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Developing and testing the effectiveness of mindfulness intervention for reducing loneliness in Hong Kong older adults: A hybrid sequential multiple assignment randomized trial, micro randomized trial experimental design study protocol

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Study protocol

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Abstract

Background

Loneliness is a growing public health concern among older adults, likewise in Hong Kong. Mindfulness-based interventions have shown promise in addressing loneliness, but often yield modest and short-lived effects. Digital delivery makes such interventions scalable but sustaining user engagement remains challenging. Adaptive interventions that integrate human support, mobile technology, and machine learning show promise, yet rigorous evidence remains limited. This study aims to develop and evaluate a machine learning-enabled mindfulness intervention to reduce loneliness and enhance well-being among older adults in Hong Kong.

Methods

Using hybrid Sequential Multiple Assignment Randomized Trial–Micro Randomized Trial (hybrid SMART–MRT), 250 lonely older adults will be randomized into one of the five first-line intervention conditions over 4 weeks; single session mindfulness intervention (SSMI) with no coaching, app-based coaching, human coaching, a combination of app-based and human coaching, or an active control. Nonresponders, defined as those who do not exhibit a decrease of at least 2.86 points on the Revised UCLA Loneliness Scale from baseline (T0) to the post-first-line assessment (T1) will be re-randomized to either intensified human coaching or booster session. Concurrently, MRTs will evaluate the proximal effects of push notifications, recommended mindfulness activities, and personalized motivational messages on engagement. Data will be collected at baseline (T0), within 1-week after each stage of intervention (T1 & T2), and three-month (T3) and six-month (T4) after completion of second-line intervention. Primary outcome is assessed by the Revised UCLA Loneliness Scale. Secondary outcomes include De Jong Gierveld Loneliness Scale, symptoms of anxiety and depression, perceived stress, and sleep quality. Potential mediators include mindfulness, perceived social support, and social network. Linear mixed models and weighted least squares regression will be used for analysis. This study is currently in the finalization phrase for intervention materials, mobile application development and personnel training. Recruitment will begin in May 2026, with data collection expected to be concluded by December 2026.

Discussion

This study will be among the first to apply a hybrid SMART–MRT design to a mindfulness-based loneliness intervention for older adults. Findings will inform the development of scalable, adaptive, and personalized interventions by identifying optimal combinations of human support and machine learning–driven digital strategies to enhance engagement and reduce loneliness.

Clinical Trial Registration

ClinicalTrials.gov, NCT07308613

Background

Loneliness is a major and growing public health concern among older adults (1). Defined as the subjective perception of a discrepancy between actual and desired social relationships, loneliness is conceptually distinct from objective social isolation but often occurs with it (2). A substantial body of evidence indicates that loneliness is associated with adverse mental and physical health outcomes (i.e., depression, anxiety, cognitive declined, cardiovascular diseases, increased mortality risk) (3–7). In Hong Kong, rapid population aging, high density urban living, and changing family structures have further increased the vulnerability of older adults to social connections (8). Studies conducted during and after the COVID-19 pandemic have reported elevated levels of loneliness and worsening mental health, particularly among socioeconomically disadvantaged older adults (9–11). Despite increasing recognition of loneliness as a public health priority, evidence for effective and scalable interventions remains mixed. Reviews of loneliness interventions among older adults report modest and inconsistent effects, with many programs limited by inadequate personalization, insufficient attention to psychological mechanisms, and poor sustainability (12–14). Although digital interventions offer considerable potential for broad reach, yet engagement often declines rapidly, particularly when interventions are static or lack supportive guidance (15, 16). Together, these limitations underscore the need for interventions that are both scalable and adaptive to individual needs.

Mindfulness-based interventions offer a promising approach to addressing loneliness by targeting key psychological processes that underlies the subjective experience of social disconnection. Mindfulness involves cultivating nonjudgmental awareness of present-moment experiences and has been shown to improve emotion regulation, reduce rumination, and attenuate maladaptive cognitive patterns such as rejection sensitivity—processes closely linked to loneliness and emotional distress (17–19). Emerging evidence suggests that mindfulness interventions can reduce loneliness and related mental health symptoms among older adults, including when delivered via telephone modalities (9–11, 20). Single-session interventions (SSIs) have gained increasing attention as a pragmatic strategy for lowering barriers to access while retaining therapeutic benefits (21, 22), particularly for older adults who may face constraints related to mobility, time, or motivation (23). However, sustaining mindfulness practice beyond an initial session remains challenging, highlighting the importance of ongoing support to promote engagement and maintenance of intervention effects.

Digital and mobile health technologies provide opportunities to extend mindfulness interventions beyond initial sessions and support engagement at scale. Smartphone applications can deliver brief exercises, facilitate self-monitoring, and prompt regular practice. Nevertheless, engagement with digital interventions often declines over time, and reminders may lose effectiveness due to habituation or poor alignment with users' daily contexts (24). Older adults show substantial heterogeneity in their responsiveness to digital prompts, influenced by contextual factors such as time of day, physical condition, mood, and prior engagement (25). These findings underscore the critical need for personalized interventions that adapt to individual users' contexts and preferences, rather than applying static, one-size-fits-all delivery approaches.

Advances in machine learning and reinforcement learning offer new opportunities to enhance personalization in digital health interventions. Just-in-time adaptive interventions aim to deliver support at moments when individuals are most receptive and most likely to benefit (15). By leveraging real-time data and repeated decision-making, machine learning algorithms can optimize the timing, frequency, and content of digital support to enhance engagement while minimizing burden. Although such approaches have shown promise in promoting behaviors such as physical activity and chronic disease self-management (26–28), their application to loneliness interventions among older adults remains limited (29).

However, human support plays a complementary but critical role in sustaining engagement with behavioral interventions. Integrating human coaching with digital platforms can enhance motivation, accountability, and relational support-elements that technology alone cannot fully provide. Yet reliance on human resources raises concerns about scalability and cost-effectiveness (30). From a public health and implementation perspective, it is therefore essential to determine how to optimally combine personalized digital interventions with targeted human support-specifically, when intensive human coaching is most beneficial, when app-based approaches are sufficient, and how interventions should adapt for individuals who do not initially respond to standard delivery.

Beyond intervention content, rigorous evaluation of adaptive and personalized strategies requires innovative experimental designs that account for individual heterogeneity and time-varying responses. Traditional randomized controlled have three critical limitations: they cannot identify optimal intervention sequences or adaptation pathways; they provide limited evidence for nonresponders; and they cannot rigorously evaluate the proximal, time-varying effects of frequently delivered digital components. To address these limitations, the present study employs a hybrid experimental design integrating a Sequential Multiple Assignment Randomized Trial (SMART) with multiple Micro-Randomized Trial (MRT) (15, 31). SMART designs address the first two limitations. SMART employs two-stage randomization: participants are initially randomized to first-line intervention, then nonresponders are re-randomized to receive either intensified human coaching or a booster session, while responders continue their assigned condition. This enables evaluation of adaptive intervention sequences—not just components, but the optimal pathway based on intermediate responses (32, 33). MRTs address the third limitation by enabling causal inference on the time-varying effects of digital components delivered repeatedly over time. Participants are randomized at each notification opportunity to receive or not receive push notifications, activity recommendations, or personalized versus standardized messages [1]. This measures whether each component increases app engagement in the subsequent 24 hours. (34, 35). Integrating SMART and MRT methodologies enables simultaneous optimization of intervention sequencing and just-in-time delivery, making this approach well suited for public health interventions targeting loneliness, where needs and engagement vary across individuals and over time. Thus, the current study aims to develop and evaluate a hybrid model of single-session telephone-based mindfulness intervention augmented with coaching and supported by mobile phone technology and machine learning approaches.

Methods

Study Design and Setting

This study will use a hybrid factorial–Sequential Multiple Assignment Randomized Trial–Micro Randomized Trial (hybrid SMART–MRT) experimental design (15). It incorporates a 2×2 + 1 factorial randomized clinical trial with five arms, a two-stage SMART, and three embedded MRTs (see Fig. 1). The 2×2 + 1 factorial structure compares four conditions of telephone-based single-session mindfulness (Tele-MF) augmented with different coaching combinations, plus one active control condition: Factor 1 (Human Coaching): presence or absence of weekly telephone coaching and Factor 2 (App-Based Coaching): presence or absence of app-based weekly check-ins. This yields four mindfulness conditions (Tele-MF only, Tele-MF + Human Coaching, Tele-MF + App Coaching, Tele-MF + both Human and App Coaching) plus one active control condition (psychoeducational program only), creating five arms total. Participants of the four mindfulness conditions will receive the 90-minute telephone-based single-session intervention (SSI) of mindfulness in week 1, followed by 4 weeks of home practice support via coaching and/or app.

At the end of week 4, nonresponders (defined as those who do not exhibit a decrease of at least 2.86 points on the Revised UCLA Loneliness Scale from baseline (T0) to the post-first-line assessment (T1) (36)) in the first-line intervention will be randomized again into two options for the second-line intervention: either 4 weeks of increased-intensity human coaching (biweekly calls of 30 minutes), or one 60-minute telephone-based booster session in week 5, whereas responders will continue their initial assigned condition. Furthermore, in the first 8-week of MRT, push notifications will be sent at one of the six specific time points throughout the day, each chosen by the participants themselves, and the participants will receive a push notification at their chosen time point with a 50% probability when they are available. In the second MRT, the push notification may or may not contain a recommended activity, whereas in the third MRT, the push notification will either consist of a personalized motivational message or a standardized motivation message. Repeated outcome measures will be assessed at five timepoints across the whole study period. This study will be conducted over a one-year period, with an expected completion date of December 2026. The study protocol adheres to the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) as outlined in Table 1 (37).

Table 1
Schedule of enrolment, interventions, and assessments for SPIRIT 2025

	Study Period							
	Enrolment		**First-Line Intervention**		**Second-Line Intervention**			**Close-out**
Timepoint	$-t_1$	t_0		t_1		t_2	t_3	t_4
Enrolment								
• Eligibility screen	×							
• Informed consent	×							
• Randomization		×						
Interventions								
• Single Session Mindfulness Intervention			×					
• App-Based Coaching			×					
• Human Coaching			×					
• App-Based and Human Coaching			×					
• Continue with Intervention					×			
• Increase intensity of human coaching					×			
• Booster session					×			
• Push notifications			×	×	×			
Assessments								
Primary Outcomes								
• Revised UCLA Loneliness Scale (62)		×		×		×	×	×
Secondary Outcomes								
• De Jong Gierveld 6-item Loneliness Scale (48)		×		×		×	×	×
• Perceived Stress Scale (49)		×		×		×	×	×
• Pittsburgh Sleep Quality Index (50)		×		×		×	×	×

	Study Period					
	Enrolment	First-Line Intervention	Second-Line Intervention			Close-out
• Hospital Anxiety and Depression Scale (63)	×		×	×	×	×
• Generalized Anxiety Disorder (52)	×		×	×	×	×
• Activities of daily living (53)	×					×
• Instructional activities of daily living (54)	×					×
• Physical Symptoms Inventory (64)	×		×	×	×	×
Mediators						
• Mindfulness Attention Awareness Scale (56)	×		×	×	×	×
• Multidimensional Scale of Perceived Social Support (57)	×		×	×	×	×
• Lubben Social Network Scale (58)	×		×	×	×	×
Demographics						
• Age, gender, number of children, education level	×					
• Marital status, living with family members	×					×
• Economic activity status, house	×		×	×	×	×
• Usage of elderly center or service	×		×	×	×	×
• Usage of community/ home care services	×		×	×	×	×
• Household income in the past month	×		×	×	×	×

Study Hypotheses

We hypothesized that different embedded adaptative interventions and sequences (Fig. 1) will have different effects on the primary outcome; loneliness and the secondary outcomes; perceived stress, sleep quality, depression symptoms and anxiety, specifically:

- In the first-line intervention, the telephone-based single session of mindfulness intervention will lead to different effects on loneliness and secondary outcomes when compared with active control (Group 1–5)
- In the first-line intervention, whether adding an application-based coaching, human coaching, or a combination of both app-based and human coaching after telephone-based single session of mindfulness intervention will have different effects in engagement of the mindfulness intervention on loneliness and secondary outcomes compared with active control and no coaching (Group 1–5)
- Among participants who do not response in the first-line intervention, whether either increasing the intensity of human coaching or adding a telephone-based human-delivered booster session in the second-line intervention will have different effects on loneliness and secondary outcomes (Group 1B + 2B+3B+4B and Group 1C + 2C+3C+4C)
- Delivery of push notification will have increase engagement with app-based coaching and have differing effects on loneliness and secondary outcomes compared with no push notifications. Push notifications delivered at optimized timings and frequencies are expected to have better effects than non-optimized notifications.
- Delivery of recommended brief mindfulness activities will have increase engagement with app-based coaching and have differing effects on loneliness and secondary outcomes compared with no recommended activities.
- Delivery of personalized motivational messages will have increase engagement with app-based coaching and have differing effects on loneliness and secondary outcomes compared with standard motivational messages.

Participants recruitment and eligibility

Participants will be recruited from community centres and academics for older adults, public housing, and word-of-mouth. Eligible participants will be (i) lonely older adults indicated by the three-item UCLA Loneliness Scale (38), (ii) aged ≥ 65 years, and (iii) possess a smartphone with either an Android or iOS operating system. Individuals will be excluded if they: (i) have cognitive impairment, (ii) are engaged in any psychotherapy and psychosocial intervention in the past year, and (iii) have psychiatric disorder, learning disability, or active suicidal ideation. To ensure equitable access, the study will provide digital literacy support for participants lacking necessary skills.

Allocation Concealment, Assignment of Interventions, and Blinding

Following the baseline assessment, participants will be randomly assigned in the first stage intervention to one the five groups in a 1:1:1:1:1 using *Random.org.* In the second stage intervention, participants who responded positivity in the first stage will be assigned to continue the existing intervention, whereas nonresponders will be re-randomized into receiving either human coaching (biweekly calls of 30 minutes) or a booster session (a single 60-minute telephone-based booster session). Participants will be informed of their assigned assignment at both stages by an independent researcher who is not involved in the assessment process.

For the MRT, all participants will receive push notifications (i) at one of the six specific time points throughout the day, (ii) may or may not contain a recommended brief mindfulness exercise (e.g. mindful breathing, body scan); and (iii) receive either a personalized or standardized motivational message. There are four framings of motivational messages: prevention framing focusing on engaging in the mindfulness exercise, promotion framing focusing on engaging in the mindfulness exercise, prevention framing focusing on not engaging in the mindfulness exercise, and promotion framing focusing on not engaging in the mindfulness exercise.

Interventions

Single Session of Mindfulness Intervention (SSMI)

The mindfulness component is adapted from the smartphone-delivered intervention developed by Lindsay, Young (39) and previously validated in the Hong Kong context for reducing loneliness and improving well-being among older adults (9–11, 36). The SSMI consists of a single 90-minute telephone-based SSI that incorporates formal and informal mindfulness exercises aimed at cultivating skills that can be integrated into daily life. Psychoeducation and group-sharing activities are included to enhance participants' confidence in managing loneliness and to support the development of a sustainable self-practice plan. Participants will receive a self-practice toolkit, containing recordings of guided mindfulness activities delivered via a mobile application, to facilitate 20 minutes of daily home practice (40, 41). All instructional content will be closely aligned with participants, focusing on topics like responding mindfully to the feelings of loneliness. The sessions will be led by a mindfulness instructor who has undergone 40 hours of training in loneliness based on our previous work.

For the human coaching, the interventionist will conduct weekly telephone calls with participants, each lasting approximately 15 minutes. Human coaching provides personalized encouragement, goal-setting, and feedback tailored to individual barriers and progress. The call will focus on reviewing participants' daily practice records, supporting goal setting and scheduling of mindfulness exercises, identifying barriers, reviewing progress, encouraging the use of social support, providing feedback and encouragement, and reinforcing the application of skills in daily life. In the second-stage intervention, the intensity of human coaching will be increased to biweekly and extending the duration of each call to approximately 30 minutes.

For the app-based coaching, the mobile application will guide participants through weekly check-ins to monitor their daily practice, review performance from the previous week, and support the setting of personalized goals and actionable steps for the coming week. Participants will be able to record their daily practice using written entries or audio recordings within the application.

For participants receiving a combination of app-based and human coaching, duplication of content between the two modalities will be minimized to ensure a seamless coaching experience. Human coaching will serve as a supplementary component to the app-based coaching, and the coach will have access to information collected through the app to provide personalized feedback and targeted support to the participant.

Psychoeducational program

To ensure all participants are informed about loneliness and its management, a standardized psychoeducational program will be provided to all study arms, including the active control group, at the beginning of the study. This program consists of general information on loneliness, effective communication strategies, and the impact of social connection on mental and physical health. Following this initial session, participants in the active control group will receive no further contact or coaching, maintaining their daily routines as usual. This design allows us to isolate the specific effects of the mindfulness intervention and coaching by controlling for the psychoeducational component across all participants.

Booster Session

The booster session will be delivered by trained interventionist and will revisit the core content of the SSMI to enhance participants' retention of key concepts and skills. This will be achieved through structured reviews and repeated rehearsal of the principal constructs and processes. Participants will also receive social reinforcement to support the maintenance of behavior change to prevent skill erosion over time. Additional topics will include challenges to implementing mindfulness, information sharing, and the establishment of short- and long-term goals.

Push Notifications

Push notifications will be sent to participants as a brief greeting that inquire whether they have engaged in mindfulness practice on the current day or during the preceding few days.

Recommended Brief Mindfulness Exercises

To facilitate engagement with brief mindfulness exercises, we will develop and provide real-time, personalized exercise recommendations. Suggested exercises will be randomly selected from a predefined list and delivered when participants have not engaged with the app for a specified period. To

avoid participant burden, activity prompts will be limited to a maximum of two per day. On average, participants will receive one exercise suggestion per day.

Motivational Messages

A list of motivational messages will be developed based on prior works that apply the Transtheoretical Model of Health Belief Model (26, 27, 42). Messages will follow four established framing types: prevention framing focused on engaging in the mindfulness exercise, promotion framing focused on engaging in the mindfulness exercise, prevention framing focused on not engaging in the mindfulness exercise, and promotion framing focused on not engaging in the mindfulness exercise (43). Motivational messages will be randomized such that a standardized motivational message is sent with a probability of 3/7, and each framed message is sent with a probability of 1/7. To minimize participant burden and reduce the risk of habituation, an average of one motivation message per day will be sent, with a maximum of two.

Machine Learning Algorithms

Receptivity Modeling for Push Notifications

To identify optimal timing and frequency for push notifications, participants' state of receptivity will be modeled using machine learning with a three-phase approach. Models will incorporate contextual factors (e.g., time of day, battery level of smartphone, GPS location, physical activity, device interactions, Wi-Fi connectivity) and intrinsic factors (e.g., age, gender, personality). Specifically, our system maintains a real-time feature table tracking the participant's most recent behavior, device state including battery level, screen brightness, network connectivity, and headphone connection status, along with rolling window statistics over 30-minute, 24-hour, and 7-day periods. Data will be spilt into training and cross-validation sets with stratified splitting to main class balance. Just-in-time response (notifications opened within 10 minutes) and delayed response (opened after 10 minutes) will be modeled as binary classification, while response delay will be modeled using regression-based estimation. Random Forests and Support Vector Machines will be applied as the primary offline predictive model, selected for inherent feature importance rankings and robust handling of mixed feature types. In addition to static models, adaptive models will be developed, as they have demonstrated up to 40% improvement in receptivity (25). Neural network and reinforcement learning approaches (e.g., deep Q-learning, advance actor critic, proximal policy optimization) will be explored to maximize the effectiveness of the push notifications.

Personalized Activity and Message Recommendation

Real-time personalized recommendations for mindfulness activities and motivational messages will be generated using participants' past behaviors, message responsiveness, and preferences of similar users. A hybrid recommender system combining item-based filtering, user-based collaborative filtering, and demographic filtering will be employed. Our system identifies user content preferences by analyzing the most frequently played practice audio type within the recent 28-day window and preferentially

recommends associated content, with fallback to random selection from general message pools when no clear preference emerges. Sequential engagement patterns and repeated use will be modeled through explicit behavioral tracking, where the system maintains daily logs of app opens, audio plays, reflections written, completions, and early exits to inform content selection.

Reinforcement Learning Optimization

Reinforcement learning algorithms will be used to determine the optimal activity, motivational message, and delivery timing and frequency to maximize app engagement over the subsequent 24 hours and minimize response delay. Our system implements a multi-armed bandit framework that divides each day into 144 ten-minute time slots, treating each as a separate "arm" with its own reward statistics. Contextual multiarmed bandit methods, including Thompson Sampling, will be applied to balance exploration and exploitation (44, 45). Models will be updated daily using linear regression and will incorporate message content, timing, day of the week, and participants' well-being measured via ecological momentary assessment. To maintain system stability and prevent policy-induced behavioral drift, adaptive planning occurs at the daily level rather than continuously, with all scheduled notifications for a given day pre-computed and logged in the adaptive daily plan table before execution (46).

Volunteer Training

Volunteers aged 50 to 70 years will be recruited as interventionist in this study to deliver the psychoeducational program, SSMI, human coaching, and booster sessions. All interventionists will undergo 10 hours of training led by an experienced mindfulness therapist, including hands-on practices and the use of standardized materials to ensure familiarity with intervention protocols. Fidelity is assessed through two mechanisms: (1) 20% of all sessions are randomly audio-recorded and evaluated by the lead therapist using a structured fidelity checklist to score adherence and quality; and (2) mandatory bi-weekly supervision meetings are held to ensure protocol consistency and resolve any issues. This dual-layer approach effectively minimizes inter-interventionist variability.

Outcome Measures

All participants will be assessed face-to-face by well-trained independent assessors, using the Chinese validated scales at baseline (T0; prior to intervention), within 1-week after first-line intervention (T1), within 1-week after second-line intervention (T2), and three-month (T3) and six-month (T4) after completion of second-line intervention.

Primary outcome

The revised UCLA Loneliness Scale (UCLA) (47) will be used to measure loneliness. UCLA is a 20-item scale, where each item is rated on a 4-point Likert scale ranging from 1 = never to 4 = always, reflecting how often participants experience feelings of loneliness. Higher scores indicate greater levels of loneliness.

Secondary outcomes

De Jong Gierveld Loneliness Scale (DJGL) (48) will also be used to measure loneliness. DJGL is a 6-item scale which distinguishes between social and emotional loneliness. Each item is rated 0 = no or 1 = yes, with higher scores reflecting greater level of loneliness.

Perceived Stress Scale (PSS) (49) will be used to measure stress level. Each item is rated on a 5-point Likert scale from 0 = never to 4 = very often, indicating how frequently participants have experienced each feeling in the past month. Higher scores indicate high level of perceived stress.

Pittsburgh Sleep Quality Index (PSQ) (50) will be used to measure sleep quality. PSQ consists of seven components such as sleep quality, latency, efficiency, duration, disturbance, consumption of sleep medication, and daytime dysfunction. Each item is rated on a 4-point Likert scale ranging from 0 = no difficulty to 3 = severe difficulty. Higher scores reflect poorer sleep quality.

Patient Health Questionnaire (PHQ-9) (51) will be used to measure depressive symptoms. PHQ-9 is a 9-item scale assessing the frequency of cognitive, somatic, and affective symptoms experienced over the past two weeks. Each item is rated on a 4-point Likert scale from 0 = not at all to 3 = nearly every day. Higher scores indicate greater severity of depression symptoms.

Generalized Anxiety Disorder (GAD-7) (52) will be used to measure anxiety severity experienced by the participants in the past two weeks. Each item is rated on a 4-point Likert scale from 0 = not at all to 3 = nearly every day. Higher scores indicate greater levels of anxiety.

Physical health will be assessed using Barthel Index of Independence in Activities of Daily Living (ADL) (53), Lawton Instrumental Activities of Daily Living Scale (IADL) (54), Wahler Physical Symptoms Inventory (WPSI) (55), self-rated health, and the presence of chronic illnesses. For ADL, participants' functional ability is assessed on a scale of 0 = dependent to 5/10 = independent. Higher scores indicating greater independence. For IADL, participants their ability in performing 8 specific tasks on a scale of 0 = dependent to 1 = independent, with higher scores indicating greater independence. For WPSI, participants will respond to 42 items assessing physical health and neurological symptoms from a scale of 0 = almost never agree to 5 = agree almost every day. Higher scores indicate greater self-reported health complaints and distress.

Mediators

The 15-item Mindfulness Attention Awareness Scale (MAAS) (56) will be used to assess mindfulness. Each item is rated on a 6-point Likert scale ranging from 1 = Almost always to 6 = Almost never. A mean score across all items will be calculated, with higher scores indicating higher levels of dispositional mindfulness.

The 12-item Multidimensional Scale of Perceived Social Support (MSPSS) (57) will be used to measure perceived social support from family, friends, and significant others. Each item is rated on a 7-point Likert scale ranging from 1 = Strongly disagree to 7 = Strongly agree. Total scores range from 12 to 84, with subscale score ranging from 4 to 28. A higher score indicates higher levels of perceived support.

The 6-item Lubben Social Network Scale (LSNS-6) (58) will be used to measure social network based on how many family members and friends they can engage with in terms of frequency of contact, closeness for discussing private matters, and availability of help. Each item is rated on a 6-point Likert scale ranging from 0 = None to 5 = 9 or more. Total scores range from 0 to 30, with a higher score indicating greater social engagement and lower risk of social isolation.

Demographics

Socio-demographic information will be collected using self-reported questionnaire, which includes participant profile (age, gender, marital status, education level, employment status, household income, and number of children), as well as healthcare and social services utilization during the past month.

Sample size

A power analysis was conducted to estimate the required sample size for this study, which uses a hybrid SMART-MRT design to detect the main effect on loneliness. Previous studies reported effect sizes ranging from 0.32 to 0.68 (59, 60). Assuming a 10% attrition rate, we will recruit 275 participants (55 per group) to ensure 250 complete the study, providing 80% power to detect a small-to-moderate effect size of 0.33. Three primary comparisons will be conducted for the first-line intervention: (1) SSMI versus active control, (2) coaching approaches, and (3) second-line re-randomization effectiveness for nonresponders. To mitigate the risk of Type I error from multiple comparisons, we applied the Bonferroni correction ($\alpha = 0.05/3$), resulting in a minimum detectable effect size of 0.46 for these contrasts.

For MRT components, power is derived from the high frequency of longitudinal decision points rather than cross-sectional participant counts. With 60 participants across the 56-day study period, and assuming a 50% availability rate for intervention delivery (60 participants × 56 days × 50% = 1,680 potential decision points), the design generates sufficient data to detect small, time-varying effects (minimal detectable effect size = 0.13, 80% power). To account for dependency structures and clustering within repeated measures, all longitudinal analyses will utilize linear mixed-effects models, treating participants as random effects to ensure accurate variance estimation. Finally, while the clinical sample is powered for loneliness outcomes, the machine learning algorithms leverage these 1,680 dense, longitudinal interaction events to ensure robust predictive performance.

Planned Statistical Analysis

Descriptive statistics will be used to summarize baseline characteristics, including socio-demographic variables and outcome measures, across all intervention groups. Following the intention-to-treat principle, linear mixed models will be used to assess the main effects on loneliness and secondary outcomes on objective 1–3. As the psychoeducational program is common to all study arms, the statistical comparisons focus on the incremental effect of the mindfulness-based intervention and coaching modalities over and above this standardized psychoeducational baseline. Specifically, we will determine (1) whether the SSMI is better than an active control, (2) whether app-based coaching, human

coaching, or a combination of both app-based and human coaching is more effective as first-line intervention by comparing subgroups 1A + 1B+1C with subgroups 2A + 2B + C and subgroups 3A + 3B+3C, and (3) for nonresponders, whether increasing the intensity of coaching or adding a booster session is more effective by comparing subgroups 1B + 2B+3B+4B and 1C + 2C+3C+4C. Analyzes will include data from all timepoints (T0, T1, T2, T3, T4). Missing values will not be replaced because mixed-effects models can accommodate participants with at least one outcome measurement under the assumption that data are missing at random. For objective 4–6, linear models will be used to assess the time-varying effects of intervention (e.g., sending a push notification versus not) on engagement outcomes, such as frequency and duration of engagement the following day. Each model will include an indicator of the randomized treatment condition (i.e., intervention vs. no intervention), time (T0, T1, T2, T3, T4), and their interaction as dependent variables. Regression parameters will be estimated using weighted least squares, with weights determined by participants' availability at each decision point. Contrasts of regression coefficients will be used to evaluate the intervention effect. Analyses will pool time-varying, longitudinal data across all participants, with separate analyses conducted for each MRT aim. Models will also be adjusted for two sets of prespecified covariates. The first set will examine moderation of the causal effect of sending a push notification with a tailored message versus no notification. The second set will include variables expected to be highly correlated with participants' app use in the subsequent 2 days, reducing noise when assessing the effect of tailored push notifications versus no notifications.

Ethical Consideration and Dissemination

This trial has been approved by the Human Research Ethics Board of The Education University of Hong Kong (2023-2024-0147) and is prospectively registered at ClinicalTrials.gov; NCT07308613. Prior to study commencement, all participants will receive detailed written and verbal information about the study, the collection of real-time behavioral data, and will provide signed informed consent. All collected data will remain anonymous and confidential. In accordance with the principle of voluntary participation, participants have the right to withdraw from the study at any time without penalty. As a token of appreciation, participants will receive supermarket vouchers upon completing the study's milestones. Findings from this trial will be disseminated through scientific conferences and peer-reviewed journals.

Results

At presence, this trial is currently in its preparation phase, which includes finalizing the intervention design, developing of the app, assessment tools, and training research personnel, which will last till April 2026. Recruitment and participant enrollment, along with volunteer training, are scheduled to begin in April 2026. Baseline assessments are expected to commence in May 2026, with data collection anticipated to complete by December 2026.

Discussion

This study introduces a novel, methodologically rigorous approach to reducing loneliness in older adults by combining mindfulness-based intervention content with adaptive delivery strategies guided by machine learning. Loneliness is increasingly recognized as a major determinant of mental and physical health in later life (3–7), yet existing interventions often show limited effectiveness, low engagement, and inadequate personalization (12–14). The proposed hybrid SMART–MRT design addresses these gaps by enabling systematic evaluation of both intervention sequencing and time-varying digital components.

A primary contribution of this study is the use of a telephone-delivered, single-session mindfulness intervention as the core therapeutic component. Single-session formats provide a pragmatic and accessible option for older adults who may experience barriers related to mobility, time, or sustained engagement (22, 59, 61). Embedding this brief intervention within an adaptive framework shifts the focus from whether mindfulness is effective to understanding how, for whom, and under what conditions it works best. Including both app-based support and human coaching as initial augmentation strategies allows direct comparison of scalability versus relational support, while the second-line re-randomization of nonresponders mirrors real-world clinical decision-making (32).

The incorporation of micro-randomized trials further advances the field by enabling causal inference on the proximal, time-varying effects of digital supports such as push notifications, activity recommendations, and motivational messages. Rather than presuming uniform benefit, this design recognizes heterogeneity in older adults' responsiveness to digital prompts (34). Machine learning and reinforcement learning methods are used to optimize the timing, content, and frequency of intervention delivery, thereby operationalizing just-in-time adaptive intervention principles. Evidence generated from these MRT components will be crucial for guiding the development of personalized digital interventions that minimize burden while maximizing engagement.

However, several limitations should be acknowledged. First, the requirement of smartphone ownership may exclude older adults who are digitally marginalized, which could reduce the generalizability of the findings. Future research could explore alternative access strategies (e.g., loaning devices, offline components) to enhance inclusivity. Second, participants with lower digital literacy may be less willing to engage with the app and intervention, introducing the risk differential engagement. To address this, targeted support strategies (e.g., technical assistance, simplified interface design) should be implemented.

Overall, this study has the potential to make meaningful contributions to interventions designed to reduce loneliness and enhance well-being. By combining mindfulness-based therapy with adaptive experimental designs and machine learning–driven personalization, it offers a scalable, data-informed framework for developing targeted interventions. The findings could have relevance not only for older adults in Hong Kong but also for broader efforts to address loneliness in aging populations worldwide, informing both research and practical applications across diverse contexts.

Declarations

Disclosures

The authors declare no conflict of interest.

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Author Contribution

KLC is the principal investigator and guarantor, responsible for the overall content and funding acquisition. VFYT, ZH, DJ, ZW, AYZ, LV, HX, PLHY, MKPS, and KLC supported the implementation of the interventions. ZH, HX, PLHY, and MKPS supported the development of machine learning in this study. VFYT and KLC were responsible for data collection, while VFYT, ZH, DJ, ZW, and AYZ conducted data analysis with the guidance of HX, PLHY, MKPS, and KLC for this study. VFYT drafted the manuscript, and all authors read, commented and approved the final manuscript.

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Data Availability Statement

Data from this study will be made available upon reasonable request. For data access, please contact KL Chou (klchou@eduhk.hk) and/or VFY Tang (vivientang.fy@gmail.com; s1135125@s.eduhk.hk).

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Figures

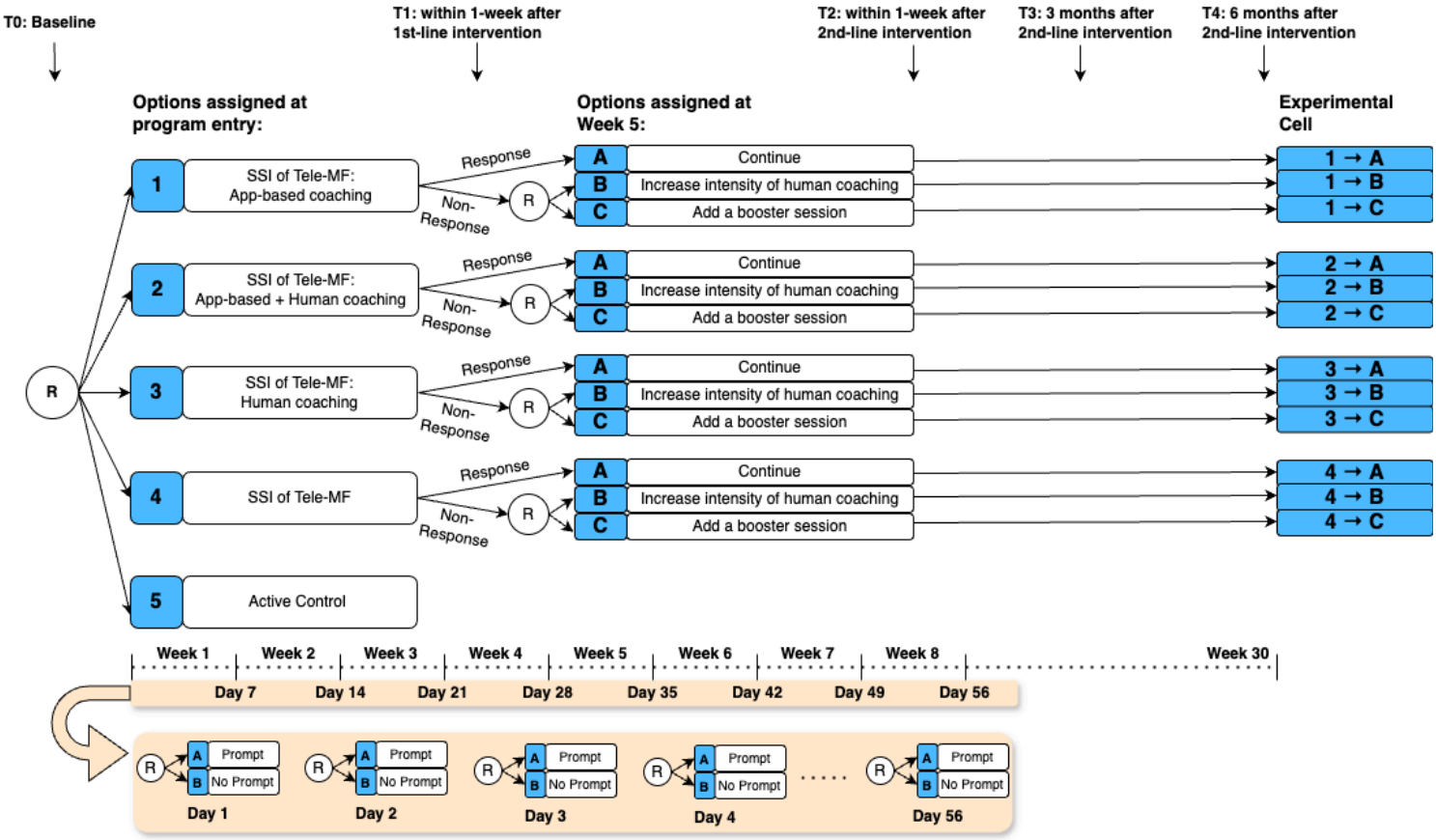


Figure 1

Hybrid SMART-MRT Design

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