

Supplementary Materials

Improving participation in breast cancer screening through a tailored reminder letter: a randomized controlled trial tackling socioeconomic inequities

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Table 1 - CONSORT 2025 checklist for RCT reporting

Section / Topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	1,2
	1b	Structured summary of the trial design, methods, results, and conclusions	1
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	1,10
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	10
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	10
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	10
	5b	Financial and other conflicts of interest of the manuscript authors	10
Introduction			
Background and rationale	6	Scientific background and rationale	2
Objectives	7	Specific objectives related to benefits and harms	2
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	3
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	2,3,4
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	5
Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	3
Eligibility criteria	12a	Eligibility criteria for participants	3
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	3
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	3,4

Outcomes	14	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	4,5
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	3
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	4,5
	16b	Explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	4,5
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	4,5
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	4,5
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	4,5
Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	4,5
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	5
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	5
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	5
	21c	How missing data were handled in the analysis	5
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	5
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	6
	22b	For each group, losses and exclusions after randomisation, together with reasons	6
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	4
	23b	If relevant, why the trial ended or was stopped	NA
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])	4,5,6
	24b	Concomitant care received during the trial for each group	NA
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	6
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: the number of participants included in the analysis	6,7,8

		- the number of participants with available data at the outcome time point - result for each group, and the estimated effect size and its precision (such as 95% confidence interval) - for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	NA
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	7,8, Supplementary
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8,9
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	9

Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123.
<https://dx.doi.org/10.1136/bmj-2024-081123>.

Table 2 - Effect of the reminder letter by characteristics of study population (ITT)

Intention-to-treat (ITT)		BC screening participation		Absolute increase	OR (95%CI)	p value
		Control group (n = 3,968)	Intervention group (n = 3,954)			
		373 (9.40%)	624 (15.78%)	+ 6.38%	1.81 (95%CI 1.58-2.07)	< .001
Age group	51-54	210 (14.85%)	338 (23.95%)	+ 9.10%	1.81 (95%CI 1.49-2.19)	< .001
	55-59	94 (9.11%)	139 (13.79%)	+ 4.68%	1.6 (95%CI 1.21-2.11)	< .001
	60-64	51 (5.34%)	93 (9.87%)	+ 4.53%	1.94 (95%CI 1.36-2.77)	< .001
	65-69	18 (3.17%)	54 (9.11%)	+ 5.93%	3.06 (95%CI 1.77-5.28)	< .001
Province	Antwerp	92 (9.40%)	158 (16.07%)	+ 6.68%	1.85 (95%CI 1.4-2.43)	< .001
	Limburg	62 (10.97%)	116 (21.21%)	+ 10.23%	2.18 (95%CI 1.56-3.05)	< .001
	East-Flanders	105 (10.04%)	161 (15.38%)	+ 5.34%	1.63 (95%CI 1.25-2.12)	< .001
	Flemish-Brabant	58 (9.63%)	86 (14.17%)	+ 4.53%	1.55 (95%CI 1.09-2.21)	0.015
	West-Flanders	56 (7.22%)	103 (13.38%)	+ 6.16%	1.99 (95%CI 1.41-2.8)	< .001
Mammo-graphic unit	Hospital	163 (9.47%)	263 (15.40%)	+ 5.93%	1.74 (95%CI 1.41-2.14)	< .001
	Mobile unit	78 (9.23%)	122 (14.35%)	+ 5.12%	1.65 (95%CI 1.22-2.23)	0.001
	Private radiologist	132 (9.42%)	239 (17.12%)	+ 7.70%	1.99 (95%CI 1.58-2.49)	< .001

Note: Counts in the intention-to-treat and per-protocol analyses are derived from separately aggregated datasets.

Table 3 - Effect of the reminder letter by characteristics of study population (PP)

Per protocol (PP)		BC screening participation		Absolute increase	OR (95%CI)	p value
		Control group (n = 3,632)	Intervention group (n = 3,545)			
		371 (10.21%)	613 (17.30%)	+ 7.08%	1.84 (95%CI 1.6-2.11)	< .001
Age group	51-54	210 (16.23%)	331 (26.12%)	+ 9.90%	1.83 (95%CI 1.5-2.22)	< .001
	55-59	94 (9.80%)	136 (15.23%)	+ 5.43%	1.65 (95%CI 1.25-2.19)	0.001
	60-64	49 (5.71%)	93 (10.90%)	+ 5.19%	2.02 (95%CI 1.41-2.9)	< .001
	65-69	18 (3.45%)	53 (9.96%)	+ 6.51%	3.09 (95%CI 1.79-5.35)	< .001
Province	Antwerp	92 (10.24%)	152 (17.72%)	+ 7.47%	1.89 (95%CI 1.43-2.49)	< .001
	Limburg	61 (11.55%)	114 (22.53%)	+ 10.98%	2.23 (95%CI 1.59-3.12)	< .001
	East-Flanders	104 (11.03%)	158 (16.99%)	+ 5.96%	1.65 (95%CI 1.27-2.15)	< .001
	Flemish-Brabant	58 (10.47%)	86 (15.47%)	+ 5.00%	1.56 (95%CI 1.1-2.23)	0.013
	West-Flanders	56 (7.90%)	103 (14.83%)	+ 6.92%	2.03 (95%CI 1.44-2.86)	< .001
Mammo-graphic unit	Hospital	162 (10.30%)	258 (16.93%)	+ 6.62%	1.77 (95%CI 1.44-2.19)	< .001
	Mobile unit	78 (9.92%)	118 (15.26%)	+ 5.34%	1.64 (95%CI 1.21-2.22)	0.001
	Private radiologist	131 (10.28%)	237 (18.99%)	+ 8.70%	2.05 (95%CI 1.63-2.57)	< .001

Note: Counts in the intention-to-treat and per-protocol analyses are derived from separately aggregated datasets.

Table 4 - SES stratified effect of the reminder letter by characteristics of study population (ITT)

Intention-to-treat (ITT)		BC screening participation		Absolute increase	OR (95%CI)	p value
		Control arm (n = 3,773)	Intervention arm (n = 3,771)			
Non-eligible for VT (n = 5,507)		301 / 2,561 (11.75%)	499 / 2,946 (16.94%)	+ 5.18%	1.53 (95%CI 1.31-1.79)	<0.001
Age group	51-54	117 (25.32%)	269 (24.86%)	/	0.97 (95%CI 0.78-1.21)	0.83
	55-59	80 (10.18%)	109 (14.03%)	+ 3.85%	1.44 (95%CI 1.06-1.96)	0.02
	60-64	33 (4.89%)	78 (11.66%)	+ 6.77%	2.57 (95%CI 1.68-3.93)	< 0.001
	65-69	11 (2.74%)	43 (10.29%)	+ 7.54%	4.06 (95%CI 2.06-8.00)	< 0.001
Mammo-graphic unit	Hospital	130 (15.48%)	208 (16.67%)	+ 1.19%	1.09 (95%CI 0.86-1.39)	0.469
	Mobile unit	74 (11.06%)	104 (15.71%)	+ 4.65%	1.5 (95%CI 1.09-2.06)	0.013
	Private radiologist	97 (9.22%)	187 (18.05%)	+ 8.83%	2.17 (95%CI 1.67-2.82)	< 0.001
Eligible for VT (proxy low-SES) (n = 2,037)		49 / 1,212 (4.04%)	99 / 825 (12.00%)	+ 7.96%	3.24 (95%CI 2.27-4.61)	<0.001
Age group	51-54	25 (3.86%)	61 (23.19%)	+ 19.34%	7.52 (95%CI 4.60-12.31)	< 0.001
	55-59	11 (5.39%)	24 (13.56%)	+ 8.17%	2.75 (95%CI 1.31-5.79)	0.006
	60-64	13 (5.86%)	221 (3.91%)	/	0.66 (95%CI 0.27-1.56)	0.34
	65-69	0 (0%)	5 (3.23%)	+ 3.23%	10.12 (95%CI 0.55-184.76) ^a	0.33
Mammo-graphic unit	Hospital	27 (3.24%)	49 (11.84%)	+ 8.59%	4.01 (95%CI 2.47-6.51)	< 0.001
	Mobile unit	0 (0%)	8 (8.89%)	+ 8.89%	17.62 (95%CI 1.001-310.16) ^a	0.005
	Private radiologist	22 (7.48%)	42 (13.08%)	+ 5.60%	1.86 (95%CI 1.08-3.2)	0.023

VT= 'Verhoogde Tegemoetkoming', Dutch term for increased reimbursement of medical expenses; ^a = Haldane-Anscombe correction applied.
Note: Counts in the intention-to-treat and per-protocol analyses are derived from separately aggregated datasets.

Table 5 - SES stratified effect of the reminder letter by characteristics of study population (PP)

Per protocol (PP)		BC screening participation		Absolute increase	OR (95%CI)	p value
		Control arm (n = 3,447)	Intervention arm (n = 3,376)			
Non-eligible for VT (n = 5,292)		299 / 2,685 (11.14%)	488 / 2,607 (18.72%)	+ 7.58%	1.84 (95%CI 1.57-2.15)	<0.001
Age group	51-54	117 (17.75%)	262 (27.26)	+ 9.51%	1.73 (95%CI 1.40-2.15)	< 0.001
	55-59	80 (11.05%)	106 (15.66%)	+ 4.61%	1.49 (95%CI 1.09-2.04)	0.011
	60-64	31 (5.21%)	78 (13.02%)	+ 7.81%	2.72 (95%CI 1.77 -4.20)	< 0.001
	65-69	11 (2.98%)	42 (11.35%)	+ 8.37%	4.17 (95%CI 2.11-8.23)	< 0.001
Mammo-graphic unit	Hospital	129 (11.55%)	203 (18.50%)	+ 6.96%	1.74 (95%CI 1.37-2.21)	< .001
	Mobile unit	74 (11.93%)	100 (16.67%)	+ 4.73%	1.48 (95%CI 1.07-2.04)	0.018
	Private radiologist	96 (10.13%)	185 (20.33%)	+ 10.20%	2.26 (95%CI 1.74-2.95)	< .001
Eligible for VT (proxy low-SES) (n = 1,531)		49/762 (6.43%)	99/769 (12.87%)	+ 6.44%	2.15 (95%CI 1.50-3.08)	<0.001

Age group	51-54	25 (10.68%)	61 (25%)	+ 14.32%	2.79 (95%CI 1.68-4.62)	< 0.001
	55-59	11 (5.61%)	24 (14.29%)	+ 8.67%	2.80 (95%CI 1.32-5.91)	0.005
	60-64	13 (6.25%)	9 (4.21%)	/	0.66 (95%CI 0.27-1.58)	0.34
	65-69	0 (0%)	5 (3.50%)	+ 3.50%	9.88 (95%CI 0.54-180.64) ^a	0.36
Mammo-graphic unit	Hospital	27 (6.62%)	49 (12.79%)	+ 6.18%	2.07 (95%CI 1.27-3.39)	0.003
	Mobile unit	0 (0%)	8 (9.64%)	+ 9.64%	17.9 (95%CI 1.02-315.56) ^a	0.005
	Private radiologist	22 (8%)	42 (13.86%)	+ 5.86%	1.85 (95%CI 1.07-3.19)	0.025

VT= 'Verhoogde Tegemoetkoming', Dutch term for increased reimbursement of medical expenses; ^a = Haldane-Anscombe correction applied.

Note: Counts in the intention-to-treat and per-protocol analyses are derived from separately aggregated datasets.

Figure 1 – Standard invitation letter for BC screening adopted by the Flemish Centre for Cancer Detection (English version, 2023)



**BEVOLKINGS
ONDERZOEK
BORSTKANKER**



Vlaanderen
is zorg

Your personal code:



Screenings
mammografie

**WE DO.
AND WHAT DO
YOU DO?**

To

Dear

Every two years, you can be screened for breast cancer free of charge. This allows us to detect any breast cancer before you notice it yourself. You decide for yourself whether to take part.

Every year, more than 200,000 women in Flanders take part in the screening.
Are you in? We have already set up an appointment for you.

HOW DO YOU PARTICIPATE?

Go to the appointment we propose here.

Date and time:

Mammography unit:

Bring the following with you:

- your identity card;
- this letter.

Do you want to reschedule the appointment or do you not want to accept this invitation?

- Call 0800 60 160 free of charge
- Visit www.borstkankeronderzoek.be
- E-mail info@bevolkingsonderzoek.be

The examination is FREE OF CHARGE if you are registered with a Belgian insurance fund.

Do you want to know how the screening works? Read about this in the enclosed leaflet.

If you have any personal questions or doubts about participating,

- discuss these with your GP.
- Visit www.bevolkingsonderzoek.be

Kind regards,



Dr Patrick Martens
Director, Centre for Cancer Detection (CvKO)



BEVOLKINGS
ONDERZOEK BE

VZW CENTRUM VOOR
KANKEROPSPORING

ADMINISTRATIEVE ZETEL
RUGGERSHOVE 4, 8000 BRUGGE

WWW.BEVOLKINGSONDERZOEK.BE
INFO@BEVOLKINGSONDERZOEK.BE



CvKO
CENTRUM VOOR
KANKEROPSPORING
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Figure 2 – Tailored reminder letter employed in the ENTER RCT (English version)



**GET CHECKED
FOR BREAST CANCER
FREE OF CHARGE**

THIS LETTER IS IMPORTANT!

Your personal code:

To _____

Don't speak Dutch? Download this letter in another language.

Deutsch, English, Español, Française, Italiano, Русский, Română,
Shqipja, Türkçe, العربية, فارسی, 中文.



SCAN THE QR CODE

Dear _____

You can get checked for breast cancer free of charge. This is **important** for your health.
Would you like to be checked? Come to your appointment.

Your appointment	What do you bring?
Date and time: Address:	  - Your ID card - This letter

The check-up is **FREE** from the age of 50 if you are a member of a Belgian health insurance company

Would you like to make a new appointment?

- E-mail : info@bevolkingsonderzoek.be
- Call toll-free: 0800 60 160 (Monday-Thursday 8-12am and 1-5pm, Friday 8-12am and 1-4pm)

Do you have questions about the check-up?

- Discuss them with your family doctor.
- Visit: www.borstkanker.bevolkingsonderzoek.be

Kind regards,

Dr. Patrick Martens
Director, Center for Cancer Screening





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