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Shifting from Traditional to Pragmatic Randomized Controlled Trials: Insights and Lessons Learned from the Toddler Oral Health Intervention

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Purpose: This article examines the implementation of the Toddler Oral Health Intervention (TOHI) protocol, emphasizing feasibility, recruitment, retention, and protocol adherence rather than clinical outcomes. It discusses encountered challenges, necessary adjustments, and key lessons learned during the shift from a traditional randomized controlled trial (RCT) to a pragmatic RCT, thereby offering guidance for future research on similar complex interventions.

Methods: The methods of the RCT study protocol are presented, including (1) recruitment of well-baby clinics and oral health coaches, (2) recruitment of the study population; (3) implementation of the intervention and (4) outcome measures, alongside with the process of implementation and gathered feedback needed for required adjustments. A systematic analysis identified key protocol elements, modifications made, and lessons learned.

Results: Specific protocol modifications, including adjustments due to the COVID-19 pandemic, demonstrate how a traditional RCT can be adapted to real-world conditions without compromising outcome reliability. Key lessons include the necessity of robust contingency planning to manage unforeseen disruptions, effective recruitment and retention strategies to sustain participant and interventionists engagement, and the adoption of standardized data collection processes to ensure data integrity. These findings underscore the importance of addressing practical and contextual factors alongside measuring effectiveness, ensuring that study outcomes are both applicable and useful in clinical practice.

Conclusion: The findings demonstrate that carefully planned and documented pragmatic adjustments not only preserve scientific rigor but also enhance the relevance and applicability of the results, maintaining the methodological robustness expected of traditional RCTs.

Keywords: pragmatic randomized controlled trials, lessons learned, real-world setting

Introduction

Randomized controlled trials (RCTs), are widely regarded as the gold standard in research methodology providing strong internal validity for establishing causality and evaluating efficacy of interventions. However, traditional RCTs often face criticism when applied to complex interventions, particularly those targeting multifaceted health issues such as ECC, as its development is influenced by health-related, environmental, and behavioral factors, including dietary factors, oral health practices, socioeconomic status and family structure.[1] Their controlled conditions, while ensuring rigor, may not reflect real-world practice, limiting external validity. Pragmatic RCTs (pRCTs) were developed to address this gap by combining the internal validity of traditional RCTs with the external validity required for practical application. As Schwartz and Lellouch explain, clinical trials test whether an intervention can work under ideal conditions, whereas pragmatic trials assess whether it *does work* in real-world settings.[2]

This article focuses on the pRCT assessing the effectiveness of the Toddler Oral Health Intervention (TOHI),[3] a complex intervention designed to prevent early childhood caries (ECC) among high-risk children, particularly those from lower socioeconomic backgrounds. TOHI was implemented in the Netherlands where, despite full

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coverage of dental costs by basic health insurance, nearly 60% of children aged 0–4 years do not access oral health professional services. In contrast, almost 90% of all parent-child dyads attend well-baby clinics (WBCs) from birth until the age of four with regular intervals.[4] Given the preventive emphasis of WBCs, these facilities can serve as a platform for delivering timely preventive oral healthcare to young children and their parents. This integration of oral health interventions at WBCs exemplifies the pragmatic approach, by leveraging existing healthcare infrastructure to improve accessibility and feasibility of delivering preventive healthcare to young children.

The TOHI study was initially conceptualized as a traditional RCT to ensure methodological rigor but was adapted into a pragmatic RCT before protocol publication to better reflect real-world conditions. This pragmatic design anticipated further adaptation during implementation to address practical challenges while aiming to maintain scientific rigor. The onset of the COVID-19 pandemic introduced additional complexities, such as safety protocols and adapting delivery methods to ensure continuity. While pRCT's require flexibility, they must still adhere to core methodological principles to insure internal validity. The TOHI trial was designed to balance real-world feasibility with scientific rigor by maintaining key components, including stratified randomization, blinded outcome assessment, and standardized data collection protocols. Process evaluations in pRCTs are essential for identifying deviations, understanding their impact, and extracting lessons for future research.

This paper examines the implementation of the TOHI protocol with an emphasis on feasibility, recruitment, retention, and protocol adherence rather than clinical outcomes. It addresses the challenges encountered, the adjustments made, and the lessons learned throughout its execution. By exploring these elements, we aim to provide practical insights for researchers conducting studies on similar complex interventions. This work highlights the potential of pragmatic trials to bridge the gap between research and real-world practice, offering a pathway to design scalable and effective intervention for addressing multifaceted public health issues like ECC.

Methods

Outline of the Randomized Controlled Trial Protocol

The TOHI trial was designed as a two-arm, individually randomized controlled trial to evaluate the effectiveness of integrating oral health promotion into routine WBC care. An oral health coach (OHC), from a regional dental clinic provided recurring consultations at nine WBCs in the Mid- and Southern Netherlands. The intervention targeted 200 parent-child dyads, complementing standard WBC care with guidance on oral health and healthy eating behaviors. A control group of 200 dyads received only standard WBC care. The intervention began when the child's first tooth erupted (age 6–12 months) and continued until the age of four. The TOHI intervention is built on three evidence-based pillars known to reduce caries: the Non-Operative Caries Treatment and Prevention (NOCTP) approach,[5] motivational interviewing (MI),[6] and the Health Action Process Approach (HAPA),[7] which targets underlying behavioral determinants. These elements were chosen for their adaptability to real-world settings and their effectiveness in promoting sustainable oral health behaviors. In addition to the intervention's content complexity, its implementation required collaboration between OHCs and WBC staff, highlighting the contextual challenges of delivering preventive oral health care outside dental practices.

The study was registered in the Netherlands Trial Register (NL8737) and adhered to SPIRIT and TIDieR guidelines.[8,9] Ethical approval was granted by the Medical Ethics Committee of the University Medical Centre Utrecht (NL60021.041.17; file number 17–133/D), confirming compliance with the Medical Research Involving Human Subjects Act (Dutch abbreviation: WMO) and the national Code of Conduct for Scientific Integrity in the Netherlands.[10]

The trial protocol[3] is in this paper structured around several main elements: (1) the recruitment of well-baby clinics (WBCs) and oral health coaches (OHCs), (2) recruitment of the study population, (3) the implementation of the intervention, and (4) outcome measurements.

Recruitment of Well-Baby Clinics and Oral Health Coaches

The study was conducted across six cities and nine WBCs. Two cities were selected based on pre-existing collaborations with local dental practices, while four additional cities were identified and approached directly by the researchers. WBCs were chosen in consultation with Public Health Services based on their location in disadvantaged neighborhoods with a high prevalence of (oral) health issues, and their stability, defined by minimal personnel turnover and organizational restructuring. This approach ensured the recruitment of a representative population of those most in need of oral health promotion.

OHCs, primarily dental hygienists with a prevention-focused mindset, were recruited. Professionals were invited to apply if they were near the WBCs or willing to commute. This process resulted in the participation of 11 OHCs in the study. To compensate for the inability to bill consultations due to the absence of agreements with health insurers, participating dental practices that deployed an OHC received a 50% reimbursement for consultations from the grant for two years.

Recruitment of the Study Population

Recruitment of parent-child dyads occurred during routine WBC visits when the child was 3 or 4-months old, as this timing allowed the intervention to commence with the eruption of the child's first primary tooth, typically around the age of 6–12 months. A record was kept on parents approached, to systematically document their decision to either consent to or decline participation in the study. The trial aimed to enroll 400 children. After written informed consent was received, dyads were allocated to either intervention of control group in a 1:1 ratio using a computerized sequence generator. Stratification was based on the location of the WBC and the mother's education level (low, medium or high) to ensure balanced groups and statistical efficiency. The estimated recruitment period was six months, based on the annual number of newborns registered at the WBCs, the daily number of children within the suitable age group seen at the WBCs, the number of days when an OHC was available for recruitment, and the estimated numbers of non-response.

A deliberate decision was made to employ an OHC for the recruitment of children instead of a WBC assistant as the OHC had been prepared to execute this task effectively. This decision was guided by three key considerations. Firstly, the target population, parents of young children from lower socioeconomic backgrounds, required a tailored approach to effectively engage parent-child dyads. Secondly, the randomized, longitudinal nature of the study necessitated clear and comprehensive communication about the randomization process and the implications of long-term participation. Thirdly, due to the lack of access to the WBCs patient records, it was important to promptly inform parents, record contact details for follow-up on enrollment, and adequately document non-response.

Implementation of the Intervention

The intervention was implemented by OHCs, including nine dental hygienists, one dental assistant and one dentist. All OHCs received training in the TOHI protocol, provided by the principal investigator and a certified MI trainer, both experienced in the NOCTP approach, HAPA and MI. Training sessions occurred every 3–4 months over the study duration, totaling 11 sessions, to ensure consistency in intervention delivery. As outlined in the study protocol,[3] consultations with the OHC were scheduled parallel to the WBC appointments. Each face-to-face consultation lasted 10–20 minutes and included caries risk assessment based on the NOCTP protocol, tailored oral health promotion strategies addressing mediating determinants (eg, outcome expectancies, action planning, coping planning) using the HAPA model, and MI to enhance parents' intrinsic motivation. If incipient caries was detected, parents received guidance on lesion cleaning, fluoride toothpaste use, and referrals to dental practices when necessary.[3] Consultation records, including age-related oral health topics, caries risk assessments, and behavioral stage evaluations, were documented and stored at the WBCs. Due to the lack of General Data Protection Regulation (GDPR)[11] compliant digital solutions, paper records were used, with scans mailed to an external datacenter to safeguard data. OHCs managed the scheduling and coordination of consultations with WBCs, streamlining the process by aligning appointments with parents' fixed WBC visit schedules, minimizing additional trips.[12]

Outcome Measurements

Data collection occurred at baseline and when the children were 24 and 48 months old. The primary outcome was cumulative caries incidence and severity at 48 months, assessed through clinical oral examinations using the merged International Caries Detection and Assessment System (ICDAS).[13] Secondary outcomes included the presence of dental plaque, self-reported oral hygiene behaviors and psychosocial constructs based on the HAPA, which were collected via an online questionnaire completed by parents.

To ensure data reliability and minimize bias, independent assessors were blinded to group allocation throughout the study. An interrater calibration process was conducted before each assessment period to ensure consistent application of merged ICDAS criteria. This process included the International Caries Classification and Management System (ICCMS) core e-learning modules,[14] an interrater reliability test developed for this study and consensus scoring if necessary to enhance the accuracy and consistency of caries detection across different assessors. Data analysis was conducted with blinding to group allocation to reduce potential bias in interpretation.

Retention Strategy

Participant retention is considered a key priority to ensure statistical power and representativeness of the study population over the four year-trial period. However, retention strategies were not originally part of the trial protocol but evolved based on early feedback and practical experience. By maintaining consistent communication and fostering a sense of study involvement, the retention approach aimed to mitigate participant dropout and long-term engagement.

Process for Identifying Lessons Learned

This article adhered to the design and methodology outlined in the published pRCT protocol,[3] providing a solid foundation for implementing the trial in a real world-setting. Practical challenges encountered during the execution of the trial required several adjustments to ensure the study's feasibility in a real-world setting. To systematically document and evaluate the implementation process and adjustments needed, the research team gathered feedback through regular training sessions with OHCs, conversations with parents and WBC employees, observations during trial execution, and team discussions. A detailed account of the adaptations made, and lessons learned, including those driven by the COVID-19 pandemic, will be presented in the results section for each protocol element.

Results

Recruitment Well-Baby Clinics and Oral Health Coaches

The recruitment of OHCs presented unexpected challenges, including the dropout of two OHCs. Replacing them required significant effort, as new dental practices had to be recruited, and additional training was necessary to familiarize these OHC's with the intervention and protocols. Unlike university-employed research staff, external partners such as dental practices are less embedded in the research structure, making replacement difficult and causing delays and disruptions. This highlights a critical lesson for pragmatic RCTs: partner dropout is an inherent risk that requires clear contingency plans, as it is harder to recover from than in traditional research settings.

Aligning the selection of WBCs with OHC recruitment and ensuring strong initial engagement from practices was also critical for maintaining consistent service delivery. Gaps in availability or inconsistent care may reduce participant engagement and compromise retention rates, particularly in interventions targeting vulnerable populations. In our study, early and structured discussions between Public Health Services and OHCs were essential for aligning expectations, clarifying responsibilities, and establishing formal agreements, ensuring a collaborative and integrated approach. Establishing formal agreements early in the process can safeguard engagement and maintain continuity in multi-stakeholder collaborations.

Financial sustainability emerged as a major challenge, as no reimbursement agreements were in place with health insurers for OHC consultations. The study relied on partial grant funding to cover 50% of the OHCs' costs during the intensive first two years. However, this funding proved insufficient for long-term sustainability, as consultations at WBCs were less profitable than similar care delivered in dental practices. Additionally, to prevent competitive disadvantages

among dental practices, recruitment restrictions were placed on participating clinics, limiting their ability to enroll new patients from the study population. While this maintained ethical transparency, it reduced the financial incentive for practices to participate. The main gain for dental practices and OHCs in the TOHI-study was based on their intrinsic motivation to help children maintain good oral health and expanding their expertise in providing high-quality preventive care for young children. For broader implementation, pragmatic trials must integrate financial feasibility into their study design by securing structured reimbursement agreements with health insurers or other parties.

Recruitment of the Study Population

Recruiting parent-child dyads presented challenges, particularly due to high non-response rates. 1407 parents were approached for participation by the OHC in the WBC waiting area during their child's 3 or 4-month visit, aiming to start the intervention when the first primary tooth erupted (typically around 6–12 months of age). However, 901 parents declined participation and follow-up calls generated little interest. Interestingly, some initially non-responsive parents later agreed to participate when their child began teething (around 8–11 months of age). This underscored the importance of timing recruitment efforts to align with parents' perceived relevance of preventive oral health care.

The role of WBC assistants emerged as a crucial factor in recruitment success. Their established relationship with parents made them effective facilitators of study enrollment. Contrary to initial expectations that the presence of OHCs would drive enrollment, engaged WBC assistants significantly improved enrollment, particularly on less busy days. Their involvement framed the project as a collaborative initiative between youth healthcare and dental care, rather than a dental-led project. This finding highlights the value of integrating local healthcare personnel as key stakeholders in participant recruitment.

Cultural and socioeconomic factors also played a role. In WBCs with large non-Western migrant communities, trust-building was important. For example, male OHC's were less effective in the recruitment phase in some communities due to cultural preferences. Additionally, initial recruitment materials, despite being adapted for literacy levels, failed to attract participants with low socioeconomic backgrounds. Later, visually appealing materials such as banners and posters were utilized which proved more effective in increasing visibility and interest resulting in 29% of participants representing this population.[15] These findings emphasize the importance of culturally sensitive outreach strategies in increasing inclusivity and representation in public health interventions.[3]

Implementation of Intervention

Adhering to the intervention protocol posed challenges, particularly because OHCs had no research experience. To address this, the research group organized comprehensive training sessions and provided ongoing guidance to ensure compliance with study requirements. Continuous monitoring by the research team helped to maintain protocol fidelity and identify deviations early. Audio recordings were made during the consultations and systematically evaluated, confirming that the OHCs met the fair integrity standards for MI.[16] On average, each dyad attended 5.5 sessions, with each session lasting approximately 18 minutes, in line with the protocol's allowance of up to 7 sessions ranging from 10 to 20 minutes in duration.[3] However, the absence of a unified technical system across the nine WBCs made tracking progress difficult. In multicenter pRCT's, implementing a unified system such as electronic patient records, for collecting all research data and monitoring progress are crucial for data quality and ensure the reliability of research findings, particularly in long-term pragmatic RCT's like TOHI.

The intervention proceeded as planned until the COVID-19 pandemic disrupted standard operations.[17] Preventive measures made in-person consultation at WBCs unfeasible, necessitating rapid adaptation. To maintain intervention continuity, alternative methods such as telephone and video consultations were introduced. However, research indicates that remote-only interventions may not be sufficient for interaction focused on learning healthy behavior.[18] Additionally, the inability to conduct regular oral examinations, which were essential for assessing caries risk, posed limitations. To address these challenges, a blended protocol was adopted, incorporating home visits alongside remote consultations. Critical developmental moments, such as the eruption of new teeth or other age-related topics, were prioritized for in-person visits to provide timely and relevant care while minimizing unnecessary contacts. This approach ensured continuity, even in the face of unforeseen circumstances like the pandemic. Home visits offered additional benefits by

providing insights into household dynamics, which enhanced the relationship between OHCs and parent-child dyads, and enabled more tailored behavioral advice.

As COVID-19 restrictions eased, returning to fixed in-person consultations at WBCs proved challenging due to changes in parents' and OHCs' work schedules, childcare responsibilities, and WBC availability. Home visits continued for later-stage consultations to maintain retention, though sustaining this level of flexibility during an intensive intervention phase (6–24 months) would have been logistically difficult due to the required frequency of consultations. However, the ability to adapt intervention methods flexibly, such as home visits, proved critical for sustaining engagement and retention during disruptions. The lessons learned from this intervention emphasize the importance of continuous monitoring and unified data collection system to maintain data quality and protocol adherence. These strategies ensured the feasibility and resilience of complex health interventions, particularly in dynamic and unpredictable contexts.

Outcome Measurements

Coordinating clinical assessments across nine WBCs in the Mid-Southern Netherlands presented major logistical challenges. The original study design planned for centrally organized assessments at the WBCs using a paired assessment model, where two assessors conducted evaluations together to enhance data accuracy and prevent recall bias. While beneficial for standardization, this approach quickly became logistically unmanageable and costly. As a result, the study shifted to single-assessor evaluations, a necessary adaptation to ensure continued data collection. However, to balance feasibility with data reliability, assessors were instructed to audio record their findings, minimizing recall bias and allowing for post-examination verification. This solution maintained assessment accuracy while significantly improving scheduling flexibility.

The COVID-19 pandemic further disrupted planning, initially preventing in-person assessments. Even after restrictions eased, shifts in WBC schedules, fluctuating parent availability and sickness led to frequent cancellations, making it difficult to conduct timely outcome measurements and manage data collection efficiently. This challenge was complemented by the centralized scheduling system, where all appointment coordination was initially handled by the principal investigator to maintain assessor blinding. As cancellations increased, this system became inefficient.

To improve scheduling, an online appointment system was introduced, allowing parents to independently select available time slots, with assessments strategically bundled within cities on specific days to optimize travel efficiency. Assessors were granted access to the system, enabling direct logistical contact with parents, allowing them to reschedule appointments directly without compromising blinding, as no group allocation was documented in the system. Additionally, the system streamlined data collection by integrating an online questionnaire, reducing administrative burden. However, some parents, particularly those with low literacy levels or limited digital proficiency, struggled with the platform. To address this, in-person assistance was provided by the assessors at the time of the appointment, ensuring inclusivity and higher participation rates.

These adaptations ensured the continuity and integrity of outcome assessments, resulting in complete caries data for 353 (88%) of participants at the 48-month. Furthermore, assessor blinding was maintained in 89% of cases at the final measurement, demonstrating that rigorous blinding can be upheld even in complex pragmatic trials.[15]

A key lesson from this study was that careful consideration of scalable and flexible scheduling solutions was essential for maintaining feasibility and data quality. The use of digital tools streamlined processes and improved efficiency, ensuring operational feasibility in a complex real-world setting while allowing for necessary adaptations to support participant diversity and engagement.

Retention of Participants

Maintaining high retention rates over a four-year study period required continuous engagement efforts as retention is crucial for preventing attrition bias and maintaining statistical power, particularly in trials with long follow-up periods.[19] To address this, a structured retention plan was implemented, incorporating proactive engagement strategies across both study arms. In both study arms, all children received birthday cards as a simple yet effective way to maintain engagement

and reinforce their participation. In the intervention group, parents also had direct access to the OHC for consultation outside regular appointments, allowing them to seek advice.

For the control group, where direct interactions with the research team were more limited, structured engagement efforts were implemented to sustain participation. To ensure participants remained engaged, a combination of strategies was used. Birthday cards were sent annually, and study assessments were conducted at 24 and 48 months as planned. To complement these, scheduled reminder letters were sent at 18 and 30 months, accompanied by small non-dental appreciation gifts. This structured approach ensured participants were reminded of their involvement about every six months, reinforcing their connection to the study despite the absence of direct contact with the research team. While we accounted for a 30% loss-to-follow-up in our calculations, the effectiveness of these strategies was evident, as retention rates reached 86% in the intervention group and 90% in the control group.[15] This level of retention, even during disruptions like the COVID-19 pandemic, is notable for a long-term trial involving young children and underscores the importance of personalized engagement efforts. A key lesson learned is that structured retention strategies should be proactively incorporated into research protocols to preserve data integrity and statistical power.

Discussion

This article demonstrates that pragmatic RCTs can balance methodological rigor with real-world feasibility, if challenges in implementation, recruitment, retention, and data-collection are systematically addressed. The TOHI trial illustrates that flexibility does not necessarily compromise internal validity as long as core methodological elements, including stratified randomization, standardized intervention delivery, robust data collection, and blinded outcome assessment and analysis, are upheld.[20] While the trial required significant adaptations, particularly due to unforeseen disruptions such as the COVID-19 pandemic, these adaptations were carefully managed and transparently documented. This ensured that the validity and reliability of findings were maintained. The lessons learned from this study provide insights for improving the design and execution of future pRCTs in public health interventions.

A key recommendation is the integration of structured quality control mechanisms to minimize bias. The preservation of blinded assessments in TOHI demonstrates that structured communication protocols can help prevent information bias, even in dynamic study environments. Additionally, the shift from paired assessments to single-assessor evaluations with audio recording allowed for greater logistical feasibility without compromising data reliability. Future pragmatic trials should consider engaging a Data and Safety Monitoring Board (DSMB)[21] to evaluate and oversee trial modifications, ensuring that necessary adaptations do not introduce systematic bias or compromise study integrity. This additional layer of oversight could help maintain scientific rigor while allowing for real-world flexibility.

Embedding contingency planning into trial design is essential to mitigate operational disruptions. The TOHI study faced challenges related to partner dropout, shifting organizational priorities, and changes in scheduling, which required ongoing adaptations. Early and structured discussions with stakeholders, alongside formal agreements, proved valuable in ensuring continuity. Future trials should consider integrating clear contingency strategies, such as maintaining backup personnel, establishing cross-organization coordination plans, and using scalable intervention delivery models that allow flexibility without compromising fidelity.

Ensuring financial sustainability from the outset is recommended, especially in long-term studies, to maintain intervention continuity. In the TOHI study, reliance on grant funding and the absence of reimbursement agreements with health insurers led practices to withdraw due to financial constraints. Without ongoing funding, long-term research efforts risk disruption and limits scalability. These findings emphasize that even among highly motivated and prevention-oriented practices, it is essential to incorporate financial incentives into study protocols and secure reimbursement agreements with health insurers or public funding bodies to support continuous service delivery throughout extended study periods.

Overcoming recruitment barriers through cultural sensitive and inclusive strategies enhance representativeness of study populations and helps address health disparities. TOHI faced difficulties in enrolling parents from lower socioeconomic backgrounds, despite adaptations in recruitment materials and strategies. This aligns with previous research that indicates that individuals from low socioeconomic background present challenges in recruitment and retention due to barriers related to trust and accessibility.[22,23] Engaging trusted community figures, such as WBC

assistants, played a key role in improving enrollment. While visually appealing materials and culturally appropriate communication can improve participation, accessibility remains a challenge, particularly for individuals with low health literacy.[24] To overcome these issues and enhance recruitment in public health interventions, it is essential to adopt effective, targeted approaches. Involving members of the target population in advisory groups helps ensure that recruitment strategies and consent procedures are tailored to their specific needs. Ethical committees should consider more flexible consent procedures by allowing alternative methods such as short videos, digital consent forms, or image-based letters.[24–26] In addition, policymakers and funding bodies can play a significant role by encouraging the use of these innovative strategies to better address health disparities and promote access to healthcare services. Collaborating with expert institutions like Pharos,[27] a leading Dutch advisory organization dedicated to reducing health disparities by enhancing health literacy and ensuring accessible health information for vulnerable populations strengthens these approaches.

Planning retention strategies in advance is essential for ensuring high participant engagement in long-term trials. In the TOHI study, high retention rates were achieved through personalized communication, structured reminders, and flexible consultation methods, such as home visits and remote sessions. These strategies were particularly effective in maintaining engagement in the control group, where fewer direct interactions required additional efforts to prevent dropout. Future studies should proactively integrate multi-channel engagement approaches, combining digital tools with personalized interactions, to sustain retention and ensure data completeness, thereby reinforcing the reliability and validity of trial outcomes.[28]

Finally, the absence of research experience among practitioners underscores the critical need for standardized data collection processes, ongoing training initiatives, and transparent documentation of any modifications to maintain trial integrity. Detailed documentation not only enhances accountability but also provides valuable insights into the contextual factors influencing study outcomes, thereby informing future research. Furthermore, leveraging digital tools can enhance operational efficiency and data completeness, but should be complemented by human-centered support to maintain feasibility and participant engagement. TOHI's implementation of an online scheduling platform streamlined data collection and reduced administrative burden, yet required additional support for participants with low digital proficiency. Future trials should consider hybrid models that combine digital automation with personalized assistance to optimize accessibility and prevent dropout while preserving operational feasibility, data completeness, and, the validity of study outcomes.

Ensuring standardized data collection and ongoing training for practitioners is essential for trial integrity. The lack of prior research experience among oral health coaches in TOHI necessitated comprehensive training and continuous monitoring. Transparent documentation of any modifications helped maintain methodological rigor while allowing for necessary adaptations. Additionally, leveraging digital tools can enhance efficiency and data completeness but must be accompanied by human-centered support. TOHI's implementation of an online scheduling platform streamlined data collection and reduced administrative burden, yet required additional support for participants with low digital proficiency. Future trials should consider hybrid models that combine digital automation with personalized assistance to optimize accessibility and prevent dropout.

In TOHI, maintaining internal validity while implementing pragmatic adaptations was mainly successful, but required significant effort and multiple adjustments throughout the study. Although certain disruptions, such as the COVID-19 pandemic, could not have been anticipated, many logistical and operational challenges might have been mitigated by integrating contingency planning directly into the trial protocol. As pragmatic trials often require protocol adjustments to align with real-world constraints, structured monitoring mechanisms, such as an independent DSMB, can help maintain scientific transparency while allowing necessary adaptations.

In conclusion, this article demonstrates that pragmatic adjustments, when carefully planned and documented, do not inherently compromise scientific rigor. Instead, they can enhance the relevance and applicability of findings while preserving methodological robustness. Researchers, policymakers, and funders should recognize the value of these approaches, as they provide a pathway for evaluating complex interventions in a manner that is both sufficient scientifically robust and practically applicable.

Data Sharing Statement

The information used to write this manuscript, including lessons learned, decisions, and modifications, primarily consists of qualitative data and meeting minutes from team discussions, which cannot be shared due to privacy considerations. The dataset analyzed during the current article is not yet available due to ongoing data collection as part of the research project. Deidentified data, code, and the data dictionary will be deposited in DataverseNL after the follow-up study is completed and will be available upon request.

Ethics Statement

Ethical approval was granted by the Medical Ethics Committee of the University Medical Centre Utrecht for review and approval. The committee provided ethics clearance (NL60021.041.17; file number 17-133/D) and stated that the research complied with the applicable rules and requirements of the Medical Research Involving Human Subjects Act (Dutch abbreviation: WMO) and with the ethics code for the conduct of research as set out in the national Code of Conduct for Scientific Integrity in the Netherlands.[10] The study's protocol adhered to the ethical standards outlined in the 1964 helsinki Declaration and its subsequent amendments or comparable ethical guidelines.

Written informed consent was obtained from all participants involved in the study, including parental or legal guardian consent for children.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, article 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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