Supplementary materials

Title of the article: Offering HPV self-sampling kits: an updated meta-analysis of the effectiveness of strategies to increase participation in cervical cancer screening.

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Supplementary materials

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1. Study protocol (including objectives, PICOS, bibliographic sources, literature search strings)

1.1. Objectives

1.1.1. Primary objectives

- update and summarize the most recent evidence on cervical cancer screening participation when under- or never-screened women are offered a self-sampling device for hrHPV testing;
- compare screening attendance when two different self-sampling invitation scenarios are used;

1.1.2. Secondary objectives

- summarize new evidence when the invitation scenario involves women getting offered an hrHPV self-sample kit upon a visit to the primary care provider.
- compare sample adequacy and test-positivity rate in self-sample versus conventional screening strategies;
- explore adherence to follow-up and detection rate of cervical precancer and cancer in screen-positive women.

1.2. Clinical questions

1) Is cervical cancer screening attendance higher when underscreened women are offered a self-sampling device for hrHPV-testing (experimental group) compared to routine invitations/reminders to contact a healthcare professional (HCP) for collection of a cervical specimen (control group).

2) How does attendance to screening vary when two different self-sampling invitation strategies are used.

1.3. PICOS components

1.3.1. Potential of strategies providing self-sampling to increase population coverage

P*opulation*: women who were irregularly screened, never screened or did not respond to one or more invitation/reminder letters recommending participation in conventional cervical cancer screening.

Intervention: providing a self-sampling device for collection of a vaginal sample, as a cervical screening method to be carried out by the women themselves.
I1: "Mail-to-All": an invitation to participate in the study accompanied by an hrHPV self-sampling kit was directly sent to the women at their home addresses;
I2: "Opt-In": offering women the possibility to obtain a self-sampling kit: women had to request the self-sampling kits to be received my mail or, alternatively, these could be collected from the local clinic/pharmacy;
I3. "Community mobilization and outreach": community campaigns with outreach supported by mass media in which attending women were offered a self-sampling kit at the end of a sensibilization session as well as, an individualized self-sampling kit delivery approach in which community healthcare workers directly contacted women at their homes or work places
I4 "Direct offer at a healthcare service": women were offered a self-sample at the end of an individual appointment (when they contact a health service for whatever reason) and were given the choice to do it on site in a private room or to take it home.

Control action:
C: Women were offered the possibility to obtain screening according to current clinical practice either after an invitation/reminder to visit a HCP or as result from opportunistic screening upon woman's request or on HCP recommendation, without organized invitation

Outcomes:
O1: Response rate in experimental and control groups;
O2: Relative response rate (experimental /control groups); response difference (experimental /control groups);
O3: Relative response rate (opt-in /mail-to-all groups); response difference (opt-in /mail-to-all groups);
O4: proportion with inadequate sample test results among screened women;
O5: test-positivity rate among screened women with satisfactory sample;
O6: adherence to further follow-up among screen-test positive women;
O7: detection rate of CIN2+ among all women, screened women, screen-positive women who complied to follow-up.

Studies:
Randomized controlled trials.

1.4. Literature retrieval strings

1.4.1. Potential of strategies providing self-sampling to increase population coverage

In Pubmed-Medline

(Cervix OR cervical) AND (HPV OR papillomavirus) AND (self-sampling OR self sampling OR self-collection OR self collection) AND (screening OR coverage OR participation OR knowledge OR acceptance)

2. PRISMA flow charts of study retrieval and selection

2.21. Meta-analysis on the response to the offer of self-sampling

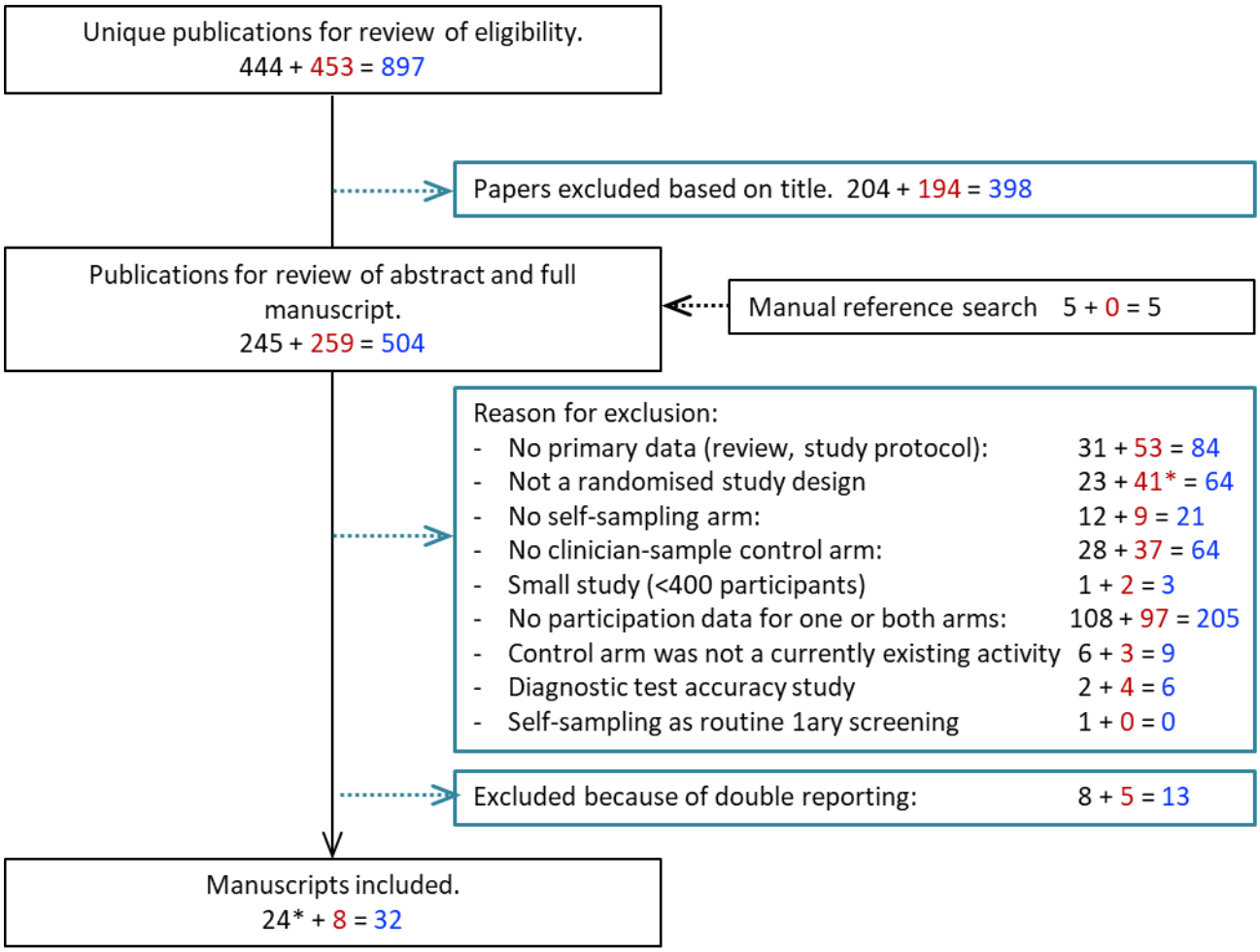

Figure S1. PRISMA flow chart summarizing the selection of eligible participation trials. Figures in black are those included in the search up to April 15, 2018[1], those in red are references retrieved up to March 31, 2022. References in blue are the sum of all searches. *One study (Zehbe et al, BMJ Open 2016)[2] included in the previous meta-analysis (Arbyn et al, BMJ 2018)[1] was excluded from the current update due to concerns raised with regards to the randomisation of women to the experimental and control intervention.

Throughout this Supplementary File, information regarding studies included in the previous meta-analysis of Arbyn et al. BMJ 20181 (retrieved until April 15, 2018) will be presented as black coloured text, whereas information on the studies newly included in this update (retrieved until March 31, 2022) will be presented in red coloured text.

4. Characteristics of the randomised trials comparing strategies including offering hrHPV self-sampling with control interventions

Table S1. Study characteristics of included RCTs fulfilling eligibility criteria.

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
1. Bais, 2007[3] The Netherlands	Randomised. Women who did not respond to the invitation for conventional screening and the first reminder 6 months later. No data on response stratified by screening history.	Direct mailing of the self-sampling kit.*	Invitation for conventional cytology with an explanatory letter.*	Mail-to-all: 2,352	272	30-50
2. Gok, 2010[4] The Netherlands	Randomised. Women who did not respond to the invitation for conventional screening and the first reminder 6 months later. Whole population: 1st screen or screened 5 years ago. Subgroup: screened >7 years ago.	Direct mailing of the self-sampling kit, preceded by a notification. *	Invitation for conventional cytology, preceded by a notification.*	Mail-to-all: 26,886	277	30-60
3. Giorgi-Rossi, 2011[5] Italy	Randomised. Women who did not respond to the invitation for conventional screening. No sufficient data on response stratified by screening history.	- Direct mailing of the self-sampling kit, preceded by a notification. - Women were offered the opportunity to receive the self-sampler device (by mail or picking it up at the clinic). If interested, they had to call a free toll number.	- Invitation for conventional cytology (prefixed date). - Invitation for hrHPV testing at the clinic (sample collected by a clinician).	Mail-to-all: 616 Opt-in: 622	- 619 - 616	35-65
4. Lazcano-Ponce, 2011[6] Mexico	Randomised. Women in poverty-reduction programme, with limited access to health services. No data on response stratified by screening history.	Door-to-door recruitment. Nurses performed home visits, in which a self-sample was taken by the woman herself.	Door-to-door recruitment. Nurses performed home visits, and made an appointment for conventional cytology in the clinic.	Community mobilization and outreach: 9,371	1,2731	25-65

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
5. Piana, 2011[7] France	Randomised. Women who did not respond to the invitation for conventional screening and had not had a cervical smear in ≥2y. No sufficient data on response stratified by screening history	Direct mailing of the self-sampling kit, preceded by a notification with an opt-out option.	Invitation for conventional cytology.	Mail-to-all: 4,400	4,934	35-69
6. Szarewski, 2011[8] United Kingdom	Randomised. Women who did not respond to ≥2 invitations for conventional screening. No data on response stratified by screening history	Direct mailing of the self-sampling kit.¥	Invitation for conventional cytology.¥	Mail-to-all: 1,500	1,500	25-64
7. Virtanen, 2011[9] Finland	Randomised. Women who did not respond to the invitation for conventional screening. No sufficient data on response stratified by screening history.	Direct mailing of the self-sampling kit, preceded by a notification (with an opt-out option).	Invitation for conventional cytology (pre-fixed appointment).	Mail-to-all: 2,397	6,302	30-60
8. Wikstrom, 2011[10] Sweden	Randomised. Women who had not participated in screening for ≥6 years. No data on response stratified by screening history.	Direct mailing of the self-sampling kit, preceded by a notification. Afterwards an additional reminder to participate was sent.	Invitation for conventional cytology, within the framework of the organised screening programme.	Mail-to-all: 2,000	2,060	39-60
9. Gok, 2012[11] The Netherlands	Randomised. Women who did not respond to the invitation for conventional screening and the first reminder. No data on response stratified by screening history.	Direct mailing of the self-sampling kit, preceded by a notification.*	Invitation for conventional cytology, preceded by a notification.*	Mail-to-all: 25,561	261	30-60

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
10. Darlin, 2013[12] Sweden	Randomised. Women who had not had any cervical smears taken for >9y. No data on response stratified by screening history.	Direct mailing of the self-sampling kit. After one month, a reminder including another self-sampling kit was sent to non-responders.	Invitation for hrHPV testing at an outpatient clinic. The invitation included several alternative appointments. A reminder was sent to non-responders.	Mail-to-all: 1,000	500	32-65
11. Sancho-Garnier, 2013[13] France	Randomised. Women who did not respond to the invitation for conventional screening and had not had a cervical smear in ≥2y. No data on response stratified by screening history.	Direct mailing of the self-sampling kit, preceded by a notification.	Invitation for conventional cytology at an outpatient clinic. The invitation included a list of centres performing the test.	Mail-to-all: 8,829	9,901	35-69
12. Broberg, 2014[14] Sweden	Randomised. Women who did not respond to ≥4 invitations for conventional screening and did not have a registered Pap smear for ≥6y (30-53y), ≥7y (54y), or ≥8y (55-62y). Data on response stratified by screening history: screened ≤10 or >10y ago; never screened.	Women were offered the opportunity to receive a self-sampling kit (by mail). If interested, they had to return a coupon using a postage-free envelope. A reminder was sent if the kit was ordered but not returned, or after 10 weeks to women who did not respond.	No particular intervention was done. Women continued to receive annual invitations until a smear was registered.	Opt-in: 800	4,000	30-62
13. Haguenoer, 2014[15] France	Randomised. Women who had not had a cervical smear in ≥3y, and did not respond to the invitation for conventional screening. No data on response stratified by screening history.	Direct mailing of the self-sampling kit.	- Invitation for conventional cytology. - No intervention.	Mail-to-all: 1,999	- 2,000 - 1,999	30-65

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
14. Arrossi, 2015[16] Argentina	Cluster randomised. Women found at home. No data on response stratified by screening history.	Door-to-door recruitment. Community health workers performed home visits, in which a self-sample was taken by the woman herself.	Door-to-door recruitment. Community health workers performed home visits and advised women to go to a health centre for a clinician-collected sample for hrHPV testing.	Community mobilization and outreach: 3,049	4,018	≥30
15. Cadman, 2015[17] United Kingdom	Randomised. Women who did not respond to the invitation for conventional screening and the first reminder. Data on response stratified by screening history: screened 0-3y, 3-5y, 5-10y and >10y ago; never screened.	Direct mailing of the self-sampling kit.	Invitation for conventional cytology.	Mail-to-all: 3,000	3,000	25-65
16. Giorgi-Rossi, 2015[18] Italy	Randomised. Women who did not respond to the invitation for conventional screening. No data on response stratified by screening history.	- Direct mailing of the self-sampling kit, preceded by a notification. - Women were invited by mail, to pick up a self-sampling device at the clinic.	- Invitation for conventional cytology at the clinic. - Invitation for hrHPV testing at the clinic (sample collected by a clinician).	Mail-to-all: 4,516 Opt-in: 4,513	- 1,998 - 3,014	30-64
17. Moses, 2015[19] Uganda	Randomised. Women who lived or worked in target city and had access to a mobile telephone. Door-to-door recruitment. No data on response stratified by screening history.	Women were provided a self-sampling kit at place of recruitment (home or workplace) and returned them to outreach workers.	Women were scheduled for VIA appointment and received a reminder call.	Community mobilization and outreach: 248	245	30-65

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
18. Enerly, 2016[20] Norway	Cohort study with random selection of women who did not have cytology, hrHPV or histology in ≥3 years. Targeted women attended information sessions. No data on response stratified by screening history.	Direct mailing of the self-sampling kit, preceded by a notification with an opt-out option.	Invitation (i.e., reminder) to complete liquid-based cytology sent to women not included in intervention group.	Mail-to-all: 800	2,593	26-69
19. Racey, 2016[21] Canada	RCT. Women with current Ontario Health Insurance Program card and no cytology in ≥30 months. No data on response stratified by screening history.	Direct mailing of the self-sampling kit, preceded by a notification with choice to opt-out. Reminder phone call 1 month after kits were mailed.	C1: Invitation letter to schedule cytology appointment C2: No invitation (opportunistic screening)	Mail-to-all: 335	C1: 331 C2: 152	30–70
20. Sultana, 2016[22] Australia	RCT. Never-screened or under-screened women (not screened in the previous 2.5 years). Data on response stratified by screening history: screened >2.5y ago; never screened.	Direct mailing of the self-sampling kit, preceded by a notification with an opt-out option.	Invitation (never-screened) or reminder (underscreened) letters for cytology.	Mail-to-all: 14,153 (7,075 un-screened; 7,078 under-screened)	2,025 (1,014 un-screened; 1,011 under-screened)	30-69
21. Kitchener, 2017[23] United Kingdom	Cluster-randomised. Phase 2 of STRATEGIC trial. Women, due for their first invitation, who in phase 1 of STRATEGIC did not respond to invitation letters (with or without pre-leaflet or with/without online booking) to screening after 6 months.	- Direct mailing of unrequested self-sampling kits - Direct mailing of requested self-sampling kits - Offered women choice between nurse navigator and self-sampling kit (*not considered for syst. rev & meta-analysis*)	No intervention beyond standard invitation.	Mail-to-all: 1,141 (32 GPs) Opt-in: 1,290 (66 GPs)	3,782 (101 GPs)	20 (Gramp-ian); 25 (Manch-ester)
22. Modibbo, 2017[24] Nigeria	RCT. Women living or working in target community not planning to move within 6 months. No data on response stratified by screening history.	Women attending a community event received a self-sampling kit to complete at home and to mail or drop off at collection sites.	Women attending a community event received a hospital hrHPV test appointment.	Community mobilization and outreach: 200	200	≥30

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
23. Kellen, 2018[25] Belgium	RCT. Population-based RCT with 2 experimental arms and 2 controls arms, including women without screening record since 8 years. No data on response stratified by screening history.	-Reminder mailing with self-sampling kit (mail-to-all); - Reminder mailing with self-sampling to be ordered (opt-in).	- Reminder mailing inviting women to have a cytology specimen taken by a clinician (=routine intervention). - No invitation.	Mail-to-all: 9,118. Opt-in: 9,098.	Reminder letter: 8,830. No reminder: 8,849.	30-64
24. Tranberg, 2018[26] Denmark	Population-based RCT with 1 control arm and 2 experimental arms (mail-to-all & opt-in) including women who did not reply to a 1st invitation and were due to a 2nd reminder. Nested in Danish screening programme. Response rates stratified for regularly screened, under-screened and never screened subgroups.	- Reminder mailing with self-sampling kit; - Reminder mailing with self-sampling to be ordered (opt-in). Women were also offered the possibility to contact a GP for collection of cytology specimen. For both arms: reminder letter if response after 4m.	Reminder mailing inviting women to have a cytology specimen taken by a clinician.	Mail-to-all: 3,265. Opt-in: 3,264.	3,262	30-64
25. Ivanus, 2018[27] Slovenia	Randomised. Women with no cytology results registered in the last 4 years and/or who had an hysterectomy. Response rates stratified for level of protection as medium and no/low protection.	- Direct mailing of the self-sampling kit - Women were offered the opportunity to order a self-sampling kit All participants had free access to cytology screening with their GP during the study.	No intervention beyond standard invitation.	Mail-to-all: 9,556 Opt-in: 14,400	2600	34 - 64

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
26. Elfström, 2019[28] Sweden	Randomised health services study. Women who did not have a screening test on record for at least 10 years, or who had been sent at least 10 annual renewed invitations and who were not blocked from invitations due to hysterectomy or screening program opt-out. No data on response stratified by screening history.	- Direct mailing of the self-sampling kit along with an invitation letter and instructions - Women were offered the opportunity to order a self-sampling kit through an online application - An invitation to call the region's coordinating midwife with potential questions and concerns regarding screening (*not considered for syst. rev & meta-analysis*)	No intervention beyond standard invitation.	Mail-to-all: 2,000 Opt-in: 2,000	2,000	33 - 60
27. Gizaw, 2019[29] Ethiopia	Cluster Randomised. Women who had never been screened. No previous hysterectomy. No data on response stratified by screening history.	Invitation to the primary healthcare unit for self-sampling, after sensitization at community/cluster level.	Invitation to go to the hospital for VIA, after sensitization at community/cluster level.	Community mobilization and outreach: 1,213	1,143	30 - 49
28. Jalili, 2019[30] Canada	Randomised. Unscreened women: no Pap test in registry and who had been registered for 5+ years. Non-responders: women who had been sent an invitation letter to be screened, but who remained unscreened. No hysterectomy; or invasive gynaecologic cancer diagnosis in the registry. No data on response stratified by screening history.	Direct mailing of the self-sampling kit + reminder letter after 8w for non-responders	No intervention beyond standard invitation.	Mail-to-all: 529	523	30 - 65

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
29. Winer, 2019[31] USA	Randomised. Women with health plan enrolment for 3 years and 5 months or longer, a primary care clinician, no Papanicolaou test within 3 years and 5 months, and no hysterectomy. No data on response stratified by screening history.	Usual care + direct mailing of the self-sampling kit. Participants, regardless of whether they chose to complete self-sampling, were advised to still receive Papanicolaou testing.	Usual care (annual patient reminders and ad hoc outreach from primary care clinics)	Mail-to-all: 9,960	9,891	30 - 64
30. Lilliecreutz, 2020[31] Sweden	Randomised. Women who did not respond to the invitation for conventional screening and had not had a cervical smear in 6y (ages 30-49) and 8y (ages 50-64) No data on response stratified by screening history.	- Direct mailing of the self-sampling kit + annual invitation - Annual screening invitation + telephone call with a midwife (within a month since invitation) offering the choice between a visit for a pap smear or an HPV self-sampling test (*not considered for syst. rev & meta-analysis*).	No intervention beyond standard invitation..	Mail-to-all: 3,068	3.538	30 - 64
31. MacDonald, 2021[33] New Zealand	Cluster randomised. Women who had not had a cervical smear in ≥4y. No data on response stratified by screening history.	Direct offer of the self-sampling kit when attending the intervention clinics. Participants randomised to receive the intervention could opt for a clinician taken HPV test or cervical smear.	Offering a cervical smear when attending the control clinics.	Direct offer at a healthcare service: 364	174	25 - 69

Author, year Country	**Study design and population**	**Scenario of invitation in self-sampling arm**	**Scenario of invitation in control arm**	**N (Self-sampling arm)**	**N (Control arm)**	**Age range (years)**
32. Brewer, 2021[34] New Zealand	Randomised. Never- and under-screened (no screening recorded for at least the last 5 years prior to enrolment) women from Maori, Pacific, and Asian ethnicities, registered at selected GP clinics.	- Direct mailing of the self-sampling kit, preceded by a notification - Direct offer of the self-sampling kit at their usual general practice, preceded by a notification	Invitation for conventional cytology (at a clinic, at an independent service providers, or with a study nurse), preceded by a notification	Mail-to-all: 1467 Opt-in: 1574	512	30 - 69
33. Veerus, 2021[35] Estonia†	Randomised. Never- and under-screened (no screening recorded from 2013-2019), women born between 1958-1983.	- Direct mailing of the self-sampling kit - Women were offered the opportunity to order a self-sampling kit from a website	/	Mail-to-all: 4000 Opt-in: 8000	/	37-62

* A telephone helpline and/or website with information was available throughout the study.
¥ Study information was available in different languages as hard copy and on the internet.
Abbreviations: BHU: Basic Health Unit; GP: general practitioner; HPV: human papillomavirus; PG: personal gynaecologist; RCT: randomised controlled trial; SRH: sexual and reproductive health; SS: self-sampling; VIA: visual inspection with acetic acid.
† This study consisting of 2 experimental arms (different hrHPV self-sampling invitation scenarios) was not accounted for in the analysis comparing participation in self-sampling vs control groups.

Table S2. Test, triage & follow-up characteristics of RCTs fulfilling eligibility criteria.

Author, year	Tests	Self-sampling device	Time of response assessment (months after invitation)	Triage of test+	Follow-up
1. Bais, 2007 Netherlands	PCR (GP5+/6+)	Cervicovaginal brush	6m	No triage	▪ Cytology + colposcopy + colpo-directed biopsy, in case of positive screen-test
2. Gök, 2010 Netherlands	HC2	Lavage (Delphi screener)	12m	Self-arm: cytology + repeat HPV	▪ Colposcopy + colpo-directed biopsy, in case of ASC-US+ ▪ Repeat testing (Pap + hrHPV) in 1y, in case of normal cytology or no cytology performed
3. Giorgi-Rossi, 2011 Italy	HC2	Lavage	3m	No triage	▪ Colposcopy + colpo-directed biopsy, in case of screen test+ and positive colposcopy ▪ Colposcopy + cytology in 1y, in case of screen test+ and negative colposcopy
4. Lazcano-Ponce, 2011 Mexico	HC2	Cervicovaginal brush (Digene)	Not documented	No triage	▪ Colposcopy (free of charge) + colpo-directed biopsy, in case of screen test+
5. Piana, 2011 France	PCR	Not documented	Not documented	No triage	▪ Cytology and colposcopy + colpo-directed biopsy
6. Szarewski, 2011 United Kingdom	HC2	Swab	6m	Cytology	▪ Colposcopy + colpo-directed biopsy, in case of triage test+ (or triage test-, by choice) (self-sampling arm) or screening test+ (control arm).
7. Virtanen, 2011 Finland	HC2	Lavage (Delphi screener)	Not documented	- <40y: cytology + repeat HPV - ≥40y: no triage	▪ <40y: Colposcopy + colpo-directed biopsy, in case of at least one positive triage test. Repeat testing (cytology + hrHPV) in 1y, in case of normal triage test. ▪ ≥40y: colposcopy + colpo-directed biopsy, in case of a positive screen test
8. Wikström, 2011 Sweden	HC2	Swab	12m	No triage	▪ Self-arm: Colposcopy + biopsy; or cytology (with/without repeat hrHPV) ▪ Control arm: Colposcopy + biopsy, in case of HSIL+; repeat cytology in case of ASC-US or LSIL
9. Gök, 2012 Netherlands	HC2	Cervicovaginal brush	12m	Cytology	▪ Colposcopy + colpo-directed biopsy, in case of ASC-US+ ▪ Repeat testing (Pap + hrHPV) in 1y, in case of normal cytology

Author, year	Tests	Self-sampling device	Time of response assessment (months after invitation)	Triage of test+	Follow-up
10. Darlin, 2013 Sweden	PCR (GP5+/6+)	Not documented	Not documented	No triage	▪ Colposcopy + colpo-directed biopsy and LBC, in case of hrHPV.
11. Sancho-Garnier, 2013 France	Abbott RT PCR	Swab (Dacron)	Not documented	Cytology	▪ Colposcopy + colpo-directed biopsy, in case of LSIL+
12. Broberg, 2014 Sweden	HC2	Plastic swab (QvinTip)	Not documented	No triage	▪ Colposcopy + colpo-directed biopsy, in case of hrHPV+ and/or abnormal cytology.
13. Haguenoer, 2014 France	INNO-LiPa	Dry nylon flocked swab.	9m 12m	Cytology	▪ Colposcopy + colpo-directed biopsy in case of ASC-US+
14. Arrossi, 2015 Argentina	HC2	Cervical brush (Qiagen)	6m	Self arm: no triage Control arm: cytology	▪ Colposcopy + colpo-directed biopsy, in case of hrHPV+ (self-sampling arm) or in case of hrHPV+ and ASC-US+ (control arm).
15. Cadman, 2015 United Kingdom	HC2	Dacron Swab	3m	Cytology	▪ Colposcopy + colpo-directed biopsy, in case of abnormal cytology.
16. Giorgi-Rossi, 2015 Italy	HC2	Lavage (Delphi screener)	3m	Primary HPV: cytology (3/6 study centers), or no triage (3/6). Primary cytology: no triage.	▪ Colposcopy + colpo-directed biopsy in case of ASC-US+ (cytology triage, or primary cytology). Repeat HPV in case of normal cytology. ▪ Cytology, and colposcopy + colpo-directed biopsy in case of hrHPV+ (no triage). Repeat double testing in 3-6 months in case of normal colposcopy and HSIL, otherwise repeat testing in 1 year.
17. Moses, 2015 Uganda	Ecoli s.r.o real-time PCR test	Dacron swab	Not documented	VIA	▪ Self arm: cryotherapy at VIA appointment, or colposcopy with treatment when indicated. ▪ VIA arm: cryotherapy at the time of screening. Referral for colposcopy and treatment when lesions were not appropriate for cryotherapy or when VIA was unsatisfactory.

Author, year	Tests	Self-sampling device	Time of response assessment (months after invitation)	Triage of test+	Follow-up
18. Enerly, 2016 Norway	CLART HPV2 test, HC2	Lavage (Delphi screener) / Evalyn brush (randomised)	Not documented	Self arm: cytology or hrHPV testing Control arm: cytology	hrHPV+ on self-sample: scheduled appointment for collection of a cervical specimen that was co-tested (cytology &hr HPV).
19. Racey, 2016 Canada	NML Luminex (linear array)	Dacron swab	Not documented	Cytology	Standard of care
20. Sultana, 2016 Australia	Cobas 4800	Nylon-tipped flocked swab	6m	HPV 16/18: no triage (directly to colposcopy) HPV other types: cytology	Colposcopy with biopsy
21. Kitchener, 2017 United Kingdom	Cobas 4800	Lavage (Delphi Screener)/ Evalyn Brush	3m 6m 12m 18m	Cytology	Colposcopy if triage by cytology was positive. Usual triage as recommended in NHS programme if cytology positive in control arm. No triage results were presented.
22. Modibbo, 2017 Nigeria	GP5+/6+-EIA PCR with LMNX genotyping	Dry flocked swab	1m	Not documented	Treatment and follow-up
23. Kellen, 2018 Belgium	RIATOL qPCR	Qvintip	12m	Cytology	Not documented.
24. Tranberg, 2018 Denmark	Self arm: Cobas 4800. Control arm: cytology, Cobas 4800 if 60-64y	Evalyn Brush	6m	Self arm: cytology	Follow-up as defined in Danish programme: ASC-US/HPV+ & LSIL+ referred to colposcopy. If self HPV+ & NILM at 1st triage: repeat cytology & HPV at 12m.

Author, year	Tests	Self-sampling device	Time of response assessment (months after invitation)	Triage of test+	Follow-up
25. Ivanus, 2018 Slovenia	HC2	Mail-to-all: Qvintip (Swab), HerSwab (Swab) and Delphi Screener (Lavage). Opt-in: Qvintip (Swab).	12m	No triage	Colposcopy + colpo-directed biopsy (if abnormal colposcopy result), in case of hrHPV+ and/or abnormal cytology.
26. Elfstrom, 2019 Sweden	Cobas 4800	Cobas PCR Swab	3m	Mail-to-all & opt-in group hrHPV positive: No triage In any arm: cytology	Mail-to-all & opt-in hrHPV+: pelvic exam, cytology + colposcopy + colpo-directed biopsy. Screen-positive women were managed in accordance with the program's standard guidelines and clinical presentation.
27. Gizaw, 2019 Ethiopia	PCR(GP5+/ GP6+)	Evalyn Brush	Not documented	hrHPV+: VIA	See&treat approach (cryotherapy)
28. Jalili, 2019 Canada	Cobas 4800	FLOQSwab	6m	No triage	Colposcopy, in case of hrHPV+ and/or abnormal cytology.
29. Winer, 2019 United States of America	Cobas 4800	Not documented	6m	Positive HPV-16 or 18: no triage Negative/unsatisfactory/hr HPV other than HPV-16 or 18: cytology	HPV-16 or 18: immediate colposcopy.
30. Lilliecreutz, 2020 Sweden	Cobas 4800	Cobas PCR Swab	6m	hrHPV+: no triage	Colposcopy + colpo-directed biopsy, in case of hrHPV+ and/or abnormal cytology.

Author, year	Tests	Self-sampling device	Time of response assessment (months after invitation)	Triage of test+	Follow-up
31. MacDonald, 2021 New Zealand	Abbott Real-time High-Risk HPV assay	Nylon-tipped flocked swab (Copan)	Not documented	No triage	Colposcopy, in case of hrHPV+
32. Brewer, 2021 New Zealand	Cobas 4800	FLOQSwab	3m	Positive HPV-16 or 18: no triage Negative/unsatisfactory/hr HPV other than HPV-16 or 18: cytology	Colposcopy, in case of hrHPV+ and/or abnormal cytology.
33. Veerus, 2021 Estonia†	Alinity m hrHPV Assay (Cobas 4800 on inadequate samples)	Qvintip and Evalynbrush	Not documented	hrHPV+: cytology	Colposcopy, in case of abnormal cytology

Abbreviations: ASC-US+: atypical squamous cells of undetermined significance or more severe results; EIA: enzyme immunoassay; HC2: Hybrid Capture 2; hrHPV: high-risk human papillomavirus; HSIL+: high-grade squamous intraepithelial lesions or more severe disease; LBC: Liquid-based cytology; LMNX: Luminex; LSIL+: low-grade squamous intraepithelial lesions or more severe disease; PCR: polymerase chain reaction; NHS: National Health Service; NILM: negative for intraepithelial lesion or malignancy; NML: Canadian National Microbiology Laboratory; RCT: randomised controlled trial; VIA: visual inspection with acetic acid.

† This study consisting of 2 experimental arms (different hrHPV self-sampling invitation scenarios) was not accounted for in the analysis comparing participation in self-sampling vs control groups.

5. Assessment of risk of bias in randomised trials

Table S3. Summary of the quality of included studies, according to the Cochrane Tool for Risk of Bias[36].

Risk of Bias	Selection		Attrition	Reporting	
	Random sequence generation	Allocation concealment	Incomplete outcome data	Reporting of timelines	Selective reporting
Bais, 2007	Low	Medium	Low	Low	Low
Gok, 2010	Low	Medium	Low	Low	Low
Giorgi-Rossi, 2011	Low	Low	Low	Low	Low
Lazcano-Ponce, 2011	Medium•	Low	Low	Medium	Medium¥
Piana, 2011	Low	Medium	Low	Medium	High¥□
Szarewski, 2011	MediumΔ	Medium	Low	Low	Low
Virtanen, 2011	Low	Medium	Low	Low	Low
Wikstrom, 2011	MediumΔ	Medium	Low	Low	Low
Gok, 2012	Low	Medium	Low	Low	Medium¥
Darlin, 2013	MediumΔ	Medium	Low	Medium	Medium¥
Sancho-Garnier, 2013	MediumΔ	Medium	Low	Low	Medium¥
Broberg, 2014	MediumΔ	Medium	Low	Medium	Low
Haguenoer, 2014	Low	Low	Low	Low	Low
Arrossi, 2015	Medium*	Low	Low	Low	Low
Cadman, 2015	Low	Low	Low	Low	Low
Giorgi Rossi, 2015	Low	Low	Low	Low	Low
Moses, 2015	Low	Low	Low	Medium	Low
Enerly, 2016	Highδ	High	Low	Low	Medium
Racey, 2016	Low	Low	Low	Medium	Low
Sultana, 2016	Low	Low	Low	Low	Medium
Kitchener, 2017	Medium	Medium	Low	Low	Low
Modibbo, 2017	Highα	Medium	Low	Low	Medium¥
Kellen, 2018	Low	High€	Low	Low	Medium€
Tranberg, 2018	Low	Low	Low	Low	Low
Ivanus, 2018	Low	Low	Low	Low	Low
Elfstrom, 2019	Low	Low	Low	Low	Low
Gizaw, 2019	Medium*	Low	Low	Medium	Medium¥
Jalili, 2019	MediumΔ	Low	Low	Low	Low
Winer, 2019	MediumΔ	Low	Low	Low	Low
Lillicreutz, 2020	Low	Low	Low	Low	Low
MacDonald, 2021	Medium*	Low	Low	Medium	Low
Brewer, 2021	Low	Low	Low	Low	Medium¥
Veerus, 2021†	Low	Low	Low	Medium	Low

High=high risk of bias, Low=low risk of bias, Medium=intermediate risk of bias.
• Non-random factor is included in design. Women assigned to the self-sampling arm who were found not at home, were reassigned to cytology.)
Δ Details of the randomisation process are not documented.
¥ Intention-to-treat analysis was not reported. If there were women who went to the clinic for conventional screening, after being invited for self-sampling, it was not documented.
□ Women in the self-sampling arm could opt-out, and those who did were excluded from the analysis (possibly leading to an artificially high participation rate in the self-sampling arm).
* Cluster-randomisation of community health workers/ Health Units to self-sampling and control arm.

Ω Intention-to-treat analysis unclear (nbs < than per protocol analysis)

δ Non-random factors in design. Investigators used randomisation to identify 800 screening non-attenders (300 each from age groups 26–34 and 35–49 years, and 200 from the age group 50–69 years). The remaining non-attenders in the study area screening programme were considered the control group.

α Randomisation occurred after enrolment.

ϵ Timing of invitation in experimental arms was different from invitation in the first control arm; compliance with cytology triage and detection rate of CIN2+ not reported.

µ Monthly-alternation as randomisation method was used to allocate women to the experimental or control arm.

† This study consisting of 2 experimental arms (different hrHPV self-sampling invitation scenarios) is only included for the secondary analysis and was not accounted for in the main analysis.

6. Participation in the experimental and control groups of RCTs

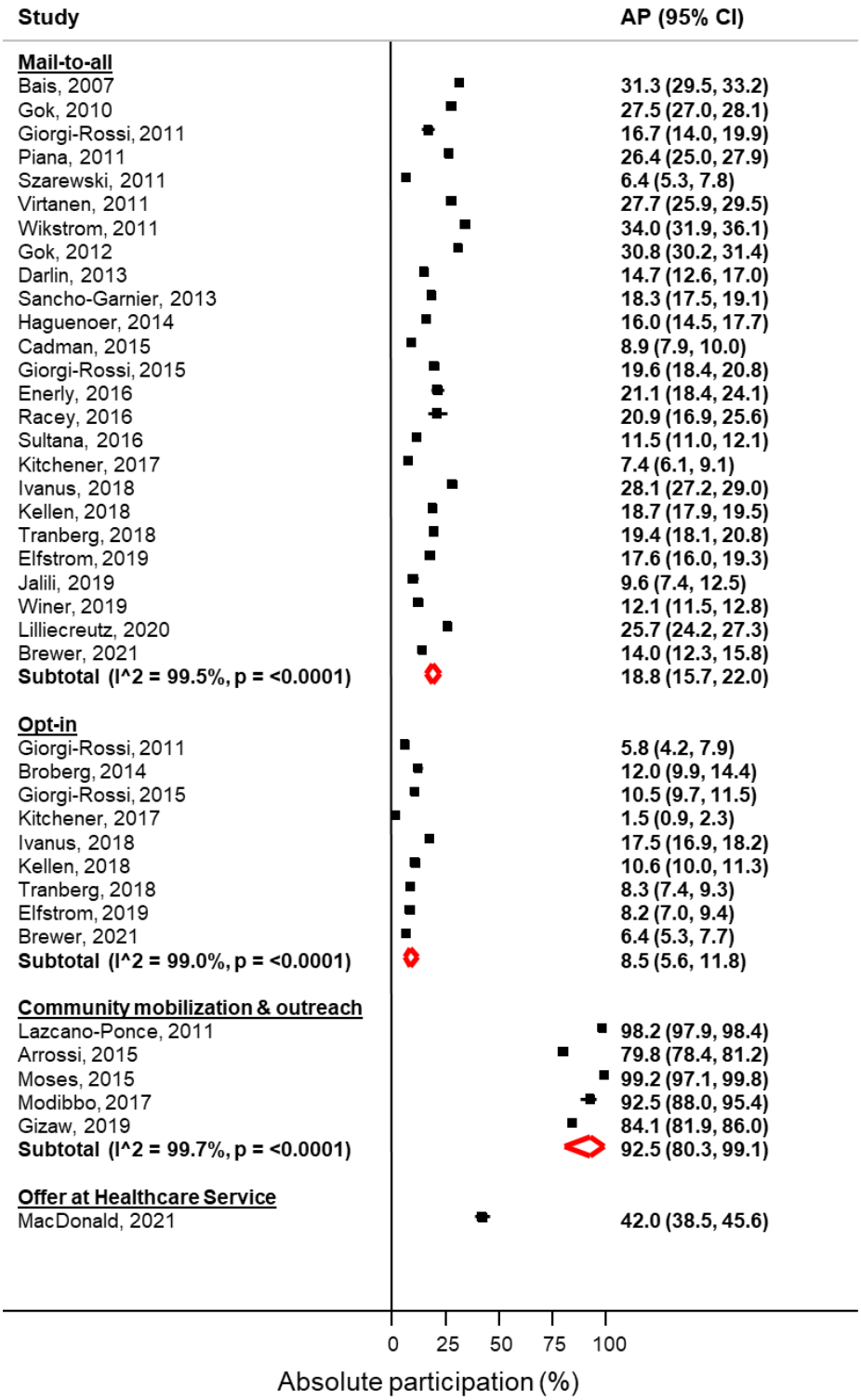

Figure S2. Participation rate in the experimental groups of randomised trials: per-protocol (PP) analysis. Only hrHPV tests on self-samples were accounted for.

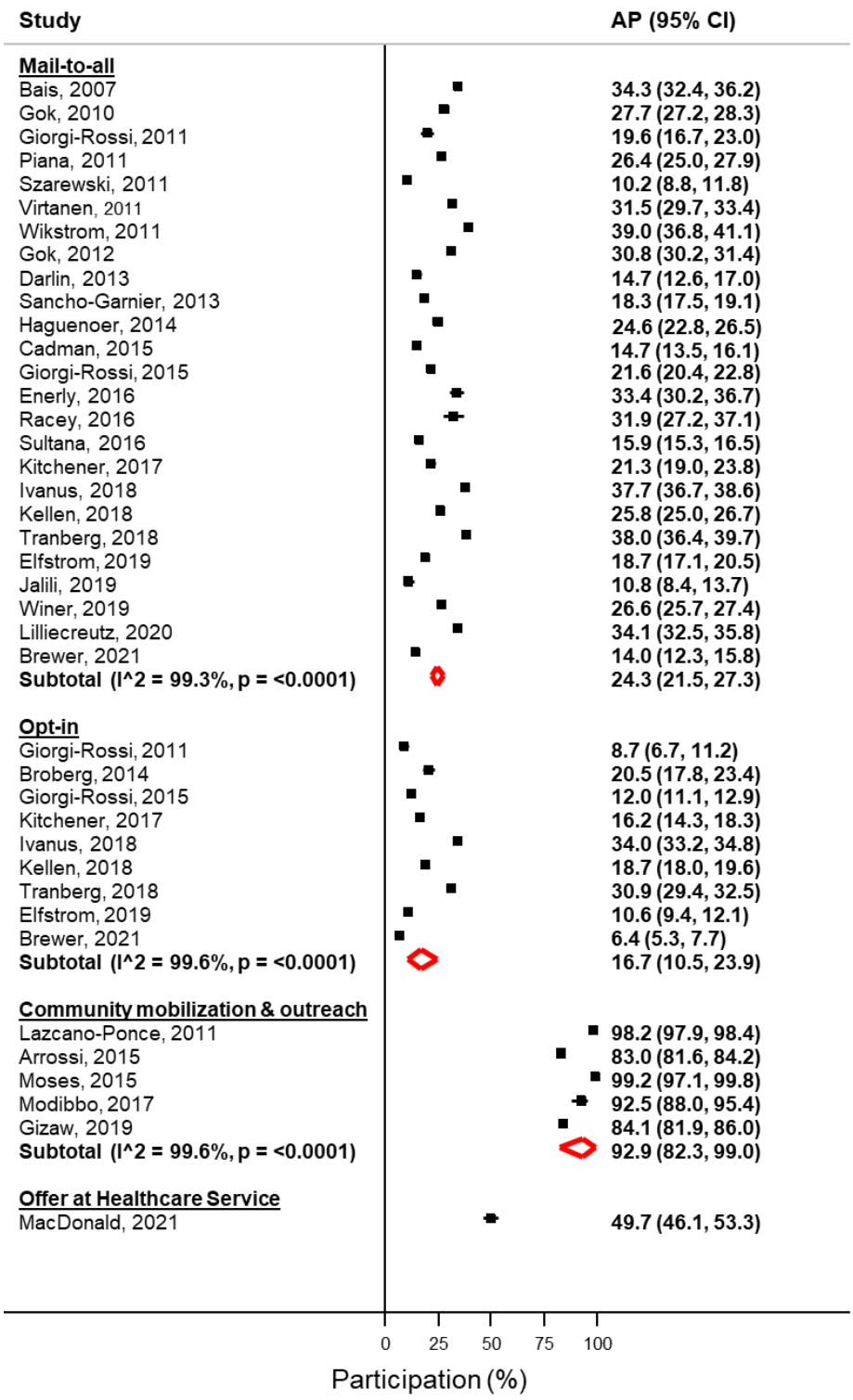

Figure S3. Participation rate in the experimental groups of randomised trials: intention-to-treat (ITT) analysis. Both, hrHPV tests on self-samples and Pap smears were accounted.

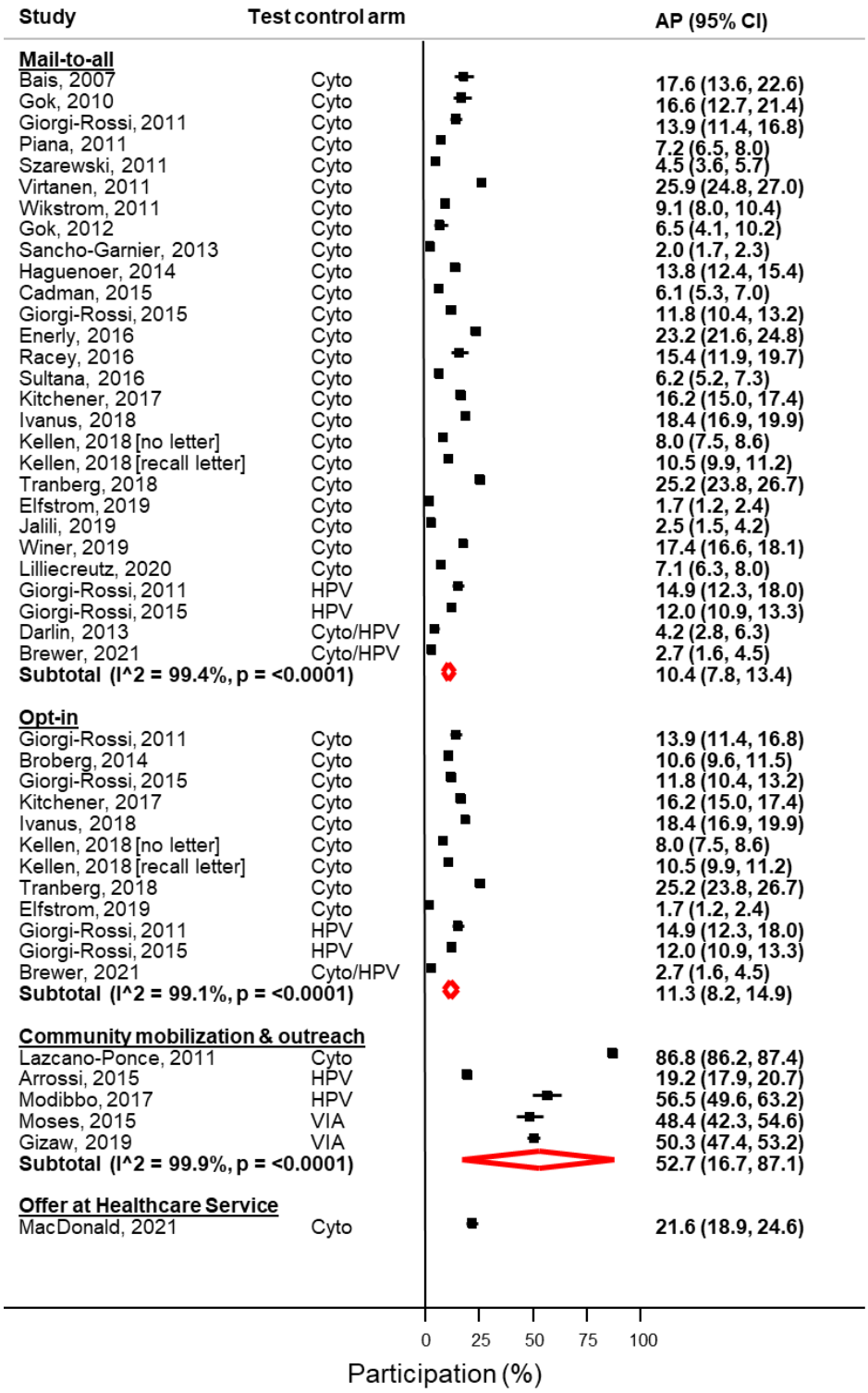

Figure S4. Participation in the control group according to the invitation scenario applied in the experimental groups.

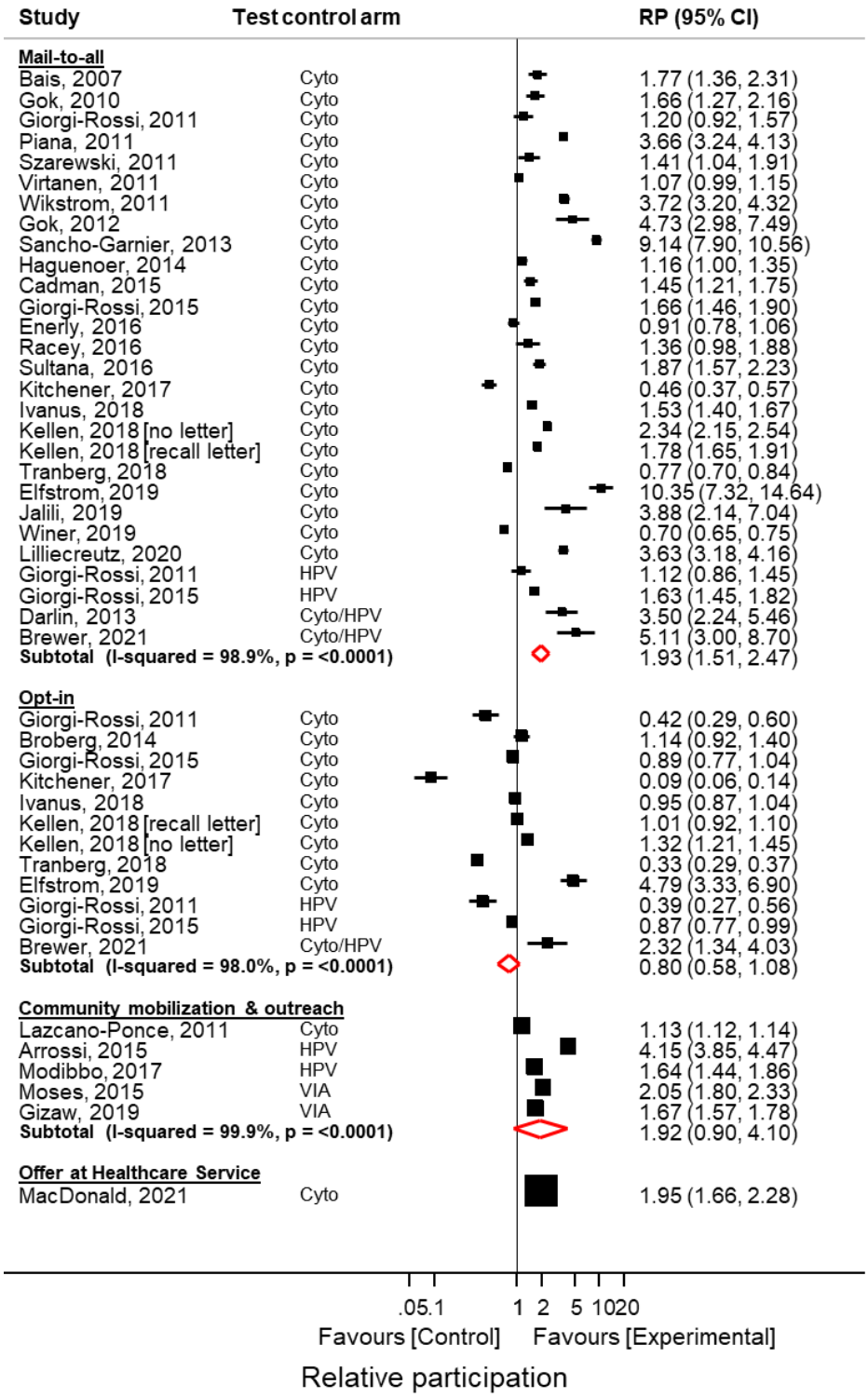

Figure S5. Relative participation (RP) in the experimental vs. the control groups of randomised trials: per-protocol (PP) analysis. Only hrHPV tests on self-samples were accounted for.

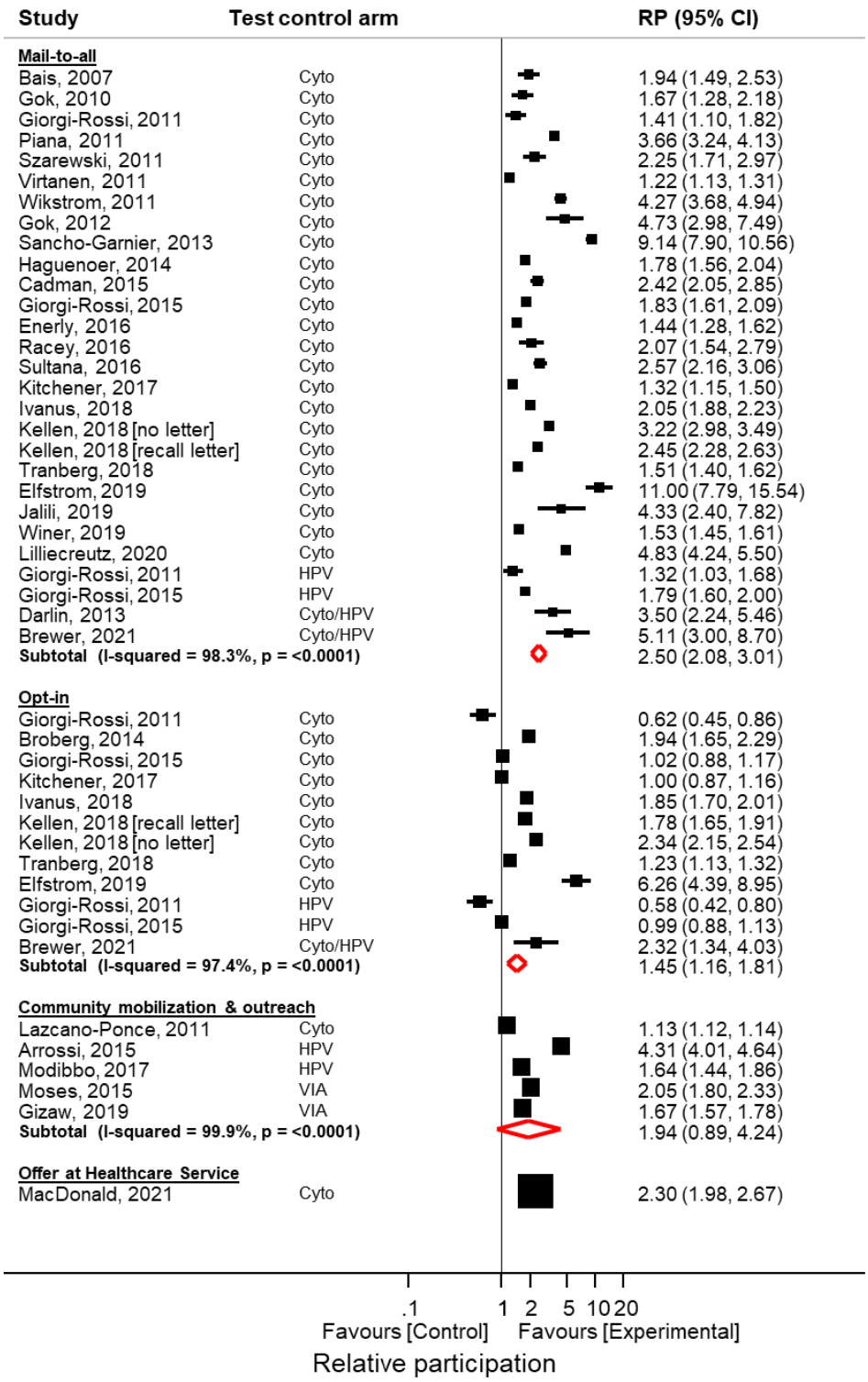

Figure S6. Relative participation (RP) in the experimental vs. the control groups of randomised trials: intention-to-treat (ITT) analysis. Both, hrHPV tests on self-samples and Pap smears were accounted.

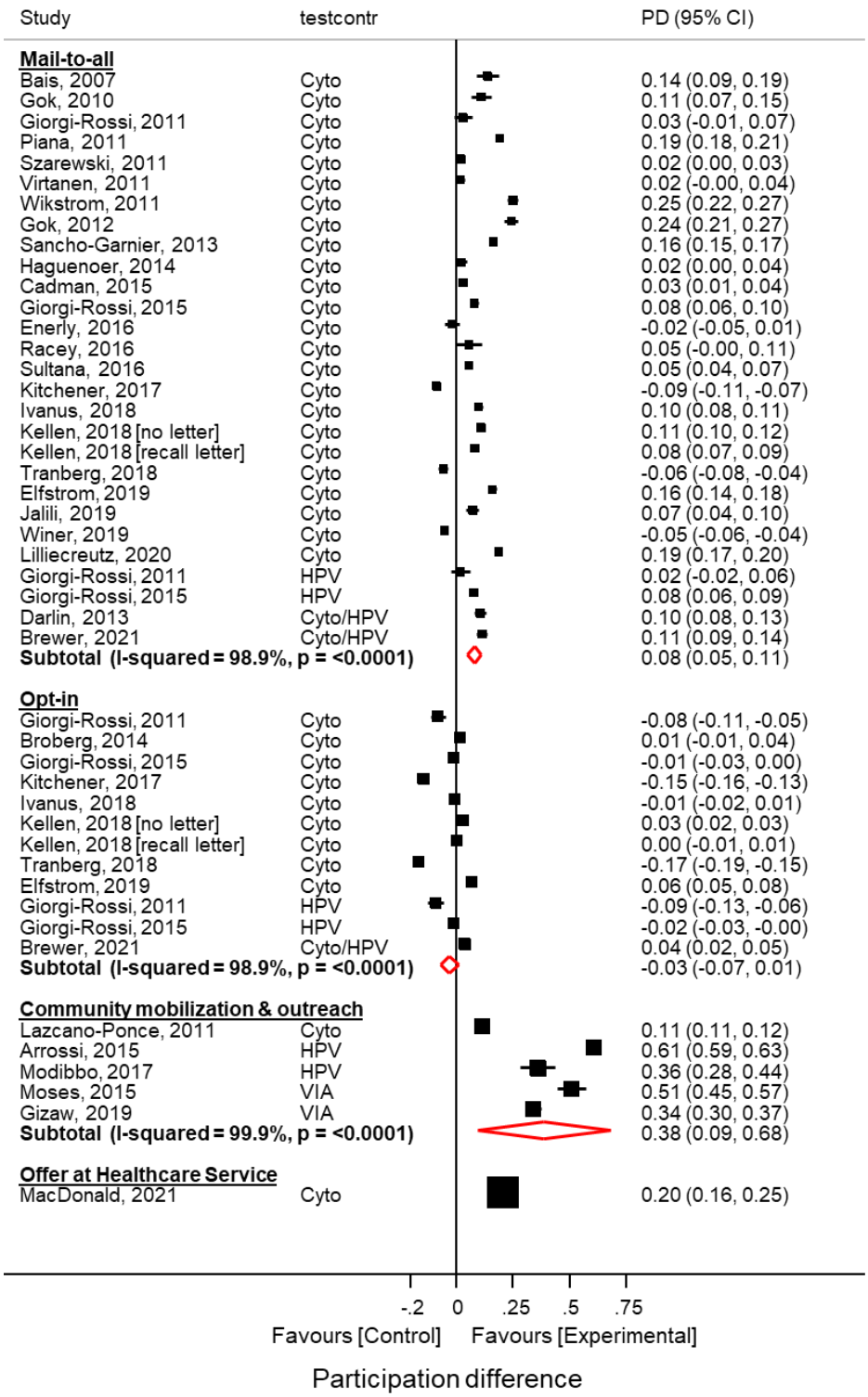

Figure S7. Participation difference (PD) in the experimental vs. the control groups of randomised trials: per-protocol (PP) analysis. Only hrHPV tests on self-samples were accounted for.

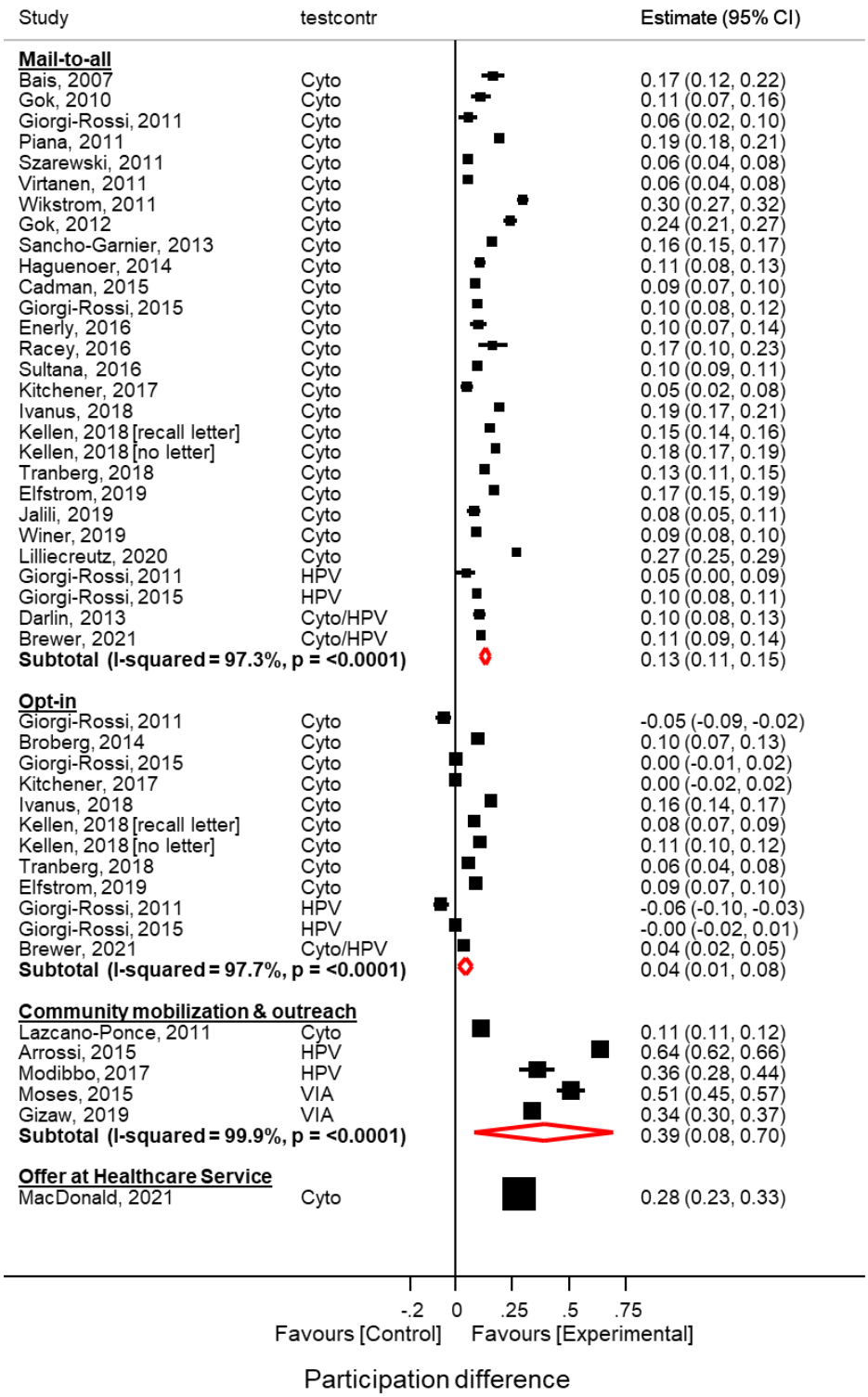

Figure S8. Participation difference (PD) in the experimental vs. the control groups of randomised trials: intention-to-treat (ITT) analysis. Both, hrHPV tests on self-samples and Pap smears were accounted for.

Table S4. Absolute proportion in self-sampling and control arm, and relative participation and participation difference in the self-sampling versus control arm, by scenario of invitation.

		Absolute participation		Relative participation	Participation difference
		Self-sampling	Control		
Scenario of invitation	**#**	%(95% CI)	%(95% CI)	(95% CI)	%(95% CI)
Per-protocol					
Mail-to-all	25/28†	18.8 (15.7, 22.0)	10.4 (7.8, 13.4)	1.93 (1.51, 2.47)	7.8 (4.7, 10.9)
Opt-in	9/12†	8.5 (5.6, 11.8)	11.3 (8.2, 14.9)	0.80 (0.58, 1.08)	-3.2 (-7.2, 0.9)
Community mobilization & outreach	5	92.5 (80.3, 99.1)	52.7 (16.7, 87.1)	1.92 (0.90, 4.10)	38.5 (9.3, 67.7)
Offer at healthcare service	1	42.0 (38.5, 45.6)	21.6 (18.9, 24.6)	1.95 (1.66, 2.28)	20.4 (15.9, 25.0)
Intention-to-treat*					
Mail-to-all	25/28†	24.3 (21.5, 27.3)	10.4 (7.8, 13.4)	2.50 (2.08, 3.01)	13.2 (11.0, 15.3)
Opt-in	9/12†	16.7 (10.5, 23.9)	11.3 (8.2, 14.9)	1.45 (1.16, 1.81)	4.4 (1.2, 7.6)
Community mobilization & outreach	5	92.9 (82.3, 99.0)	52.7 (16.7, 87.1)	1.94 (0.89, 4.24)	39.1 (8.4, 69.9)
Offer at healthcare service	1	49.7 (46.1, 53.3)	21.6 (18.9, 24.6)	2.30 (1.98, 2.67)	28.1 (23.5, 32.7)

*Certain studies reported that certain women, allocated to the self-sampling arm, had a Pap smear taken. The sum of self-samples taken + Pap smears taken, were counted in the ITT analyses. In studies, where no such cases were reported, the number of events in the PP and ITT analyses were considered as equal.
[#] Number of studies. †Giorgi-Rossi, 2011 & Giorgi-Rossi, 2015 had 2 control groups (one in which Pap smear was taken by a clinician and another in which a sample for hrHPV testing was taken by a clinician). Kellen, 2018 also had 2 control arms (one with recall letters and another without recall letters.

Table S5. Test for publication bias (small sample effects) in the relative participation (experimental vs control groups).

Scenario	Analysis	Harbord's p-value
Mail-to-all	Per-protocol	0.588
	Intention-to-treat	0.588
Opt-in	Per-protocol	0.859
	Intention-to-treat	0.393

7. Participation in the experimental groups: Opt-in vs. Mail-to-all

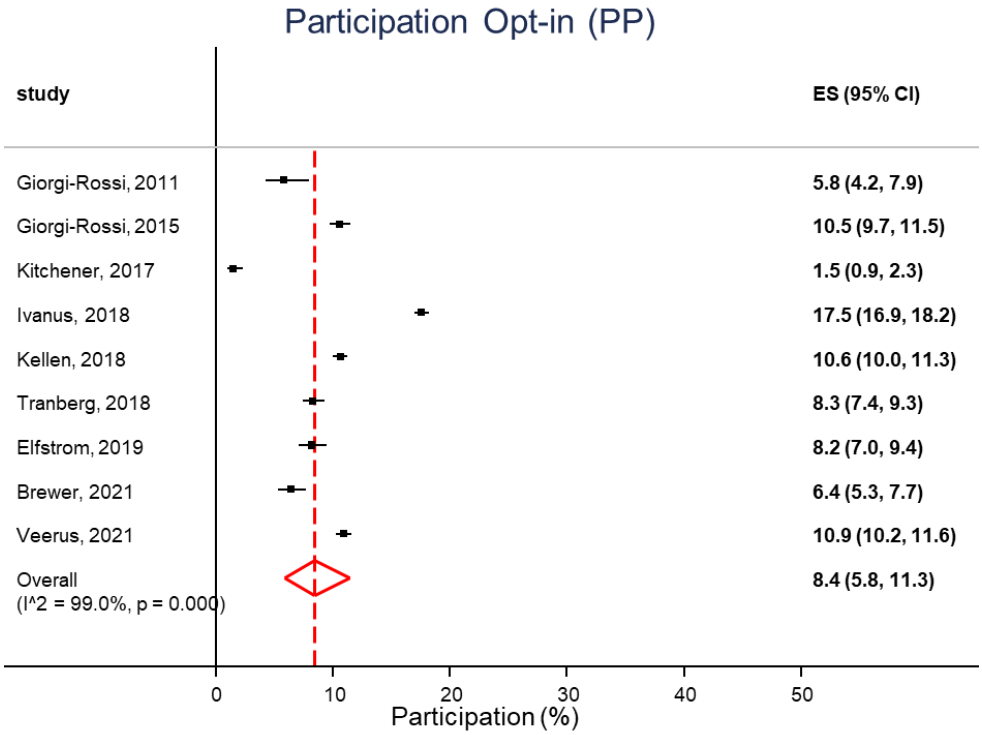

Figure S9. Participation rate in Opt-in invitation scenario of randomised trials with two experimental groups: per-protocol (PP) analysis. Only hrHPV tests on self-samples were accounted for.

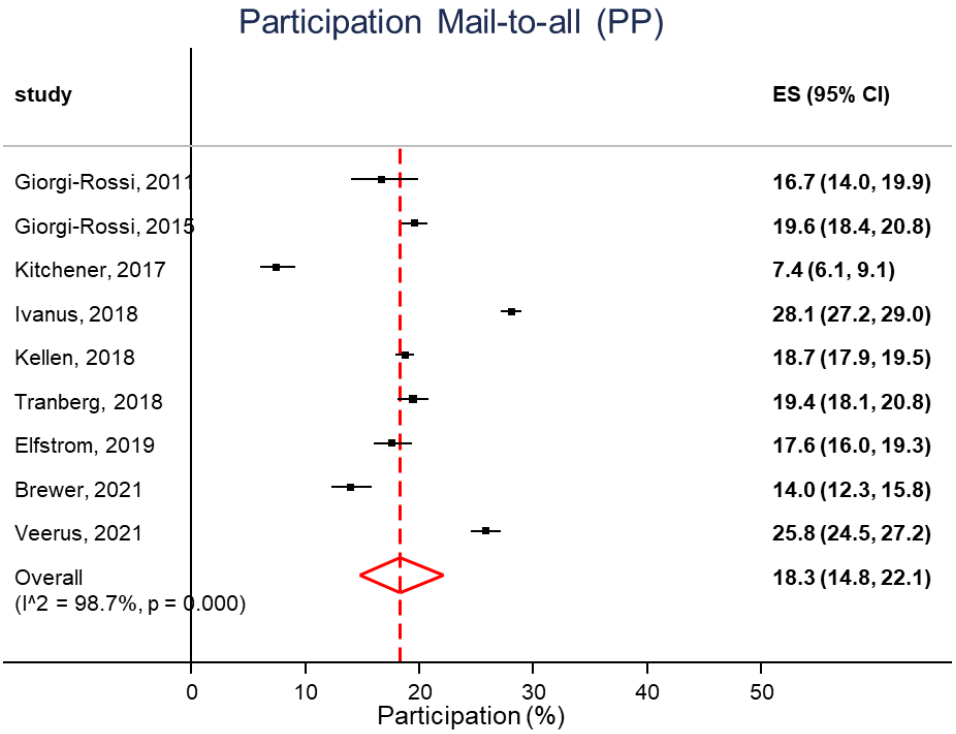

Figure S10. Participation rate in Mail-to-all invitation scenario of randomised trials with two experimental groups: per-protocol (PP) analysis. Only hrHPV tests on self-samples were accounted for.

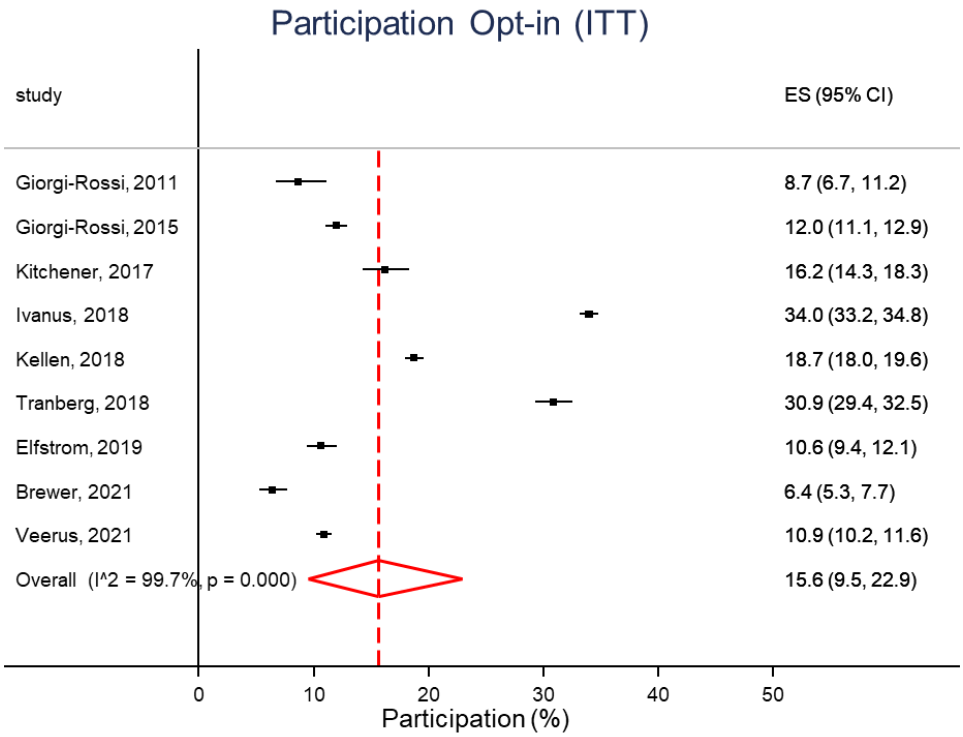

Figure S11. Participation rate in Opt-in invitation scenario of randomised trials with two experimental groups: intention-to-treat (ITT) analysis. Both, hrHPV tests on self-samples and Pap smears were accounted.

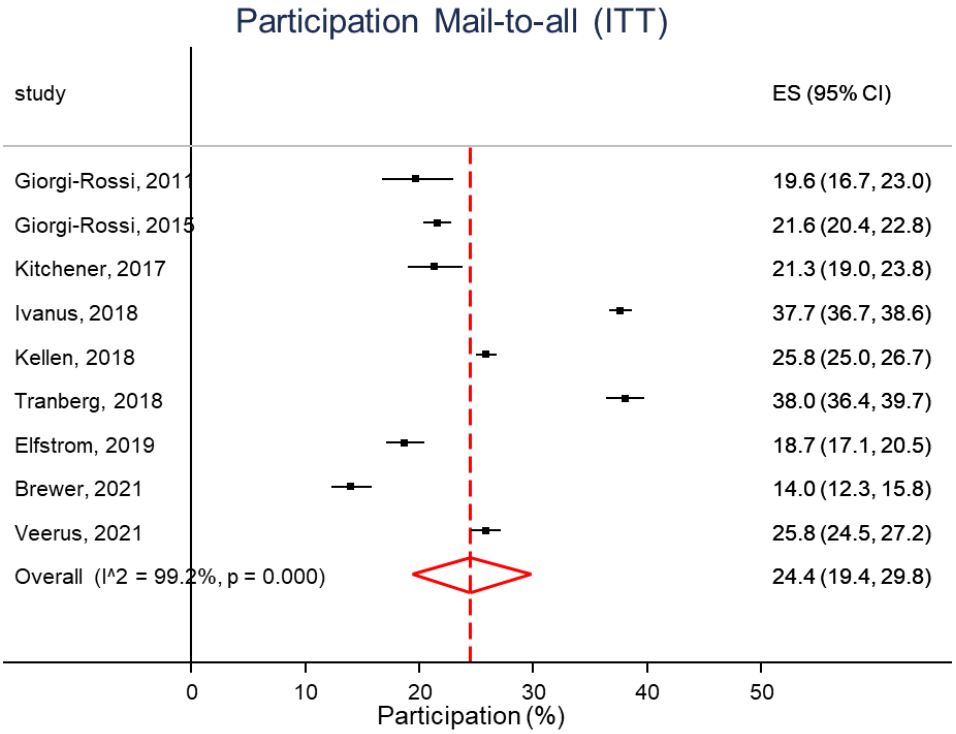

Figure S12. Participation rate in Mail-to-all invitation scenario of randomised trials with two experimental groups: intention-to-treat (ITT) analysis. Both, hrHPV tests on self-samples and Pap smears were accounted.

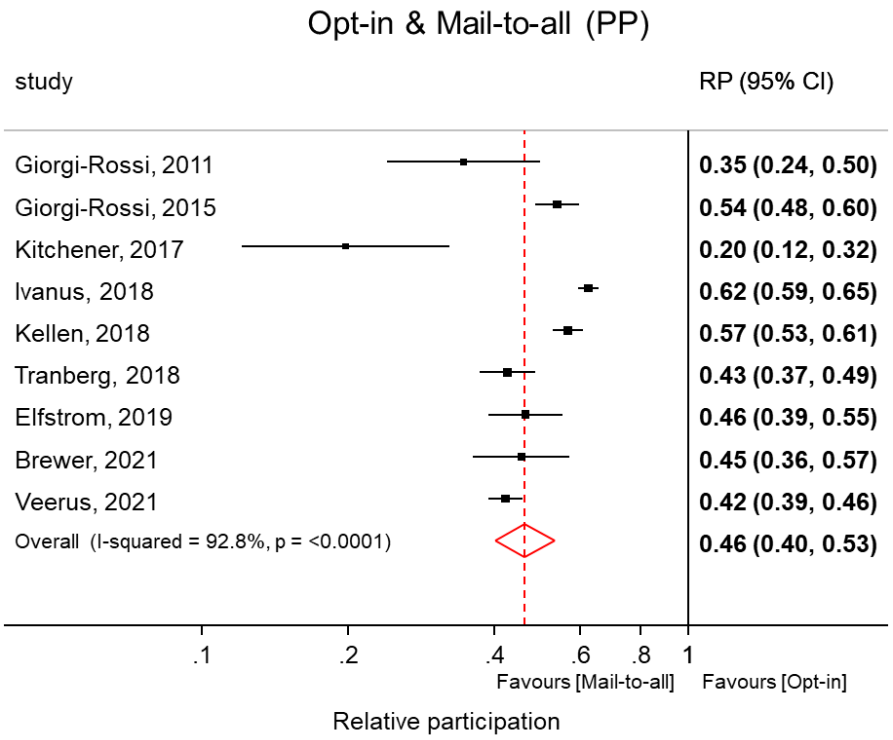

Figure S13. Relative participation (RP) in the Opt-in vs. Mail-to-all experimental groups of randomised trials: per-protocol (PP) analysis. Only hrHPV tests on self-samples were accounted for.

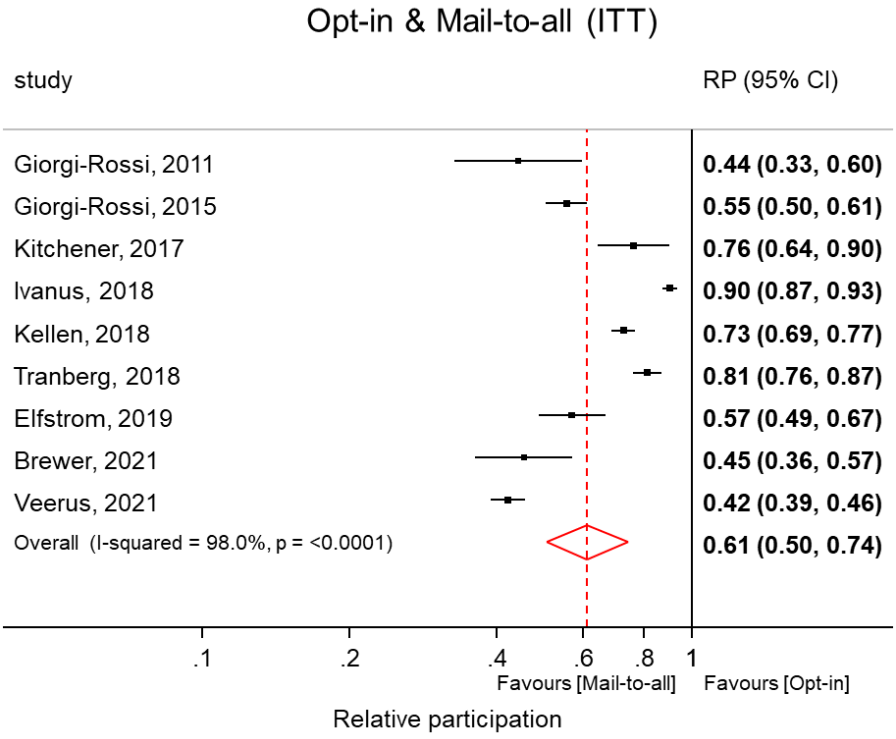

Figure S14. Relative participation (RP) in the Opt-in vs. Mail-to-all experimental groups of randomised trials: intention-to-treat (ITT) analysis. Both, hrHPV tests on self-samples and Pap smears were accounted for.

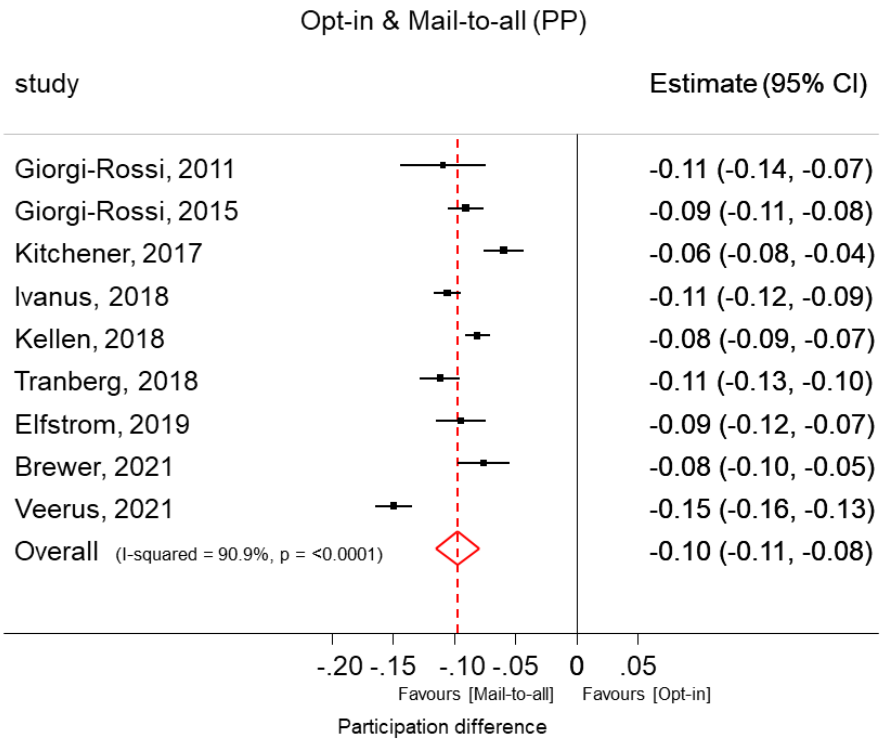

Figure S15. Participation difference (PD) in the Opt-in vs. Mail-to-all experimental groups of randomised trials: per-protocol (PP) analysis. Only hrHPV tests on self-samples were accounted for.

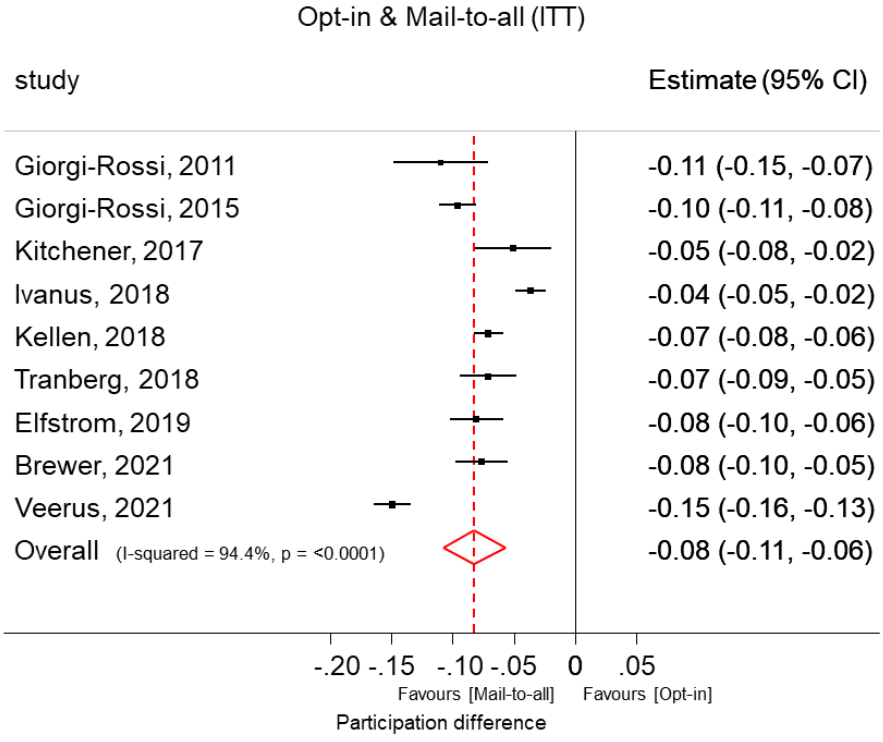

Figure S16. Participation difference (PD) in the Opt-in vs. Mail-to-all experimental groups of randomised trials: intention-to-treat (ITT) analysis. Both, hrHPV tests on self-samples and Pap smears were accounted for.

Table S6. Absolute proportion in self-sampling arm, and relative proportion and difference in the Opt-in vs. Mail-to-all self-sampling invitation scenarios.

		Absolute participation		Relative participation	Participation difference
		Opt-in	Mail-to-all		
Analysis	**#**	%(95% CI)	%(95% CI)	(95% CI)	%(95% CI)
Per-protocol	9	8.4 (5.8, 11.3)	18.3 (14.8, 22.1)	0.46 (0.40, 0.53)	-9.7 (-11.5, -8.0)
Intention-to-treat*	9	15.6 (9.5, 22.9)	24.4 (19.4, 29.8)	0.61 (0.50, 0.74)	-8.2 (-10.8, -5.7)

*Certain studies reported that certain women, allocated to the self-sampling arm, had a Pap smear taken. The sum of self-samples taken + Pap smears taken, were counted in the ITT analyses. In studies, where no such cases were reported, the number of events in the PP and ITT analyses were considered as equal.

8. Specimen adequacy, test-positivity rate, follow-up adherence, detection of CIN2+

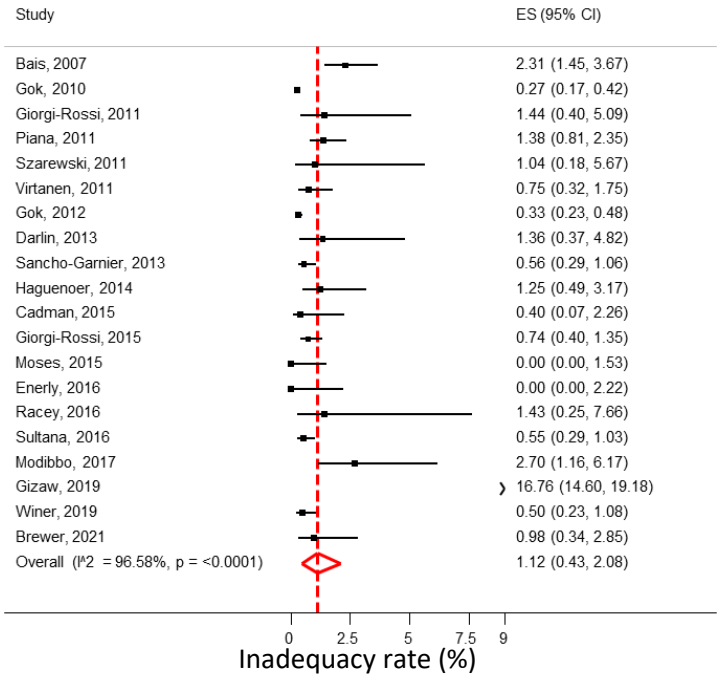

Figure S17. Proportion of self-samples that was inadequate for hrHPV-testing.

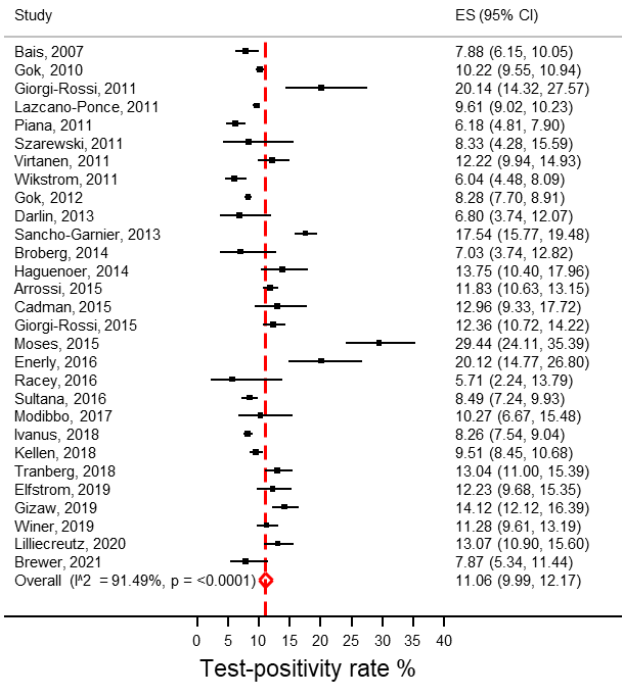

Figure S18. hrHPV test-positivity in self-samples (experimental arm).

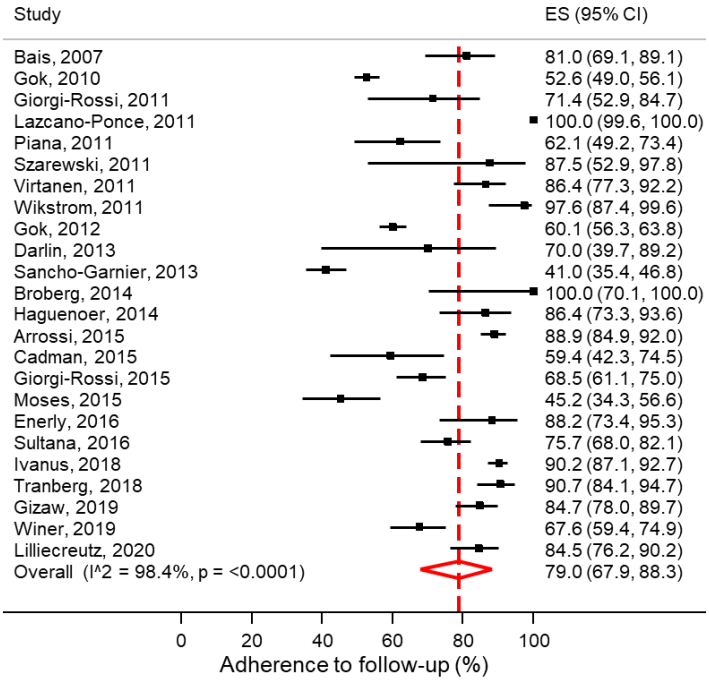

Figure S19. Follow-up adherence among women with a positive test result on their hrHPV self-sample (in the self-sampling arm).

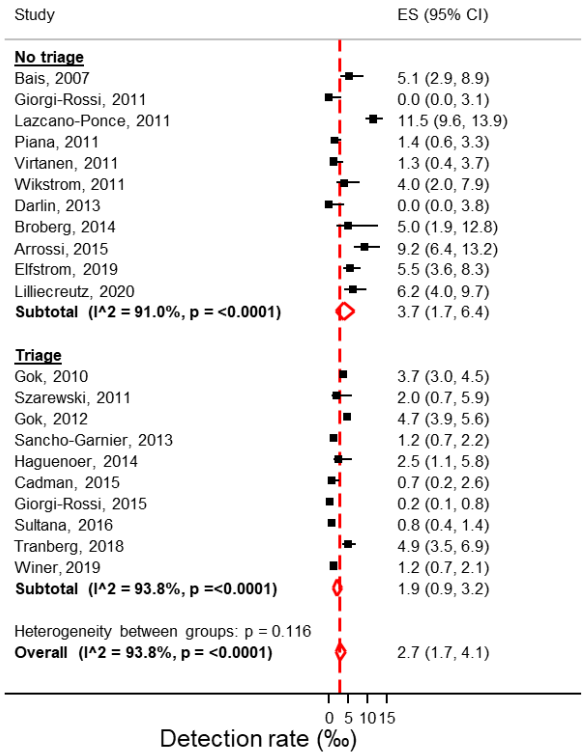

Figure S20. Detection of CIN2+ per 1000 invited women in the self-sampling arm, stratified by triage policy.

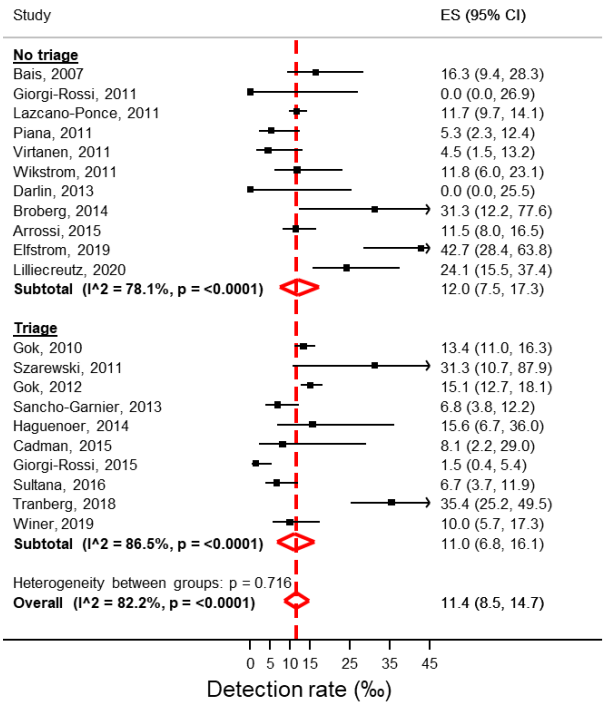

Figure S21. Detection of CIN2+ per 1000 screened women in the self-sampling arm, stratified by triage policy.

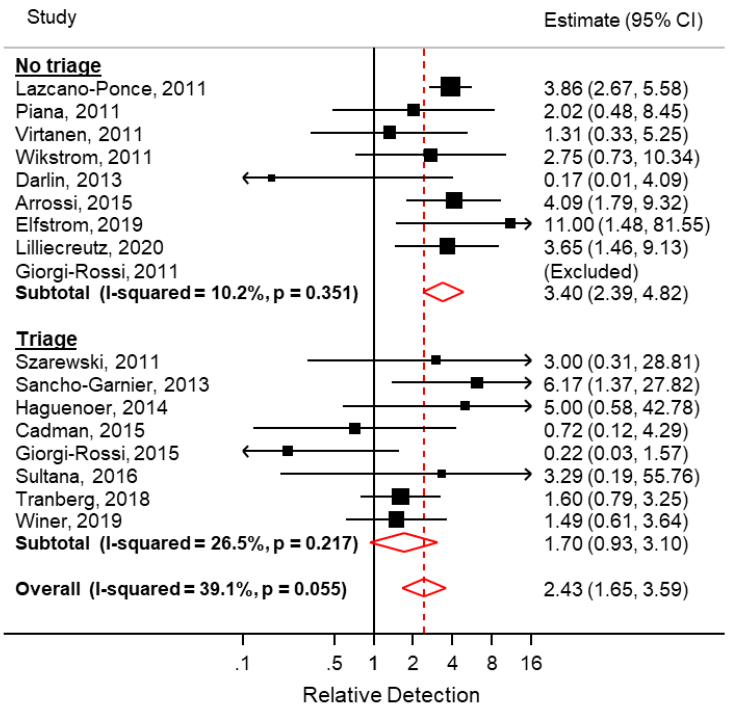

Figure S22. Relative detection of CIN2+ in the self- compared to the control arm among invited women, by triage policy in the self-sampling arm.

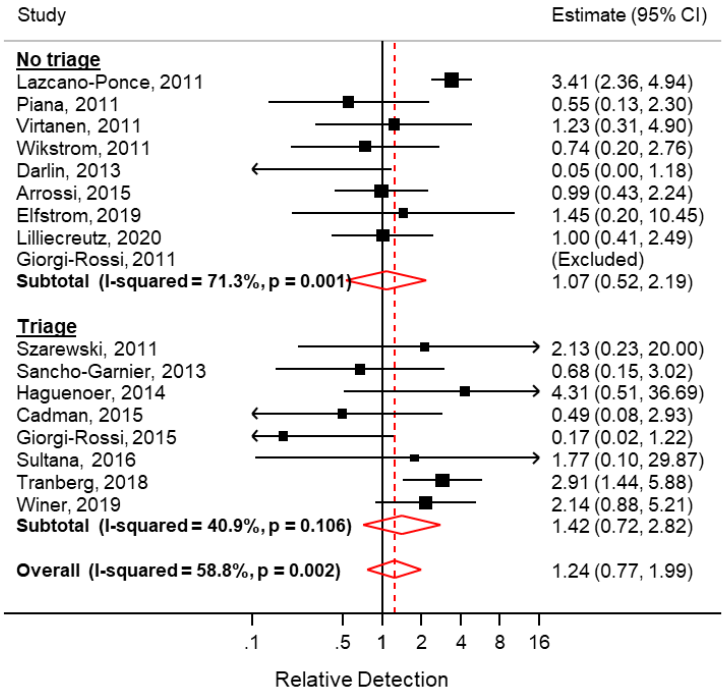

Figure S23. Relative detection of CIN2+ in the self-sampling compared to the control arm among screened women, by triage policy in the self-sampling arm.

Table S7. Absolute proportion in self-sampling arm, and relative proportion and difference in the self-sampling arm vs. control arm (cytology) for four parameters.

Parameter	#	Absolute proportion self-sampling arm (95% CI)	#	Relative proportion (95% CI)	Proportion Difference (95% CI)
Inadequate sample	20	1.1% (0.4, 2.1%)	-	-	-
Test-positivity*	29	11.1% (10.0, 12.2%)	-	-	-
Compliance to follow-up	24	79.0% (67.9, 88.3%)	11	0.93 (0.84, 1.04)	-6.7% (-17.4, 4.0%)
CIN2+/1000 invited	21	2.7‰ (1.7, 3.2‰)	17	2.43 (1.65, 3.59)	1.8‰ (0.6, 3.1‰)
CIN2+/1000 screened	21	11.4‰ (8.5, 14.7‰)	17	1.24 (0.77, 1.99)	3.3‰ (-0.4, 7.1‰)

* Test-positivity of hrHPV-test in the self-sampling arm (per-protocol). # Number of studies.

9. References

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