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STUDY PROTOCOL

The Impact of Online Interactive Platform Services on Oral Health Behaviors in Older Adults With Mild Cognitive Impairment: Protocol for a Randomized Controlled Trial

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Purpose: Older adults with mild cognitive impairment (MCI) are at a high risk for oral health decline. To address this, we designed an intervention to improve oral health behaviors specifically for elderly individuals with MCI. Here we describe the protocol for a study with the following aims: to enhance oral health behaviors through online education tailored to the cognitive load of older adults and to maintain or delay cognitive decline.

Patients and Methods: This randomized, parallel, single-blind controlled trial will evaluate the effectiveness of an oral health behavior intervention based on an online interactive platform (e-COM[OH]) in older adults with MCI. The participants will be randomly assigned to two groups. The intervention group will receive oral health behavior training through an online platform consisting of four modules: Games, Health Knowledge, Health Skills, and Symptom Reporting Center. The control group will follow the hospital's official account and receive general oral health education. The primary outcome will be the oral health behavior score, assessed using an oral health behavior questionnaire. The secondary outcomes will include social support, perceived stress, cognitive level, oral health-related quality of life, and oral health status. Participant enrollment will begin in April 2024 and is expected to be completed in November 2024.

Conclusions: This trial will evaluate whether the e-COM(OH) WeChat mini-program is suitable to improve the oral health behaviors and cognitive functions of older adults with MCI. If its effectiveness is validated and e-COM(OH) is deemed acceptable, appropriate, and feasible, it could serve as a strategic approach to address oral health issues and prevent cognitive decline in older adults with mild cognitive impairment.

Trial Registration: The trial has been registered on the www.chictr.org.cn registration platform on 19 April 2024 (registration number: ChiCTR2400083250).

Keywords: aged, cognitive dysfunction, internet, oral hygiene, randomized controlled trial

Introduction

The number of individuals with cognitive impairment (ICIs) is growing rapidly and is projected to reach 139 million by 2050,[1] imposing a significant economic burden globally. China has the highest proportion of ICIs.[2] The decline in cognitive ability among older adults leads to various other health issues, including oral problems. Previous studies[3–5] have indicated a significantly increased prevalence of cognitive impairment among individuals with oral diseases such as periodontitis. As cognitive levels decline, ICI may neglect or lack the capacity for oral hygiene; thus, they are more susceptible to oral diseases

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than are individuals with normal cognition (NC).[6,7] In addition, neglected oral health problems, such as periodontitis and tooth loss, in the elderly can exacerbate psychological problems,[8] thereby reducing the overall survival rate.[9]

Mild cognitive impairment (MCI) represents the optimal window[10] for intervention, transitioning from reversible cognitive impairment to irreversible dementia. At this stage, older adults experience a progressive decline in memory and cognitive function while retaining basic life and behavioral capabilities, which lies between normal aging and dementia.[11] Our goal is to improve the oral health behavior of elderly individuals with cognitive impairment through early intervention, thereby delaying or preventing serious oral problems. Therefore, intervention measures remain urgent to improve the oral health of MCI, enhance the quality of oral health, and delay or maintain the decline in cognitive level.[12]

To this end, we designed an oral health behavior intervention program for MCI based on our preliminary studies and the Capability-Opportunity-Motivation-Behavior (COM-B) model[13] that can systematically characterize the influencing factors for behaviors and clarify physiological-psycho-social variables. Previous study[14–16] indicated that the oral health behavior of MCI was primarily influenced by emotions and social support and indirectly affected by oral health knowledge and self-efficacy. The oral health behavior of older adults with MCI was poorer than that of older adults with NC, consistent with previous findings.[17]

Smartphone-based interventions are effective measures for improving cognitive levels and behavioral changes in MCI.[18,19] With the aging population and widespread use of smartphones, mobile healthcare has become essential for managing oral health issues, acquiring oral health knowledge, and improving oral hygiene.[20] WeChat is a major application for online communication in China, and its built-in mini-programs are convenient and user-friendly for old adults.[21,22] Utilizing smartphones as an online platform, we established an interactive platform to provide social support and set four modules: cognitive exercise games, oral health knowledge and skills, quizzes, and symptom management services that are accessible offline.

Accordingly, in this study, an electronic intervention for Oral Health based on the COM-B model (e-COMB[OH]) WeChat Mini program was designed for MCI (Figure 1).

Aims

This randomized controlled trial (RCT) will focus on elderly individuals with MCI to enhance their oral health behaviors and delay or maintain a decline in cognitive abilities. Specifically, we aim to achieve the following goals:

1. Explore the effectiveness of e-COMB(OH) on (a) oral health behavior (primary outcome), (b) cognitive level (secondary outcome), (c) perceived stress (secondary outcome) and social support (secondary outcome).
2. Explore the acceptability, appropriateness, and feasibility of e-COMB(OH) as an oral health behavior intervention among adults with MCI and analyze the underlying mechanisms.

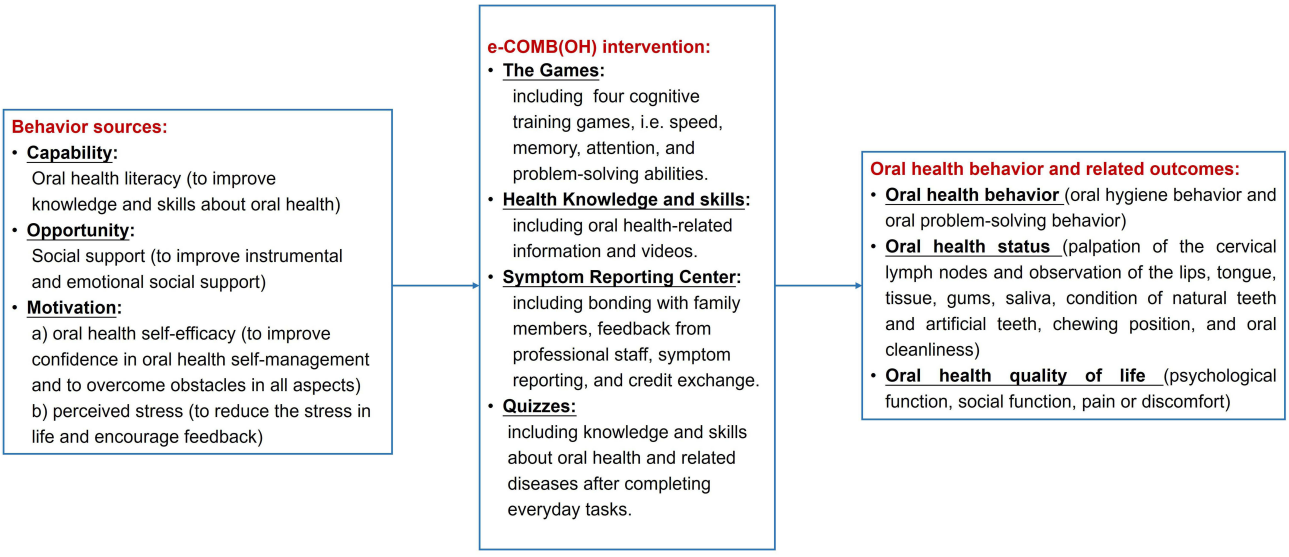

Figure 1 Conceptual framework of the e-COMB(OH) intervention.

Materials and Methods

Study Design

This randomized, parallel, single-blind controlled trial will employ allocation concealment and blinded assessors. The research will be conducted in four communities in the main urban area of Chongqing, China, namely Shapingba, Jiulongpo, Yuzhong, and Yubei. Participants will be recruited through poster placement, family doctor contacting and in-person recruiting ourselves at local community health service centers. Participant enrollment began in April 2024 and continued until November 2024. A flowchart of the study is presented in Figure 2.

The recruited participants will be randomly assigned to the intervention group (online platform-based oral health behavioral interventions) or the control group in a 1:1 ratio. Outcome assessments will be conducted at baseline and 3 months after the intervention. After the intervention, semi-structured interviews will be conducted to explore the participants' views, needs, and suggestions for the intervention. The study protocol strictly adheres to the CONSORT 2010 checklist for reporting RCT designs.

Participants

Inclusion and Exclusion Criteria

The inclusion criteria are as follows: (1) age ≥ 65 years; (2) diagnosis of mild cognitive impairment; (3) no oral treatment in the past 3 months; (4) no participation in other cognitive function-related training in the past year; (5) residing in the main urban area, capable of communicating in Mandarin or Sichuan dialect; (6) personal voluntary participation and/or consent from the caregiver to participate in this study; (7) possession of a smartphone/tablet and/or the ability to use one with the assistance of a family member. Mild cognitive impairment is assessed by experienced neurologists or

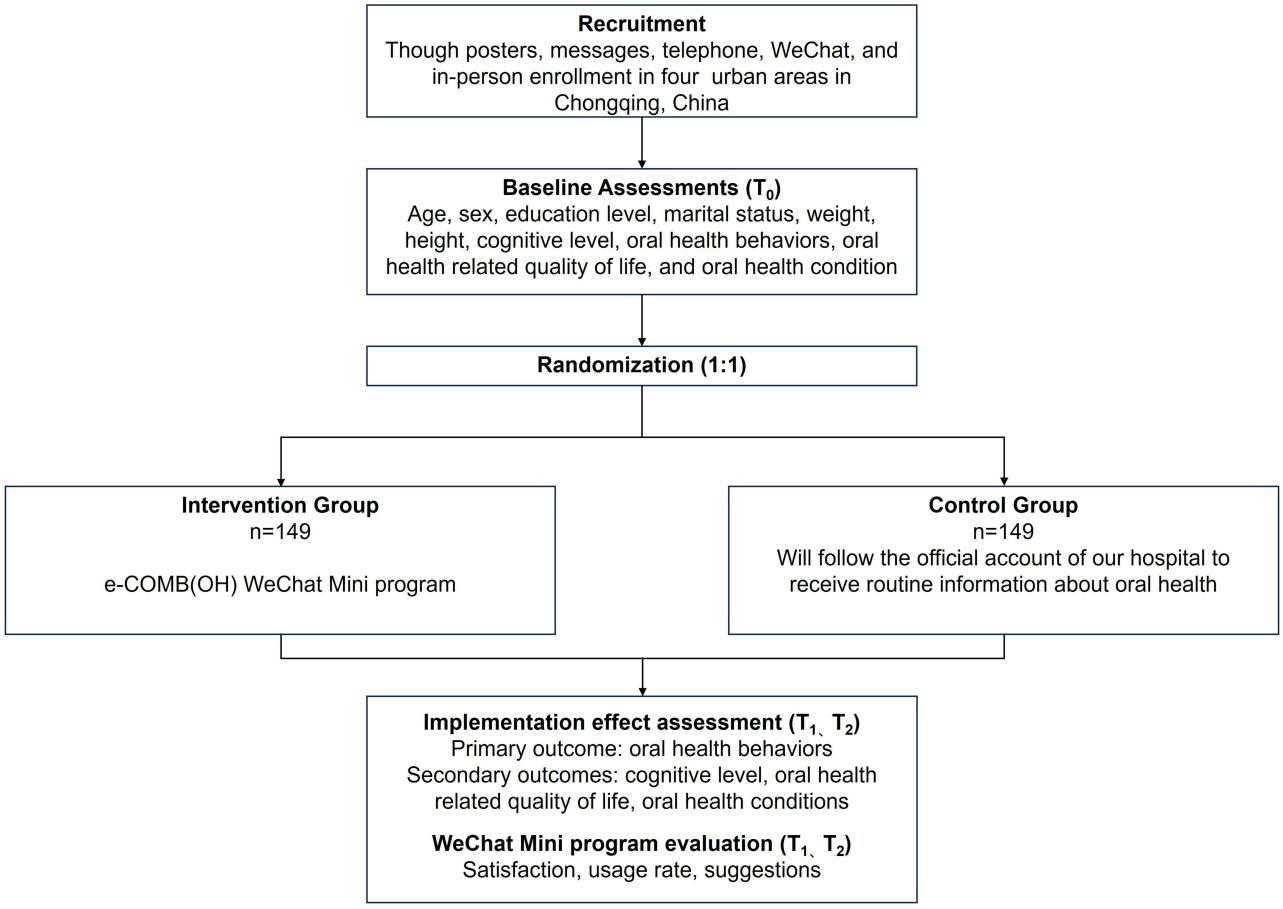

Figure 2 Study design of the e-COMB(OH) WeChat Mini program.

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geriatricians using the Petersen criteria,[23] which concern (1) the chief complaint or informed person reports of cognitive impairment; (2) neuropsychological tests showing impairment in one or more cognitive areas (executive function, memory, language, or visuospatial); (3) normal ability of daily living; (4) dementia diagnosis has not been reached.

The exclusion criteria are as follows: (1) severe physical disabilities or inability to complete oral care; (2) presence of other mental disorders, severe systemic illnesses, or tumors; (3) inability to undergo oral examinations; (4) currently receiving medication related to cognitive enhancement, such as donepezil and rivastigmine; (5) participation in other clinical intervention trials.

Intervention

The e-COMB(OH) WeChat Mini Program

The e-COMB(OH) WeChat Mini program is an MCI-oriented comprehensive 3-month smartphone intervention designed to improve oral health behaviors and maintain or prevent cognitive decline. A screenshot and translation of the e-COMB (OH) WeChat Mini program into English are shown in Figure 3. The WeChat Mini program is based on the COM-B model[13] and our previous research on knowledge, family supervision, and feedback. The necessity, scientific rigor, and practical relevance of the program have been validated through a Delphi expert consultation.

Content and Use of the e-COMB(OH) WeChat Mini Program

The e-COMB(OH) WeChat Mini program comprises four modules: games, health knowledge, health skills, and symptom reporting.

Figure 3 Interface of the e-COM(OH) WeChat Mini program. A Chinese version of the e-COM(OH) WeChat Mini program. B English translation of the e-COM(OH) WeChat Mini program.

The game module includes four types of games targeting speed, memory, attention, and problem-solving abilities: digital balloon, card matching, color shock, and guess the picture, which aims to maintain or slow cognitive decline in the elderly.

The health knowledge and health skills modules are built around a battery of oral health themes that include (1) oral health problems, (2) dental care, (3) healthy diet, (4) chronic disease, (5) prevention and healthcare, (6) dental skills, (7) diet guidance, and (8) exercise to enhance or maintain basic knowledge of oral hygiene and oral function, enabling the elderly to have a better understanding of oral diseases and age-related cognitive decline. The content under each theme includes videos and articles, which are available as audio files.

The symptom reporting center module includes family relationship bonding, credit exchange, communication with healthcare professionals, and feedback. Participants can strengthen relationships with family members, gain family support, participate in health support plans and interventions, seek help from healthcare professionals when facing problems, and check points for prizes.

Participants must follow our WeChat official e-COMB(OH) account to receive push notifications, including daily tasks three times a week, feedback messages from doctors and nurses, and reminders. The everyday tasks will include games, health knowledge, health skills, and daily review. Tasks notifications will be pushed three times a week on Wednesdays, Fridays, and Sundays, totaling 30 minutes per session, including games for 15 minutes[24] and health knowledge, health skills, and daily review for 15 minutes.[25] The intervention will last for 3 months.[26,27]

In addition, we will adopt a points-based reward system to enhance the participants' motivation to use the platform. Completing a daily task earns 10 points, and participants can redeem corresponding prizes once they have accumulated 100 points.

Intervention Group

The intervention group will be offered the e-COMB(OH) WeChat mini-program. We will use the management platform to provide participant authorization and enrollment when individuals agree to participate in the study. Participants will use their mobile phone numbers as usernames to receive a verification code via a message or directly use WeChat for login. Upon completion of the login, participants will provide basic information, such as name, sex, age, and oral health behavior habits, and this will be considered a successful registration.

The WeChat Mini program retains the participant's login information for the next use unless the participant logs out of the personal account in the Personal Center module.

Control Group

The control group members will follow the official WeChat account of our hospital, which provides oral health-related information three times a week. They will also be invited to join a WeChat Group. Following the intervention group's task schedule, oral health-related knowledge will be shared in the WeChat group for participants to learn. No additional modifications will be made. This will continue for a total of 3 months. Figure 4 illustrates the participant timeline.

Outcome Measures

Primary Outcome Measures

The primary outcome measure to evaluate intervention effectiveness will be oral health behavior scores. The Oral Health Behavior Scale[28] will be used for measurements at baseline and after 12 weeks. The scale comprises 12 items and two dimensions: oral hygiene behavior and oral problem-solving behavior. The scale uses a five-point Likert scoring system ranging from 1 (never) to 5 (always). The scores range from 12 to 60 points, with higher scores indicating better oral health behaviors.

Secondary Outcome Measures

Secondary outcome measures will include cognitive level, perceived stress, and social support to analyze the potential paths and mechanisms of the intervention.

	STUDY PERIOD			
	Enrollment	Allocation (T_0)	EOI (T_1)	EOS (T_2)
TIMEPOINT	0	0	3 months	6 months
ENROLLMENT:				
Informed consent	×			
Eligibility screening	×			
Allocation		×		
INTERVENTIONS:				
Intervention		×	×	
Control		×	×	
ASSESSMENTS:				
Sociodemographic information	×			
Oral health behaviors questionnaire	×		×	×
Geriatric oral health assessment index	×		×	×
Clinical dental examination	×		×	×
WeChat Mini program process evaluation			×	×

Figure 4 SPIRIT figure presenting the participant timeline.
Abbreviations: EOI, end of intervention; EOS, end of study.

The cognitive level will be evaluated using the Mini-Mental State Examination (MMSE).[29] The cognitive domains assess orientation to time and place, registration, attention/calculation, recall, language (including naming, repetition, comprehension, reading, and writing), and copying. A score of <27 indicates cognitive impairment.

Perceived stress will be assessed using the Perceived Stress Scale-10 (PSS-10),[30] which is usually used to evaluate participants' subjective experiences of stress over the past month. The scale includes two dimensions (stress coping and stress perception) with 10 items (6 negative items and 4 positive items). It is scored on a Likert-type 5-point ranging from 0 (never) to 4 (always). The total score ranges from 0 to 40; the higher the score, the greater the perceived stress.

Social support will be assessed using the Interpersonal Support Evaluation List-12 (ISEL-12)[31] which assesses three aspects: (1) perceived availability of appraisal, (2) belonging, and (3) tangible social support. The scale has 12 items (6 negative items and 6 positive items), and each is scored on a 4-point scale ranging from 0 (definitely false) to 3 (definitely true). The total score (0–36) is computed by reversing the positive item scores and summing all item scores. A higher score indicates a greater perception of stress.

Oral health-related quality of life will be measured using the Geriatric Oral Health Assessment Index (GOHAI),[32] a scale that consists of three dimensions: psychological function, social function, and pain or discomfort, with a total of 12 items. GOHAI employs a 5-point Likert scale (1–5), with three reverse-scored items. The total score ranges from 12 to 60 points, with higher scores indicating a better oral health-related quality of life in the elderly.

The oral health status will be assessed using the Brief Oral Health Status Examination,[33] comprising 10 items, including palpation of the cervical lymph nodes and observation of the lips, tongue, tissue, gums, and saliva; condition of natural and artificial teeth; chewing position; and oral cleanliness. The instrument utilizes a 3-point scoring system (0–2), with a total score ranging from 0 to 20. Higher scores indicate a poorer oral health status.

WeChat Mini Program Implementation Evaluation

Semi-structured interviews will be conducted with participants to evaluate the e-COMB(OH) WeChat Mini program implementation indicators, including acceptability, appropriateness, and feasibility.[34]

The entire interview process will be audio recorded, and non-verbal cues from the respondents will be meticulously documented. Each interview will be limited to 30–40 min, with the option of promptly terminating the session if abnormal emotional responses are observed. After the interviews, the recordings will be promptly transcribed into text and returned to the respondents to confirm the authenticity of the interview information. The interviews will be concluded once it is confirmed that no new themes have emerged from the data. The primary interview questions include the following: (1) Over the past 3 months, what has been your main experience using the "e-COMB(OH)" WeChat mini-program for oral health management? Has it led to substantial changes in your behavior? And (2) How have your family members or healthcare providers supported you during your use of the program? (3) What obstacles did you encounter while using the program and how did you address them? (4) What suggestions or feedback do you have regarding the content and scheduling of the "e-COMB(OH)" WeChat mini-program? What other issues do you perceive and what recommendations do you have for improvement?

Sample Size Calculation

This study will be conducted as a parallel, RCT with an intervention group and a control group, with the primary outcome measure being the oral health behavior score. The final comparison of intervention effects between the groups will be conducted using *t*-test. Based on a previous similar study[35] showing effect sizes for oral hygiene condition scores of 66.8±32.6 (intervention group) and 55.8±34.4 (control group), we have assumed $\alpha = 0.05$ (two-sided) and $1\text{-}\beta = 0.80$, with the effect size set at 0.32. Using G*Power 3.1 (HHU, Düsseldorf, Germany), the calculated sample size for the intervention and control groups is N1 = N2 = 124. Assuming a dropout rate of 20% among study participants, the required sample size is N1 = N2 = 149, resulting in a total sample size of 298 patients.

The semi-structured interview sample size must be 11–12 individuals and the data will be saturated when no new information can be obtained.[36]

Randomization

Professional statisticians will generate a random number table using a computer; these numbers will then be used to allocate participants into sealed envelopes in a 1:1 ratio. The participants will randomly receive an envelope containing a random number table and will be assigned to either the intervention or control group based on whether the number is odd or even, while maintaining a 1:1 ratio between the two groups.

Allocation

A random number table will be generated by specialized statisticians not involved in participant recruitment. The researchers responsible for recruiting the participants will be unaware of the random numbers inside the sealed envelopes.

Implementation

The allocation sequence generated by specialized statisticians will be used to distribute sealed envelopes containing random number tables to the recruited participants, including the first author and another author. Participants will then be assigned to either the intervention or control group based on random numbers obtained.

Blinding

This study falls under the category of a non-pharmacological intervention trial, making it impractical to implement blinding for both participants and interveners. Blinding will be applied solely to assessors and analysts who are not involved in participant recruitment or random allocation.

Statistical Analysis

This study follows the CONSORT 2010 statement for reporting RCTs. The quantitative data will be analyzed using IBM SPSS version 27.0 (IBM, Armonk, NY, USA). Descriptive analysis will be conducted for the main variables. Quantitative data will be presented as medians, interquartile ranges, means, and standard deviations, while qualitative data will be presented as frequencies and percentages. For group comparisons, the chi-square test or Fisher's exact test will be used for qualitative data, and the *t*-test will be employed for quantitative data following a normal distribution. If the data are skewed, the Wilcoxon rank-sum test will be used. The Shapiro–Wilk test will be used to assess the distribution of continuous variables. The significance level will be set at a two-tailed $P < 0.05$.

A linear mixed-effects model will be used to analyze the repeated-measures data. For metrics with statistical significance, a Bonferroni post-hoc test (at a 5% significance level) will be conducted to assess differences between T0 and T1. Following the intention-to-treat (ITT) principle, outcome measures will be analyzed using both the Full Analysis Set (FAS) and per-protocol (PP) sets to evaluate trial efficacy. The missing values in the FAS will be handled using the Last Observation Carried Forward (LOCF) method. If the results of both datasets yield consistent conclusions, then the reliability of the trial outcomes will be considered high. Cohen's d will be applied to measure the effect size, calculated from the mean and standard deviation of two independent groups. The effect size will be categorized as small (0.2–0.5), medium (0.5–0.8), and large (> 0.8).[37] Adherence will be assessed by tracking the number of daily tasks completed by participants.

Qualitative data will be transcribed using Microsoft Word v16.7 (2019), and content analysis will be performed using QRS NVivo 12 Plus (QRS International, Doncaster, Australia), a computerized qualitative informatics tool. We will then use the Colaizzi method for the analysis.[38]

Data Storage and Management

Baseline data encompassing general information and intervention outcomes will be collected at the time of participant enrollment through face-to-face one-on-one interviews using paper questionnaires. Data entry will be conducted using Epidata 3.1 software, and storage will be managed using Excel 2019. General information includes sex, age, marital status, and educational level. The intervention outcomes include oral health behaviors, oral health-related quality of life, oral health examinations, and cognitive capability.

Data from cognitive training, oral health knowledge, and skill learning through online platforms will be exported from the online platform backend and organized for storage in Excel 2019.

If a participant prematurely withdraws from the study, all previous data will be retained and the reasons for withdrawal will be recorded. The authors will be responsible for the management and storage of data files, including informed consent forms and original paper-based data. Access to the anonymized data files for future research purposes can be requested from the authors.

Ethics and Dissemination

The study protocol has been approved by the Ethics Committee of the Affiliated Stomatological Hospital of Chongqing Medical University (Approval No. 2023–047) and conforms to the principles of the Declaration of Helsinki. Before the start of the study, the purpose, content, and related risks will be explained to the participants. Participants who agree to join in the study can only enter the study after signing informed consent.

We will anonymize the participants using numerical coding, whereby each individual is assigned a unique code correlated with the corresponding participants' names and securely stored in an encrypted file. The custodianship of this

file will be entrusted to designated personnel to facilitate the precise identification of participants during subsequent follow-up visits.

The findings of this study will be disseminated as a peer-reviewed article in an international journal with the consent of all the researchers involved. Additionally, promotions through social media channels will be employed.

Trial Status

Participant enrollment began on April 30, 2024 and will end on November 30, 2024. The trial registration number is ChiCTR2400083250 (registered on April 19, 2024).

Discussion

To the best of our knowledge, the e-COMB(OH) Mini program will be the first smartphone-based intervention for older adults with mild cognitive impairment to improve their oral health behaviors and cognitive levels. A previous study illustrated that older adults with MCI could use smartphones for cognitive training with excellent results.[18,26,39] However, there are few intervention platforms for oral health training designed for MCI.[20,40] This trial will determine whether the oral health behaviors of individuals with MCI could be improved using an online platform.

This study has several strengths. First, the study protocol strictly follows the 2010 Consolidated Standards of Reporting Trials checklist for RCTs. To minimize selection bias, the participants will be randomly assigned to either the control or intervention group using a random number table. To reduce observer bias, blinding will be implemented for outcome assessors and data analysts. To prevent allocation bias, we will employ the sealed envelope method to conceal the allocation scheme from both researchers and participants before assignment. Additionally, to mitigate bias resulting from dropouts or noncompliance, we will conduct an ITT analysis. RCTs can generate robust data revealing causal relationships, allowing us to draw valid conclusions regarding the effectiveness of interventions such as the e-COMB(OH) program. Therefore, RCTs are considered the gold standard for clinical research.[41]

Second, in addition to the RCT, descriptive qualitative interviews will be conducted to supplement the quantitative data, aiming to better understand the acceptability, appropriateness, and feasibility of the e-COMB(OH) intervention during the trial. These three aspects are regarded as key indicators of intervention success,[42] and a mixed-methods research design enhances the validity of clinical research.[43] Questionnaires will be used to collect numerical data from all participants, and the responses will be statistically analyzed. This approach will provide objective and generalizable insights, helping us understand the acceptability of the intervention, its suitability for the target population, and its ease of implementation. On the other hand, the qualitative component involves in-depth semi-structured interviews, which will yield richer insights into participants' personal experiences, attitudes, and perceptions regarding the intervention. By analyzing their narratives, we can identify specific factors that influence their acceptance of e-COMB(OH), their recognition of its relevance to their needs, and the challenges they encounter during its practical application.

Third, in this intervention strategy, we will address three categories of behavioral change sources defined by this model: enhancing capability through oral health knowledge and skills, improving opportunity via symptom reporting and question-and-answer sessions, and fostering motivation through cognitive training games and quizzes. We have refined the intervention content and dosage through a pilot study and Delphi expert consultation.[24,25]

Finally, online interventions for MCI will consider the specific needs and challenges of older users to enhance their experiences on digital platforms. The key features include the following:

(1) Accessibility. The platform interface utilizes user-friendly fonts, colors, and icons tailored for older adults.

(2) Simplified operations. It offers streamlined processes with one-click functionality and intuitive navigation, such as "click here if you feel oral discomfort."

(3) Multisensory feedback. Voice prompts are integrated to assist users in understanding the outcomes of their actions.

(4) Support and education. Clear, comprehensible video tutorials and online support are provided to help participants familiarize themselves with platform features.

(5) Social interaction. The platform incorporates family account options, enhancing users' sense of engagement and belonging. These considerations are designed to optimize the digital experience of older adults.

This study has some limitations. The e-COMB(OH) will only include patients with MCI from Chongqing, China; no other regions will participate. Therefore, there is insufficient regional representation for application in the general population of older adults with MCI. In the future, we intend to conduct a multicenter, large-scale study to extend the WeChat Mini program to the whole country.

The e-COMB(OH) WeChat Mini program can potentially benefit individuals with MCI nationwide and extend to older adults with NC.

Considering that oral health problems have become a global public health challenge,[44] and that the number of older adults with cognitive impairment is increasing,[45] it is vital to improve their oral health behaviors. If effective and feasible in patients with MCI who live in a family or community setting, the e-COMB(OH) WeChat Mini program has the potential to become an evidence-based, simple, convenient, and low-cost tool to aid individuals with MCI by promoting oral health behaviors, delaying or maintaining cognitive decline, and guiding the development of feasible and personalized interventions for healthcare professionals.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

The study protocol has been approved by the Ethics Committee of the Affiliated Stomatological Hospital of Chongqing Medical University (Approval No. 2023-047) and conforms to the principles of the Declaration of Helsinki. Participants who agree to join the study can only enter the study after signing informed consent.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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