Aniqsaaq (To Breathe): Study protocol to develop and evaluate an Alaska Native family-based financial incentive intervention for smoking cessation

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ABSTRACT

Background: Alaska Native and American Indian (ANAI) communities in Alaska are disproportionately affected by commercial tobacco use. Financial incentive interventions promote cigarette smoking cessation, but family-level incentives have not been evaluated. We describe the study protocol to adapt and evaluate the effectiveness and implementation of a remotely delivered, family-based financial incentive intervention for cigarette smoking among Alaskan ANAI people.
Methods: The study has 3 phases: 1) qualitative interviews with ANAI adults who smoke, family members, and stakeholders to inform the intervention, 2) beta-test of the intervention, and 3) randomized controlled trial (RCT) evaluating intervention reach and effectiveness on verified, prolonged smoking abstinence at 6- and 12-months post-treatment. In the RCT, adult dyads (ANAI person who smokes [index participant] and family member) recruited throughout Alaska will be randomized to a no-incentives control condition ($n = 328$ dyads) or a 6-month incentive intervention ($n = 328$ dyads). All dyads will receive cessation support and family wellness materials. Smoking status will be assessed weekly for four weeks and at three and six months. Intervention index participants will receive escalating incentives for verified smoking abstinence at each time point (maximum $750 total); the family member will receive rewards of equal value.
Results: A community advisory committee contributed input on the study design and methods for relevance to ANAI people, particularly emphasizing the involvement of families.
Conclusion: Our study aligns with the strength and value AIAN people place on family. Findings, processes, and resources will inform how Indigenous family members can support smoking cessation within incentive interventions.
Clinical Trials Registry: NCT05209451

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1. Introduction

In Alaska, cigarette smoking prevalence among Alaska Native and American Indian (ANAI) people is more than double that of non-Native adults (37% vs. 17%) [1]. Unlike other U.S. Indigenous populations, tobacco was not available to ANAI communities before contact with outside traders and, thus, it is not used in traditional ceremonies [1,2]. Despite concerted efforts by Alaska Tribal Health System (ATHS) organizations and the State of Alaska health department, current smoking cessation strategies, most of which are individual-focused, have not effectively reduced smoking prevalence among ANAI people [1,3,4]. Alaska's geography (largely remote and roadless) and harsh climate further limit treatment access and reach. Without effective cessation strategies, many ANAI health disparities persist, including lung and cardiovascular disease morbidity and mortality [1,5,6]. Annually, smoking costs Alaska $575 million in direct medical expenditures and $261 million in lost productivity from smoking-related deaths [1].

Given challenges and resultant service-delivery gaps, ATHS leaders emphasize the critical need for novel, accessible, effective smoking cessation interventions for ANAI people. We describe our study protocol to adapt and evaluate the effectiveness and implementation of an innovative, remotely delivered, culturally relevant, ANAI family-based financial incentive intervention for smoking cessation. The study name, Aniqsaaq (pronounced ahh-nik-suk), means "to breathe" in the Alaska Native Inupiaq language. Although the name originates from the Inupiaq language, its meaning has universal relevance statewide.

Based on behavioral economics, financial incentive interventions are evidence-based [7] and offer a simple public health approach to promote smoking cessation. Behavioral economic theory provides a framework to understand when and how people make choices [8,9]. Its central tenet is that although humans are hard-wired to act instinctively, they may need a nudge to make decisions in their best interest [8]. Financial incentives provide an immediate non-nicotine reward for smoking abstinence addressing a major barrier to smoking cessation, delayed discounting [8,10]. Delayed discounting or impulsive choice is a preference for smaller, more immediate outcomes (e.g., nicotine effects) over larger delayed outcomes (e.g., health, money saved from not smoking) with delayed rewards more likely to be discounted [11]. Randomized controlled trials (RCTs) of interventions providing total cash payments of $750 to $1650 for biochemically verified smoking abstinence have demonstrated >2-fold increases in the smoking abstinence rates a full year after the rewards were discontinued compared with no incentives (odds ratios: 2.48–2.72) [12–14]. Technological innovations in remote monitoring and providing immediate monetary rewards enhance potential intervention reach and scalability [15]. McDonell and colleagues found that an incentive-based intervention was acceptable and effective for reducing alcohol use among ANAI communities, including in Alaska [16]. No published studies have evaluated financial incentive interventions for smoking cessation among ANAI people.

Family relationships could be another means to support smoking cessation within a financial incentive intervention [8,9]. Research in the general population documents the influence of naturally occurring social support networks (e.g., family members) on smoking cessation [17, 18]. Moreover, social influence from family/friends was associated with successful cessation among individuals receiving a financial incentive intervention [19]. A pilot study [20] rewarding pregnant women for smoking abstinence included optional enrollment and support training for a family member; 57% opted to include a family member. The biochemically verified cessation rates at the end of eight weeks of treatment were higher than in prior trials offering incentives during pregnancy (63% vs. 34%), although the study did not compare abstinence rates for women with and without a family member enrolled, nor include rewards for the enrolled family member. While promising, studies using collective rewards with naturally occurring social networks (e.g., coworker teams) have not focused on family supports [21]. As noted in our prior

tobacco treatment studies [3,4,22] and supported by community input into designing this study, family is a strong cultural value shared by all ANAI ethnicities and an important motivator for quitting smoking expressed by ANAI people who smoke statewide in Alaska. This is consistent with the ANAI cultural value of interdependence, which is a relationship-based, collaborative approach to decision making and lifestyle changes, and reliance on family systems rather than individual strengths [23,24].

Addressing these gaps, our study aims to: (1) Adapt an effective 6-month financial incentive intervention for ANAI adults who smoke and family members; (2) Conduct a RCT to evaluate participant reach and treatment effectiveness of the family-based incentive intervention compared with the control condition on biochemically confirmed, prolonged smoking abstinence at 6- and 12-months post treatment; and (3) Evaluate key process indicators relevant to intervention adoption, implementation, and maintenance (e.g., perceived feasibility, perceived challenges), and conduct a cost-effectiveness analysis to support further adaptation and dissemination. We hypothesize that the intervention will be associated with greater prolonged smoking abstinence compared to a no-incentives control condition.

2. Methods

Our study was approved by the Alaska Area and Mayo Clinic Institutional Review Boards and the Alaska Native Tribal Health Consortium (ANTHC). The trial design is in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement for RCTs [25], and the trial is registered with the Clinical Trials Registry (NCT05209451). The research team includes ANAI persons and has multidisciplinary expertise that includes implementing culturally relevant health and wellness interventions with ANAI communities, tobacco treatment, incentive interventions for addictions, mixed methods, implementation science, biostatistics, and health economics.

The study incorporated a community-based participatory approach into all research processes [26], as requested by Tribal leaders in ANAI communities [27]. Since November 2018, we repeatedly sought input on the research questions and study design with the ANTHC Research Consultation Committee, a community advisory committee constituted of ANAI individuals. Members advise researchers on various projects. The make-up of the group varies based on availability, but all are ANTHC employees with a self-reported interest in research with ANAI people and includes people from urban and rural Alaska and/or with family from or living in these communities.

We will continue to consult with this committee for input on study implementation and dissemination activities. We also discussed the study with the statewide Alaska Native Elders Health Advisory Board staffed by ANTHC. Study results will be shared with all study participants via mailed newsletters.

2.1. Projected financial incentive intervention

The intervention will include evidence-based financial incentive components leveraging concepts from behavioral economic theory [8, 9]. Based on initial community feedback and the literature, we plan to include the intervention components described in Table 1 and will make adaptations using input from our Aim 1 formative work.

2.2. Study overview

We will conduct the research in three phases (Fig. 1). In phase 1, we will use qualitative in-depth interviews to culturally adapt the intervention so that it promotes healthy traditional and current lifestyle and practices and values that will resonate with ANAI people. In phase 2, we will beta-test the intervention. In phase 3, we will conduct a RCT to evaluate intervention reach, effectiveness, adoption, implementation, and longer-term maintenance, including cost.

Table 1
Planned family-based financial incentive intervention components.

Component	Description	Rationale
Intervention duration	• Six months.	• The relapse rate is usually relatively small after 6–12 months of abstinence [28].
Smoking status check-ins	• Cigarette smoking abstinence among index participants will be assessed and reinforced six times: weekly for four weeks, then at 3 and 6 months. • Both the index participant and enrolled family member will receive a $25 gift card for each smoking status check-in completed regardless of test results.	• Relapse occurs rapidly after a quit attempt, thus abstinence needs to be reinforced early on [28]. Sustained early smoking abstinence is predictive of long-term success [29]. Our incentive schedule will reinforce both initial and sustained cessation. • Remuneration for time for smoking status check-in completion may enhance retention of dyads.
Remote objective monitoring of smoking status	• Index participants will receive 1) the iCO™ Smokerlyzer®, a portable, handheld breath CO monitor that connects to a mobile device/tablet and 2) Alere™ iScreen mouth swab tests for cotinine. At each of the six smoking status check-ins, index participants will submit results to research staff via app or video call.	• Remote monitoring enhances intervention reach and scalability and allows for rapid biochemical testing proximal to obtaining self-reported smoking status.
Definition of verified cigarette smoking abstinence among index participants	• Self-reported cigarette smoking abstinence during the past 7 days with negative tests of breath CO (0–3 ppm) and saliva cotinine <30 ng/ml; if NRT, e-cigarettes, or ST use is reported, with a positive cotinine test, the participant has a negative CO test.	• Reinforcement of abstinence is contingent on objective evidence of smoking abstinence. • Breath CO measurement can verify abstinence within the previous 24 h [30]. It is not confounded with detection of use of ST, NRT, or e-cigarettes because CO criterion for abstinence below 4–5 ppm provides better sensitivity and specificity for differentiating between those smoking and not smoking, and especially for comparing light smoking (<10 cpd) to heavier smoking [31, 32]. • Cotinine is the major metabolite of nicotine and its presence in saliva indicates cigarette use in the past 6–7 days. Its specificity for cigarette smoking is excellent except for persons using nicotine-containing medications, ST, or e-cigarettes [30]. Thus, combining breath CO and cotinine measures is optimal.
Escalating incentive scheme and reward value	• Index participant will receive cash rewards for abstinence six times: $50, $75, $100, $125,	• Escalating reinforcement programs produce longer periods of smoking abstinence compared

Table 1 (*continued*)

Component	Description	Rationale
	$175, $225 (weekly for four weeks then at 3 and 6 months); maximum $750 total. • The enrolled family member will receive cash or non-cash rewards at the equivalent value earned by the index participant (maximum $750 total).	with constant rewards [33]. • Prior studies used total payment amounts ranging from $750-1650 and all had similar effects on smoking abstinence. We chose the lowest value of $750 to enhance sustainability of the intervention while considering the context of the overall cost of living in Alaska, the seventh most expensive US state [34] and also taking into account the potential total combined incentive of $1500/dyad.
Immediacy of rewards	• We will pay rewards as soon as smoking status check-ins are completed, using text messages to notify each dyad participant of the reward earned. We will use a reloadable credit card for prompt payment of financial rewards to index participants.	• Immediacy of reinforcement is an important parameter to effective incentive interventions [35]. Delayed rewards are usually discounted, but are about twice as effective when delivered immediately [35].
Reset	• If the index participant tests positive for smoking or has a missed assessment, he/she will receive no reward for that check-in. The value of the next incentive earned for smoking abstinence will be reset to the value of the last reward attained, and the escalation scheme will start again at this value.	• Reset is a key parameter of effective incentive interventions to ensure rewards are contingent on smoking abstinence and to allow participants to continue their participation without loss of any rewards earned previously [36].
Regret aversion	• If the index participant is not abstinent, each dyad participant will get feedback via text message that they will not receive a reward at that time point but will be encouraged to continue their participation.	• Anticipated regret, is an important principle of behavioral economics; when facing a decision, individuals might anticipate regret from smoking, and thus choose to eliminate or reduce this possibility [36].
Text messages	• After each of the six smoking status assessments, study staff will deliver a standardized text message to each dyad participant on reward value earned for smoking abstinence and reinforce continued participation.	• Text messages will reduce delays in receiving information on rewards earned at smoking status check-ins.

Table note: CO = carbon monoxide, ST = smokeless tobacco including Iqmik (an Alaska homemade product), NRT = nicotine replacement therapy.

2.3. Participants and recruitment

For all study phases, we will recruit ANAI adults who smoke cigarettes (index participants) and adult family members statewide. We will advertise on social media platforms (e.g., Facebook), Tribal newsletters, newspapers, and websites, including organizations serving families.
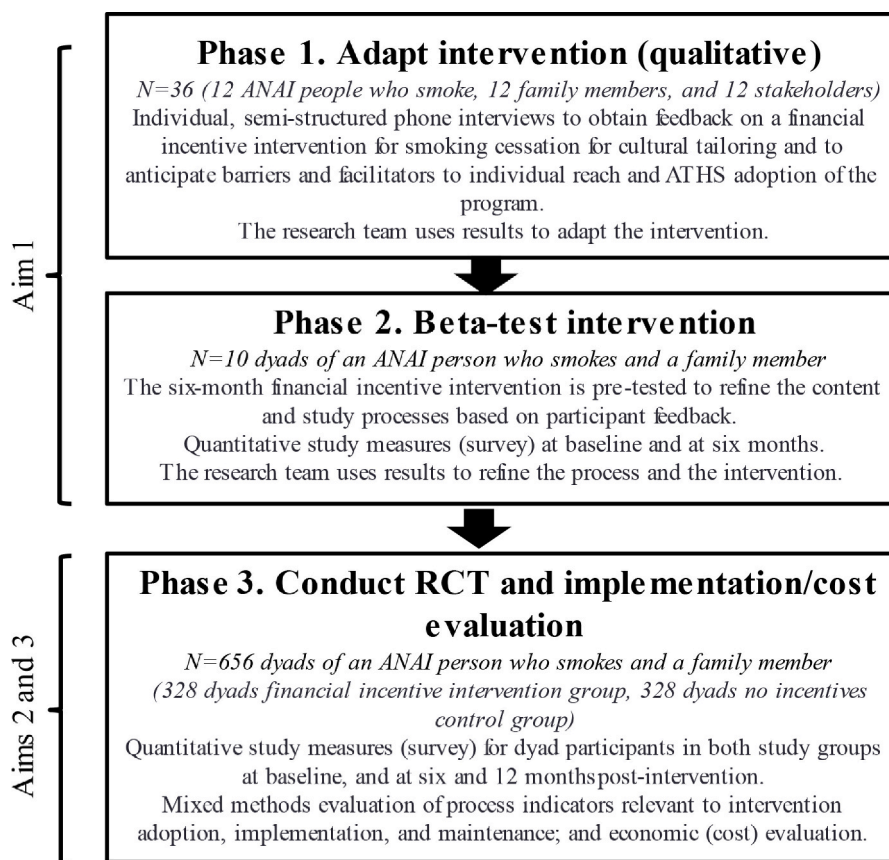
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│           Phase 1. Adapt intervention (qualitative)       │
│   N=36 (12 ANAI people who smoke, 12 family members, and  │
│              12 stakeholders)                             │
│   Individual, semi-structured phone interviews to obtain  │
│   feedback on a financial incentive intervention for      │
│   smoking cessation for cultural tailoring and to         │
│   anticipate barriers and facilitators to individual      │
│   reach and ATHS adoption of the program.                 │
│   The research team uses results to adapt the             │
│   intervention.                                           │
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│              Phase 2. Beta-test intervention              │
│   N=10 dyads of an ANAI person who smokes and a family    │
│              member                                       │
│   The six-month financial incentive intervention is       │
│   pre-tested to refine the content and study processes    │
│   based on participant feedback.                          │
│   Quantitative study measures (survey) at baseline and    │
│   at six months.                                          │
│   The research team uses results to refine the process    │
│   and the intervention.                                   │
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│      Phase 3. Conduct RCT and implementation/cost         │
│                    evaluation                             │
│   N=656 dyads of an ANAI person who smokes and a family   │
│              member                                       │
│   (328 dyads financial incentive intervention group,      │
│       328 dyads no incentives control group)              │
│   Quantitative study measures (survey) for dyad           │
│   participants in both study groups at baseline, and at   │
│   six and 12 months post-intervention.                    │
│   Mixed methods evaluation of process indicators          │
│   relevant to intervention adoption, implementation, and  │
│   maintenance; and economic (cost) evaluation.            │
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Fig. 1. Alaska Native family-based financial incentive intervention study overview.

Recruitment advertisements will include the study name, Aniqsaaq and its meaning (to breathe), and a blanket toss photo. The blanket toss was first used to sight whales during a whale hunt and now used during gatherings and celebrations statewide to reflect community and family supporting and uplifting each other [37]. Screening, informed consent, and enrollment will occur by phone or online. Index participant and family member participant eligibility criteria are included in Table 2.

ATHS stakeholders will be invited by ANTHC research staff to participate in the Phase 1 formative work through phone and email correspondence using a statewide list to ensure urban and rural representation. ANAI and non-ANAI adult stakeholders will be eligible to participate if they are at least 18 years old and work within the ATHS or otherwise support ANAI people in tobacco treatment or health education, advocate for tobacco treatment, and/or serve as an Elder or Tribal leader.

To enhance feasibility and generalizability, we place no eligibility restrictions on family member's relationship type, place of residence, or smoking status. Family-based smoking and addiction treatment studies often conceptualize family as an individual's closest emotional connections, with no single immutable definition [40]. ANAI community members suggested we involve one family member as the "agent of change" and allow the index participant to define and select who they consider family. Involving one family member is consistent with successful family-focused smoking cessation [41] and addiction [40,42] treatment models. In ANAI communities, extended family is defined as a network of relations across different households that affects one's identity and role in the community, transmits culture, and conserves family patterns [43]. In prior RCTs [44] of social support interventions for smoking cessation, about half of support persons did not live with the person who smoked. Of 497 rural ANAI Alaskan households, 50% experienced a change in household members in one year [45]. Some index participants may live alone, or a trusted/safe family member may

not reside in the same household. Domestic violence is a concern in Alaska where, irrespective to race or ethnicity, 43% of women and 30% of men report having experienced intimate partner violence, sexual violence, or stalking [46]. Alaska ranks third in the nation for lifetime prevalence of intimate partner violence against women [46]. Index participants will be encouraged to select someone they trust to support them in quitting. We will allow the participant to change their selected family member if needed, although we anticipate changes mid study will be rare.

Because the literature offers little guidance [47], we will explore the effect of the selected family member's smoking status in the context of our research. National data indicate 44% of adults who smoke are exposed to others who smoke in their home [48]. Thus, other adults who smoke may best better reflect the social support network within populations with a high smoking prevalence, such as ANAI people [48]. The option to include a family member who smokes enhances recruitment feasibility. We will explore if family member smoking status moderates intervention effects and whether intervention effects are found on family members' smoking status in Phase 3 of our study to inform future research in this area.

2.4. Phase 1 (qualitative)

This formative phase will use behavioral economic theory [8,9], cultural variance [49,50], and dissemination and implementation [51, 52] frameworks to design intervention messages and parameters, and to anticipate potential facilitators and barriers to reach and future adoption within the ATHS. We will solicit input from ANAI adults who smoke, family members, and ATHS stakeholders to develop messaging that resonates with ANAI values as well as healthy traditional and current lifestyle, practices, and activities.

We will conduct semi-structured, individual phone interviews with

Table 2

Index participant eligibility and rationale for index participants and family members in all three study phases.

Study Inclusion Criteria	Rationale
Index participants	
ANAI person (based on self-reported race/ethnicity) residing in Alaska. Both men and women will be included.	An estimated 27,712 ANAI adults using tobacco (i.e., 37% of total ANAI persons ages 21 and older [1,38]) are potentially eligible.
Aged ≥21 years	Legal smoking age in Alaska is 21 years
Self-report cigarette smoking in the past 7 days and *(phases 2 and 3 only)* biochemically verified with breath expired air CO ≥ 4 ppm and saliva cotinine ≥30 n/ml (positive Alere™ iScreen result).	Incentives are offered for smoking abstinence with the intervention. Thus, it is important to verify the individual currently smokes at study enrollment.
Smoked ≥3 cigarettes per day (cpd) over the past 3 months. *Phases 2 and 3 only*: Current smoking status will be biochemically verified.	Includes "light" smoking as prior studies found that ANAI people reporting "light" smoking (7.8 cpd) have cotinine concentrations equivalent to White "heavy" smoking (15 cpd), due to nicotine metabolism differences [39].
Cigarettes are the main tobacco product used if other nicotine/tobacco products are used.	Cigarette smoking paired with ST use is prevalent in some Alaska rural regions [1]; thus, results are more generalizable if other tobacco use is allowed.
Considering or willing to make a quit attempt.	Study promotes quitting smoking.
No use of cessation pharmacotherapy or stop smoking program in the past 3 months.	Study promotes quitting smoking.
Has an adult family member who would be supportive of their efforts to quit smoking and (in phases 2 and 3) will enroll in the study.	Study focuses on ANAI families. Phases 2 and 3 enroll dyads and thus requires a family member to also enroll.
No other index participant from the same household has enrolled.	Facilitates obtaining different perspectives in phase 1. Mitigates potential lack of independence of households/social networks in phases 2 and 3. Reduces the risk for cross-condition contamination in phase 3.
Phases 2 and 3 only: Owns or has access to a mobile phone or tablet with internet and text messaging capabilities (or will be loaned an iPad with data plan remuneration for the study duration).	Facilitates completion of the six smoking check-ins and receiving text messages during the treatment phase.
Phase 3 only: Has not participated in a prior study phase.	Mitigates potential lack of independence of households/social networks and reduces the risk for cross-condition contamination.
Provides informed consent.	Verbal consent in phase 1, written consent in phases 2 and 3.
Family member participants	
Defined as family by the index participant.	Initial community feedback suggested a broad definition of family member and includes household or non-household members, and individuals who smoke or do not smoke.
Both men and women and all races will be included.	
Aged ≥21 years.	Enrolled family members may also smoke. The legal smoking age in Alaska is 21 years.
Provides informed consent.	Verbal consent in phase 1, written consent in phases 2 and 3.
Enrolled to support only one index participant.	Facilitates obtaining different perspectives in phase 1. Mitigates potential lack of independence of households/social networks in phases 2 and 3. Reduces the risk for cross-condition contamination in phase 3.
Phases 2 and 3 only: Owns or has access to a mobile phone or tablet with internet and text messaging capabilities (or will be loaned an iPad with data plan remuneration for the study duration).	Facilitates receiving text messages during the treatment phase.
Phase 3 only: Has not participated in a prior study phase	Mitigates potential lack of independence of households/social networks and reduces the risk for cross-condition contamination.

Table note: ANAI = Alaska Native or American Indian, CO = carbon monoxide, ST = smokeless tobacco.

three groups: (1) ANAI adults who smoke, (2) family members, and (3) ATHS stakeholders (see section 2.3). With 10–15 interviews recommended per group to reach data saturation [53]; thus, we estimate 12 interviews per group. Participants will be purposefully sampled [54] to maximize diversity in the index participants' sex, rural/urban location, and residence with family member; and family member smoking status.

Interviews conducted by trained research staff will last about 60 min. A brief description of the intervention will be sent to participants for review before or during the interview. A semi-structured moderator guide was developed using the above-noted frameworks [8,9,49–52]. Supplemental Table S1 includes the interview topics, sample questions, and prior community feedback where obtained. With permission, interviews will be audio recorded with the participant's permission and then transcribed. Each participant will be mailed a $25 gift card.

We will use content analysis [55] supplemented with QSR NVivo software (version 10) to code for themes and present the results to our community advisory committee for feedback to guide development of recruitment messaging and intervention refinement before beta-testing. We will create a content library of about 10 text messages for delivery to each index participant and family member and develop program materials describing the intervention's incentive schedule and reward scheme. Intervention delivery will be standardized via a manual for trained research staff.

2.5. Phase 2 (beta-testing)

We will recruit a sample of 10 adult dyads, each comprised of an ANAI person who smokes (index participant) and a family member (see section 2.3). All participants in the 10 dyads will receive resources and referral information on cessation treatment, family wellness, and social support. Each dyad will also receive the preliminary 6-month financial incentive intervention (Table 1) adapted using the phase 1 qualitative work. Beta-testing will enable the investigative team to obtain feedback from dyad participants after intervention exposure to ensure the program works as intended and identify any technical difficulties. After reviewing descriptive summaries of these data with the community advisory committee, we will make any needed intervention refinements before initiating the RCT.

2.6. Phase 3 (RCT)

2.6.1. Study design

Using a Hybrid Type 1 Implementation design [56], we evaluate the intervention's effectiveness and use the RE-AIM framework [57] to collect data relevant to assessing future adoption, implementation, and maintenance potential within the ATHS. The trial will utilize a two-arm, parallel groups, randomized, controlled design (see Fig. 2 for CONSORT Diagram) enrolling a new sample of dyads, each comprised of an ANAI person who smokes (index participant) and a family member (see section 2.3). Before the trial, the study statistician will generate the random allocation sequence enabling randomized dyads with 1:1 allocation to the incentive intervention or no-incentive control condition within *stratified blocks* based on index participant's sex (men/women), location (rural/urban), residence with family member (yes/no), and the family member's current smoking status (yes/no); all potential variables related to treatment outcomes [58,59]. Treatment condition allocation will be unknown to study staff or investigators before assignment, with participants completing baseline measures before being informed of their assignment. The treatment phase is six months. Dyad participants in both study groups will complete study measures at baseline, and 6- and 12-months post treatment, and will be mailed a $25 gift card for completion of each.
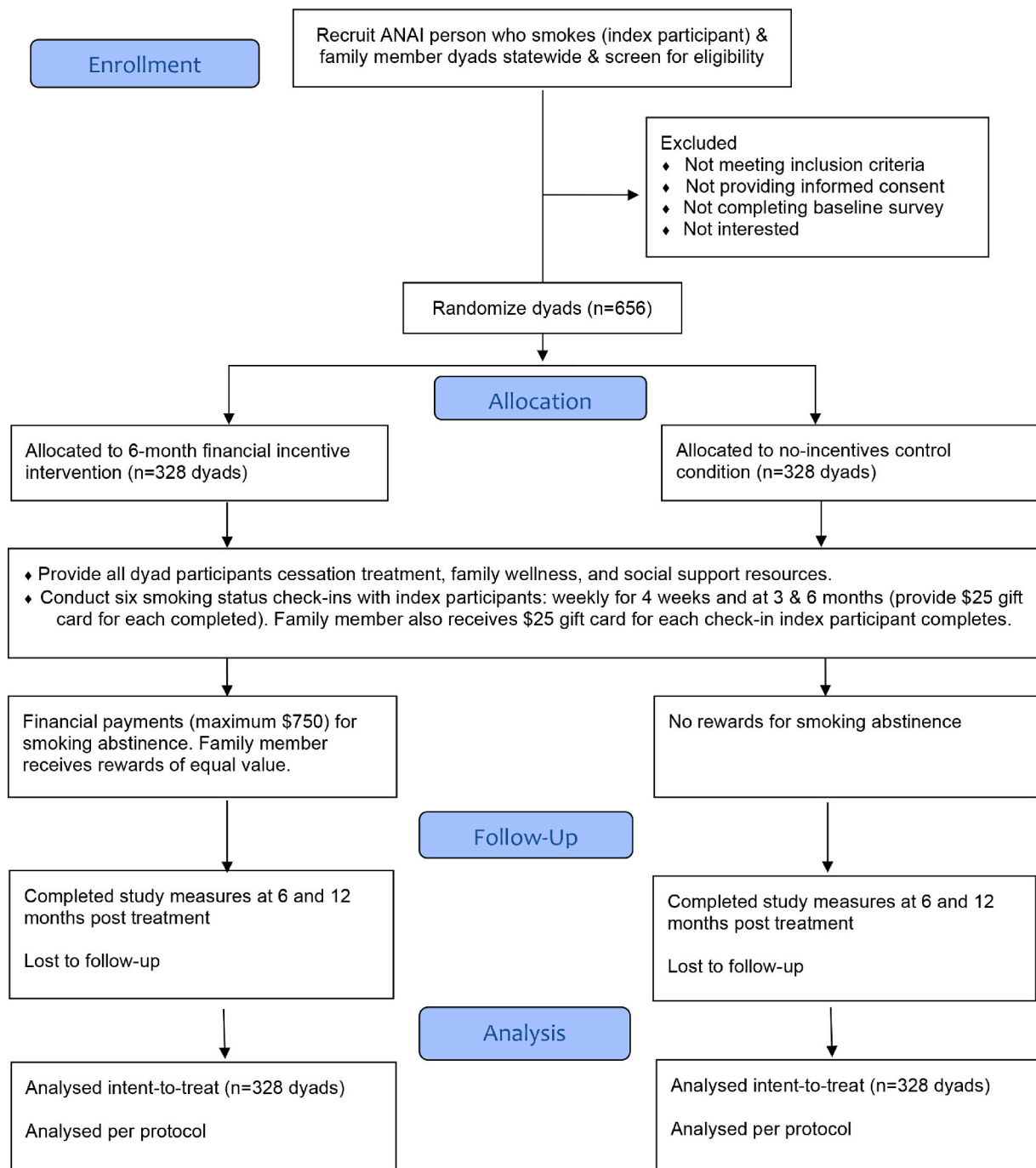
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│  Enrollment  │      │ Recruit ANAI person who smokes (index participant) & │
└──────────────┘      │ family member dyads statewide & screen for eligibility│
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Excluded
- Not meeting inclusion criteria
- Not providing informed consent
- Not completing baseline survey
- Not interested

Randomize dyads (n=656)

Allocation

Allocated to 6-month financial incentive intervention (n=328 dyads)

Allocated to no-incentives control condition (n=328 dyads)

- Provide all dyad participants cessation treatment, family wellness, and social support resources.
- Conduct six smoking status check-ins with index participants: weekly for 4 weeks and at 3 & 6 months (provide $25 gift card for each completed). Family member also receives $25 gift card for each check-in index participant completes.

Financial payments (maximum $750) for smoking abstinence. Family member receives rewards of equal value.

No rewards for smoking abstinence

Follow-Up

Completed study measures at 6 and 12 months post treatment

Lost to follow-up

Completed study measures at 6 and 12 months post treatment

Lost to follow-up

Analysis

Analysed intent-to-treat (n=328 dyads)

Analysed per protocol

Analysed intent-to-treat (n=328 dyads)

Analysed per protocol

Fig. 2. ANAI family-based financial incentive intervention for smoking cessation CONSORT trial design.

2.6.2. Sample size calculation

Our primary outcome is continuous (prolonged) abstinence from the end of the 6-month treatment period to 12 months post treatment. Although family-level rewards could amplify intervention effects, we conservatively based our sample size calculation on three prior trials using individual incentives [12–14]. From these trials, we estimate 3% of our control group will continue to be abstinent from smoking at 12 months post treatment compared to 9% of the intervention group. If we randomly assign 328 dyads to each of the two study arms, the study will have 90% power with two-sided 5% significance to detect the estimated difference between study groups for the primary intent-to-treat (ITT) analysis. Attrition in prior studies ranged from 10% to 20% at 12 months post treatment [12,14]. Assuming 20% attrition (262 dyads per group),

the study would have 82% power for mediational/secondary analyses.

2.6.3. Six-month treatment phase

Dyad participants in both study groups will receive generic, existing resources and referral information on evidence-based tobacco/nicotine cessation treatments (EBCTs), including Alaska's Tobacco Quitline, regional Tribal cessation programs, and smokefree.gov; ANTHC family wellness resources on general health topics (e.g., injury prevention, household air quality); and regional links to programs for domestic violence. Family member participants will additionally receive generic, existing evidence-based tips to support individuals who smoke in cessation [60], including quitting together as a supportive action. Providing resource and referral information is consistent with the

current standard-of-care for tobacco use in the ATHS.

As in Etter and Schmid [12], smoking status check-ins among index participants in both study groups will be conducted six times during the 6-month treatment phase: weekly for the first month, then at three and six months. This incentive schedule reinforces both initial and sustained abstinence. We will obtain biochemical verification of self-reported smoking abstinence remotely using expired air carbon monoxide (CO) and salivary cotinine at each assessment among index participants. Breath CO measurement can verify abstinence within the previous 24 h and salivary cotinine, in the past 6–7 days [30]. All index participants will receive two types of test instruments: the iCO™ Smokerlyzer®, a small, portable, handheld breath CO monitor that connects to a mobile device/tablet and works through a downloaded app, and Alere™ iScreen oral fluid devices with an easy-to-use mouth swab to assess saliva cotinine [61]. Index participants perform the tests and display the results during a video call with study staff or submit pictures of themself through a secure app. In both study conditions, the index participant and family member will each receive a $25 gift card for each of the six smoking status check-ins completed by the index participant, regardless of the test results (i.e., $150 total each for the index participant and family member).

For dyads randomized to the intervention condition, the novel treatment is escalating cash rewards for the index participant achieving biochemically verified cigarette smoking abstinence at smoking status check-ins and the enrolled family member's reward of equal value (see Table 1). At each check-in, index participants will earn a cash reward with self-reported abstinence in the past 7 days and negative tests of breath CO (0–3 ppm) and saliva cotinine <30 ng/ml; or if nicotine replacement therapy (NRT), e-cigarettes, or smokeless tobacco (ST) use is reported with a positive cotinine test, the CO test is negative [30,62]. At each scheduled check-in, each dyad participant will receive a standardized text message from study staff to provide information about the test results and rewards earned (or not earned).

2.6.4. Study measures

Each dyad participant will complete online study measures three times: at baseline and at six and 12 months after the 6-month treatment phase (Table 3). Our outcomes focus on combustible cigarette smoking, based on recommendations from a Society for Research on Nicotine and Tobacco workgroup updating definitions and measurements of abstinence in clinical trials of smoking cessation interventions [30,62]. Biochemically confirmed abstinence from smoking at each follow-up assessment will be defined as self-reported abstinence during the past seven days (not even a puff), with negative breath CO test (0–3 ppm) and negative iScreen OFD test (i.e., saliva cotinine <30 ng/ml); or if NRT, e-cigarettes/vaping, or ST use is reported with positive cotinine test, the CO test is negative [30,62]. Continuous (prolonged) abstinence, our primary outcomes, is defined as self-report of smoking abstinence from the end of the 6-month treatment period to 12 months post treatment, with biochemical verification at three times: the end of the 6-month treatment phase and at 6- and 12-months post treatment.

2.6.5. Implementation process measures

We will use mixed methods to explore RE-AIM process indicators relevant to program reach, adoption, implementation, and setting-level maintenance (Table 4). To evaluate the overall reach and representativeness of participants and intervention effectiveness, we will utilize quantitative data collected in the RCT. To explore factors relevant to future widespread dissemination, we will invite 12 index participants and 12 family members from the intervention group to participate in a semi-structured, individual phone interview at the study end. Individuals will be purposefully sampled to maximize diversity in sex, rural/urban, and intervention "dose" completed. To explore factors relevant to adoption, implementation, and maintenance, we will also conduct interviews with 12 ATHS stakeholders, first inviting the same stakeholders who participated in Phase 1 then recruiting additional

Table 3
Phase 3 (RCT) dyad participant measures.

Measures		Post-treatment follow-up	
	Baseline	6 Months	12 Months
Index participants			
Socio-demographics	X		
Subsistence lifestyle information	X		
Cigarettes per day, time to first cigarette [63]	X		
Other nicotine/tobacco product use	X	X	X
Household tobacco exposure [64]	X		
Communal Orientation Scale [65] (interdependence, cultural mediator)	X	X	
Monetary Choice Questionnaire [66] (delayed discounting, behavioral economics theory-based mediator)	X	X	
Partner Interaction Questionnaire [67] (cessation-specific support received from enrolled family member, mediator)	X	X	
Self-reported cigarette smoking status (past 7 days and since last assessment)		X	X
Expired breath CO (iCO Smokerlyzer) and saliva cotinine (Alere™ iScreen oral fluid test)		X	X
Self-reported cessation treatment utilization		X	X
Quit attempts		X	X
Potential for cross-treatment contamination [68]: self-reported exposure to common components (e.g., resource materials) and unique elements (e.g., rewards for smoking abstinence) across study groups		X	X
Family member participants			
Socio-demographics	X		
Type of relationship with index participant and perceived closeness [69]	X		
Partner Interaction Questionnaire [67] (cessation-specific support provided to index participant)	X	X	X
Self-reported cigarette smoking status, nicotine/tobacco product use (past 7 days and since last assessment)	X	X	X
Self-reported cessation treatment utilization		X	X

stakeholders if needed. We will adapt interview questions from the RE-AIM planning literature [70] and track program delivery costs, thereby identifying implementation barriers and facilitators and support plans for future adaptation and dissemination of the intervention to adopting organizations.

2.6.6. Statistical methods

We will quantitatively describe potential and actual *reach* and use quantitative and qualitative data to evaluate *implementation fidelity* (Table 4). To understand the success of recruitment strategies, we will summarize and compare the numbers screened, eligible, and enrolled by rural/urban location and Alaska region; and compare social media to other advertisements using the chi-square/analysis of variance/Kruskal-Wallis test as appropriate. We will examine baseline demographics of dyad participants to determine any significant differences between intervention and control groups using the chi-square test (categorical variables) and the two-sample t-test/rank-sum test (continuous variables). Outcome criteria will include comparing the percentage of dyad participants completing the 12-month post-treatment measures (i.e., retention) and the proportion of index participants completing all six smoking status check-ins during the 6-month treatment phase (fidelity) between groups using the chi-square test. We will compare time to drop out between study groups using Cox proportional hazards regression and explore differences in the proportion of index participants completing all six smoking status assessments by the stratification factors (index participant's sex, rural/urban location, residence in the same household; and family member's smoking status) using chi square.

To evaluate *effectiveness*, we will summarize the <u>primary outcome</u> of

Table 4
Phase 3 (RCT) implementation process measures and data sources.

RE-AIM OUTCOMES		
Reach	• # and % of the total screened who are aged 21+ years, use tobacco, and identify as Alaska Native or American Indian (based on statewide denominator = 27,212) to gauge future dissemination potential. • Participation rate: # and % of randomized index participants/total eligible. • Reasons for ineligibility • Secondary analysis comparing # and % enrolled from different advertisements and sample representativeness (i. e., sex, Alaska region).	Advertising; screening and enrollment records; Alaska state tobacco surveys, e.g., BRFSS [1], & census data [38]
Effectiveness	Biochemically verified smoking abstinence at 6- and 12-months post treatment. Primary outcome: prolonged abstinence at 12 months post treatment.	See section 2.6.4
Adoption	Descriptive information from potential future adopting settings (Tribal Health Organization #, type, size)	Semi-structured interviews conducted at the end of the study
Implementation (fidelity)	• % of index participants completing all six smoking status check-ins during the 6-month treatment phase, demographic characteristics associated with fidelity, and trial retention of dyads. • Description of potential training, workflow, and resource needs and estimates of start-up; implementation costs for future adopting agencies (see cost-effectiveness, below).	Intervention process data; baseline and follow-up measures; research team meeting minutes; program tracking records; interviews

Potential maintenance	• <u>Individual level</u>: 6- and 12-months post-treatment outcomes.
	• <u>Setting level</u>: index participant, family member, and Alaska Tribal Health System organizational perspectives of intervention and barriers and facilitators to maintenance including:
	  o Alaska Tribal Health System stakeholder buy-in, perceived feasibility, alignment with community and organizational priorities.
	  o Willingness to allocate resources required to maintain the intervention after the trial, staff availability, workflow capability, costs, Tribal Health Organization policies.
		Semi-structured interviews conducted at the end of the study

COST-EFFECTIVENESS		
Potential return on investment	• Actual program delivery costs: incentives and rewards provided per dyad enrolled; gift cards provided per dyad for the six smoking status check-ins completed, research staff time. • Intervention costs per index participant quit at 12 months post intervention and estimated health care savings.	Program tracking records; data/models from the literature [71] on estimated reduction in annual health care costs for cessation

biochemically confirmed continuous (prolonged) smoking abstinence rate among the index participants for each study group (point estimate and 95% CI) and compare the rates between conditions using logistic regression. Using an ITT approach, participants lost to follow-up or lack biochemical confirmation will be classified as smoking. We will use logistic regression to examine condition differences on secondary outcomes: point prevalence smoking abstinence rates, self-reported EBCT utilization, and self-reported abstinence from all nicotine/tobacco product use among the index participants. We will include stratification factors in the model for all regressions to control for their effects and additionally incorporate baseline variables that differ significantly between groups, use of EBCT, change in enrolled family member, and any observed cross-treatment contamination effects. To assess mediation (e. g., Communal Orientation Scale), we will follow procedures suggested by MacKinnon [72], fitting three regression models to the data. Using logistic regression, an exploratory analysis will examine potential treatment effects among enrolled family members by current smoking at baseline (yes/no).

We will analyze qualitative interview data for themes related to future *adoption, implementation,* and *maintenance* of the intervention using content analysis [55] supplemented with QSR NVivo software, including coding for barriers, facilitators, priorities, and feasibility.

Return on investment will assess *cost-effectiveness.* We will evaluate program delivery costs, including gift cards and incentives/rewards, and staff time for intervention implementation on a per-person basis. Because duration of follow-up (one year) will be insufficient to measure differences in smoking-related healthcare costs between the intervention and control groups, annual per-person healthcare costs associated with smoking abstinence will be estimated from the literature [1,71,73, 74]. We will apply these cost data and the difference in abstinence rates between study groups to estimate the net cost savings from implementing the proposed intervention [75]. The estimates will be projected to the larger ANAI population size and extended time frame in the short to mid-term, incorporating sensitivity analyses on cost savings for a change in smoking abstinence rates [74,75].

3. Results

Over four years, the ANAI community advisory committee provided input on our study idea, design, and methods, particularly emphasizing the involvement of families. Members also contributed to the intervention components (e.g., types of family-level rewards), the definition of family, family member selection and inclusion criteria, and recruitment messaging (see Supplemental Table S1). Importantly, we iteratively refined aspects of the study to incorporate this feedback and repeatedly shared with committee members how their feedback was used to revise the study methods.

4. Discussion

This study addresses a need identified by ATHS leaders for novel, accessible, and effective smoking cessation interventions. This trial is the first incentive intervention for commercial smoking cessation among Indigenous people. Our study aligns with the strength and value ANAI people place on family. Findings, processes, and resources will inform how Indigenous families can support smoking cessation within incentive interventions.

Study strengths are the participatory approach, formative work to culturally tailor and adapt the intervention, and virtual delivery of the intervention and study procedures. Including process indicators to inform future intervention adoption, implementation, and maintenance, as well as the cost analysis, will identify strategies for future dissemination. Our study will contribute knowledge to the field on the importance of the family member's smoking status on cessation outcomes.

Study limitations are the RCT is not designed to evaluate the effectiveness of individual versus family-level financial incentives or

distinguish between familial social support and family-level incentives. However, prior studies confirm individual and group-based incentive programs are equally effective [13,21], and a family approach aligns with ANAI cultural values-important considerations for future acceptance and adoption. The study is limited to adults aged 21 and older but we plan to expand the inclusion of other age groups in future work. While our sample is restricted to ANAI people in Alaska, the intervention has potential for application to other Indigenous communities aiming to focus on commercial tobacco use.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Unrelated to this project, Dr. Prochaska has provided consultation to pharmaceutical and technology companies that make medications and other treatments for quitting smoking. Dr. Prochaska also has served as an expert witness in lawsuits against tobacco companies. The authors reported no other potential conflict of interest.

Data availability

No data was used for the research described in the article.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101129.

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