Research Protocol

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A Health App for Post-Pandemic Years (HAPPY) for people with physiological and psychosocial distress during the post-pandemic era: Protocol for a randomized controlled trial

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Abstract

Objective: This article describes a protocol for a randomized controlled trial to evaluate the effects of a three-level Health App for Post-Pandemic Years (HAPPY) on alleviating post-pandemic physiological and psychosocial distress.

Methods: Convenience and snowball sampling methods will be used to recruit 814 people aged 18+ with physiological and/or psychosocial distress. The experimental group will receive a 24-week intervention consisting of an 8-week regular supervision phase and a 16-week self-help phase. Based on their assessment results, they will be assigned to receive interventions on mindfulness, energy conservation techniques, or physical activity training. The waitlist control group will receive the same intervention in Week 25. The primary outcome will be changes in psychosocial distress, measured using the Kessler Psychological Distress Scale (K10). Secondary outcomes will include changes in levels of fatigue (Chinese version of the Brief Fatigue Inventory), sleep quality (Chinese version of the Pittsburgh Sleep Quality Index), pain intensity (Numeric Rating Scale), positive appraisal (Short version of the 18-item Cognitive Emotion Regulation Questionnaire), self-efficacy (Chinese version of the General Self-efficacy Scale), depression and anxiety (Chinese version of the 21-item Depression Anxiety Stress Scale), and event impact (Chinese version of the 22-item Impact of Event Scale–Revised). All measures will be administered at baseline (T0), Week 8 after the supervision phase (T1), and 24 weeks post-intervention (T2). A generalized estimating equations model will be used to examine the group, time, and interaction (Time × Group) effect of the interventions on the outcome assessments (intention-to-treat analysis) across the three time points, and to compute a within-group comparison of objective physiological parameters and adherence to the assigned interventions in the experimental group.

Conclusions: The innovative, three-level mobile HAPPY app will promote beneficial behavioral strategies to alleviate post-pandemic physiological and psychosocial distress.

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Smart health, COVID-19, psychosocial distress, intervention, physical activity

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Introduction

Studies indicate that during the pandemic, people, particularly COVID-19 survivors, were more likely to experience symptoms of distress, including physical fatigue, decreased sleep quality, and body pain, than during normal times.[1–3] The abovementioned impacts on health potentially affected everyone during the COVID-19 pandemic.[3,4] These negative impacts on physical and psychological health also seem to be persisting in the post-pandemic era. It is estimated that there will be a mental health crisis in the general population in the aftermath of the pandemic due to the delayed negative impacts of COVID-19 and the associated non-pharmaceutical public health interventions, such as social distancing, quarantining, and lockdowns.[5–8] Studies have shown that around 10%–30% of people who have contracted COVID-19 present with post-COVID-19 conditions, or "Long COVID,"[9,10] and that among all the symptoms, physical and psychological complications such as depression, anxiety, and reduced quality of life are commonly reported.[10] This indicates an urgent need to identify an evidence-based intervention to address the health issues of people whose health has been affected by COVID-19.

Smart health is defined as the provision of medical and public healthcare services by using mobile technologies, such as mobile phones, tablet devices, personal digital assistants (PDAs), and other wireless devices.[11] Mobile apps (i.e., mHealth [mobile health]) are more effective than traditional methods, such as purely direct supervised sessions, in promoting sustained positive health behavior.[12,13] This is especially applicable in addressing the long-term distress caused by the pandemic.[14] Increased evidence shows that health-related apps serve as a platform for patients to continuously monitor and manage their own physical and psychological health, using embedded interventions and e-learning materials.[15–17] Ongoing engagement through interventions, reminders, and encouragements delivered via these apps can lead to sustainable healthy behavior and the achievement of a lifelong healthy lifestyle. This long-term empowerment can have a direct impact on one's daily routine, which could include cognitive and behavioral therapy, as well as overall health management and planning.[18,19] Recognizing the positive impacts of health-related apps, there has been an increase in the number of apps designed to empower patients' self-management abilities across various diseases.[20–22]

The adoption of mHealth apps for disease control and for the self-management of psychological health became increasingly important during the COVID-19 pandemic. Studies have shown that mHealth apps developed by organizations and institutions in 19 countries focused on contact tracing and quarantine by means of GPS technology and other surveillance techniques, as well as on symptom monitoring with the provision of management advice.[23] Other systematic reviews provided evidence of how psychotherapeutic mHealth systems such as adapted versions of Cognitive Behavioral Therapy (CBT) and psychoeducation programs could ameliorate different mood disorders arising from the pandemic for college students, children (aged $\geq$10 years), and older people.[24–26]

Despite the promising growth of the mHealth apps, most of them were developed during the pandemic with a focus on delivering non-systematic, general virtual healthcare to people with COVID-19 symptoms.[27–29] In addition, investigations to determine the process quality and mid- to long-term effects of mHealth interventions in mitigating physiological and psychosocial distress at the population level have been very limited.[14] This research gap was the impetus behind our effort to develop a 24-week intervention guided by an innovative three-level (Prevention, Protection, and Progression) Health App for Post-Pandemic Years (hereafter, HAPPY) and driven by the Transactional Model of Stress and Coping Theory (TMSCT) to address the COVID-related physical and psychosocial distress symptoms of people during the post-pandemic era.

The TMSCT emphasizes the use of appraisals to evaluate the harm, threats, and challenges that result in the process of coping with stressful events.[30] The level of stress experienced (in the form of thoughts, emotions, and behaviors) as a result of external stressors depends on an individual's appraisal of the situation, which involves making a judgment about whether the internal or external demands exceed that individual's resources and ability to cope when the demands exceed the resources.[30] Positive affect, which is defined as an internal feeling state that occurs when a goal has been attained,[31] will be elicited when individuals are capable of resolving stressors with the utilization of both internal (e.g., cognitive appraisals, emotion regulation) and external resources (e.g., social support, access to new knowledge and skills). On the other hand, negative affect, which is defined as an internal feeling state that occurs when one has failed to achieve a goal or avoid a threat,[32] and the associated bodily stress reactions will be elicited as a result of unresolved distress. Definitions of the concepts involved in the TMSCT are shown in Table 1.

Table 1. Transactional model of stress and coping process.

Concept	Definition
Primary appraisal	Evaluation of the significance of and judgment of whether the encounter is irrelevant, benign, or stressful
Secondary appraisal	Evaluation of controllability of the encounter in relation to coping resources, and what can be done
Coping efforts	Strategies used to mediate primary and secondary appraisals evaluating whether any given option will achieve the desired outcome in the context of both the individual and the encounter
Problem-focused coping	Strategies directed at managing or altering the distress encounter
Emotion-focused coping	Strategies directed at regulating emotional responses and the way a person feels and thinks about the stressful situation
Coping	Behavioral and cognitive efforts used to manage internal and/or external demands which are appraised as harmful and exceeding an individual's resources
Treatment	Application of the Health App for Post-Pandemic Years (HAPPY) to assist in making more favorable appraisals leading to more positive outcomes. The HAPPY app is concerned with reducing stress levels and improving coping, emotional well-being, and health behaviors

Objectives and hypothesis

This protocol describes a randomized controlled trial (RCT) designed to evaluate the immediate effects (8 weeks after weekly supervised sessions; i.e., on the 8th week) and the mid-term effects (at 6 months when the intervention has been completed; i.e., on the 24th week) of the HAPPY app in alleviating people's physiological and psychosocial distress during the post-pandemic era. It is hypothesized that the experimental group will (1) exhibit greater improvement in physiological and psychosocial distress and (2) have a more positive appraisal mindset, greater self-efficacy, and more sustainable self-management ability than participants in the waitlist control group.

Methods

Trial design

The research design entails a two-arm, assessor-blinded, parallel design RCT with an experimental group and a waitlist control group. After completing baseline assessments (T0), participants will be randomly allocated to the experimental group or waitlist control group. Those in the experimental group will be assigned to receive interventions of mindfulness, energy conservation techniques (ECT), or physical activity (PA) training based on their baseline assessment results. The experimental group will participate in the 24-week intervention. Previous studies have observed that health-related behavior gradually relapsed when using mHealth over the short term.[12] In our study, we aim to investigate the sustained effects of the HAPPY app beyond the completion of all supervised sessions, for a period of 4 months. Hence, 24 weeks is considered an optimal duration to observe the sustainable effects of the interventions on changes in health behavior.[33]

The intervention consists of an 8-week regular supervision phase, which will be conducted face-to-face in community centers by a well-trained research assistant (RA), and a 16-week self-help phase. Of the eight sessions, the basic features and functions of the HAPPY app will be introduced to the participants in the first two sessions. The participants will then be able to start using the app. In the remaining six sessions, the participants will be provided with guidance on practicing the assigned interventions. Participants can then self-practice them at home for 16 weeks. The waitlist control group will receive health materials during the waiting period and receive the same intervention in Week 25.

On the 8th week (T1), immediately after the phase of supervision, a blinded assessor will re-assess all participants on measurements used at baseline. At 6 months (i.e., on the 24th week) when the intervention has been completed (T2), all participants will receive a follow-up assessment to determine whether the effects of the intervention have been maintained. A flowchart of the trial design is listed in Figure 1, and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram is listed in Figure 2.

Participants

Settings and recruitment. Participants who are young to middle-aged adults will be recruited from the general population, while older adults will be recruited from our community partners, including district community health centers, residential care homes, day activity centers, and nursing homes.

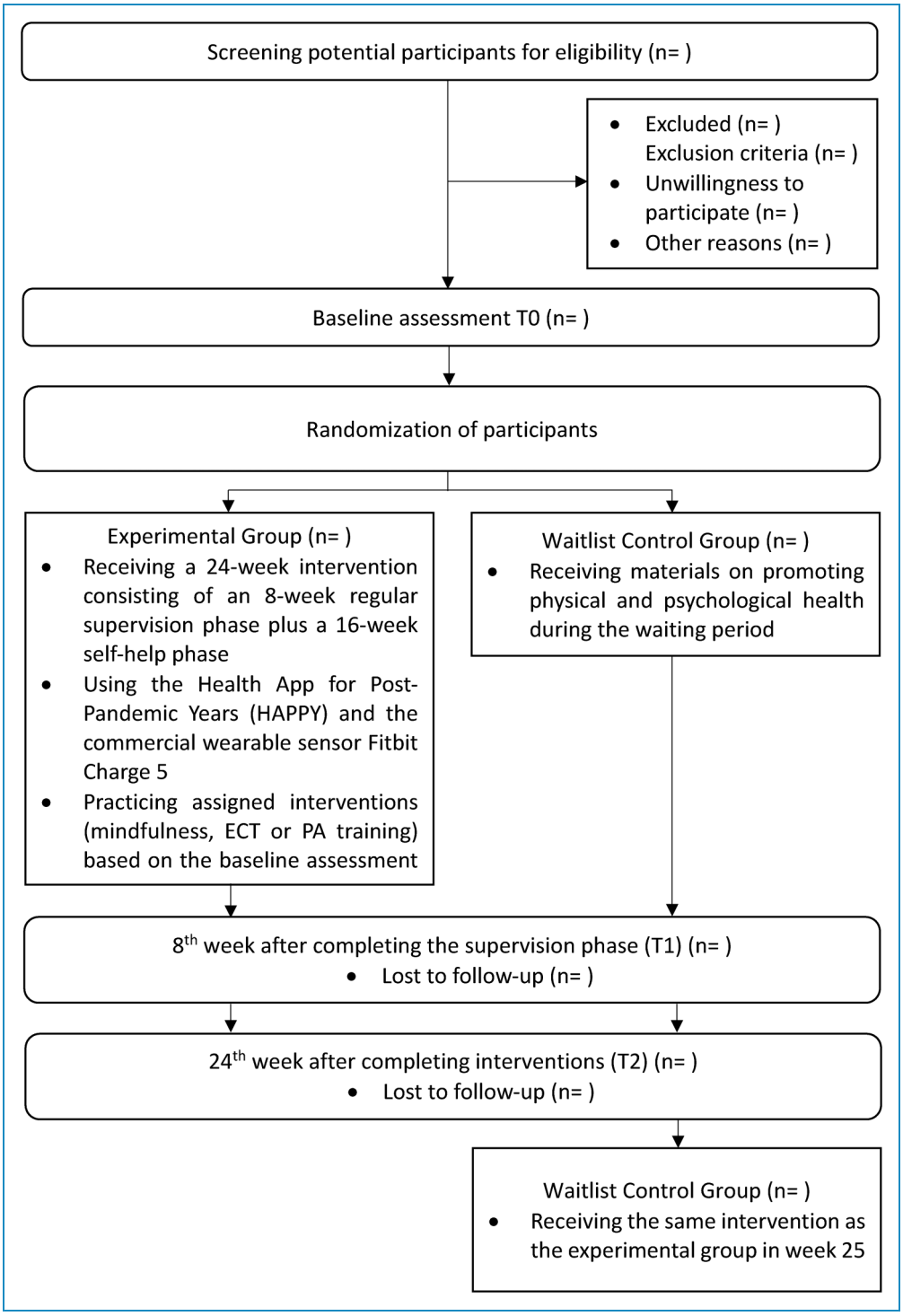

Figure 1. Trial design flowchart (interventions of mindfulness, ECT, or PA training).
ECT: energy conservation techniques; PA: physical activity.

Convenience and snowball sampling methods will be used to recruit participants, through the strategies as publicizing and promoting the study by uploading e-posters on the website of our collaborating partners; sending out recruitment posts via social media, including Facebook and Instagram; displaying posters in the venues of our community partners, and encouraging recruited participants to refer relatives and friends with physiological or psychosocial distress.

We will recruit participants in cohorts, with each cohort comprising 72 participants. We will only recruit the second

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	Close-out
TIMEPOINT	$-t_1$	0	t_1	t_2
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
Mindfulness			X	X
ECT			X	X
PA training			X	X
**Waitlist controls*				X
ASSESSMENTS:				
Sociodemographic data	X			
K10	X		X	X
BFI-C	X		X	X
CPSQI	X		X	X
NRS	X		X	X
CERQ-short	X		X	X
CGSS	X		X	X
DASS-21	X		X	X
CIES-R	X		X	X
Physiological data (collected by Fitbit Charge 5)	X		X	X
SF-FFMQ (for Mindfulness-based intervention only)			X	X
Revision quiz of ECT (for ECT intervention only)			X	X

Figure 2. Standard protocol items: recommendations for interventional trials (SPIRIT) diagram.
t_1 = Week 8; t_2 = Week 24 (6-month post-intervention).
*The waitlist control group will start the intervention in Week 25.
Abbreviations: ECT: energy conservation techniques; PA: physical activity; K10: Chinese version of the Kessler Psychological Distress Scale; BFI-C: Chinese version of the Brief Fatigue Inventory; CPSQI: Chinese version of the Pittsburgh Sleep Quality Index; NRS: Numeric Rating Scale; CERQ-short: short version of the 18 item Cognitive Emotion Regulation Questionnaire; CGSS: Chinese version of the General Self-efficacy Scale; DASS-21: Chinese version of the 21-item Depression Anxiety Stress Scale; CIES-R: Chinese version of the Impact of Event Scale–Revised; SF-FFMQ: Chinese version of the 20-item short-form Five Facet Mindfulness Questionnaire.

cohort after completing the activities with the first cohort. Once the interventions are completed, the participants will be required to return their devices and materials to us so that they can be used by other participants. The devices and materials required for conducting physical training and mindfulness will be described in detail in the section on intervention procedures. This approach will help us minimize the number of devices and materials needed to conduct the trial.

Eligibility criteria. The inclusion criteria are: (1) 18 years of age or older; (2) able to communicate in Cantonese to ensure that they can understand the instructions; and (3) owner of a smartphone with Internet access. At the time of recruitment, the participants should (4) exhibit psychosocial distress, as measured by a cut-off value of ≥20 using the Chinese version of the Kessler Psychological Distress Scale (K10)[34]; and/or (5) exhibit physiological symptoms, which refer to a complaint that one has experienced one of the following symptoms for at least 3 days in the past week: physical fatigue, as measured by a cut-off value of ≥4 on the Chinese version of the Brief Fatigue Inventory (BFI-C)[35]; decreased sleep quality as measured by a cut-off value of >5 on the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI)[36]; or pain, including headaches, upset stomach, and other forms of pain as measured by a cut-off value of >3 on the 11-point Numeric Rating Scale (NRS).[37]

Individuals will be excluded if they (1) are unable to provide informed consent; (2) have impaired vision in which they report an inability to clearly see the texts and graphics on a mobile phone or tablet; (3) have a hearing impairment, in which they report an inability to clearly hear the audio guide on the app, and/or (4) have been diagnosed with an intellectual disability (e.g., Down's syndrome) or cognitive impairment based on their self-reported medical history.

Ethics, consent, and permission. Ethical approval to conduct this study has been obtained from the Human Subjects Ethics Review Committee of The Hong Kong Polytechnic University (HSEARS20220318003). The trial protocol is registered with ClinicalTrials.gov (NCT05459896). This study protocol conforms with the SPIRIT reporting guidelines,[38,39] and the SPIRIT Checklist is listed in Appendix 1.

All potential participants will be referred to the research team by other collaborators. Written informed consent (see Appendix 2) will be obtained from each participant, to whom all aspects of the study will be explained and questions answered prior to the commencement of the study. Participants will be made aware that their participation is voluntary and that not agreeing to take part will not have a negative impact on the usual care provided by the service providers. A well-trained RA who is blinded to the group allocations of centers and participants will screen all potential participants for their eligibility to participate in the study.

Participants will be given assurances throughout the study that their data will be kept confidential in accordance with the Privacy Ordinance. Hard copies of the questionnaires will be stored in a locked cabinet in the Principal Investigator's (PI) office. All participants will be given a unique identification number. This identification number will be used on all collected measurements. The personal data of the participants will be handled and stored by the PI using encrypted Excel and SPSS files. Only the PI, the Co-Investigators (Co-Is), and delegated research personnel will have access to the personal data during and after the study. The participants' personal data will be kept until 2030, following the guidelines of the Institutional Review Board of The Hong Kong Polytechnic University and the Personal Data (Privacy) Ordinance, which require a retention period of 7 years.[40,41] All of the data will be deleted permanently after the aforesaid storage period. For the Fitbit Charge 5 wearable sensor data and Light Detection and Ranging (LiDAR) motion data, all data will be encrypted and stored in the computers and servers of the Hong Kong Polytechnic University. The reasons for using a Fitbit Charge 5 and a LiDAR scanner during the research project have been addressed in the Information Sheet and will be emphasized during the introduction of the research project to the participants.

Procedure

Randomization and allocation. A biostatistician who is not affiliated with this study will randomize all participants into either the experimental group or the waitlist control group at a 1:1 ratio. The allocation concealment will be done by using sequentially numbered, opaque, sealed envelopes containing the group allocation on a written insert, based on predetermined, computer-generated random numbers. Participants in the experimental group will then be assigned to receive interventions of mindfulness, ECT, or PA training based on their baseline assessment results. To avoid selection biases, the allocation to the study groups will be concealed from the researchers until the recruiting of participants and the baseline assessment have been completed.

Intervention procedures. The intervention can be divided into three levels, namely Level 1: Enhancement of Self-Awareness (Assessment); Level 2: Intervention Hub; and Level 3: Self-Management with Learning Modules. App flow diagrams illustrating the functionalities of the HAPPY app are shown in Figure 3(a)–(f).

Level 1: Enhancement of Self-Awareness (Assessment). The aim of this level is to assess and monitor the participants' risk of developing physiological and psychosocial distress.

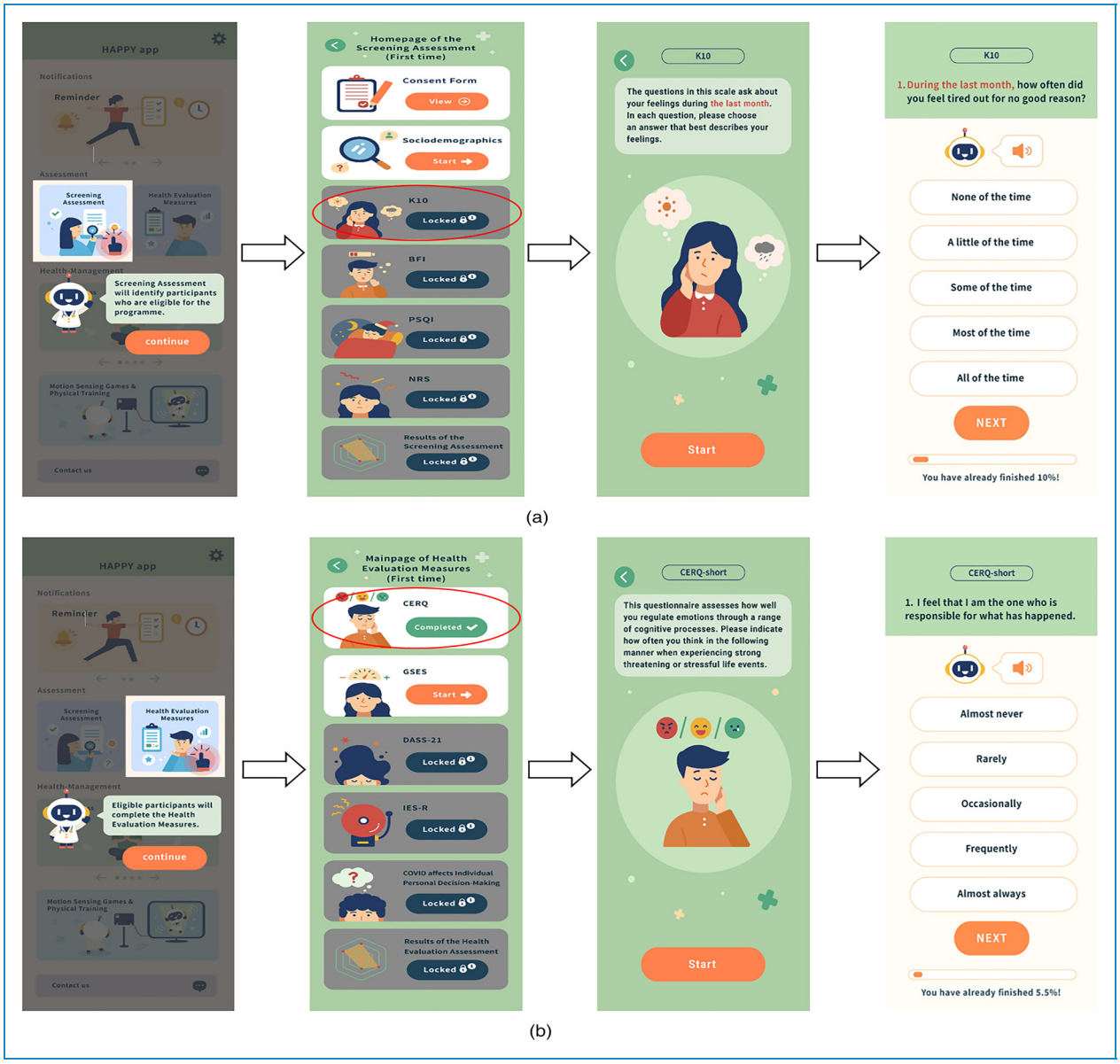

Figure 3. (a) An app flow diagram showing the screening assessment on Level 1 Enhancement of Self-Awareness. (b) An app flow diagram showing the health evaluation measures on Level 1 Enhancement of Self-Awareness (c) An app flow diagram showing the mindfulness-based intervention on Level 2 Intervention Hub. (d) An app flow diagram showing the energy conservation techniques (ECT) on Level 2 Intervention Hub. (e) An app flow diagram showing physical activity training on Level 2 Intervention Hub. (f) An app flow diagram showing self-management on level 3 Self-Management with Learning Modules. (continued)

The HAPPY app is embedded with an Artificial Intelligence-based Digital Health Assistant (DHA)[42,43] to perform the three main functions of screening, risk stratification, and triaging. First, the DHA will conduct baseline and regular assessments of the participants. After data collection, it will use the embedded risk calculator to analyze scores obtained from different assessments to recognize and evaluate the participants' distress symptoms. The participants will then be triaged to receive three different types of interventions in the Intervention Hub at Level 2. At this level, the participants will be facilitated in developing an intention to actively manage their distress symptoms by increasing their risk awareness (knowing their profile under different assessments).

Level 2: Intervention Hub. The aim of this level is to recommend different types of interactive interventions to participants in the experimental group. The mechanism is

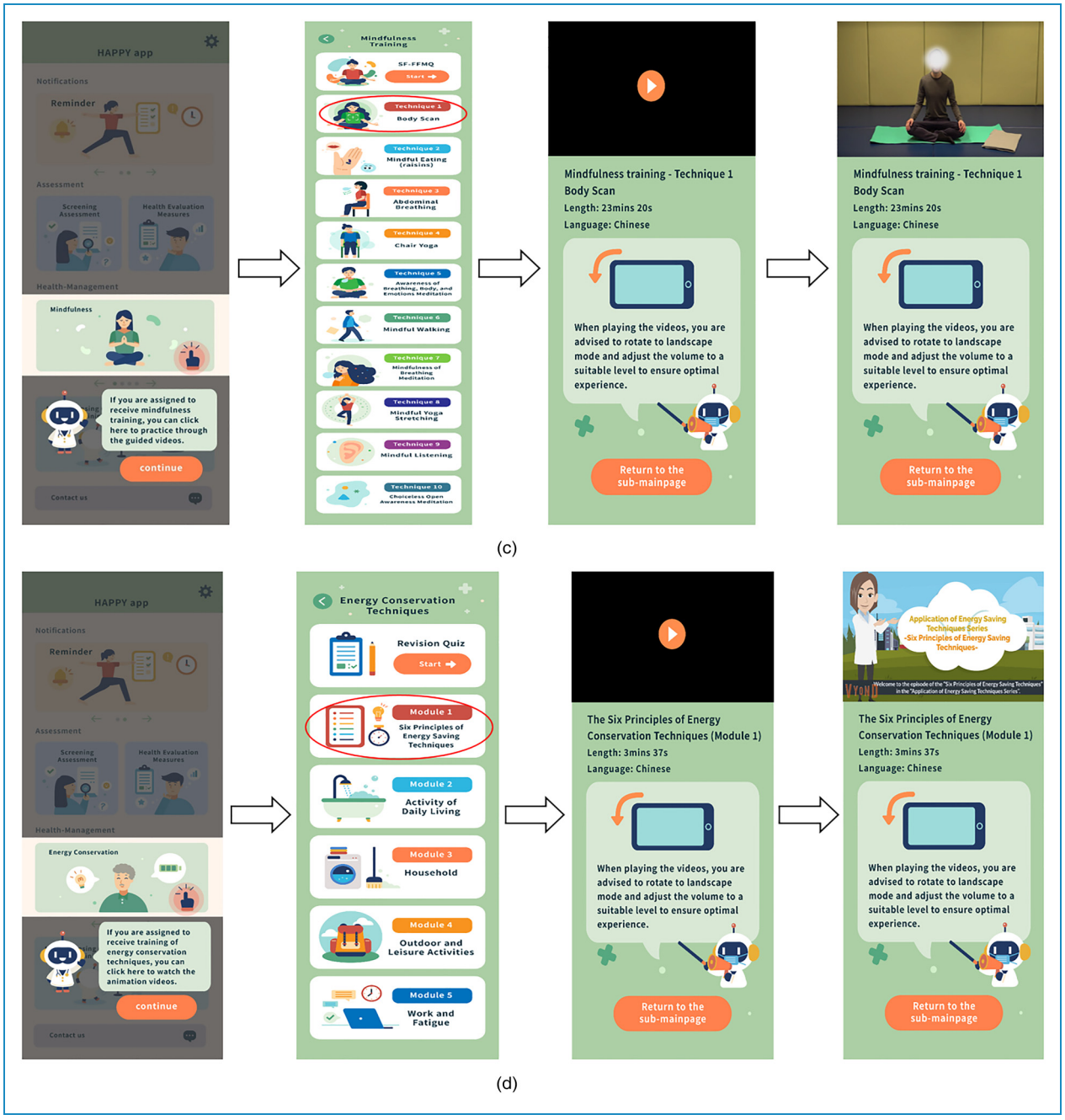

Figure 3. Continued.

based on their assessment results at Level 1 and their level of engagement in different interventions. All of the collected data related to their assessment results and level of engagement in interventions will be analyzed by the DHA so that continual intervention modifications/reminders can be made. For instance, if a participant is found to have poor adherence to physical training, which was originally assigned to him, a reminder will be automatically sent to him to continue practicing physical training. On the other hand, if the poor adherence was caused by a consistent feeling of fatigue based on the assessment in Level 1, the app will recommend another intervention, such as ECT, to that particular participant. The algorithm for recommending different interventions to participants in the experimental group is illustrated in Figure 4.

Mindfulness-based intervention: The concept of a mindfulness-based intervention is derived from Mindfulness-Based Stress Reduction (MBSR), which offers mindfulness meditation, yoga techniques, and a range of coping strategies to

Figure 3. Continued.

manage both psychological and physiological distress.[44,45] A certified mindfulness practitioner who is experienced in collaborating with different tertiary institutions to offer MBSR training has been invited to audio record and demonstrate 10 mindfulness techniques. Table 2 gives a detailed description of the 10 mindfulness techniques. Participants will be given a yoga mat and are encouraged to practice mindfulness at least twice per week.

Energy conservation techniques: The ECT intervention consists of five modules developed by a team of experienced occupational therapists. The first module is about the six energy conservation principles derived from the Pulmonary Rehabilitation Educational Booklet.[46] From the second to fifth modules onwards, participants will learn to apply the six principles of energy conservation to different domains in daily life, including self-care,

household, outdoor activities, and workplace. Throughout the 24-week intervention, one thematic module will be released each week, and participants are encouraged to work through the previous module to unlock the new module in the next week. One module takes about 5 min to complete. Participants will be asked to complete the revision quiz after completing all of the modules to evaluate their understanding of the techniques.

Physical activity training: For the PA training, we adopted a gaming approach to design motion-based exercises and resistance exercises to enhance the participants' engagement. In the motion-based exercises, participants will interact with virtual objects to achieve training tasks. Their body movements will be captured digitally using an 11-inch Apple iPad Pro (third generation) with an LiDAR scanner[47] combined with gamification and augmented reality (AR) in real time. The motion-based exercises consist of four levels of exercises that become progressively difficult, and each level takes about 2.5 minutes to complete.

The resistance exercises are composed of 15 types of movement patterns with three to four levels per type. Each exercise posture has been designed with a specific number of repetitions, sets, and rest times following the standard workout protocol delivered by a professional sports trainer. The LiDAR motion scanner on the iPad Pro will capture the real-time body movement data of the participants and estimate their joint point positions (i.e., skeleton data) in 3D space, as illustrated in Figure 5. Studies have shown that the built-in LiDAR technology in the iPad Pro can capture real-time 3D motion and depth estimates with reasonable accuracy, compared to industrial 3D scanners and the Vicon system, a gold standard for capturing human motions.[48,49]

The participants' performance will be scored based on the correctness of their postures in an embedded award system, with cumulative scores to upgrade their exercise levels. Real-time visual and audio instructions, as well as immediate feedback for posture correction will also be provided to the participants by the DHA to enhance their understanding of their performance and to monitor their engagement in the intervention.

During the supervised sessions, the interventionist will demonstrate the gamified exercises using an iPad Pro. Participants will be invited to try the exercises in the class. Table 3 lists the equipment required for the gamified exercises.

Each participant will be given the abovementioned devices to practice PA training at home during the 16-week self-help phase. A demonstration video instructing participants on setting up the devices, such as connecting the iPad Pro to the TV at home using the HDMI cable and adapter, maintaining a spacious area for playing the gamified exercises, and ensuring an internet connection, will be sent to the participants. In addition, participants are advised to wear the Fitbit Charge 5 while doing the exercises so that data on moderate-to-vigorous physical activity (MVPA) can be obtained and the intensity of the exercise can be determined. They are also encouraged to follow the health guidelines of the World Health Organization (WHO) to do at least 150–300 minutes or 75–150 minutes of moderate- or vigorous-intensity exercise, respectively, or an equivalent combination of moderate- and vigorous-intensity activity throughout the week.[50]

Level 3: Self-Management with Learning Modules. The learning modules developed at Level 3 are consistent with the TMSCT and will run concurrently with the three interventions in Level 2 to empower the participants to self-manage their health behaviors over both the short- and long-terms by integrating and maximizing both their internal and external resources.[30,51] This level consists of six thematic modules to be delivered in the format of animated videos. The first module includes information about "Long COVID" with management guidelines. In the second module, it conveys information about ways to deal with difficult feelings arising in the post-pandemic period. The third module focuses on restricting cognitive biases through the use of positive thought patterns. The fourth module consists of information about sleep hygiene and relaxation techniques. The last module addresses self-care and personal growth.

Similar to the intervention schedule of ECT, participants will be asked to complete a thematic self-management module each week before moving on to the subsequent modules. One module takes about 5–15 minutes to complete.

The waitlist control group will receive the same intervention as the experimental group in Week 25. During the waiting period, the control group will receive materials on promoting physical and psychological health.

Intervention fidelity

The protocol of the supervised sessions has been outlined in Appendix 3. It will be used to guide the implementation of all interventions in the experimental group to ensure standardization throughout the study. All supervised sessions must follow the program protocol and will be run by the same interventionist to ensure intervention consistency. Independent researchers with prior training in PA, mindfulness, and ECT will observe the supervised sessions conducted by the interventionist on a monthly to bimonthly basis using a pre-designed checklist to monitor intervention fidelity. This will ensure that the interventions are executed by the interventionist as intended. If the scores on the checklist fall below 80% of the total checked items, a quality assurance meeting will be arranged to reinforce the skills required to deliver the

interventions to the participants. Achieving a fidelity rate of >90% will be considered acceptable based on the recommendations of the NIH Behavior Change Consortium.[52]

Treatment compliance

Data on compliance with different interventions will be collected and analyzed. For the PA training, compliance will be calculated by the scores obtained from the two motion-based games and the resistance training recorded on the dashboard. For the mindfulness-based intervention, ECT, and self-management with learning modules, both the start time and play time of the animated videos will be recorded. Compliance with the Fitbit wearable sensor can be reflected from the participants' daily wear time and record of physiological data. Overall compliance will be determined by calculating the percentage of measurements/duration of exercise time/frequency of watching animated videos that took place within the timeframe of the study, as mandated by the protocol.

Measures

The experimental and waitlist control groups will be assessed on a variety of outcomes at baseline (T0), 8 weeks after the weekly supervised sessions (T1), and after 24 weeks when the intervention has been completed (T2).

Primary outcomes. The participants' level of psychological distress will be assessed using the 10-item Chinese version of the Kessler Psychological Distress Scale (K10).[34] Each item is rated on a 5-point Likert scale, and the total score is obtained by summing up all of the items and ranges from 10 to 50. A cut-off value of ≥20 indicates psychosocial distress.[53] This scale was validated among 871 university undergraduates. A factor analysis revealed that the Kappa value was 0.70, indicating a moderate level of inter-rater agreement. The Cronbach's alpha was 0.80, which showed an acceptable level of internal consistency.[34]

Secondary outcomes. The self-perceived level of fatigue will be evaluated using the nine-item Chinese version of the Brief Fatigue Inventory (BFI-C).[35] The first three items measure fatigue severity and the other six items assess fatigue interference with daily activities, including general activity, mood, walking ability, normal work (including both work outside the home and housework), relations with other people, and enjoyment of life. All items are rated on an 11-point Likert scale, with a total score obtained by averaging all of the items and ranging from 0 to 10. A cut-off value of ≥4 indicates moderate-to-severe fatigue.[35,54] This scale was validated among 249 Chinese patients. Moderate-to-high correlation coefficients (from −0.44 to −0.71) indicated high convergent validity. The Cronbach's alpha were between 0.90 and 0.92 for the items of fatigue interference and fatigue severity, respectively.[35] This supports the view that the BFI-C is a reliable and valid instrument.

The subjective assessment of sleep quality will be measured using the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI).[36] The scale consists of 19 items grouped under seven domains, namely sleep duration, sleep latency, habitual sleep efficiency, sleep disturbances, subjective sleep quality, the use of sleep medications, and daytime dysfunction. Each item is rated on a 4-point Likert scale, with a total score ranging from 0 to 21. A cut-off value of >5 indicates poor sleep quality.[36] This scale was validated among 87 participants with primary insomnia and 157 healthy controls. An acceptable test–rest reliability of 0.85 for all subjects and one of 0.77 for primary insomniacs were reported, indicating that the CPSQI is a valid and reliable assessment tool.[36]

The intensity of the pain felt by each participant will be measured using the Numeric Rating Scale (NRS).[55–57] It is a single, 11-point numeric scale with 0 representing "no pain" and 10 representing "the worst pain imaginable." A cut-off value of >3 indicates pain of moderate-to-severe intensity.[55] The intraclass correlation of the scale was 0.95, and it had good convergent validity of 0.94 against the Visual Analog Scale (VAS). This supports the view that the NRS is a reliable and valid instrument.[37]

Cognitive emotion regulation refers to how well an individual regulates emotions through a range of cognitive processes.[58] Cognitive emotion is measured using the Short version of the 18-item Cognitive Emotion Regulation Questionnaire (CERQ-short) extracted from the validated long version of the Chinese Cognitive Emotion Regulation Questionnaire (CERQ-C).[58,59] The scale consists of nine conceptually distinct subscales, namely self-blame, other-blame, rumination, catastrophizing, positive refocusing, planning, positive reappraisal, putting into perspective, and acceptance. Each subscale contains two items rated on a 5-point Likert scale. Individual subscale scores are obtained by summing up the related items, with a total score ranging from 2 to 10 and with higher scores indicating more frequent use of a specific cognitive strategy.[58] The long version of the CERQ-C was validated among 791 individuals. Moderate internal consistency (Cronbach's $\alpha = 0.83$) and an interclass correlation coefficient of 0.79 were reported, indicating that the CERQ-C is a reliable and valid instrument.[59]

Self-efficacy refers to the ability of an individual to cope with daily hassles and adapt to stressful life events.[60] It is measured using the Chinese version of the General Self-efficacy Scale (CGSS). The scale consists of 10 items rated on a 4-point Likert scale, with a total score obtained by summing up all of the items, and ranging from 10 to 40, with higher scores indicating higher self-efficacy.[60] CGSS has been shown across different studies to be a reliable and valid instrument.[60,61]

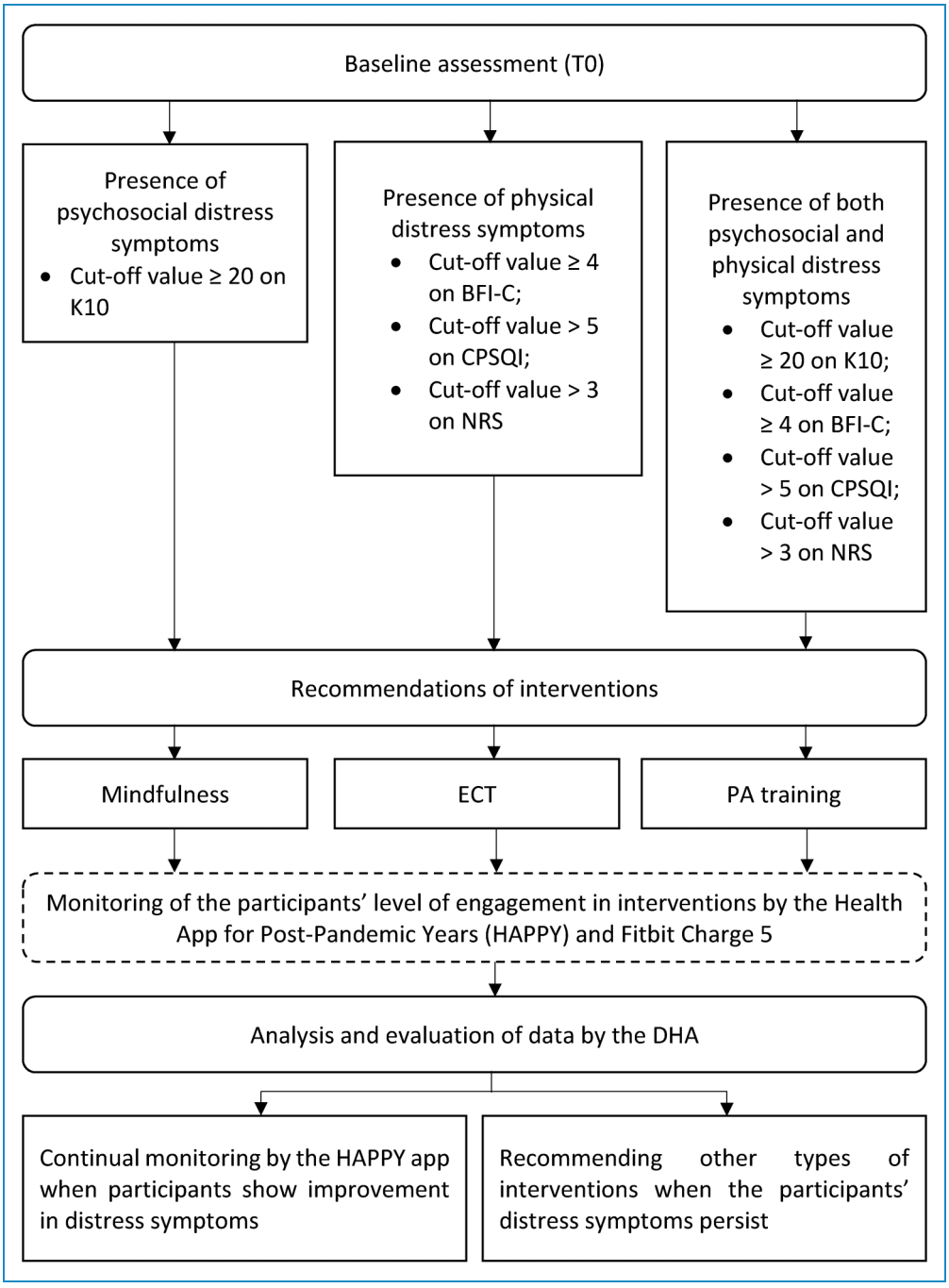

Figure 4. Algorithm for recommending different interventions to participants in the experimental group based on their assessment results at Level 1 and level of engagement.
Abbreviations: K10: Chinese version of the Kessler Psychological Distress Scale; BFI-C: Chinese version of the Brief Fatigue Inventory; CPSQI: Chinese version of the Pittsburgh Sleep Quality Index; NRS: Numeric Rating Scale; ECT: energy conservation techniques; PA: physical activity; DHA: Digital Health Assistant.

Symptoms of depression and anxiety will be measured using the Chinese version of the 21-item Depression Anxiety Stress Scale (DASS-21).[62] The scale originated from the DASS-42 and consists of three subscales, namely depression, anxiety, and stress. Each subscale contains seven items rated on a 4-point Likert Scale. Individual subscale scores are obtained by summing up the related items and range from 0 to 21, with higher scores indicating more severe symptoms of that particular domain.[62,63] This scale was validated among 1815 Chinese college students. Moderate convergent

Table 2. The 10 mindfulness techniques.

No. of techniques	Mindfulness techniques
1	Body scan meditation
2	Mindful eating (raisins)
3	Abdominal breathing
4	Chair yoga
5	Awareness of breathing, body, and emotions meditation
6	Mindful walking
7	Mindfulness of breathing meditation
8	Mindful yoga stretching
9	Mindful listening
10	Choiceless open awareness meditation

Table 3. Equipment required for the gamified exercises.

Equipment required	Function of the equipment
An 11-inch Apple iPad Pro (third generation)	To capture the participants' real-time body movements using a built-in LiDAR motion scanner
A protective case for the iPad Pro	To protect the device
An ultra-high-definition high speed 4K/8K HDMI cable	To connect the iPad Pro to a TV receiver via an adapter to provide the viewing experience
A USB-C digital AV multiport adapter	To connect the iPad Pro to a HDMI cable to mirror the display
An iPad tripod	To stabilize the iPad Pro and adjust its height up to 67 inches
A wearable sensor Fitbit Charge 5	To record objective physiological data during the exercise

validity was reported via significant correlations with the Chinese Beck Depression Inventory ($r_1 = 0.51$ and $r_2 = 0.64$) and the Chinese State-Trait Anxiety Inventory ($r = 0.41$), respectively. The Cronbach's alpha ranged between 0.80 and 0.92 for the three domains and the overall DASS-21 scale, respectively.[62] This supports the view that the DASS-21 is a reliable and valid instrument.

Subject distress brought on by the pandemic will be assessed using the Chinese version of the 22-item Impact of Event Scale–Revised (CIES-R).[64–66] The scale consists of three constructs, namely intrusion (eight items), avoidance (eight items), and hyperarousal (six items). Each item is rated on a 5-point Likert Scale, with a total score ranging from 0 to 88, with higher scores indicating a higher risk of post-traumatic stress disorder (PTSD) symptomatology.[67] This scale was validated among 60 subjects. The external validity of intrusion ($r = 0.54$), avoidance ($r = 0.53$), and hyperarousal ($r = 0.64$) with the General Health Questionnaire-20 were moderate.[64] The Cronbach's alpha ranged between 0.83 and 0.89, which showed an acceptable level of internal consistency.

Other measurements. Participants assigned to receive the mindfulness-based intervention will be asked to complete the Chinese version of the 20-item short-form Five Facet Mindfulness Questionnaire (SF-FFMQ).[68] The SF-FFMQ is a psychological scale to measure dispositional mindfulness with regard to experiences, thoughts, and actions in daily life. The scale is comprised of five subscales, namely observing our reactions to the external world and perceiving the inner world within us (observation), describing this reaction and experience to ourselves and others (description), acting with consciousness (awareness), not judging our inner experience and behaving with self-acceptance and empathy (non-judgment), and not reacting to negative thoughts and experiences (non-reactivity).[69] Each item is rated on a 5-point Likert scale, with items on awareness and non-judgment reversely coded.[70] Individual subscale scores are obtained by averaging the related items and range from 1 to 5, with higher scores indicating higher levels of mindfulness.[69,70] The Chinese SF-FFMQ was validated among 535 participants. Both exploratory and confirmatory factor analyses supported the validity of the scale. The Cronbach's alpha was 0.73, which showed an acceptable level of internal consistency.[68]

Participants who are assigned to receive the ECT intervention will be asked to complete the 30-item revision quiz developed by a team of experienced occupational therapists. The revision quiz aims to assess the participants' level of understanding of ECT and its application in daily life. The quiz consists of three sections, namely self-care activities (eight items), household activities (10 items), and work and general activities (12 items), adding up a total of 30 items for the entire quiz.

The objective physiological parameters of the participants in the experimental group will be collected, including their step counts, walking distance, heart rate, MVPA, active minutes, and sleep tracking. An MVPA minute will

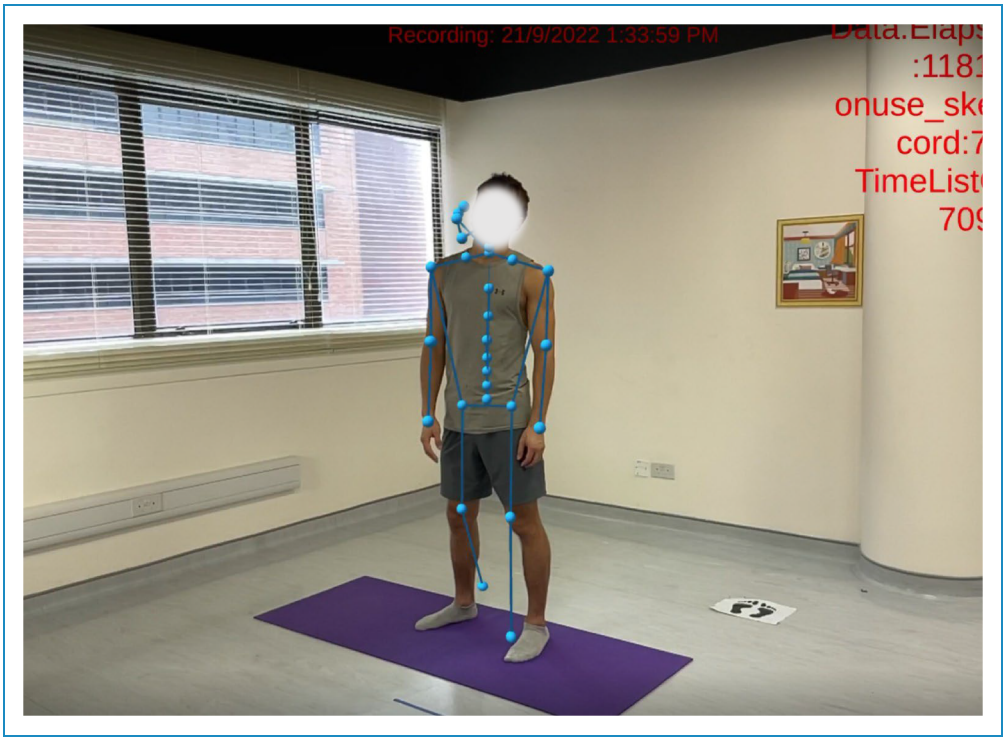

Figure 5. Illustration of the tracking of human body movements with captured joint points using an iPad Pro device with a LiDAR motion scanner.

be defined as a minute in which the Fitbit wearable sensor recorded physical movements (i.e., vector magnitude) of above 2021 counts/minute or greater than 3 metabolic equivalents (METs).[71,72] Only a minimum of 10 min of continuous MVPA will be counted as valid minutes because only such sessions are considered beneficial by the WHO.[71,73] A stride count of zero with missing heart rate data will be used to determine non-wearing time, while zero strides with non-missing heart rate data will be regarded as sedentary time.[74] Only MVPA minutes measured on valid days (i.e., Fitbit wear time >10 h/day) will be entered into the data analysis.[71,72,75,76] Fitbit wearable sensors have been shown to have high sensitivity (91.96%) and moderate specificity (67%) in measuring MVPA.[72] Participants will be asked to wear the sensor for approximately 21 hours per day throughout the intervention period, except during bathing, aquatic activities, and charging of the sensor. We will teach the participants to use different features of the sensor and sync the data with the HAPPY app on a weekly basis. Participants can then self-monitor their conditions on the weekly health report generated by the HAPPY app.

Data collection and management

All assessments will be completed face-to-face by a blind assessor in collaborating community centers at the three time points. At the baseline assessment, the assessor will administer a series of physical and psychological questionnaires using the HAPPY app in order to collect data on the participants' physical and psychosocial distress symptoms. Sociodemographic data will also be collected, including gender, age, level of education, marital status, employment status, and living conditions.

The retention of participants will be promoted via follow-up telephone contact from the RA and a supermarket coupon of HK$100 as compensation for their time and travel cost after completing each assessment time point, with a total of HK$300 for the three assessment time points. The data management plan includes the cross-checking of data using computed and manually scored totals and range checks for data values.

The research team has prepared safety guidelines (see Appendix 4) for preventing falls for participants who are assigned to receive PA training at home. Standard guidelines for managing symptoms of intolerance of PA training will be used. For example, a target heart rate (THR) will be identified for each participant. Those at the beginner level will be advised not to exceed 50%–60% of their THR, with the figure being 60%–70% for those at the advanced level.[77] The PI will give individual participants advice on an ad hoc basis to ensure their safety. The research team will also set up a hotline to support participants with high distress levels after the interventions. A well-trained RA with a master's degree in psychology will identify signs

of distress and provide preliminary counseling services to the participants. If the distress symptoms persist, the RA will refer the case to the PI, a registered nurse, and the Co-Is, a psychologist and an occupational therapist, to offer expert consultation to the distressed participants.

Sample size

We conducted a priori power analysis using the web-based software GLIMMPSE and employing a general linear mixed model. We set the level of significance (α) at 0.05, the power (1–β) at 0.8 for a two-tailed test, the number of repeated measures at three (i.e., T0, T1, and T2), the number of groups at two (i.e., the experimental and the control groups), and the allocation ratio between the two groups at 1:1. To estimate the effect, we referred to previous studies on psychological distress that employed three intervention components (i.e., mindfulness, PA training, and psychoeducation).[78,79] We assumed that the effect would be sustainable until the follow-up session, so we carried the mean values of the outcomes from T1 to T2. To estimate the interaction effect (i.e., Group × Time), we set the expected mean and standard deviation of the primary outcome in two groups at three time points, referring to the values observed in the previous study.[78,79] We took a conservative approach and estimated the sample size as 678. We assumed an overall dropout rate of 20%.[80] The total sample size was estimated to be 814 people, with 407 in each group.

Statistical analysis

The data will be analyzed using the statistical package SPSS version 28.0 for Windows.[81] An intention-to-treat analysis will be applied to the variables. Descriptive statistics will be generated for the sociodemographic and outcome data at baseline. Normality assumptions for the variables will be checked. Missing data will be handled by mean imputation, that is, replacing missing values of the variable by the mean of non-missing cases of that variable.

The baseline characteristics of the participants in the two groups will be compared using an independent-samples *t*-test for the continuous variables, a chi-square test for the independence of the categorical variables, and the Mann–Whitney *U* test for the ordinal variables. Three generalized estimating equations (GEE) will be used to make comparisons between the two groups of the group effect, time effect, and their interaction in the outcome assessments across the three time points (baseline [T0], 8 weeks after weekly supervised sessions [T1] and after 24 weeks when the intervention has been completed [T2]). We will interpret the results primarily using unadjusted models because this is an RCT without other known or anticipated important prognostic variables.[82,83] GEE will also be used to compute a within-group comparison of objective physiological parameters, including step counts, walking distance, heart rate, MVPA, active minutes, and sleep stages collected by the Fitbit Charge 5 in the experimental group.

In addition, the LiDAR data collected from the participants' 3D motion capture will be segmented into different body parts to identify patterns and trends in human body movements. A time series analysis will be used to quantify movement patterns, such as changes in joint angles and velocities.

Mixed-effects modeling will be used to measure the adherence of those in the experimental group to the three assigned interventions (mindfulness, ECT, or PA training). A sensitivity analysis will be conducted to compare the results of different methods of analysis, including between intention-to-treat and per-protocol analyses, and models adjusted for different covariates, such as demographic characteristics, clinical conditions, and participation in the other training programs during the study period. $P < 0.05$ will be considered statistically significant.

Limitations

Four limitations are identified in this study, but strategies have been implemented to attenuate their potential negative impacts. First, most of the outcome variables will be measured using self-reported questionnaires, which may lead to response bias and social desirability bias. To mitigate these biases, we will keep the participants' information anonymous. Second, the physical training, mindfulness, and energy conservation interventions will be delivered using technological devices, including mobile apps, a wearable sensor Fitbit Charge 5, and an iPad Pro. Therefore, participants with a lower level of digital literacy, such as older adults, may find it difficult to self-practice the interventions or could encounter technical issues, such as interruptions to their Wi-Fi connection while using the HAPPY app. To address this challenge, an interventionist will provide detailed instructions on how to use the HAPPY app during the supervised sessions. We will also send a demonstration video to participants on how to set up the iPad Pro and TV for the 3D motion-based games. Furthermore, a hotline for technical support will be set up to answer enquiries from the participants. Third, the accuracy of LiDAR detection is influenced by the exercise types and the visibility of human joints. To address this problem, we will collect real-time body movement data from the participants two to three times for each exercise posture and take the average of the data to minimize the mean absolute error. Last but not least, in the real world, participants may not have access to the same level of support or resources provided in the clinical trial. To enhance the usability of the HAPPY app, we will collect feedback from the participants and continue to modify the app to make it more user-friendly. In addition, we may consider conducting an implementation study after the completion of this trial to provide more scientific evidence about the application of the HAPPY app.

Conclusions

The mobile HAPPY app, supported by the DHA, offers an innovative and effective three-level intervention to promote beneficial behavioral strategies to alleviate the physiological and psychosocial distress of people in the post-pandemic era. By enhancing and promoting positive appraisal, self-efficacy, and self-management, the innovative platform and intervention developed in this study can be adapted and integrated into different primary healthcare services, thus further extending the reach and impact of this mobile HAPPY app.

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Data sharing: After completing the analyses, the datasets that were used will be made available from the corresponding author upon reasonable request.

Dissemination: The findings of the study will be written up by the research team in academic publications.

Ethical approval: Ethical approval for this study has been obtained from the Human Subjects Ethics Review Committee of The Hong Kong Polytechnic University (HSEARS20220318003). The trial protocol was registered with ClinicalTrials.gov (NCT05459896) on 15 July 2022.

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