; range=0-42;↑score =↑severity)							1.748 (2, 72)	.18	0.505 (1, 36)	.48	0.386 (2, 72)	.68	0.009
Experimental group	16.632 (2.112)	15.937 (2.510)	13.841 (2.127)	–0.695	–2.79	–2.096							
Control group	18.421 (2.112)	16.316 (2.112)	16.774 (2.120)	–2.105	–1.647	0.458							
CIES-R[p] (range=0-88;↑score=↑risk of PTSD[q])							4.076 (2, 72)	.02	0.027 (1, 36)	.87	0.650 (2, 72)	.53	0.002
Experimental group	23.737 (3.220)	21.842 (4.430)	18.146 (3.224)	–1.895	–5.591	–3.697							
Control group	23.526 (3.220)	17.684 (3.220)	19.199 (3.229)	–5.842	–4.328	1.515							

[a]Values represent pooled mean differences. Statistical significance was assessed using pairwise *t* tests based on estimated marginal means, with Bonferroni adjustment for multiple comparisons. Degrees of freedom were estimated using the Satterthwaite approximation and were 72.0 for all within-group pairwise contrasts.

[b]Guidelines for interpretation of f^2 indicate that 0.02 is a small effect, 0.15 is a medium effect, and 0.35 is a large effect (Cohen 1992).

[c]T0: baseline.

[d]T1: 8 weeks.

[e]T2: 24 weeks.

[f]K10: Kessler Psychological Distress Scale.

[g]*P*<.05.

[h]*P*<.005.

[i]Not applicable.

[j]BFI-C: Brief Fatigue Inventory–Chinese.

[k]CPSQI: Chinese Pittsburgh Sleep Quality Index.

[l]NRS: Numeric Rating Scale.

[m]CERQ-short: Cognitive Emotion Regulation Questionnaire- short form.

[n]CGSS: Chinese General Self-Efficacy Scale.

[o]DASS-21: 21-item Depression Anxiety Stress Scale.

[p]CIES-R: Chinese Impact of Event Scale–Revised.

[q]PTSD: posttraumatic stress disorder

Discussion

Principal Findings

The feasibility of this pilot study is supported by a high adherence rate of 93.33% (14/15) among participants in the 8-week sessions, along with strong recruitment (38/43, 88.37%) and retention rates (34/43, 79.07%). The dropout rate was low at 10.5% (4/38), and no adverse events were reported. The HAPPY app was well received, demonstrating good acceptability and offering a positive user experience.

Given the small sample size and limited statistical power, significant differences in outcome measurements were not observed between the experimental and control groups over time. However, small but noticeable effect sizes (ie, group-by-time effects) suggest some intervention impact. Nonetheless, a significant decrease in distress levels, reflected in K10 scores, was noted in the experimental group from baseline to immediately after the 8-week (T1) supervised session and 16 weeks (T2) after the supervised sessions, while the control group showed changes only from T0 to T2. This delayed improvement in the control group may reflect the natural recovery of mental well-being over time, consistent with gradual adaptation and the development of emotional resilience in the absence of intervention. In contrast, participants in the experimental group who received timely and appropriate mHealth support through the app demonstrated a significant reduction in distress levels within 8 weeks, with further improvements observed at the 16-week follow-up. Moreover, similar trends were noted in the experimental group with regard to reduced fatigue, improved sleep quality, and reduced PTSD-related symptoms, as reflected in the BFI-C, CPSQI, and CIES-R scores, respectively. However, these changes were not significantly different between groups over time, highlighting the potential efficacy of the intervention.

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Comparison With Prior Work

Recent literature highlights the vital role of mHealth technologies in supporting self-management and remote care. A systematic review of 10 studies showed positive effects of mHealth interventions on enhancing health in older adults aged 65 years or older. Most mHealth interventions were used for therapy, information provision, self-help, monitoring, and mental health consultations. These interventions helped protect older adults and health care providers, accelerated health service delivery, reduced costs, and decreased morbidity and mortality risks [2]. Another review noted increased downloads of mental mHealth apps, especially meditation apps, reflecting a rise in mental health issues and the demand for accessible interventions [48]. However, most of these apps lack evidence for clinical effectiveness and integration into care, presenting opportunities to improve evidence-based design, usability, effective assessment, and integration into existing workflows for managing mental challenges like distress.

A scoping review examined 8 studies and identified mHealth interventions as a frequently used approach for supporting rehabilitation in individuals with post-COVID symptoms, with the included studies reporting improvements in overall health, breathlessness, fatigue, and daily activities. However, because the scoping review was designed to map existing evidence due to the pilot study's limited statistical power rather than evaluate intervention effectiveness, these findings should be interpreted cautiously. Additionally, most studies lacked a control group. Therefore, more research with a strong study design and larger sample sizes is still required to address study biases to provide stronger evidence [10].

To our knowledge, relatively few controlled feasibility studies have examined app-based interventions targeting both physical and psychological distress symptoms using a blended format that combines supervised instruction with subsequent self-management. In the present study, the HAPPY app was delivered through 8 weekly face-to-face supervised sessions followed by a 16-week self-management phase, allowing us to evaluate both immediate feasibility and the potential for sustained support over 24 weeks.

Another study used a multimodal hybrid program with 3 weekly face-to-face sessions combined with app-based interventions. This included cognitive exercises, physical activity, respiratory exercises, a Mediterranean diet, sleep hygiene, social activation, and motivational interviewing, and was designed to support self-management and rehabilitation in adults with persistent symptoms [49]. This approach is similar to ours, which combines supervised sessions with mHealth technology to sustain therapeutic effects and empower participants to self-manage distress symptoms. Both studies are still in the data collection stages, so the effectiveness of these interventions remains unconfirmed. These studies, alongside our findings, highlight the need for further research to determine the effectiveness of hybrid mHealth interventions for managing persistent distress symptoms.

Uniqueness of the HAPPY App

The HAPPY app is distinct in its design with a unique 3-level framework of prevention, protection, and progression, and guided by the TMSCT [13]. Unlike many mHealth apps developed during the pandemic that provided nonsystematic, general virtual health care [50], the HAPPY app was designed as a structured self-management intervention to support individuals experiencing physical and psychosocial distress. Its design incorporates problem-focused coping strategies through level 2: intervention hub, which provides targeted interventions to manage the source of stress, and emotion-focused coping strategies through level 3: self-management learning modules, which include modules on emotional and cognitive regulation, mental health coping strategies, and management of persistent distress symptoms.

The app also emphasizes long-term engagement by offering personalized content and self-management tools to encourage sustainable behavioral changes. While the pilot study did not yield statistically significant results, the relatively acceptable dropout rate (n=4, 20%) suggests that the majority of participants were willing to continue using the app for self-management of their psychological well-being, demonstrating its potential acceptability and feasibility. However, further research with a larger sample size and robust study design is necessary to confirm the app’s effectiveness and sustainability in alleviating distress-related symptoms.

Strengths and Limitations

This study was the first mHealth-based clinical trial designed to empower self-management and enhance both physiological and psychological well-being, specifically targeting distress symptoms. We assessed the feasibility, acceptability, and preliminary efficacy of the HAPPY app for managing physical and psychological distress symptoms. Participants in the experimental group used the app for 24 weeks, beginning with an 8-week supervised phase supported by trained RAs, followed by a 16-week self-management phase. The findings demonstrate the intervention's feasibility and acceptability. Preliminary results indicate a reduction in distress levels immediately after the supervised phase, sustained through the self-management phase. Additionally, there was reduced fatigue, improved sleep quality, and reduced PTSD-related symptoms, highlighting the potential effectiveness of our interventions.

However, several limitations of this pilot study should be noted. First, as a feasibility and pilot study, the sample size was determined based on recommendations for pilot trials rather than for hypothesis testing, and the study was not designed to provide definitive evidence of intervention effects. Furthermore, group allocation was based on participants’ smartphone models rather than randomization, potentially introducing allocation bias. To address this, the app has been upgraded for use on both Android and iOS platforms for a full randomized controlled trial (RCT) with sufficient sample size to reduce the risk of bias and provide adequate statistical power to detect effects. Second, the use of the CIES-R should be interpreted cautiously, as the instrument was originally developed to assess post–traumatic distress in relation to past traumatic events. Third, a limitation of this pilot study is that the HAPPY app required an 8-week

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face-to-face supervised phase. This limits the generalizability of the findings to a fully virtual mHealth intervention. Future studies could shorten the supervised component or replace it with remote onboarding or in-app guidance to improve scalability. Fourth, participants' use of concurrent health care, psychological support, medications, or other interventions was not systematically assessed. These factors may have contributed to changes over time in both groups and potentially obscured between-group differences. Finally, the pilot study relied mainly on self-reported scales for outcome assessments, which may introduce reporting bias. In the main study, participants will wear a wearable sensor (eg, Fitbit Charge 5/6 [Fitbit LLC]) to collect objective data like moderate-to-vigorous physical activity (MVPA), step count, and sleep quality, providing a more accurate reflection of participants' health outcomes.

Implications for Future Research and Clinical Practice

The findings from this pilot study provide valuable insights for designing a future RCT with a larger sample size and more rigorous methods. Future research should focus on evaluating the long-term efficacy and sustainability of the HAPPY app in alleviating distress-related symptoms, while also assessing its usability and effectiveness across diverse populations to determine its potential as a scalable and accessible mental health intervention. In the definitive trial, the app will be deployed on both Android and iOS platforms to enable random allocation and reduce selection bias. Objective usage data, such as login frequency, session duration, and feature-level engagement, will be collected to complement self-reported outcomes and provide a more comprehensive assessment of intervention fidelity and engagement.

In clinical practice, the HAPPY app demonstrates the potential for mHealth technologies to support scalable and accessible management of persistent symptoms and associated psychological distress. By integrating evidence-based frameworks such as the TMSCT into mHealth interventions, these tools can address both immediate and long-term health challenges. Future integration of mHealth technologies could involve their use as complementary resources alongside traditional health care, particularly in public health initiatives, primary care, and mental health services. Personalized interventions, real-time monitoring, and AI-driven adaptability could enhance accessibility, improve continuity of care, and reduce the burden on health care systems. However, further research is needed to validate these possibilities and guide their implementation in practice.

Conclusions

This pilot study explored the use of the HAPPY app to enhance self-management and psychological well-being in individuals experiencing persistent physical and psychological distress symptoms. With high adherence and retention rates, the HAPPY app demonstrated preliminary feasibility and acceptability for supporting the self-management of physical and psychological distress symptoms. Despite a small sample size limiting statistical power, preliminary results indicated reduced distress, fatigue, and PTSD-related symptoms. Future studies will address limitations by using randomized trials with larger sample sizes, collecting objective data through wearable sensors, and upgrading the app for use on Android and Apple platforms to enable broader application.

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Data Availability

The data that support the findings of this study are not publicly available because the full clinical trial evaluating the HAPPY app is still under development and the related data have not been deposited in a public repository. The data underlying this study are owned by The Hong Kong Polytechnic University. Requests for data access are subject to approval by the University.

Generative AI Use

Claude Sonnet was used for language editing and sentence refinement during manuscript revision. The authors reviewed, verified, and edited all content and take full responsibility for the final manuscript.

Authors' Contributions

Conceptualization: JYWL, DM, FHYL
Funding acquisition: DHKS
Methodology: JYWL, DM, FHYL
Project administration: RWYW
Resources: LY, DSKC, RYCK, GCHF, TC, SCL, VTYN
Supervision: JYWL

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Visualization: RWYW
Writing – original draft: JYWL, RWYW, PYM
Writing – review & editing: JYWL, RWYW, PYM
SCL and JYWL are co-corresponding authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT 2010 statement: extension to randomized pilot and feasibility trials.
[PDF File (Adobe PDF File), 135 KB-Multimedia Appendix 1]

Multimedia Appendix 2

CONSORT-EHEALTH checklist.
[PDF File (Adobe PDF File), 1193 KB-Multimedia Appendix 2]

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Abbreviations

BFI-C: Brief Fatigue Inventory–Chinese
CERQ-C: Cognitive Emotion Regulation Questionnaire–Chinese
CERQ-short: Cognitive Emotion Regulation Questionnaire– short form
CGSS: Chinese General Self-Efficacy Scale
CIES-R: Chinese Impact of Event Scale–Revised
CONSORT: Consolidated Standards of Reporting Trials
CPSQI: Chinese Pittsburgh Sleep Quality Index
DASS-A: Depression Anxiety Stress Scales-Anxiety
DASS-D: Depression Anxiety Stress Scales-Depression
DASS-21: 21-item Depression Anxiety Stress Scale
ECT: energy conservative technique
HAPPY: health app for postacute pandemic years
K10: Kessler Psychological Distress Scale
LiDAR: light detection and ranging
MBSR: mindfulness-based stress reduction
mHealth: mobile health
MLM: multilevel modeling
MVPA: moderate-to-vigorous physical activity
NRS: Numeric Rating Scale
PHEIC: Public Health Emergency of International Concern
PTSD: posttraumatic stress disorder
RA: research assistant
RCT: randomized controlled trial
TMSCT: transactional model of stress and coping theory
VAS: Visual Analog Scale
WHO: World Health Organization

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