

Efficacy of a CBT-based WeChat Mini-Program smoking cessation intervention ('Quit for Heart') tailored for CVD patients in China: a randomised controlled pilot study

Rongrong Chen, Jinsong Tang, Luyao Zou, Zitang Zhou, Shengjie Xu, He Huang, Yanhui Liao

Submitted to: Journal of Medical Internet Research
on: September 22, 2025

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 26

Figures..... 27

 Figure 1 28

 Figure 2 29

CONSORT (or other) checklists..... 31

 CONSORT (or other) checklist 0..... 32

Efficacy of a CBT-based WeChat Mini-Program smoking cessation intervention ('Quit for Heart') tailored for CVD patients in China: a randomised controlled pilot study

Rongrong Chen¹ MD; Jinsong Tang¹ MD; Luyao Zou¹; Zitang Zhou¹; Shengjie Xu¹ MD; He Huang¹ MD; Yanhui Liao² MD, PhD

¹ Sir Run Run Shaw Hospital, Zhejiang University School of Medicine Hangzhou, Zhejiang, P. R. China. CN

² Sir Run Run Shaw Hospital, Zhejiang University School of Medicine Hangzhou, Zhejiang, P. R. China CN

Corresponding Author:

Yanhui Liao MD, PhD

Sir Run Run Shaw Hospital, Zhejiang University School of Medicine
3 East Qingchun Road, Hangzhou, Zhejiang, P. R. China (310016).
Hangzhou, Zhejiang, P. R. China
CN

Abstract

Background: Smoking cessation is critical for Chinese patients with cardiovascular disease (CVD) or CVD risk factors, yet the efficacy of smartphone-delivered interventions for this group remains to be evaluated.

Objective: To evaluate the efficacy of the 12-week smartphone-delivered CBT-based programme ("Quit for Heart") for smoking cessation among Chinese CVD patients.

Methods: A two-arm, parallel-group, individually randomised, double-blind, controlled pilot trial. 108 participants (from 214 randomised) with CVD/CVD risk factors in China were analysed for data integrity. Intervention group received CBT modules, personalized quit plans, and progress tracking; control group got automated reminders. Assessments (during intervention/follow-up) included primary outcome (biologically verified continuous smoking abstinence at week 26 after quit date) and secondary outcomes (seven-day point prevalence abstinence, self-reported continuous abstinence, physiological parameters [blood pressure, heart rate], predictive factors [baseline psychological metrics, disease profiles]). Assessments occurred during the intervention and follow-up.

Results: No significant group differences in abstinence (adjusted OR range: 0.56–1.04; $p=0.14$ – 0.87) but better trends for intervention. Survival analysis showed intervention group's longer relapse-free duration trend (log-rank $p=0.095$). DBP moderately decreased with abstinence (Cohen's d : -0.63 to -0.72 at weeks 2–4). Baseline anxiety (DASS; OR=35.18, $p=0.045$) and lower quit will (OR=0.003–0.145, $p=0.08$ – 0.086) predicted relapse. Anxiety correlated with SBP elevation ($\beta=3.93$, $p<0.05$), depression with heart rate increases ($\beta=4.27$, $p<0.05$). Obesity elevated BP (SBP $\beta=9.83$, DBP $\beta=8.34$; $p<0.01$), hyperlipidemia lowered it ($\beta=-3.61$ to -5.10 , $p<0.05$). Attrition exceeded 80% by week 26.

Conclusions: "Quit for Heart" demonstrated potential feasibility for smoking cessation in this high-attrition pilot study. Baseline anxiety, disease profile and motivation levels predicted relapse. Future research requires enhanced retention strategies and objective outcome validation. Clinical Trial: ClinicalTrials.gov Identifier: NCT06747182. Website: <https://clinicaltrials.gov/study/NCT06747182>

(JMIR Preprints 22/09/2025:84538)

DOI: <https://doi.org/10.2196/preprints.84538>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to the public.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <https://www.jmir.org/>

No. Please do not make my accepted manuscript PDF available to anyone. I understand that if I later pay to participate in <https://www.jmir.org/>



Original Manuscript

Efficacy of a CBT-based WeChat Mini-Program smoking cessation intervention ('Quit for Heart') tailored for CVD patients in China: a randomised controlled pilot study

Rongrong Chen¹, M.D., Jinsong Tang¹, M.D., Luyao Zou¹, B.E., Zitang Zhou¹, B.E., Shengjie Xu^{2*}, M.D., He Huang^{2*}, M.D., Yanhui Liao^{1*}, M.D.

Affiliations:

1. Department of Psychiatry, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Hangzhou, Zhejiang, P. R. China
2. Department of Cardiology, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Hangzhou, Zhejiang, P. R. China

*Corresponding authors:

Shengjie Xu, 3 East Qingchun Road, Hangzhou, Zhejiang, P. R. China (310016).

E-mail: srrshxsj@zju.edu.cn

He Huang, 3 East Qingchun Road, Hangzhou, Zhejiang, P. R. China (310016).

E-mail: huanghell@zju.edu.cn

Yanhui Liao, 3 East Qingchun Road, Hangzhou, Zhejiang, P. R. China (310016).

E-mail: liaoyanhui@zju.edu.cn

Contact: +86-18814898844

Running title: 'Quit For Heart' for CVD Patients

Sources of support/funding: YLiao received technical supports from the Ethosth Technology Inc. No specific funding program was received in this research.

Declarations of competing interests: The authors declare no completing interests.

Manuscript word count: 3449

Abstract word count: 279

Number of references: 35

Trial registration: ClinicalTrials.gov Identifier: NCT06747182. Website: <https://clinicaltrials.gov/study/NCT06747182>

Contributors: Rongrong Chen, Jinsong Tang, Luyao Zou, and Zitang Zhou contributed to the conception, data acquisition, and execution of the study. Shengjie Xu, He Huang, and Yanhui Liao supervised the study design, data interpretation, and manuscript revision. All authors critically reviewed the manuscript and approved the final version for submission. Yanhui Liao is the guarantor.

Data sharing: De-identified participant data underlying the results reported in this article are stored securely on institutional servers. Data access can be considered upon reasonable scientific request to the corresponding authors, subject to institutional review board approval and a data-sharing agreement.

Acknowledgements: This study received technical support from Ethosth Technology Inc. We thank the participants for their involvement. Ethical approval was granted by the Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (Approval #20200129-33).

Abstract

Background: Smoking cessation is critical for Chinese patients with cardiovascular disease (CVD) or CVD risk factors, yet the efficacy of smartphone-delivered interventions for this group remains to be evaluated.

Objective: To evaluate the efficacy of the 12-week smartphone-delivered CBT-based programme ("Quit for Heart") for smoking cessation among Chinese CVD patients.

Methods: A two-arm, parallel-group, individually randomised, double-blind, controlled pilot trial. 108 participants (from 214 randomised) with CVD/CVD risk factors in China were analysed for data integrity. Intervention group received CBT modules, personalized quit plans, and progress tracking; control group got automated reminders. Assessments (during intervention/follow-up) included primary outcome (biologically verified continuous smoking abstinence at week 26 after quit date) and secondary outcomes (seven-day point prevalence abstinence, self-reported continuous abstinence, physiological parameters [blood pressure, heart rate], predictive factors [baseline psychological metrics, disease profiles]). Assessments occurred during the intervention and follow-up.

Results: No significant group differences in abstinence (adjusted OR range: 0.56–1.04; $p=0.14$ – 0.87) but better trends for intervention. Survival analysis showed intervention group's longer relapse-free duration trend (log-rank $p=0.095$). DBP moderately decreased with abstinence (Cohen's d : -0.63 to -0.72 at weeks 2–4). Baseline anxiety (DASS; OR=35.18, $p=0.045$) and lower quit will (OR=0.003–0.145, $p=0.08$ – 0.086) predicted relapse. Anxiety correlated with SBP elevation ($\beta=3.93$, $p<0.05$), depression with heart rate increases ($\beta=4.27$, $p<0.05$). Obesity elevated BP (SBP $\beta=9.83$, DBP $\beta=8.34$; $p<0.01$), hyperlipidemia lowered it ($\beta=-3.61$ to -5.10 , $p<0.05$). Attrition exceeded 80% by week 26.

Conclusions: "Quit for Heart" demonstrated potential feasibility for smoking cessation in this high-attrition pilot study. Baseline anxiety, disease profile and motivation levels predicted relapse. Future research requires enhanced retention strategies and objective outcome validation.

Keywords: Mobile health (mHealth); Smoking cessation; Cardiovascular diseases; Cognitive behavioural therapy; Pilot study.

Abbreviations: CBT: cognitive behavioural therapy; CVD: cardiovascular disease; SBP: systolic blood pressure; DBP: diastolic blood pressure; HR: heart rate; CCA: complete case analysis; ITT: intention-to-treat; SMS: short message service; ePRO: electronic patient-reported outcome; GAD-7: Generalized Anxiety Disorder-7; DASS: Anxiety Stress Scales-21.

Implications: This pilot study demonstrates the potential feasibility of a CBT-based digital intervention ("Quit for Heart") for smoking cessation among Chinese CVD patients, despite high attrition challenges. It identifies baseline anxiety and low motivation as key relapse predictors and suggests short-term cardiovascular benefits from cessation. The findings underscore the need for enhanced retention strategies and integrated psychological support in future scalable mHealth interventions for high-risk populations.

Introduction

Smoking persists as a major global public health challenge, exhibiting substantial regional disparities in prevalence and disease burden (1). In China, adult smoking prevalence declined from 30.8% to 26.7% during 2007–2018 (2). Adolescent smoking (ages 15–24) doubled from 8.3% to 19.9%, with strong comorbidity with alcohol use (OR=7.5) (3). Critically, smoking among patients with cardiovascular comorbidities remained persistently high (53.9%–50.8%) (4), aligning with projections of 2 million annual tobacco-related deaths by 2050 (5). Meanwhile, control policies remained inadequate (5). These patterns establish tobacco as a modifiable risk factor requiring urgent clinical interventions.

The cardiovascular impacts of smoking necessitate targeted cessation strategies. Paradoxically, current smokers show better systolic pressure control than nonsmokers (OR=0.78), yet heavy smoking elevates diastolic pressure and hypertension risk (OR=3.89) (6,7). Nevertheless, cohort studies confirm cessation significantly reduces hypertension incidence (OR=0.30) and cardiovascular disease (CVD) risk independently of baseline parameters or short-term weight fluctuations (8–10). However, heavy ex-smokers (≥ 8 pack-years) retain CVD risks equivalent to current smokers for decades, underscoring the need for early intervention (11,12). These findings establish cessation as a cornerstone cardiovascular intervention.

Digital cessation interventions support clinical potential. Automated programmes (text/multi-platform) achieve higher abstinence rates (17.8%) versus controls (RR=1.58) at 3–12 months, while smartphone apps combined with pharmacotherapy enhance outcomes (OR=1.79) despite limited standalone efficacy (OR=1.25) (13,14). Video counseling matches telephone efficacy overall but excels in clinical subgroups (e.g., women with HIV), whereas text messaging yields strong short-term effects (RR=2.10) and acceptance-commitment therapy (ACT) apps achieve 28% abstinence at 12 months via engagement (15–17). Personalization and theory-based design (e.g., CBT/TTM) improve effectiveness, though early dropout remains high (38.6% by day 7) despite predictive analytics (AUC=0.66) (14,18,19). While tailored tools benefit vulnerable groups, outcome heterogeneity and small samples limit generalizability (20,21).

Persistent challenges constrain digital interventions for CVD secondary prevention. Programmes (e.g., SMS/video) improve medication adherence and short-term cessation (22,23), yet impacts on hard CVD outcomes remain unproven. Trials report modest quit rates, typically limited to short follow-up (24,25), with interventions like Japan's DTx requiring standard programme integration for efficacy (26). Key limitations include inconsistent cessation integration in digital cardiac rehabilitation (27), suboptimal retention (37–57%) due to early disengagement (28,29), and insufficient scalable strategies for diverse populations (30,31).

This pilot study evaluated a CBT-based digital cessation program for CVD-risk patients, measuring feasibility via retention dynamics (40% attrition by week 4) and physiological outcomes.

Materials and methods

Study Design

This randomised controlled double-blind pilot trial compared smartphone app-delivered CBT intervention to a minimal-intervention control in mainland China (Oct 2022–Apr 2023). Recruitment combined online (WeChat/Weibo) and offline channels (hospitals/communities). Approved by the Zhejiang University SRRSH Ethics Committee (#20200129-33) and registered at ClinicalTrials.gov (NCT06747182), it followed CONSORT guidelines. Procedures complied with ethical standards (electronic informed consent via ePRO, data anonymization with unique identifiers, identifier deletion post-trial). Outcome assessors remained separate from intervention teams for bias minimization, alongside blinded statistical analysis. No serious adverse events occurred; all de-identified data are securely stored.

Participants and Recruitment

Participants were recruited in mainland China through online platforms (e.g., WeChat and Weibo) and offline channels (hospitals and communities) between October 2022 and April 2023. Eligibility criteria mandated that participants be adults aged ≥ 18 years who smoked ≥ 5 cigarettes per day with ≥ 100 lifetime cigarettes consumed, diagnosed with cardiovascular diseases (CVDs) or possessing ≥ 1 major CVD risk factor (e.g., hypertension or diabetes), and expressing will to quit within 30 days. Exclusion criteria included individuals with severe psychiatric disorders, smartphone application usage incapability, or concurrent participation in other smoking cessation programmes. All enrolled participants provided electronic informed consent via an ePRO system, with baseline data collected using anonymized user identification codes. Participants retained the right to withdraw at any time without penalty, and data handling ensured deletion of personal identifiers post-trial.

Procedures

Following ePRO-informed consent, participants completed a baseline assessment collecting demographics (age, gender, education, BMI), smoking history (cigarettes/day, Fagerström Test nicotine dependence), CVD risk factors/diagnoses, and psychological metrics (motivation, VAS-assessed self-efficacy, quality-of-life). An Interactive Web Response System (IWRS) randomized participants 1:1 to intervention or control. The 26-week trial involved parallel baseline and weeks 1-4, 8, 12, 16, 20, and 26 assessments post-quit; all participants commenced quitting within the timeframe. Data collection used anonymized identifiers. Assessors remained blinded until trial completion. Passive recording measured the intervention group's in-app engagement (logins, feature usage).

Baseline Data Collection

Baseline data were collected via ePRO system post-consent, covering demographics (age, gender, education, BMI), smoking history (daily cigarettes, lifetime consumption, Fagerström Test for nicotine dependence), CVD status (diagnoses/risk factors), and psychological metrics (motivation, VAS-assessed self-efficacy, quality-of-life). The assessment used validated instruments, with anonymization via unique identifier codes.

Randomisation and Blinding

Randomisation was conducted using an Interactive Web Response System (IWRS), with participants allocated in a 1:1 ratio to either the intervention or control group. Stratification factors included sex, age group (≤ 45 years vs. >45 years), education level (≤ 15 years vs. >15 years), number of cigarettes smoked per day ($5-20$ vs. >20), and prior quit attempts. Due to the pilot study's scale limitations, final group balancing was not achieved for some demographic variables. Allocation concealment was maintained through the IWRS, and study investigators were blinded to treatment allocation until all data collection was complete. Outcome assessors remained blinded to group assignments until after data analysis, ensuring minimization of bias throughout the trial.

Intervention

The intervention group received a 12-week CBT-based smartphone programme via a WeChat Mini-Program ("Quit for Heart"), which included personalized quit plans (abrupt cessation or gradual reduction), craving management tools, progress tracking features (e.g., cigarettes avoided and financial savings), family support integration, relaxation techniques, and SOS strategies for relapse prevention. CBT modules were delivered weekly during the initial 12 weeks, focusing on cognitive restructuring, behavioural substitution, and relapse prevention, with daily motivational messages in the first 4 weeks, biweekly feedback from weeks 5-12, and monthly reinforcement thereafter. In-app engagement metrics, such as logins and feature usage, were passively recorded. The control group received a minimal-intervention approach through a basic WeChat Mini-Program designed solely for daily smoking status logging, devoid of any active therapeutic components or behavioural support. Both groups were assessed at identical time points, and participants in the

intervention group received follow-up messages at weeks 16, 20, and 26 to reinforce cessation efforts.

Measures

Rigorously assessed at weeks 4 and 26, the primary outcome was biochemically verified 26-week continuous abstinence, requiring ≤ 5 self-reported cigarettes smoked since baseline and urinary cotinine < 200 ng/mL (verified via mailed strips with video-confirmed testing). Secondary outcomes, determined via ePRO questionnaires at all follow-ups (weeks 1, 2, 3, 4, 8, 12, 16, 20, 26), included seven-day point and self-reported continuous abstinence. Supplementary measures included physiological parameters (blood pressure, heart rate), predictive factors (baseline psychological metrics, disease profiles), cravings, and self-efficacy assessed via Visual Analogue Scale (VAS). Programme acceptability was quantitatively evaluated at week 4 using Likert-scale ratings. All psychological measures (PHQ-9 depression, GAD-7 anxiety, DASS-21 stress, FTND nicotine dependence) employed validated instruments to ensure accuracy.

Data Analysis

The data retention criteria stipulated that subsequent measurements must exhibit a completion rate greater than 0% to be included in analyses. Participant screening, baseline eligibility, baseline attendance, and attrition rates at each time point throughout the study were illustrated in Fig. 1. Attrition rates were compared between groups using the Chi-square test. Owing to high attrition, complete case analysis (CCA) instead of Intention-to-treat analysis (ITT) was applied for outcomes, resulting in datasets of $n=52$ at week 4 and $n=16$ at week 26. Baseline demographic and clinical characteristics were evaluated through pairwise comparisons, employing independent t-tests for normally distributed continuous variables and Mann-Whitney U tests for non-normally distributed or ordinal data, as appropriate for individual comparisons.

For subsequent measurements, distinct statistical approaches were utilised based on the outcome type. Physiological parameters—specifically systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR)—were analysed using linear mixed-effects models with restricted maximum likelihood (REML) estimation. These models tested fixed effects of the parameters, covariates, and group differences in the week 4 dataset. Pairwise comparisons were also used to examine the differences between groups in abstinence and physiological parameters. Line plots were used to demonstrate the trends of physiological parameters. Relapse-free duration was assessed via survival analyses, incorporating log-rank tests with censoring for missing data to handle incomplete follow-up. Relapse proportions were examined using logistic regression, which generated adjusted odds ratios (ORs) to account for confounding variables. A significance level of $\alpha=0.05$ was applied for mixed models and exploratory endpoints to accommodate the study's design.

All statistical analyses were performed using Python version 3.12, with specific libraries including Statsmodels (version 0.14.4) for modelling, NumPy (version 2.2.3) for numerical operations, and pandas (version 2.2.3) for data management. To ensure robustness and minimize errors, the entire data analysis process was independently reviewed and verified by two researchers, adhering to best practices for reproducibility and accuracy in scientific reporting.

Results

Recruitment, Attrition, and Analysis Strategy

Trial enrollment began in October, 2022, and follow-up data collection ended in November, 2023. A total of 256 potential participants were screened for eligibility, and 214 were eligible and sent for randomisation. The CONSORT flow diagram illustrating the process of the RCT and the status of retention was shown in **Fig. 1**. No significance was found between the attrition rates of two groups.

This pilot study examined the feasibility and preliminary outcomes of a digital smoking

cessation intervention targeting patients with CVDs or CVD risk factors. Due to extensive missing data (>80% attrition by week 26, >40% attrition by week 4), intention-to-treat (ITT) analyses were deemed inappropriate, and primary results focused on complete case analysis (CCA) at week 4 (n=52: control=28, intervention=24) and week 26 (n=16: control=9, intervention=7) as a secondary exploratory endpoint. The baseline characteristics of full dataset were shown in **Table S1** and the baseline characteristics of week 4 dataset prepared for mixed models were shown in **Table S2**. All analyses adopted an α -level of 0.05 and results with borderline significance and possibly statistically significant ($p < 0.1$) were reported given limited statistical power.

Groupwise Comparison of Abstinences

No statistically significant differences were observed between the intervention and control groups for the primary endpoints (relapse event, defined as smoking >5 cigarettes per week in a specified period), as illustrated in **Fig. 2**. Survival analysis in the full dataset (n=108) for relapse-free duration approached marginal significance (log-rank $p = 0.095$ overall, $p = 0.094$ for 7-day), with the survival curves indicating a trend toward better outcomes in the intervention group, where relapse events were less frequent compared to the control group. However, data quality was compromised by missingness (missing data were treated as censored). Similarly, survival analysis in the CCA dataset (n=16) showed non-significant trends consistent with the full dataset (log-rank $p = 0.47$ overall, $p = 0.62$ for 7-day), but the small sample size precluded meaningful interpretation. Pairwise comparison results, as shown in **Table 1**, between groups of No-relapse status across weeks 1-26, using Chi-square or Fisher's exact test, revealed no group-wise divergence (p -values: 0.19-1.00; FDR q -values: 0.38-1.00), though the intervention group consistently demonstrated lower relapse rates in these analyses, aligning with the observed survival curve trends.

Trends of Blood Pressure and Heart Rate

The trends of blood pressure and heart rate were shown in **Fig. 3**. We found an overall reduction trend in the diastolic blood pressure curve and several medium-size results were found in group-wise comparison (w2: $p = 0.0085$, corrected $p = 0.2461$, Cohen's $d = -0.72$; w4: $p = 0.0246$, corrected $p = 0.2461$, Cohen's $d = -0.63$), which might indicate the short-term effect of smoke cessation on diastolic blood pressure. However, no specific trend was found in systolic blood pressure and heart rate.

The mixed-effects linear regression analyses for systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) revealed distinct patterns of association with baseline covariates and smoking cessation interventions, as shown in **Table 2**. The complete results of these models were presented in supplemental materials (**Table S3**). Models were estimated using restricted maximum likelihood (REML), with group- and time-specific random intercepts. Due to computational singularity in covariance matrices (group $\times$ time variance approached zero, $SE > 10^6$), final models excluded non-convergent random interaction terms, retaining only group-level random intercepts as validated by likelihood ratio tests. DBP models showed the highest reliability among all 3 models (Log-likelihood: DBP -912.7205 > HR -946.6692 > SBP -956.1442) and the significant results were as follows.

Neither time ($p =$ SBP: 0.726; DBP: 0.791; HR: 0.963) nor group $\times$ time interaction ($p =$ SBP: 0.172; DBP: 0.294; HR: 0.520) reached statistical significance in all three models. Other results revealed significant cardiovascular parameter associations across three domains. Disease profiles showed obesity exerted the strongest positive effects (SBP: $\beta = 9.83$, DBP: $\beta = 8.34$, HR: $\beta = 5.74$; all $p < 0.01$) while hyperlipidemia reduced SBP/DBP ($\beta = -3.61/-5.10$, $p < 0.05$). Psychological measures demonstrated baseline GAD-7 scores negatively predicted all parameters ($\beta = -5.02$ SBP, -4.04 DBP, -3.09 HR; $p < 0.01$) whereas DASS anxiety increased SBP/HR ($\beta = 3.93/4.27$, $p < 0.05$). Information concerning cessation displayed largest effect magnitudes – previous app use substantially lowered all parameters ($\beta \approx -8.05$ to -8.82 , $p < 0.001$) while cessation method elevated SBP/DBP ($\beta = 8.00/9.70$,

$p \leq 0.001$). Effect sizes ranged from moderate (WHO scale $\beta \approx -1.81$ to -3.85) to large (obesity $\beta > 5.7$ across parameters), with relapse events (whether smoke > 5 cigarettes per week in week 1) specifically reducing SBP ($\beta = -7.44$, $p = 0.001$). The trends of longer period relapse event (such as week 2, week 3, etc.) were not calculatable due to singular matrix problems.

Associations of Baseline Factors with Relapse Events

Pairwise comparisons and logistic regression revealed significant associations between baseline factors and smoking relapse events (defined as smoking > 5 cigarettes/week within specific timeframes), as shown in **Table 3**. Baseline anxiety measured by DASS scale consistently predicted higher relapse risks across multiple timepoints: it showed strong associations with week 2/4 episodic relapse (OR=35.183/4.785, $p = 0.045/0.033$) and week 4 sustained relapse (OR=4.785, $p = 0.033$). Conversely, baseline will to quit demonstrated protective trends against episodic relapse at weeks 2/4 (OR=0.003/0.097, $p = 0.086/0.083$) and sustained relapse at week 3/4 (OR=0.145/0.097, $p = 0.08/0.083$), though these only approached marginal significance. Concerning disease profiles, several diseases showed complex associations with relapse events. Some diseases showed protective trends, including arteriosclerosis (sustained w1: OR=0.13, $p = 0.0559$; complete separation occurred at w4 sustained and w2/4 episodic) and coronary heart disease (week 4 sustained/episodic: OR=0.14/0.14, $p = 0.0674/0.0674$). Obesity (week 2 sustained/episodic: OR=3.73/3.16, $p = 0.0286/0.0479$), diabetes (week 12: OR=7.77, $p = 0.0492$) and hypertension (week 8 episodic: OR=5, $p = 0.0439$) exhibited opposite effects, increasing relapse risk in different time points. These findings underscore the complex temporal dynamics of relapse predictors, with anxiety demonstrating the most robust association across measurement timepoints and methodologies. It is notable that due to sample size limit (w8/w12: $n = 41/31$) and unbalanced grouping of these variables, several results achieved complete separation (arteriosclerosis) and some results lack independency between sustained and episodic data, leading to the lack of credibility.

Discussion

The findings of this pilot study provide preliminary evidence on the feasibility and physiological impacts of a digital smoking cessation intervention among cardiovascular disease (CVD)-risk populations. The observed high attrition rates ($> 40\%$ at week 4; $> 80\%$ at week 26) necessitated a shift from intention-to-treat (ITT) to complete case analysis (CCA) for primary outcomes, reflecting challenges in sustaining engagement in digital health interventions for high-risk groups. These results align with prior systematic reviews highlighting the variable attrition rates in mobile app-based cessation programmes, particularly among individuals with chronic comorbidities(13,14,27).

This pilot study represents a methodologically innovative approach to digital smoking cessation interventions for CVD-risk populations in China. Unlike many previous app-based trials that often lacked rigorous blinding procedures (13,22), our study implemented a double-blind RCT design with active control (automated logging-only Mini-Program) and stratified randomisation. Meanwhile, the programme was based on a novel CBT delivery system based on WeChat Mini-Programs rather than standard SMS/text messaging platforms prevalent in prior research (23,31). By embedding evidence-based components (personalized quit plans, craving management tools, and family support integration) within a dominant social media platform in China, we developed a cultural adaptive approach for smoking cessation in Asian countries as previous research had suggested (32).

The short-term reduction in diastolic blood pressure (DBP) at weeks 2 and 4 (Cohen's $d = -0.72$ to -0.63) suggests potential cardiovascular benefits of early smoking cessation, consistent with longitudinal studies demonstrating blood pressure normalization post-cessation(9,10). However, the lack of significant time or group $\times$ time effects on systolic blood pressure (SBP) or heart rate (HR) may reflect insufficient statistical power due to limit of sample size, as seen in other pilot trials with

similar limitations (17,21). The strong associations of obesity with elevated SBP/DBP/HR ($\beta=5.74-9.83$, all $p<0.01$) agree with evidence that post-cessation weight management is critical for mitigating CVD risks (33). Conversely, the paradoxical SBP/DBP reduction associated with hyperlipidemia ($\beta=-3.61/-5.10$) warrants further investigation, as this contradicts typical cardiometabolic risk profiles (2,3).

Notably, our findings reveal modest physiological and behavioural patterns that include mixed outcomes in digital cessation research. The superior cardiovascular parameter improvements among participants with prior cessation application use experience ($\beta\sim-8.05$ to -8.82 , $p<0.001$) support meta-analytic findings on the additive benefits of digital tool familiarity (15,34). However, the lack of long-term follow-up data (week 26: $n=16$) precludes conclusions about sustained efficacy, which is a limitation common to early-phase cessation trials. Baseline anxiety (measured by DASS scale) emerged as a robust predictor of relapse across multiple timepoints ($OR=4.79-35.18$, $p\leq 0.045$), consistent with literature emphasizing psychological comorbidities as barriers to sustained abstinence (18,28). Conversely, baseline will to quit showed marginally protective trends ($OR=0.097-0.145$, $p=0.08-0.083$), aligning with behavioural theories positing intrinsic motivation as a determinant of intervention adherence (14). These partially support previous literature that digital interventions targeting psychological factors affecting CVD risk work better (30). These physiological benefits happened even though quit rates were similar between groups, suggesting that quitting act (regardless of outcomes) might protect the heart through ways other than just reducing nicotine intake, possibly by reducing anxiety and regulating the nervous system (7,35). While abstinence outcomes showed non-significant group differences, the trend toward prolonged relapse-free survival (log-rank $p=0.095$ overall, $p=0.094$ for 7-day) and lower relapse rates at all time points (p -values: $0.19-1.00$; FDR q -values: $0.38-1.00$) in the intervention group is consistent with the effect sizes reported in Japanese DTx trials where digital tools augmented standard programmes (26). Meanwhile, relapse associations with clinical comorbidities varied. While arteriosclerosis showed protective effects ($OR=0.13-0.14$), diabetes ($OR=7.77$) and obesity ($OR=3.16-3.73$) increased risk. This pattern mirrors the complex link between disease burden and quitting behaviours found in population studies (3,4).

The alarmingly high attrition ($>40\%$ at week 4; $>80\%$ at week 26) represents a critical methodological challenge that mirrors systemic engagement barriers in digital health. Our dropout patterns (most attritions happened before week 4) validate previous evidence that early disengagement predicted sustained non-adoption (19). The high attrition might also be associated with our middle-aged population (47.89 ± 10.47) with technologic literacy disparities, consistent with previous evidence that older users prefer structured telephone support (31).

Future research in digital smoking cessation might achieve better outcomes by addressing these gaps highlighted by our study and related literature. First, developing culturally adapted digital retention strategies for elderly populations is critical. Promising approaches include blended care models combining app-based CBT with telephone support, features to engage family involvements, and simplified interfaces using voice-based interaction. Second, developing cost-effective verification systems, such as integrating CO sensors into WeChat platform similar to Japan's CureApp system (26), offers a potential solution. Third, precision engagement algorithms should be developed, using early-usage predictors to trigger timely interventions when engagement drops significantly. Crucially, integrating these solutions within clinical pathways is vital, as demonstrated by the SPRINT INDIA trial where healthcare provider involvement substantially increased user response rates compared to standalone apps (23).

Our study has several limitations requiring acknowledgment. The modest sample size ($n=108$) and computational singularities limited statistical power for time-dependent analyses, particularly in physiological parameters where clinically meaningful effect sizes (e.g., 5-mmHg SBP reduction) may have been obscured. High attrition introduced selection bias toward digitally literate

participants, restricting generalizability to rural and elderly populations, which is a limitation prevalent across digital cessation trials (27,30). Reliance on self-reported 7-day abstinence without biochemical verification remains problematic, though this reflects real-world implementation constraints. Finally, the underrepresentation of ethnic minorities and low-SES groups precludes assessment of health equity impacts.

Conclusions

This pilot study underscores the feasibility and challenges of implementing a smartphone-based CBT intervention for smoking cessation in Chinese patients with CVD risk. Despite comparable abstinence rates between groups, high attrition (>80% at 26 weeks) limited conclusive inferences, corroborating real-world adherence barriers. Physiological parameter analyses linked elevated blood pressure and heart rate to baseline anxiety and nicotine dependence, emphasizing the interplay between psychological factors and cardiovascular health. While relapse-free survival trends approached marginal significance, sample size constraints precluded robust interpretation. The absence of biochemical validation for self-reported 7-day abstinence and underrepresentation of diverse socioeconomic cohorts further caution generalizability. These findings align with prior digital cessation trials, highlighting the need for enhanced retention strategies and culturally tailored adaptations. Future research should prioritize scalable retention measures, objective outcome verification, and pragmatic designs to optimize efficacy in high-risk populations. The study preliminarily supports the role of digital interventions in clinical tobacco control but calls for methodological refinements to address attrition and selection biases.

References

1. Reitsma, M. B. Spatial, temporal, and demographic patterns in prevalence of smoking tobacco use and attributable disease burden in 204 countries and territories, 1990-2019: a systematic analysis from the global burden of disease study 2019. *Lancet Lond Engl* [Internet]. 2021 June 19 [cited 2025 Apr 7];397(10292). Available from: <https://pubmed.ncbi.nlm.nih.gov/34051883/>
2. Shah A, Shah J, Shah N, Shah R. Smoking prevalence and chronic diseases in China. *Lancet Respir Med*. 2019 Mar;7(3):e10.
3. Wang M, Luo X, Xu S, Liu W, Ding F, Zhang X, et al. Trends in smoking prevalence and implication for chronic diseases in China: serial national cross-sectional surveys from 2003 to 2013. *Lancet Respir Med*. 2019 Jan;7(1):35-45.
4. Zhang M, Yang L, Wang L, Jiang Y, Huang Z, Zhao Z, et al. Trends in smoking prevalence in urban and rural china, 2007 to 2018: findings from 5 consecutive nationally representative cross-sectional surveys. *PLoS Med*. 2022 Aug;19(8):e1004064.
5. Li S, Ma C, Xi B. Tobacco control in China: still a long way to go. *Lancet Lond Engl*. 2016 Apr 2;387(10026):1375-6.
6. Dong-Qing Z, Chang-Quan H, Yan-Ling Z, Bi-Rong D, Qing-Xiu L. Cigarette smoking is associated with increased diastolic blood pressure among chinese nonagenarians/centenarians. *Blood Press*. 2014 June;23(3):168-73.
7. Liu X, Byrd JB. Cigarette smoking and subtypes of uncontrolled blood pressure among diagnosed hypertensive patients: paradoxical associations and implications. *Am J Hypertens*. 2017 June 1;30(6):602-9.
8. Clair C, Rigotti NA, Porneala B, Fox CS, D'Agostino RB, Pencina MJ, et al. Association of smoking cessation and weight change with cardiovascular disease among adults with and without diabetes. *JAMA*. 2013 Mar 13;309(10):1014-21.
9. L D, D DP, G R, V S, O R, R I, et al. Not smoking is associated with lower risk of hypertension: results of the Olivetti Heart Study. *Eur J Public Health* [Internet]. 2014 Apr [cited 2025 Apr 3];24(2). Available from: <https://pubmed.ncbi.nlm.nih.gov/23543678/>
10. Wang X, Dong JY, Cui R, Muraki I, Shirai K, Yamagishi K, et al. Smoking cessation, weight gain and risk of cardiovascular disease. *Heart Br Card Soc*. 2022 Mar;108(5):375-81.
11. Cho JH, Shin SY, Kim H, Kim M, Byeon K, Jung M, et al. Smoking cessation and incident cardiovascular disease. *JAMA Netw Open*. 2024 Nov 4;7(11):e2442639.

- 12.Yao Z, Tasdighi E, Dardari ZA, Jha KK, Osuji N, Rajan T, et al. Association between cigarette smoking and subclinical markers of cardiovascular harm. *J Am Coll Cardiol*. 2025 Mar 18;85(10):1018–34.
- 13.Guo YQ, Chen Y, Dabbs AD, Wu Y. The effectiveness of smartphone app-based interventions for assisting smoking cessation: systematic review and meta-analysis. *J Med Internet Res*. 2023 Apr 20;25:e43242.
- 14.Sha L, Yang X, Deng R, Wang W, Tao Y, Cao H, et al. Automated digital interventions and smoking cessation: systematic review and meta-analysis relating efficiency to a psychological theory of intervention perspective. *J Med Internet Res*. 2022 Nov 16;24(11):e38206.
- 15.Bricker JB, Santiago-Torres M, Mull KE, Sullivan BM, David SP, Schmitz J, et al. Do medications increase the efficacy of digital interventions for smoking cessation? Secondary results from the iCanQuit randomized trial. *Addict Abingdon Engl*. 2024 Apr;119(4):664–76.
- 16.Byaruhanga J, Atorkey P, McLaughlin M, Brown A, Byrnes E, Paul C, et al. Effectiveness of individual real-time video counseling on smoking, nutrition, alcohol, physical activity, and obesity health risks: systematic review. *J Med Internet Res*. 2020 Sept 11;22(9):e18621.
- 17.Li S, Qu Z, Li Y, Ma X. Efficacy of e-health interventions for smoking cessation management in smokers: a systematic review and meta-analysis. *Eclinicalmedicine*. 2024 Feb;68:102412.
- 18.Vinci C. Cognitive behavioral and mindfulness-based interventions for smoking cessation: a review of the recent literature. *Curr Oncol Rep*. 2020 May 16;22(6):58.
- 19.Yu LQ, Amato MS, Papandonatos GD, Cha S, Graham AL. Predicting Early Dropout in a Digital Tobacco Cessation Intervention: Replication and Extension Study. *J Med Internet Res*. 2024 Nov 27;26:e54248.
- 20.Martinez Agulleiro L, Patil B, Firth J, Sawyer C, Amann BL, Fonseca F, et al. A systematic review of digital interventions for smoking cessation in patients with serious mental illness. *Psychol Med*. 2023 Aug;53(11):4856–68.
- 21.Zhou X, Wei X, Cheng A, Liu Z, Su Z, Li J, et al. Mobile phone-based interventions for smoking cessation among young people: systematic review and meta-analysis. *JMIR Mhealth Uhealth*. 2023 Sept 12;11:e48253.
- 22.Pfaeffli Dale L, Whittaker R, Jiang Y, Stewart R, Rolleston A, Maddison R. Text message and internet support for coronary heart disease self-management: results from the Text4Heart randomized controlled trial. *J Med Internet Res*. 2015 Oct 21;17(10):e237.
- 23.SPRINT INDIA trial collaborators. Secondary prevention with a structured semi-interactive stroke prevention package in India (SPRINT INDIA): a multicentre, randomised controlled trial. *Lancet Glob Health*. 2023

Mar;11(3):e425-35.

- 24.Ögmundsdóttir Michelsen H, Sjölin I, Bäck M, Gonzalez Garcia M, Olsson A, Sandberg C, et al. Effect of a lifestyle-focused web-based application on risk factor management in patients who have had a myocardial infarction: randomized controlled trial. *J Med Internet Res*. 2022 Mar 31;24(3):e25224.
- 25.Pfaeffli Dale L, Dobson R, Whittaker R, Maddison R. The effectiveness of mobile-health behaviour change interventions for cardiovascular disease self-management: a systematic review. *Eur J Prev Cardiol*. 2016 May;23(8):801-17.
- 26.Nomura A. Digital health, digital medicine, and digital therapeutics in cardiology: current evidence and future perspective in Japan. *Hypertens Res Off J Jpn Soc Hypertens*. 2023 Sept;46(9):2126-34.
- 27.Wongvibulsin S, Habeos EE, Huynh PP, Xun H, Shan R, Porosnicu Rodriguez KA, et al. Digital health interventions for cardiac rehabilitation: systematic literature review. *J Med Internet Res*. 2021 Feb 8;23(2):e18773.
- 28.Baker TB, McCarthy DE. Smoking treatment: a report card on progress and challenges. *Annu Rev Clin Psychol*. 2021 May 7;17:1-30.
- 29.Ferguson J, Docherty G, Bauld L, Lewis S, Lorgelly P, Boyd KA, et al. Effect of offering different levels of support and free nicotine replacement therapy via an english national telephone quitline: randomised controlled trial. *BMJ [Internet]*. 2012 Mar 23 [cited 2025 Apr 9];344(mar23 2):e1696-e1696. Available from: <https://www.bmj.com/lookup/doi/10.1136/bmj.e1696>
- 30.Gold N, Yau A, Rigby B, Dyke C, Remfry EA, Chadborn T. Effectiveness of digital interventions for reducing behavioral risks of cardiovascular disease in nonclinical adult populations: systematic review of reviews. *J Med Internet Res*. 2021 May 14;23(5):e19688.
- 31.Upadhyay S, Duah A, Francois V, Allen SI. A scoping review of interventions for tobacco cessation among african american individuals. *Curr Addict Rep*. 2025;12(1):46.
- 32.Goh KW, Ming LC, Al-Worafi YM, Tan CS, Hermansyah A, Rehman IU, et al. Effectiveness of digital tools for smoking cessation in asian countries: a systematic review. *Ann Med*. 2024 Dec;56(1):2271942.
- 33.Ninomiya Y, Kawasoe S, Kubozono T, Tokushige A, Ichiki H, Salim AA, et al. Association between weight gain following smoking cessation and development of hypertension in the future. *Hypertens Res Off J Jpn Soc Hypertens*. 2024 May;47(5):1167-74.
- 34.Brin M, Fontalvo S, Hu D, Cioe P, Huang MC, Xu W, et al. Validating the information technology (IT) implementation framework to implement mHealth technology for consumers: a case study of the Sense2Quit app for smoking cessation. *Int J Med Inf*. 2025 May 20;202:105977.

35.Crabb AB, Allen J, Taylor G. What if I fail? Unsuccessful smoking cessation attempts and symptoms of depression and anxiety: a systematic review and meta-analysis. *BMJ Open*. 2025 May 2;15(5):e091419.

Figures

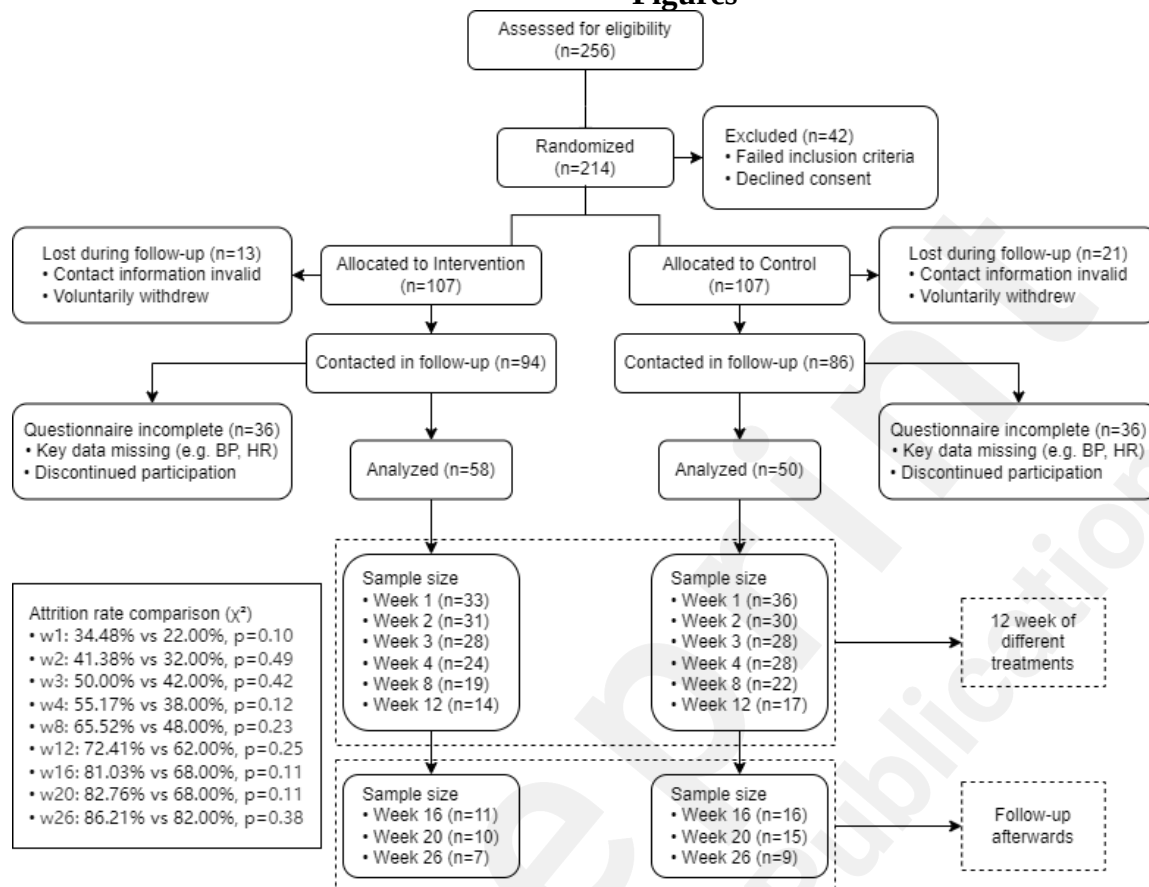


Fig. 1 The CONSORT flow diagram illustrating the process of the RCT and the status of attrition rate. The attrition rates were compared between the two group using Chi-square test and no significant difference was found between intervention and control group.

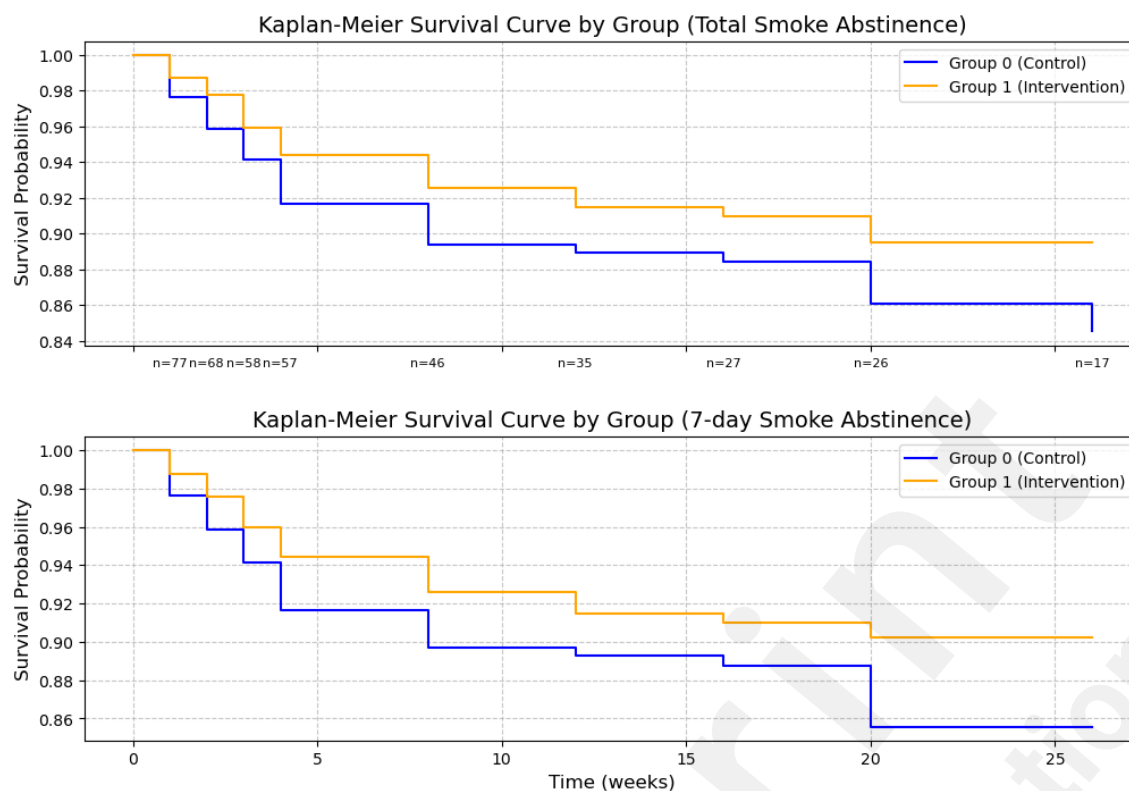


Fig. 2 The survival curve of overall abstinence and 7-day abstinence by group in full dataset. Showing the status of patient attempting to regain smoking (> 5 cigarettes per week in certain period) in the whole period (above) and recent 7 days (Below). Log-rank test were used to examine the difference between the two groups.

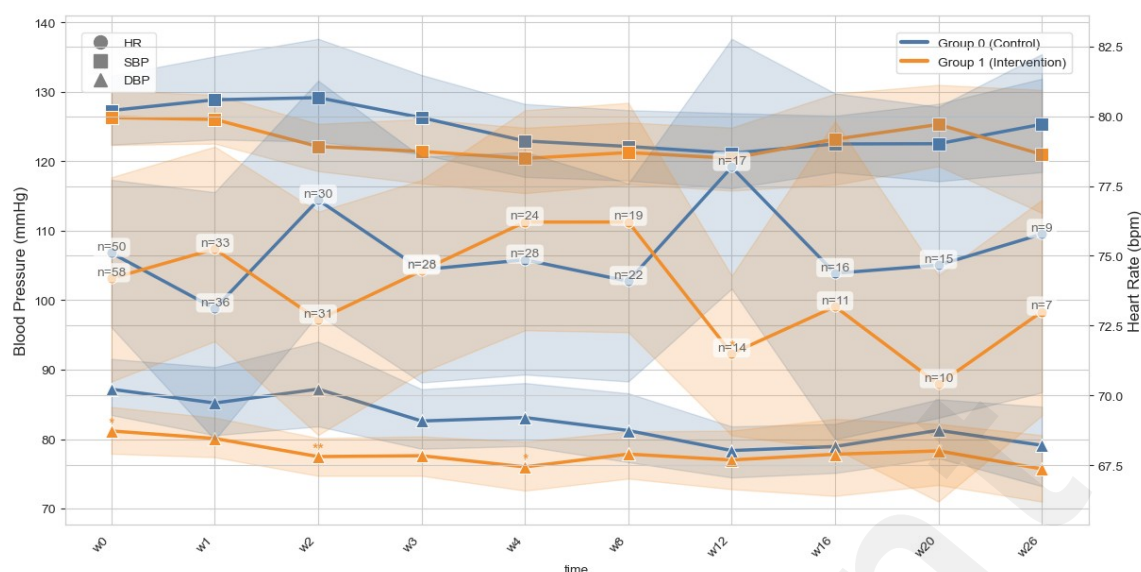


Fig. 3 The Trends of Blood Pressure and Heart Rate. Showing systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) changes in the 26 weeks. The data was divided by groups and showed changing sample counts at each time points due to attrition. We used “*” for $p < 0.05$ and “**” for $p < 0.01$ to demonstrate the results of group-wise comparisons (Independent T-test or Mann-Whitney U test based on sample distribution). FDR method were also performed for the p values in the comparisons but weren’t shown in the plot due to limited statistical efficacy.

Tables

Table 1. The Comparison of No-Relapse Status between Groups. The table showed the consistent/7-day No-Relapse Status of both groups. The comparisons between the 2 groups were performed using Chi-square test or Fisher Exact test depending on the distribution of the samples and p value was corrected through False Discovery Rate (FDR) using Benjamini-Hochberg method. Due to high attrition across time, no comparison across time was performed.

Table 1. Comparison of No-Relapse Status between Groups				
Time Points	Control Group	Intervention Group	P Value	Q Value (FDR)
Consistent No-relapse Status				
Week 1	49/56 (87.50%)	54/62 (87.10%)	0.21	0.38
Week 2	47/56 (83.93%)	56/62 (90.32%)	0.43	0.58
Week 3	49/56 (87.50%)	56/62 (90.32%)	1.00	1.00
Week 4	55/56 (98.21%)	59/62 (95.16%)	0.44	0.58
Week 8	55/56 (98.21%)	61/62 (98.39%)	0.85	0.85
Week 12	53/56 (94.64%)	60/62 (96.77%)	0.62	0.70
Week 16	55/56 (98.21%)	62/62 (100.00%)	1.00	1.00
Week 20	48/56 (85.71%)	56/62 (90.32%)	0.67	0.75
Week 26	49/56 (87.50%)	55/62 (88.71%)	0.47	0.58
7-day No-relapse Status				
Week 2	48/56 (85.71%)	56/62 (90.32%)	0.63	0.90
Week 3	49/56 (87.50%)	55/62 (88.71%)	1.00	1.00
Week 4	47/56 (83.93%)	56/62 (90.32%)	0.44	0.88
Week 8	50/56 (89.29%)	56/62 (90.32%)	1.00	1.00
Week 12	55/56 (98.21%)	59/62 (95.16%)	0.62	0.88
Week 16	55/56 (98.21%)	61/62 (98.39%)	1.00	1.00
Week 20	52/56 (92.86%)	61/62 (98.39%)	0.19	0.76
Week 26	56/56 (100.00%)	62/62 (100.00%)	1.00	1.00

Table 2. The short-term (4 weeks) mixed-effects linear regression analyses for systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR). All fixed effect results with $p < 0.10$ were shown in the table, with Coefficients and 95%CI showing the impact of each variables to the physiological variables.

Table 2. The mixed-effects linear regression analyses for SBP, DBP and HR

Variable	Coefficient (SE)	z- value	P- value	95% CI
Fixed Effects (SBP)				
Hypertension	4.312 (1.681)	2.566	0.01	1.018 to 7.606
Hyperlipemia	-3.607 (1.707)	-		-6.954 to -
Obesity	9.833 (1.885)	5.215	1	0.261 6.138 to
Cessation method	7.999 (2.428)	3.294	0.001	13.528 3.239 to
Previous application use	-8.817 (1.826)	-	<0.00	12.758 -12.396 to -
DASS anxiety score at Baseline	3.926 (1.984)	4.827	1	5.237
DASS depression score at Baseline	3.008 (1.624)	1.979	0.048	0.038 to 7.814
GAD-7 score at Baseline	-5.022 (1.213)	1.852	0.064	-0.176 to
WHO score at Baseline	-3.851 (0.867)	-4.14	1	6.192
Relapse event at Week 1	-7.435 (2.235)	-	<0.00	-7.400 to -
Fixed Effects (DBP)				
Hypertension	2.549 (1.402)	1.818	0.069	-0.199 to
Hyperlipemia	-5.095 (1.425)	-	<0.00	5.298
Obesity	8.342 (1.573)	5.302	1	-7.887 to -
Cessation method	9.696 (2.026)	4.785	1	2.302
Previous application use	-8.792 (1.524)	-	<0.00	5.259 to
Will to quit at Baseline	-1.757 (0.840)	2.092	0.036	11.426
GAD-7 score at Baseline	-4.039 (1.012)	-3.99	1	5.725 to
WHO score at Baseline	-2.346 (0.724)	3.241	0.001	5.725 to
Relapse event at Week 1	-2.476 (1.865)	1.327	0.184	13.668
Fixed Effects (HR)				
Arteriosclerosis	-3.925 (2.024)	-		-11.779 to -
Obesity	5.737	3.165	0.002	5.805

	(1.812)			9.289
Previous application use	-8.049 (1.756) 2.390	- 4.584	<0.00 1	-11.490 to - 4.608 0.861 to
FTND score at Baseline	(0.780) 4.270	3.064	0.002	3.918 0.532 to
DASS anxiety score at Baseline	(1.907) -3.094	2.239 -	0.025	8.007 -5.380 to -
GAD-7 score at Baseline	(1.166) 1.903	2.654	0.008	0.809 0.051 to
PSQI score at Baseline	(0.945) -1.806	2.014 -	0.044	3.756 -3.440 to -
WHO score at Baseline	(0.834)	2.166	0.03	0.172

Table 3. Associations of Baseline Factors with Smoking Relapse Events Across Timepoints. Showing the relationships of baseline factors (including demographic data, psychological data and disease profiles) and the occurrence of relapse events (defined as smoking >5 cigarettes/week within specific timeframes). Groupwise comparisons for categorical variables were made through Chi-square test or Fisher exact test based on sample size and logistic regression were applied for all variables. Only results with $p < 0.10$ were shown in the table.

Table 3. Associations of Baseline Factors with Smoking Relapse Events Across Timepoints

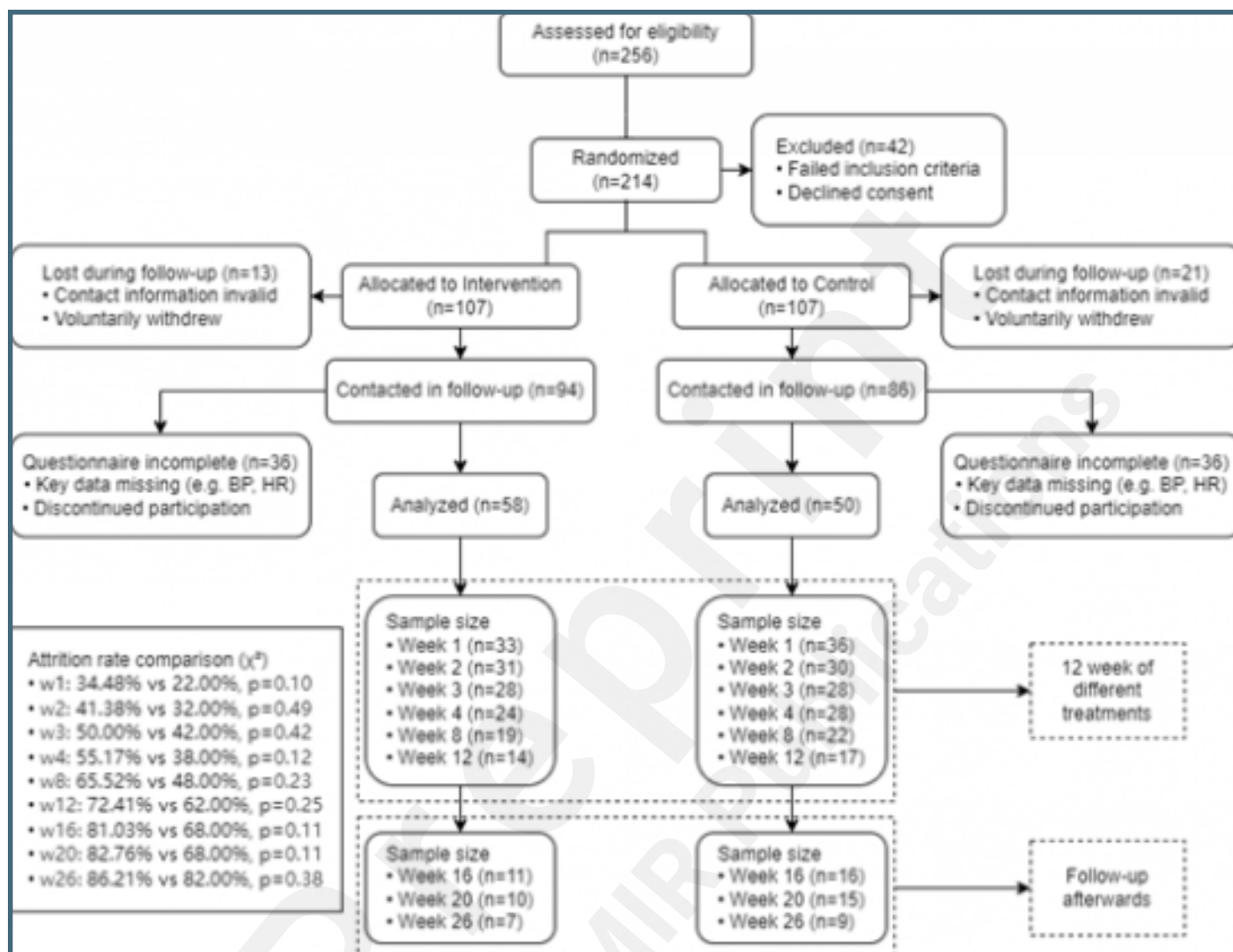
Time points	Variables	Group 0 rate	Group 1 rate	Crude OR	P value	OR(logistics)	P value(logistics)
Overall relapse events							
Categorical variables							
Week 1	arteriosclerosis	20.50%	3.30%	7.46 (0.95-58.49)	0.0406	0.13	0.0559
Week 2	obesity	7.00%	21.90%	0.27 (0.08-0.87)	0.0415	3.73	0.0286
Week 4	coronary heart disease	16.90%	2.90%	6.90 (0.87-54.67)	0.038	0.14	0.0674
Week 4	arteriosclerosis	17.00%	0.00%	nan (nan-nan)	0.0113	0	0.991
Week 12	diabetes	1.90%	13.30%	0.13 (0.02-0.99)	0.0782	7.77	0.0492
Continuous variables							
Week 3	will to quit at baseline					0.145	0.08
Week 4	DASS anxiety at baseline					4.785	0.033
Week 4	will to quit at baseline					0.097	0.083
7-day relapse events							
Categorical variables							
Week 2	arteriosclerosis	15.90%	0.00%	nan (nan-nan)	0.0196	0	0.991
Week 2	obesity	8.10%	21.90%	0.32 (0.10-0.99)	0.055	3.16	0.0479
Week 4	coronary heart disease	16.90%	2.90%	6.90 (0.87-54.67)	0.038	0.14	0.0674
Week 4	arteriosclerosis	17.00%	0.00%	nan (nan-nan)	0.0113	0	0.991
Week 8	hypertension	3.60%	15.90%	0.20 (0.04-0.96)	0.0589	5	0.0439
Week	diabetes	1.90%	13.30%	0.13	0.07	7.77	0.0492

12		(0.02- 0.99)	82		
Continuous variables					
Week 2	will to quit at baseline			0.003	0.086
Week 2	DASS pressure at baseline			0.211	0.089
Week 2	DASS anxiety at baseline			35.183	0.045
Week 4	DASS anxiety at baseline			4.785	0.033
Week 4	will to quit at baseline			0.097	0.083

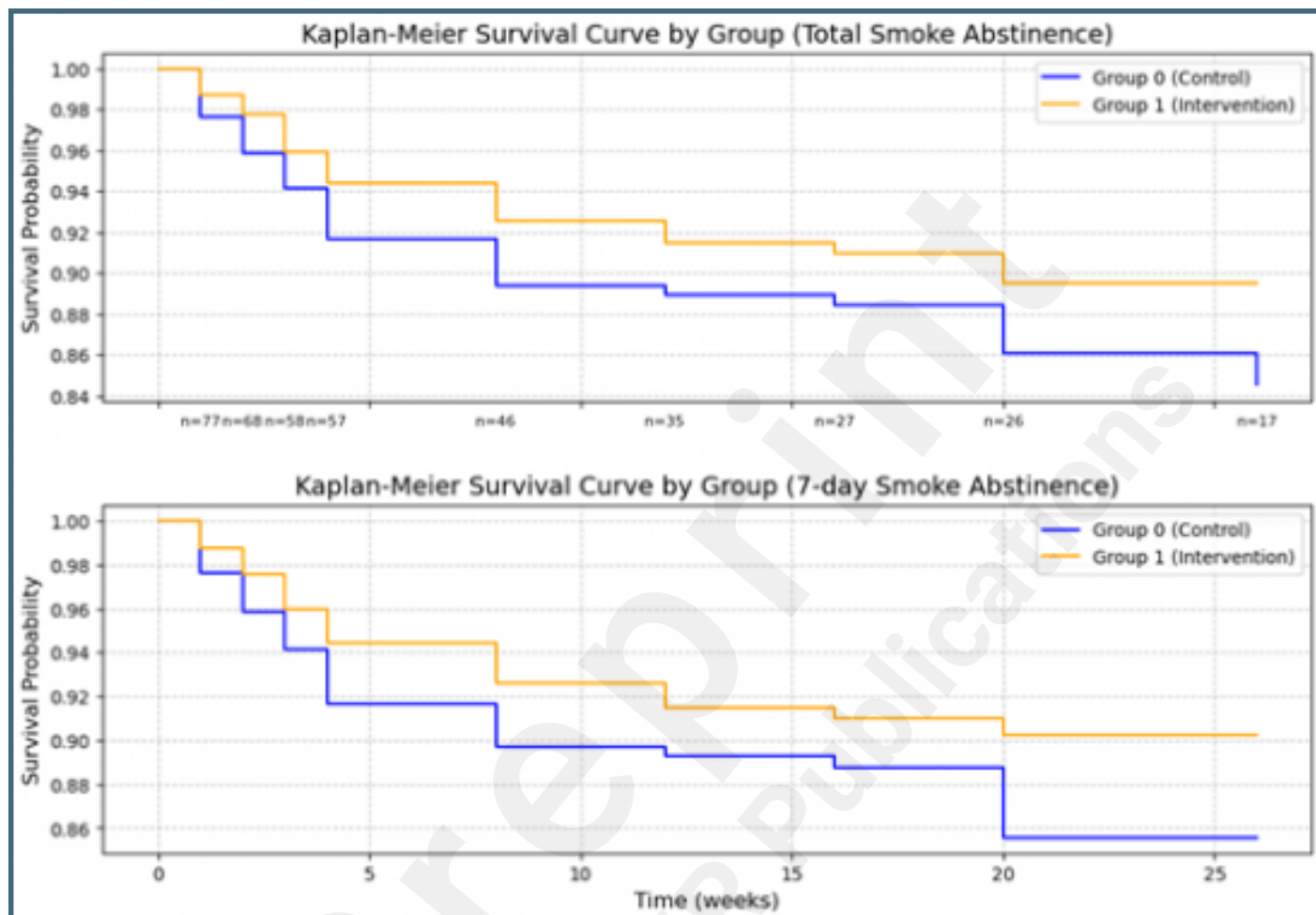
Supplementary Files

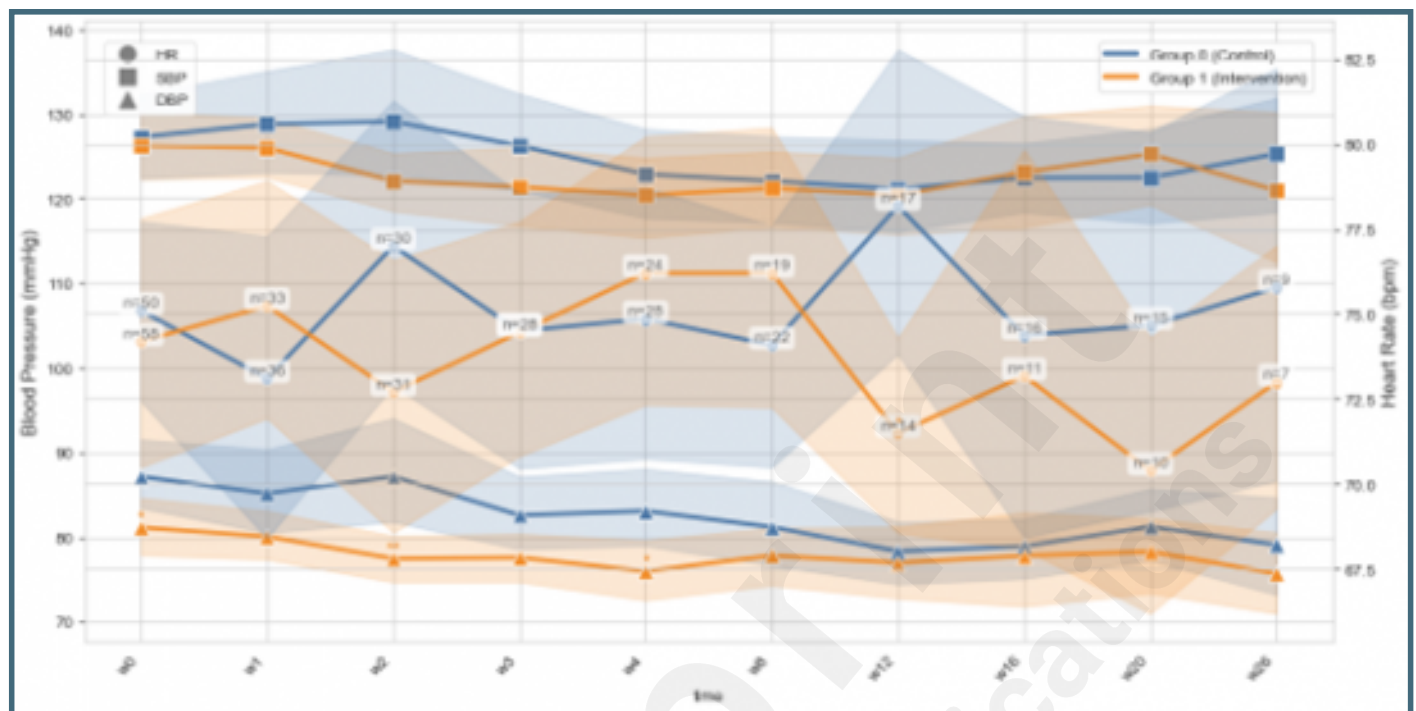
Figures

The CONSORT flow diagram illustrating the process of the RCT and the status of attrition rate. The attrition rates were compared between the two group using Chi-square test and no significant difference was found between intervention and control group.



The survival curve of overall abstinence and 7-day abstinence by group in full dataset. Showing the status of patient attempting to regain smoking (> 5 cigarettes per week in certain period) in the whole period (above) and recent 7 days (Below). Log-rank test were used to examine the difference between the two groups.





CONSORT (or other) checklists

CONSORT checklist and supplemental tables.

URL: <http://asset.jmir.pub/assets/c14ae0ecfc801e6ec2ced38d8bc0e9c6.pdf>

