

BMJ Open Stepwise strategy to improve Cervical Cancer Screening Adherence (SCAN-CC): automated text messages, phone calls and face-to-face interviews: protocol of a population-based randomised controlled trial

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ABSTRACT

Introduction Screening is highly effective for cervical cancer prevention and control. Population-based screening programmes are widely implemented in high-income countries, although adherence is often low. In Portugal, just over half of the women adhere to cervical cancer screening, contributing for greater mortality rates than in other European countries. The most effective adherence raising strategies are based on patient reminders, small/mass media and face-to-face educational programmes, but sequential interventions targeting the general population have seldom been evaluated. The aim of this study is to assess the effectiveness of a stepwise approach, with increasing complexity and cost, to improve adherence to organised cervical cancer screening: step 1a—customised text message invitation; step 1b—customised automated phone call invitation; step 2—secretary phone call; step 3—family health professional phone call and face-to-face appointment.

Methods A population-based randomised controlled trial will be implemented in Portuguese urban and rural areas. Women eligible for cervical cancer screening will be randomised (1:1) to intervention and control. In the intervention group, women will be invited for screening through text messages, automated phone calls, manual phone calls and health professional appointments, to be applied sequentially to participants remaining non-adherent after each step. Control will be the standard of care (written letter). The primary outcome is the proportion of women adherent to screening after step 1 or sequences of steps from 1 to 3. The secondary outcomes are: proportion of women screened after each step (1a, 2 and 3); proportion of text messages/phone calls delivered; proportion of women previously screened in a private health institution who change to organised screening. The intervention and control groups will be compared based on intention-to-treat and per-protocol analyses.

Ethics and dissemination The study was approved by the Ethics Committee of the Northern Health Region Administration and National Data Protection Committee. Results will be disseminated through communications in scientific meetings and peer-reviewed journals.

Strengths and limitations of this study

- Randomised controlled trial, using a stepwise approach, with increasing complexity and cost of interventions, to improve adherence to organised cervical cancer screening.
- Interventions tested are technological and innovative.
- Use of a population-based approach and not specific groups or minorities.
- Contamination of interventions may occur, because randomisation units are individuals and not primary care units.
- Unavailability of women's mobile phone may restrict intervention delivery.
- The study is restricted to women aged below 50 years, and therefore the findings may not apply to older women with limited digital literacy skills.

Trial number NCT03122275

INTRODUCTION

Cancer is one of the most important causes of morbidity and mortality, especially in high-income countries.¹ A substantial part of cancer cases can be detected earlier and undergo treatment with curative intent.² Improvements in early detection of cancer may be achieved through increases in population awareness, enabling early consultation with health professionals, and screening programmes.² Cervical cancer screening is one of the oldest and most effective screening programmes, with relevant decreases in mortality since its implementation.³ Although the increasing coverage of vaccination against high-risk human papillomavirus strains is expected to play a major role in the prevention of cervical

cancer,⁴ screening will still be needed, at least for non-vaccinated women and high-risk groups. With the expected decrease in the number of women eligible for screening, cost reduction, including variable costs (invitation and screening), may be needed to guarantee sustainability.

Currently, in Portugal cervical cancer screening is recommended to be performed every 5 years, for women aged between 25 and 65 years.⁵ Women registered at a primary care unit are invited to perform cervical cancer screening through a written letter. At a national level, just over half⁹ of the invited women adhere to the cervical cancer screening and 23.5%⁶ have never performed screening during life. Limited adherence to screening is expected to contribute to greater cervical cancer mortality rates in Portugal (age-standardised mortality rate: 4.9/100 000),⁷ in comparison with the average in Europe's rate (27 countries, age-standardised mortality rate: 3.7/100 000).⁷

Different strategies to increase adherence to cervical cancer screening have been developed and evaluated, including interventions based on patient reminders (written letters,⁸⁻¹³ operator-dependent phone calls^{11 12 14 15} or text messages¹⁶), small media¹⁷⁻²⁰ (videos, brochures, pamphlets or fact sheets), mass media²¹ and face-to-face educational programmes.^{20 22}

Results from a systematic review,²³ including studies conducted in high-income countries, enrolling both deprived and non-deprived women, show overall increases in cervical cancer screening adherence of just over 10% with printed or phone reminders, and 4% and 8% when using small media or one-on-one education, respectively. Regarding the strategies based on the use of reminders, phone calls are more effective and cost-effective (37% uptake, costing US\$67/response) than text messages (24% uptake, costing US\$100/response) or written letters (19% uptake, costing US\$133/response).¹⁶ To our knowledge, no automated (machine performed) and customised phone calls have been used or compared with other methods. Additionally, text messages have been tested as cervical cancer screening reminders or invitation methods,¹⁶ but with no patient customisation or built-in mechanisms for reply to the messages. This method was tested as appointment reminders in hospitals²⁴ and primary healthcare services,²⁵ with 10% increases in adherence to scheduled appointments, but also as part of obesity control programmes.²⁶ Some of these programmes allow for patient interaction, enabling them to make a data input on their health status or simply reply after receiving the intervention.²⁶ This bidirectional approach could be used for cancer screening invitation and appointment scheduling, by allowing the invited people to confirm their interest to be screened, using a text message or a reply to an automatic phone call. A recent systematic review on the use of automated telephone communication systems highlighted the effectiveness of unidirectional/bidirectional phone-delivered interventions on the uptake increase of screening programmes.²⁷

Educational programmes aiming to increase adherence to cervical cancer screening have been implemented using face-to-face interventions with trained professionals,^{20 22} sometimes using support videos or pamphlets²⁰ or delivered through motivational phone call.²⁸ These programmes are highly tailored to each patient, and therefore difficult to implement at a population level, because these are resource-intensive activities. In a population-based approach, a multistage intervention is needed, implementing first, cheaper and easier-to-use interventions such as text messages and automated phone calls. Women refractory to these strategies should receive more expensive and patient-tailored interventions such as phone calls performed by trained professionals as reminders or face-to-face appointments to provide information on cervical cancer screening. Most of the interventions described in the literature target only deprived populations^{8 15 18} or from an ethnic group/social minorities^{15 18 19 29} and only a few cases use multistage approaches, where different interventions (written letter invitation, written letter reminder, phone call reminder) were sequentially applied till women adhere to screening.⁸

Objectives

The aim of this study is to assess the effectiveness of a stepwise approach, with increasing complexity and cost, to improve adherence to organised cervical cancer screening, in relation to the standard of care (invitation by written letter), implemented through three steps:

Step 1a: customised text message invitation;

Step 1b: customised automated phone call invitation;

Step 2: secretary phone call;

Step 3: health professional phone call and face-to-face appointment.

As primary objectives, we intend to test the superiority of the intervention based on step 1 (1a+1b), and multistage interventions based on steps 1 and 2, and steps 1–3. The secondary objectives will be the following:

1. To test the non-inferiority of interventions based on step 1a and step 1 (1a+1b), considering a non-inferiority limit of 5%;
2. To test the superiority of the specific components of the multistage intervention corresponding to step 2 and step 3;
3. To quantify the differences in adherence to cervical cancer screening, for the intervention based on step 1 (1a+1b) and multistage interventions based on steps 1 and 2, and steps 1–3, between: a) urban and rural areas; b) younger and older populations; c) deprived and non-deprived populations; d) never versus ever users of organised screening; e) history of regular versus irregular participation in organised screening programmes.
4. To quantify the differences in adherence to cervical cancer screening when using a positive or a neutral content of text messages and automated phone calls, in step 1.

5. To estimate the proportion of women who were undergoing performing cervical cancer screening in private healthcare services who started to be screened in an organised cervical cancer screening programme, after a health professional face-to-face appointment at their primary care unit.

Intention-to-treat analysis will be used as primary strategy for all comparisons between interventions and control. Secondary per-protocol analysis will also be conducted.

The current interventions intend to be inexpensive and easy to implement so they can be used both in high-income and low-income countries, at a population level, as strategies to increase the adherence to cervical cancer screening.

METHODS AND ANALYSIS

Setting

The study will be conducted among women with a medical registration at two primary healthcare areas in the north of mainland Portugal, namely *Porto Ocidental*, serving densely populated urban areas near the coast, and *Marão e Douro Norte*, located inland, covering scarcely populated and predominantly rural areas. These were selected because they have low adherence to cervical cancer screening: 32% for *Porto Ocidental* and 61% for *Marão e Douro Norte*.³⁰

Design

This investigation is based on a population-based randomised controlled trial, with a parallel design, as depicted in figure 1.

Women eligible for cervical cancer screening will be randomised 1:1 within each primary healthcare unit.

The intervention will comprise invitation to screening, through the following sequential steps:

Step 1: automated text messages (step 1a)/automated phone calls (step 1b);

Step 2: manual phone calls performed by secretaries, implemented 1–2 months after step 1, among women remaining non-adherent 1 month after step 1;

Step 3: health professional phone call and appointments, implemented 1–2 months after step 2, among women remaining non-adherent 1 month after step 2.

Intervention stops whenever the participants adhere to organised screening or after undergoing the whole intervention. Control will be the standard of care (invitation by written letter).

Participants

Inclusion criteria

- Women aged between 25 and 49 years, and eligible for cervical cancer screening (having started sexual activity, not hysterectomised, not undergoing cervical cancer treatment);
- Medical registration at any of the primary healthcare units selected for this study.

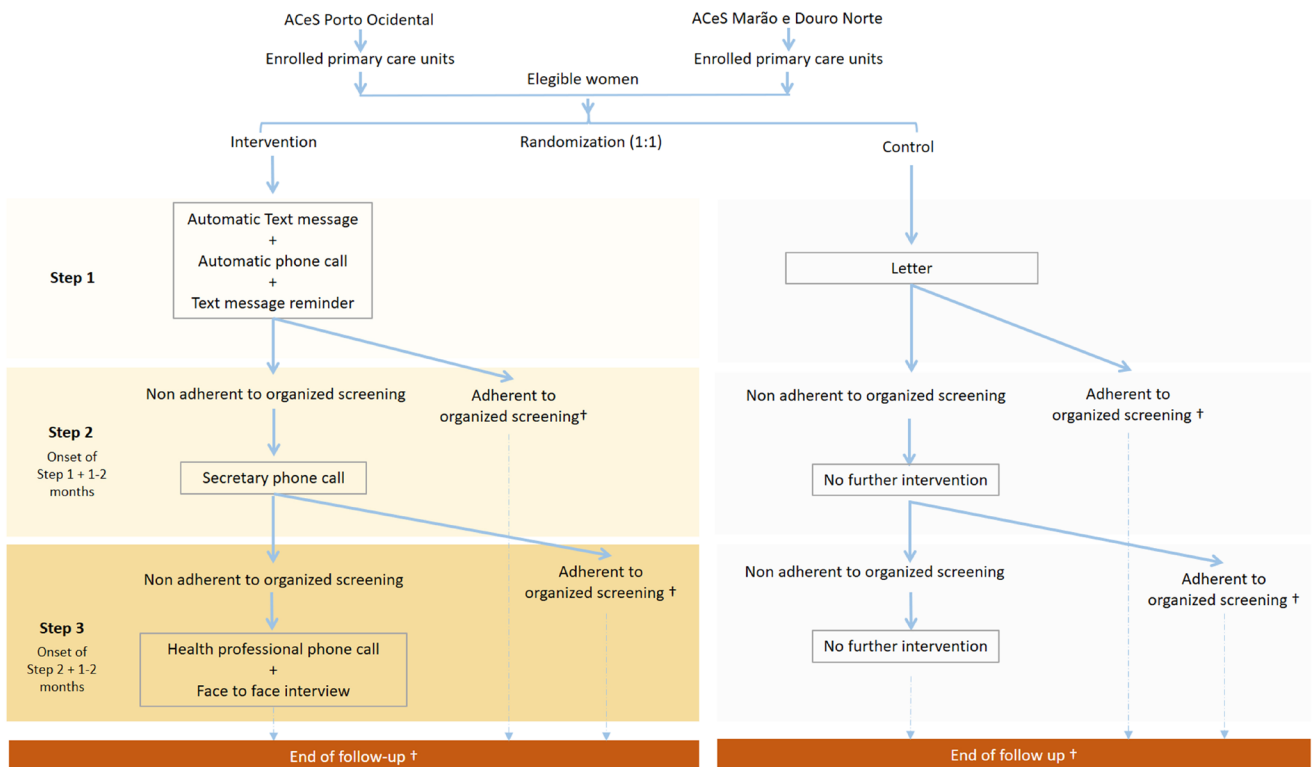


Figure 1 Study design of the stepwise strategy to improve cervical cancer screening adherence. *Outcome assessment.

Although cervical cancer screening programmes are recommended for women with ages till 65 years, will only be considered for this study those younger than 50 years, who are expected to have higher levels of digital literacy, and therefore more likely to benefit from this type of intervention. Nevertheless, this may limit the possibility of generalising our findings to older women who are less proficient in the use of mobile technology.

Exclusion criteria

No mobile phone number available at the National Health Service database.

Intervention

The intervention comprises different strategies for invitation to cervical cancer screening, to be applied sequentially, in three steps.

Step 1 (1a+1 b): automated text messages/phone calls

Women randomised to the intervention arm will be assigned a date and hour for screening by the primary healthcare unit secretaries, who will then upload the women's phone number, first and last name, name of the primary care unit and appointment date/hour in the software selected for implementation of step 1: File-2Mail V.2.2, Smart IVR V.1.1, Smart Message V.3.1 and Speech2Go V.1.1. Personalised text messages (step 1a), with a maximum length of 320 characters, and phone calls (step 1b), with a maximum duration of 30s, will then be automatically assembled and sent to the study participants.

When a screening invitation is accepted, either in step 1a or step 1b, a text message reminder will be sent to women 24–48 hours before the appointment (figure 2 reminder message).²⁵

Step 1a: automated text messages

Two models of invitation text message will be randomised 1:1 within each primary healthcare unit (figure 2); invitation message 1 has a neutral style (close to the usual written invitation letter) and invitation message 2 has a gain-frame and positive style of writing.³¹ The content validity of the invitation messages was tested among a few potentially eligible women, and modifications were implemented, namely the name of the primary care unit and information stating that the appointment has no copayments was added to the original text message.

Women are asked to confirm their interest to undergo cervical cancer screening at the proposed date and time, answering the invitation with a text message saying 'CONFIRM'. If they do not confirm within 24 hours, they will additionally receive an automated phone call (step 1b).

Step 1b: automated phone calls

A phone call invitation will be performed in after-hours period (17–20 hours), using a humanised female voice, and follows the same structure of the text messages (figure 2 and figure 3 invitation phone call 1 and 2). Women will receive phone call 1 if they do not answer the invitation message 1 and receive phone call 2 if they did not answer the invitation message 2.

Women are asked to press the number 1 for appointment confirmation or the number 2 if they want to receive a phone call from the primary care unit secretary. The audio message will be repeated three times in the same call, or until women provide the feedback required.

If women do not answer the phone call or do not press the number 1 or 2, a new automated phone call will be scheduled for the next day, for a maximum of 3 days (figure 3).

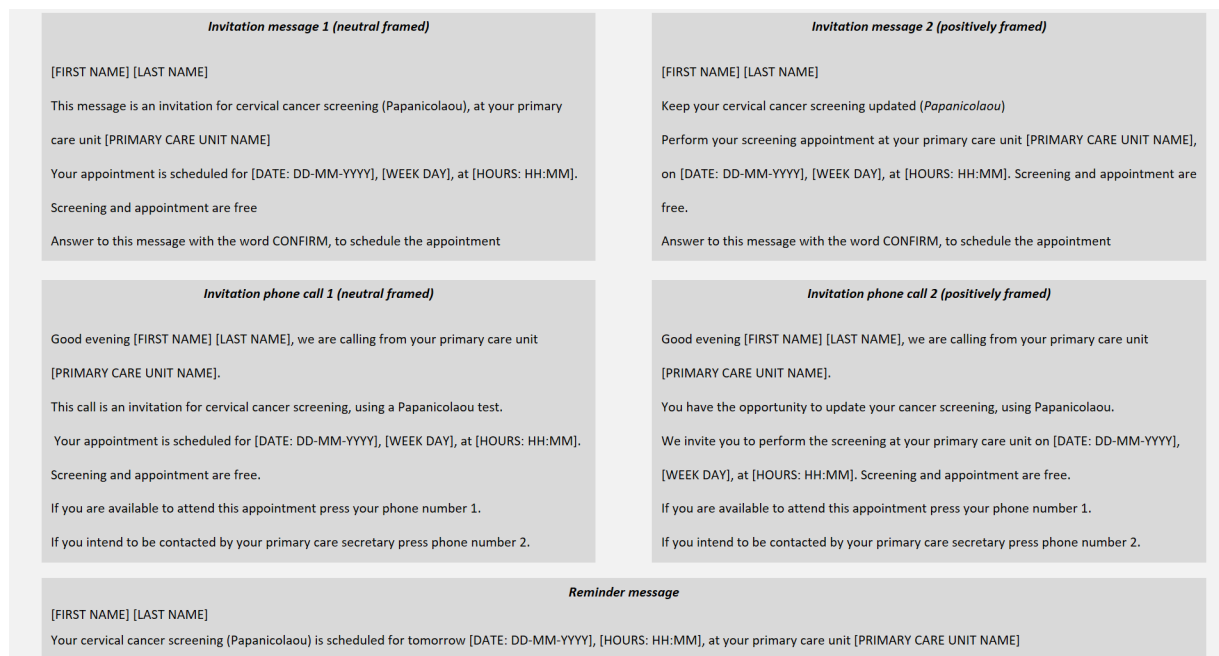


Figure 2 Content for text messages and phone calls.

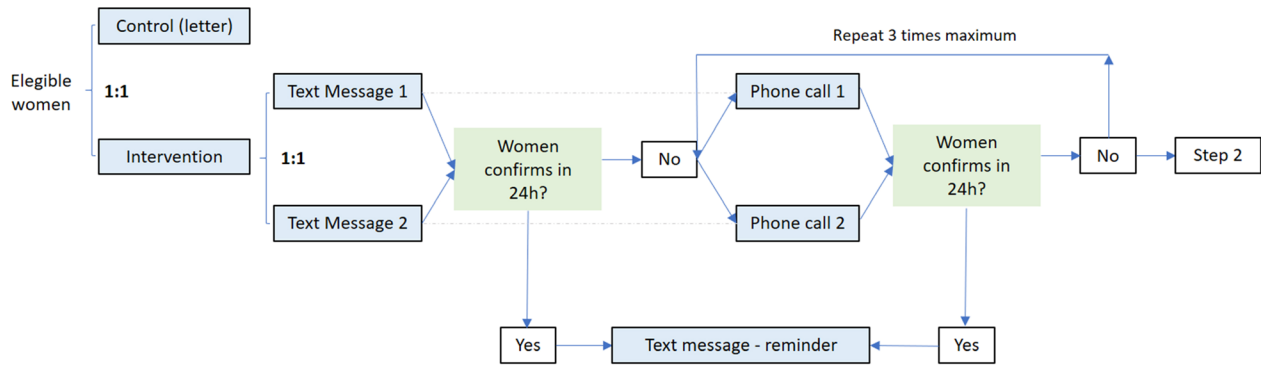


Figure 3 Flow of step 1 interventions: written letter, text messages and automated phone calls.

Step 2: secretary phone call

Women who do not confirm the appointment in step 1 or do not attend organised cervical cancer screening are enrolled in step 2. This comprises an invitation phone call performed in after-hours period (17–20 hours), by the secretary of the corresponding primary care unit. Secretaries will be trained by the research team and will follow a predefined script (see online supplementary appendix 1). If women do not answer the call, it will be repeated daily, for a maximum of 3 days. A date and hour for cervical cancer screening will be scheduled for women who agree to participate.

Step 3: health professional phone call and face-to-face appointment

Women who do not answer the phone during step 2, or do not participate in organised cervical cancer screening after the scheduled appointment, will be enrolled in step 3. This comprises a phone call and a face-to-face appointment performed by a health professional from the primary care unit (family nurses or resident medical doctors), specifically trained for this step of the intervention. Phone calls will be performed in after-hours period (17–20 hours), aiming to schedule an appointment, using a predefined script (see online supplementary appendix 2). If women do not answer the call, it will be repeated daily, for a maximum of 3 days. During appointments, screening will be described and doubts clarified using the standard North Portugal cervical cancer screening pamphlet. Health professional will identify possible barriers felt by women and will try to overcome them using predefined arguments (see online supplementary appendix 3). Additionally, women who agree to participate will be screened after the interview or scheduled for another date, defined according to their and the Service's convenience.

Outcomes

The primary outcome is defined as follows:

Adherence to cervical cancer screening

Proportion or cumulative proportion of women who performed cervical cancer screening on the scheduled date, among those who were invited, after step 1 or sequences of steps from 1 to 3, as applicable.

The secondary outcomes are defined as follows:

Adherence to cervical cancer screening (steps 1a, 2 and 3)

Proportion of women who performed cervical cancer screening on the scheduled date, among those who were invited, after step 1a, after step 2 or after step 3.

Text message status

Proportion of text messages received with confirmation, from those that were sent.

Automated phone call status

Proportion of automated phone calls delivered, from those that were attempted.

Change from opportunistic to organised screening

Proportion of women undergoing opportunistic cervical cancer screening in a private health institution who change to organised cervical cancer screening.

The index dates for adherence assessment will be the following: (1) the day after the appointment date, for text message invitation, secretary phone calls and written letters; (2) 2 months after the intervention based on face-to-face interviews conducted by health professionals.

Sample size

Sample size was estimated considering the use of two-sided tests, for a significance level of 5% and a statistical power of 90%, intending the comparison of intervention and control groups regarding the outcomes defined as part of the primary objective.

Step 1 (1a+1 b)

We estimate an adherence to screening based on invitation through a written letter of 40% (based on SiiMA

Rastreios *software*: Portuguese software for cancer screening), and we intend to detect an increase to 50% with the intervention based on step 1. We expect this 10% increase because two different techniques of invitation will be used (text message and automated phone call) and an electronic reminder will be sent 24 hours prior to the appointment.²³ The minimum sample size determined for each group is 519 women.

Steps 1 and 2

We expect a 45% cumulative adherence proportion in the control group, after the interventions based on steps 1 and 2; an increase in relation to the expected adherence in the control group after steps 1, from 40% to 45%, may be anticipated because for step 2 there will be a longer period between baseline and outcome assessment. We expect a cumulative adherence proportion of 60% in the intervention group, which is a conservative estimate, considering the published effectiveness of phone calls.^{11 12} The minimum sample size determined for each group is 244 women.

Steps 1–3

We expect 50% and 70% cumulative adherence proportion in the control and intervention groups, respectively after the interventions based on steps 1–3. In the control group, an increase in comparison to the expected adherence after steps 2, from 45% to 50%, may be anticipated due to the longer period between baseline and outcome assessment. The magnitude of increase in adherence in the intervention group was estimated based on the previously observed effectiveness of face-to-face appointments in other settings.²⁰ The minimum sample size determined for each group is 134 women.

The overall sample size needed is 1038 (519×2), determined by step 1 interventions, since the remaining primary outcomes require a smaller sample size. Nevertheless, a 10% greater number of participants will be recruited to account for the potential withdrawal of one healthcare unit before the completion of the stepwise intervention. We anticipate that the drop-out rate of individual participants will be lower than 1%, during the steps 2 and 3 of the intervention; this low value is expected because we will use an opt-out strategy, so that only women who actively express their willingness for not receiving further interventions are considered as dropouts.

The statistical analysis for accomplishment of secondary objectives are exploratory and therefore the sample size was not determined to consider them. Nevertheless, the sample size defined for the study is expected to have enough power to test the superiority of the isolate effect of step 1b, step 2 or step 3. Additionally, the sample size is also enough to test non-inferiority secondary objectives, assuming one-sided tests, a significance level of 2.5%, power of 90%, an adherence proportion in control group of 40% and 50% in experimental group and a non-inferiority limit of 5%.

Randomisation

Women will be randomised 1:1 into the intervention or control groups (figure 1). A woman randomised to the intervention or control will belong to that study arm until the end of the study. Primary care units will extract a list of eligible women for screening, fulfilling study criteria, from SiiMA Rastreios *software* (national software for cancer screening eligibility). Principal investigator will generate the randomisation sequence through a newer version of Excel Office 365. All women registered and fulfilling eligibility criteria will be assigned to intervention or control by the primary care unit secretaries. If a woman is randomised to the intervention group, she will be randomised again to receive a neutral or a positively framed invitation text message/automated phone call on a 1:1 ratio (figure 3). There will be no blinding of the participants, health professionals or elements of the research team.

Contamination is possible, especially because screening can be obtained for free in both groups and women exposed to interventions may live geographically near women belonging to control group. Therefore, the participation of women from the intervention arm may influence the adherence of women in the control group. Contamination will dilute the effect of the interventions to be tested, and all the effectiveness estimates computed will be conservative. Although we cannot accurately predict the extent of the contamination, we may speculate that it will increase with the complexity of the interventions, being higher for step 3 than for step 1. Zip-code randomisation would contribute to minimise contamination, but it would not be feasible due to the unavailability of complete zip-codes on SiiMA Rastreios. We did not opt for randomisation of primary care units because the number of randomisation units available is low.

Data collection

Information about adherence to cervical cancer screening after interventions or standard of care (invitation letter) will be obtained using the national software for cancer screening eligibility—SiiMA Rastreios. This platform will also be used to collect data about women's previous participation in cervical cancer screening.

Patient appointment confirmation obtained from text messages and phone calls will be saved directly by the software into the study laptop database.

Sociodemographic characteristics, including age, education level, parity, marital and employment status and type of job will be manually extracted from the electronic medical record (EMR). Age and parity will be collected as continuous variables and all the others as categorical. Education level will comprise the categories lower than 9 years of education, 9–11 years, 12 or more years. Marital status will be coded as single, married or divorced. Employment status will be defined as student, employed, unemployed or retired and the occupation as upper white collar, lower white collar, high skilled blue collar and low skilled blue collar.

All the information written in the database will be pseudo-anonymised, using a unique identifier and only the principal investigator will have the encryption key. Only members of the research team will have access to the database. All medical data will be collected from EMR by medical doctors belonging to the research team.

Statistical analysis

Intention-to-treat analysis will be used as the primary strategy for all comparisons between interventions and control. Two secondary per-protocol analyses will also be conducted, considering only the following subsets of participants:

1. women who receive the invitation
 - experimental arm: women who receive a text message/phone call, as confirmed by the software used for automated delivery of the intervention
 - control arm: women who received a written letter, that is, no invitation letter returned
2. women who have an appointment scheduled:
 - experimental arm: women who confirm the appointment by replying to the text message or automatic phone call invitation
 - control arm: women assumed to have received the invitation letter with the appointment scheduled, that is, letter not returned.

Adherence proportions will be determined for step 1a, step 1b, step 1a+1b, step 2, step 3 and sequences of steps from 1 to 3. Differences of adherence proportions between the intervention and control groups will be tested using χ^2 test or Fisher's exact test as appropriate. Binary logistic regression may be used to control for confounding, or in secondary analyses of the isolate effects of steps 1b, 2 and 3. Adherence to screening will be considered as the dependent variable. Independent variables will include study arm and potential confounders selected among age, education, marital status, number of children, employment status, type of living area (rural vs urban), previous adherence to cervical cancer screening and deprivation index.

Additionally, a stratified analysis will be performed, using as strata variables age (high vs low), rurality (rural vs urban), deprivation (deprived vs non-deprived), regularity of previous participation (regular vs irregular participation) and previous participation (ever vs never participation).

Missing data are expected to be low for all the variables obtained from medical records, because they are collected on a regular basis by all general practitioners during appointments, using a structured entry form. No imputation of missing data is being planned.

All tests are two-tailed, with a *p* value of 0.05 indicating statistical significance for superiority objectives or one-tailed with a *p* value of 0.025 for non-inferiority objectives.

Ethics and dissemination

This study was approved by Portuguese regional ethics committee—*Comissão de Ética da Administração Regional de Saúde do Norte* (number: 20/2017) and by National Data Protection Committee (number: 11467/2016). The trial was registered and assigned the number NCT03122275.

For step 1 interventions (automated text messages/phone calls) obtaining an informed consent is not feasible, however, we consider that the benefits for participants and society outweigh the ethical aspects raised and the ethics committee recognised it. Women participating or not will not influence access and type of healthcare provided.

In steps 2 and 3, the secretaries or health professionals will explain the study and obtain verbal informed consent during the phone calls. In step 3, the health professionals will obtain written informed consent from all participants undergoing this step of the intervention.

All the software used to perform automated text messages and phone calls follow the Health Insurance Portability and Accountability Act protocol and article number 8 of the European Convention of Human Rights.

A manuscript addressing the primary objective of this trial will be submitted for publication in a peer-reviewed journal. Additional manuscripts will be submitted for publication, intending to answer the secondary objectives. Communications in national and international scientific meetings are also expected. Technical reports will be made available to the primary care units and institutions involved in this study.

Contributors All the authors of the manuscript follow the four criteria of authorship defined by ICMJE. A description of responsibilities/author can be found below: JâF-M. Protocol responsibilities: conceptual design of the research project, drafted the first version of the protocol manuscript and final manuscript production. Study implementation responsibilities: responsible for study presentation and enrolment of all primary care units, intervention implementation, data collection and analysis and manuscript writing. RM. Protocol responsibilities: conceptual design of the research project and critical review of the manuscript. Study implementation responsibilities: responsible for study presentation and enrolment of the primary care units from ACeS Marão e Douro Norte, intervention implementation and data collection. AêM. Protocol responsibilities: conceptual design of the research project and critical review of all protocol drafts. Study implementation responsibilities: responsible for study presentation and enrolment of the primary care units from ACeS Porto Oriental, intervention implementation. NL. Protocol responsibilities: conceptual design of the research project and critical review of all versions of the manuscript. Study implementation responsibilities: responsible for the supervision of the study implementation, data collection and analysis and writing of the manuscripts. All the authors gave a final approval of the version to be published and agreed to be accountable for all aspects of the work.

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Competing interests None declared.

Ethics approval Comissão de Ética da Administração Regional de Saúde do Norte (number 20/2017) and Portuguese National Data Protection Committee (number 11467/2016).

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