



# A randomised controlled trial of volitional and motivational interventions to improve cervical cancer screening uptake

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## ARTICLE INFO

Handling Editor: M Hagger

### Keywords:

Cervical cancer screening  
Behaviour change intervention  
Brief intervention  
Implementation intention intervention  
Volitional behaviour change intervention

## ABSTRACT

### Objective.

Cervical cancer is the fourth most common cancer to occur in women worldwide. In the UK, the NHS cervical screening programme invites eligible individuals to take part in screening every 3–5 years. At present, around 70% of individuals attend screening when invited. The present study aimed to test the effectiveness of a volitional and a motivational intervention alone and in combination on screening uptake at 16-week follow up.

### Methods.

14,536 participants were recruited from the list of eligible participants invited for screening in Yorkshire, Humber and the North East regions of England in December 2021. They were randomised to a social norm-based motivational intervention (SNA); implementation intention-based Volitional Help Sheet (VHS); combined intervention (SNA + VHS); or treatment as usual control. The primary outcome was screening uptake measured via patient screening records at 16 weeks.

### Results.

Of the 14,466 participants with eligible data for analysis, 5793 (40.0%) attended for cervical cancer screening in the 16 weeks after the intervention mailing. Both age and deprivation influenced screening uptake, with lower uptake in the youngest individuals and those from more deprived areas. Compared to control, there was no evidence of any benefit from the VHS implementation intervention alone (Adj.OR = 0.99, 95% CI 0.90 to 1.10), the SNA motivational intervention alone (Adj.OR = 0.89; 95% CI: 0.80 to 0.99), or the combined intervention (Adj.OR = 0.96, 95% CI 0.86 to 1.06).

### Conclusion.

The study did not support any benefit of either VHS or SNA interventions alone or in combination on cervical cancer screening uptake. It did demonstrate alarmingly low levels of screening uptake at 16 weeks which were well below the average rate. Future research needs to urgently investigate and understand the barriers to uptake following on from the COVID-19 pandemic.

## 1. Introduction

Cervical cancer is the fourth most common cancer to occur in women worldwide (World Health Organisation, 2022). Cervical screening aims to prevent cervical cancer by identifying and treating precancerous lesions. Survival is increased when the lesions are caught at an early stage, and the EU recommends cancer screening should be offered on a population-level basis in organised screening programmes (European Council, 2003). At present, no countries report attendance at the 85%

rate recommended by European guidelines (Gianino et al., 2018). Screening uptake is also associated with age, where it is lowest in the youngest along with the oldest age groups of invitees (25–29 and 60–64 years; Cancer Research UK, 2021).

The NHS cervical screening programme was first introduced in 1988 and uses a ‘call-recall’ system where women are sent invitations, re-invitations and reminders to take part in the screening. Cervical screening has not reached its target of 80% since 2005 and has been decreasing year on year (NHS England, 2022). 70.2% of invited

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<https://doi.org/10.1016/j.socscimed.2023.115800>

Received 9 September 2022; Received in revised form 18 January 2023; Accepted 20 February 2023

Available online 22 February 2023

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individuals attended screening in 2020–21 (NHS Digital, 2022; Public Health England, 2021). Uptake is negatively associated with deprivation (Moser et al., 2009), ethnic minority group populations, and those from low socioeconomic status areas (Douglas et al., 2016; NHS Digital, 2019).

Implementation intentions are a psychological intervention that comprises an individual planning the context in which he/she will perform a particular behaviour. They involve an individual planning when and where they will perform a particular behaviour in the form of an if-then statement (“If I encounter situation *x*, then I will do *y*!”; “When I receive my cervical cancer screening letter I will think about the benefits of getting screened”). In doing so, they help an individual to, first identify an opportunity to act, even when there appear to be multiple barriers, because choosing a critical future situation in which to act is assumed to make the mental representation of this situation highly activated and accessible (Gollwitzer, 1999). Second, the mental link, upon encountering the critical situation, leads one to act in a more immediate (Gollwitzer and Brandstätter, 1997), efficient and automatic fashion, that is not dependent on conscious awareness (Sheeran et al., 2005). Implementation intentions have been successfully applied to a range of health behaviours (Armitage, 2016; de Bruijn et al., 2017; Hall et al., 2014; O’Connor et al., 2015).

Two studies (Sheeran and Orbell, 2000; Walsh, 2005) have used implementation intentions in relation to promoting cervical screening attendance. The first study (Sheeran and Orbell, 2000) demonstrated they can increase attendance for cervical cancer screening in a single rural practice setting. Women received the following instructions. “You are more likely to go for a cervical smear if you decide when and where you will go. Please write in below when, where, and how you will make an appointment.” The results showed that women randomised to form implementation intentions were significantly more likely to attend for screening compared to women in the control condition (92% vs 69% attendance rate). A second study (Walsh, 2005) targeted prior non-attenders recruited from the Irish Cervical Screening Programme register. Despite using the same intervention as Sheeran and Orbell, this study failed to observe a significant effect on attendance. It is unclear whether the lack of significant effects was attributable to low awareness of cervical screening or low motivation to screen among this group of previous non-screeners (only 18% screening rate).

Both studies are limited in a number of important ways. First, they use ‘simple’ implementation intentions that do not help participants identify barriers to attendance and/or help participants to plan to overcome these barriers. Recent research has shown that the barriers are numerous and vary across different socioeconomic groups and by age. For example, Waller et al. (2012) and Marlow et al. (2017) found that reasons for non-attendance may be different in older compared to younger women. They showed that the barriers reported were more likely to be practical in younger women and more likely to be negative attitudes towards screening in older women. To date, no studies have utilised the Volitional Help Sheet (VHS) technique to help facilitate the formation of implementation intentions within the context of cervical cancer screening.

Social norms theory suggests that people inaccurately perceive the attitudes and/or behaviours of important others, e.g., they underestimate the numbers of other women who attend for cervical screening (Berkowitz, 2005; Schultz et al., 2007). There is a large amount of research to investigate social norms theory and Social Norms Approach (SNA) interventions in health risk behaviours such as alcohol and drug use (Burchell et al., 2013; Lewis and Neighbors, 2006; Perkins, 2014). These studies suggest that individuals tend to overestimate performance of these behaviours. Fewer studies have investigated the SNA in cancer screening behaviours (Sieverding et al., 2010, 2010b; Stoffel et al., 2021; Stoffel et al., 2019; von Wagner et al., 2019), particularly cervical cancer screening. SNA interventions rely on providing information regarding the behaviour or cognitions relating to a specific behaviour in people similar to the individual. It has been suggested that

individuals tend to underestimate the extent to which their peers engage in health protection behaviours (Perkins, 2014) which may discourage performance of the behaviour. Interventions are more successful when the information provided relates to peers who individuals can identify with in terms of specific characteristics such as being of a similar age or gender (Dempsey et al., 2018).

Recent studies have supported the effectiveness of social norms interventions, including providing verbal quantifiers (e.g. ‘a large number of people eligible to participate do so’, Stoffel et al. (2019); and providing high uptake rate information (von Wagner et al., 2019) as increasing screening intentions. In a study on bowel cancer screening uptake, we found that combining a social norm intervention with implementation intention increased screening uptake but only in specific groups of individuals, whereby the youngest participants were more likely to attend screening, but all other individuals did not differ to the usual care control (Wilding et al., 2020a,b).

## 2.1. Aim

The present study aimed to test an implementation intentions-based VHS and/or a SNA-based motivational intervention to increase cervical cancer screening uptake in a sample of women in the Yorkshire, Humber and North East regions of England. This was a randomised controlled trial (RCT) using a factorial design to examine the effectiveness of SNA and VHS interventions alone and in combination, compared to usual care.

## 2. Methods

### 2.1. Participants and design

Participants were individuals sent a routine cervical cancer screening invitation between 6th and December 12, 2021.

The research design employed a 2 × 2 factorial randomised controlled trial in order to assess the influence of both a volitional intervention (VHS) and a motivational intervention (SNA), individually and in combination as compared with usual care. The trial protocol was pre-registered at ISRCTN (registration number ISRCTN15082468). Intervention groups were randomly allocated by individual. All participants subsequently received a letter of invitation to the study plus study information sheet. These materials were sent and received separately from the routine invitation to screening materials sent by the cervical cancer screening service. Participants received the intervention materials within a week of their screening invitation and all intervention materials were sent after the screening invitations had been sent out.

### 2.2. Ethical approvals

The study received the following approvals: The Cervical Screening Programme Research Advisory Committee CSPRAC\_0050, 12/10/20; North East -Newcastle & North Tyneside 1 Research Ethics Committee 21/NE/0033, 25/03/21; NHS Confidentiality Advisory Group (CAG) approval for Health Service (Control of Patient Information) Regulations 2002 (‘section 251 support’) 21/CAG/0021, 30/03/21; Public Health England Office of Data Release and CSPRAC\_050 (ODR1920\_239), 19/05/21; NHS England DRAB approval CSPRAC\_050 (ODR1920\_239), 20/07/21.

### 2.3. Interventions and procedure

Participants were randomised to one of four experimental conditions in order to evaluate the individual and combined effects of: (1) a motivational intervention using a SNA leaflet, and (2) a volitional intervention using a Volitional Help Sheet (VHS).

All participants received an initial letter of invitation for cervical cancer screening and a standard NHS information booklet (usual care).

Each participant was allocated to one of four conditions: a Volitional Help Sheet (VHS) intervention based on implementation intentions, a motivational intervention based on the Social Norms Approach (SNA), both of these interventions combined (SNA + VHS), or usual care (no intervention). Random allocation occurred via a random number generator where one of the four conditions was applied to each row of the list of participants. The randomisation sequence was generated by the statistician and the rest of the research team remained blinded to the allocation procedures.

The implementation intentions intervention pack contained an information sheet and a short task (the VHS; supplementary file 2) designed to help participants to construct effective 'if-then' plans. This involved drawing lines to connect barriers likely to be encountered (IFs) with effective responses (THENS) to aid participants' decision-making process with regards to attending cervical cancer screening. The list of barriers and responses identified was based on qualitative pilot studies across a range of ethnic and socioeconomic groups (Wilding et al., 2020a,b; supplementary file 1).

The motivational intervention pack contained an information sheet and a motivational-intervention leaflet with information regarding the social norms surrounding cervical cancer screening (i.e., how many women are up-to-date with screening) and was designed to motivate participants to attend cervical screening (supplementary file 2). The combined intervention received both sets of materials, with the

motivational materials placed first.

### 2.4. Outcomes

The primary outcome measure was whether participants had attended for cervical cancer screening 16 weeks following receiving an invitation letter, as recorded in the National Health Application and Infrastructure Services (NHAIS) database which is populated following screening appointment attendance. Data were also recorded on age, area-level socioeconomic deprivation derived from the 2019 Index of Multiple Deprivation (IMD) based on individual postcodes, and previous cervical cancer screening invitation.

### 2.5. Sample size

In total 14,536 individuals were included in the study randomisation and intervention; participants were allocated to condition as follows: Control N = 3612; SNA only N = 3603; VHS only N = 3691; Combined N = 3630. Fig. 1 shows the flow of participants through the study. A total of 83 participants were not included in the analyses due to moving out of the area, with similar numbers in each condition being lost in this way (Fig. 1). Therefore analyses were based on 14,453 participants. As missing data (approximately 0.6%) represented well below the criterion of 5% missing (Schafer, 1999) we did not impute missing values. This

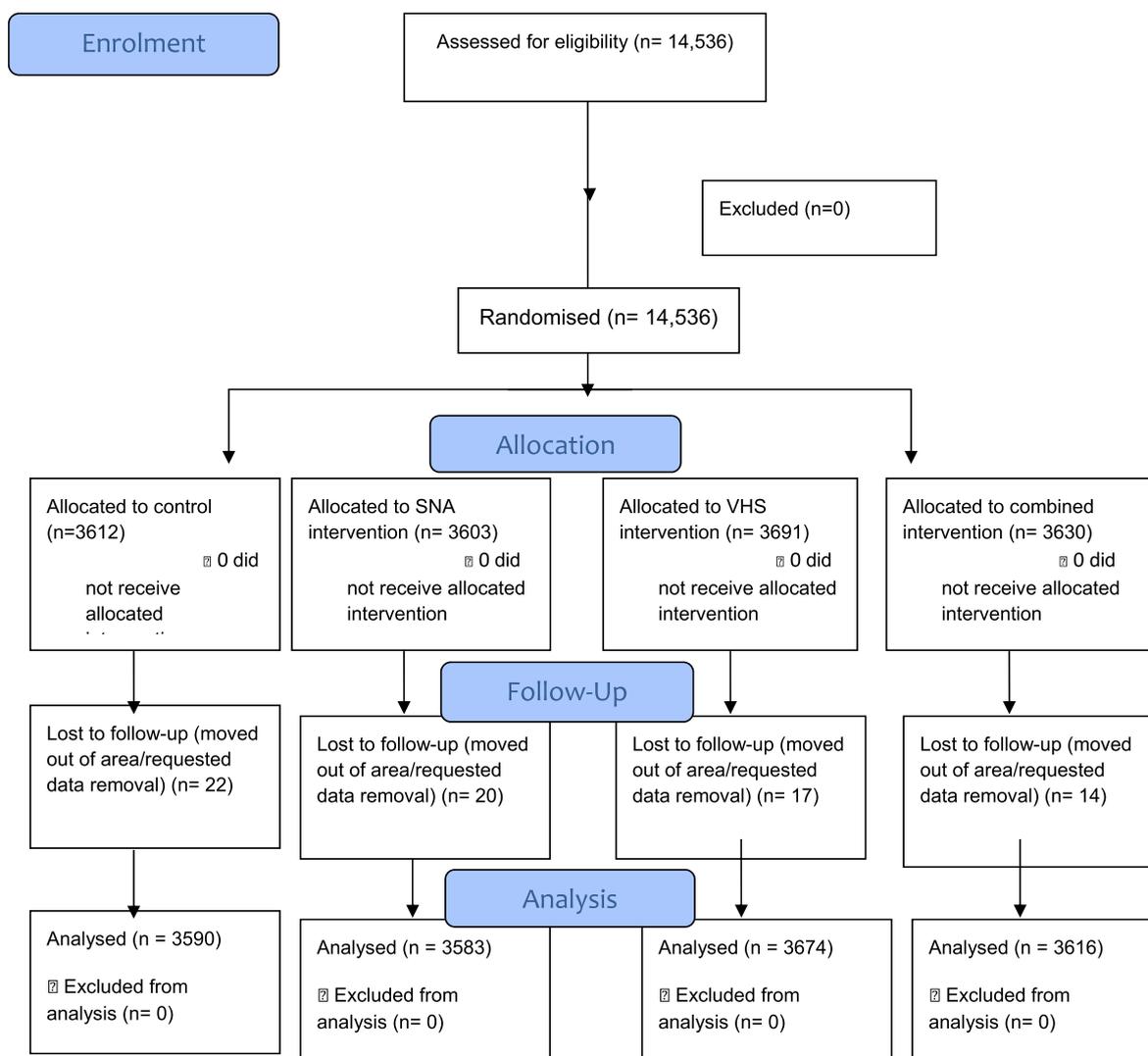


Fig. 1. Flow diagram of participants through the trial.

sample size provided 80% power to detect a 3.3% difference in response rates for each intervention condition against control.

### 2.6. Analysis summary

In order to describe the data and provide comparisons with other samples we report screening rates by age and deprivation. To test differences in rates of screening between 4 conditions, a logistic regression model was used for the primary outcome of samples being returned within 16 weeks with intervention group as a fixed effect adjusting for participants' age, IMD, and previous screening history. Both adjusted and unadjusted estimates are presented as the primary results (to aid comparisons  $d_+$  effect sizes are also reported; computed using the method described by Chinn, 2000). In order to account for the effect of multiple testing, a  $p$  value of  $p < .01$  was used to indicate significance of findings. All analyses were conducted using Stata version 15.1. Data analysis scripts and outputs are available in supplementary files 2–3.

### 3. Results

Of the 14,466 participants with eligible data for analysis, 5793 (40.0%) attended for cervical cancer screening in the 16 weeks after the intervention mailing.

A smaller proportion of the youngest age group of women (aged 24–30) attended screening ( $N = 835$ , 30.7%) compared to any of the other age groups (aged 30–40;  $N = 1969$ , 42.5%; aged 40–50,  $N = 1452$ , 41.5%; aged 50+,  $N = 1537$ , 42.6%). Just under one third of women from the IMD area of greatest deprivation attended screening (31.5%,  $N = 1511$ ) compared to just under half of those from the two quintiles of lowest deprivation (quintile 4: 45.0%,  $N = 1105$ ; quintile 5: 49.6%,  $N = 1011$ ) and just over 40% of individuals from quintiles 2 ( $N = 1086$ , 40.1%) and 3 ( $N = 1080$ , 43.8%) (see Table 1).

#### 3.1. Primary outcomes

The effect of intervention on the primary endpoint of attendance for screening at 16-week follow up is reported by condition in Table 2.

Compared to control, there was no evidence of any benefit from the VHS implementation intervention alone ( $-0.6\%$  difference; Unadj. OR = 0.98, 95% CI 0.89 to 1.07,  $d_+ = -0.01$ ; Adj. OR = 0.99, 95% CI 0.90 to 1.10,  $d_+ = -0.006$ ), the SNA motivational intervention alone ( $-1.7\%$  difference; Unadj. OR = 0.93, 95% CI 0.85 to 1.02,  $d_+ = -0.04$ ; Adj. OR = 0.89; 95% CI: 0.80 to 0.99,  $d_+ = -0.06$ ), nor the combined intervention ( $-1.2\%$  difference; Unadj. OR = 0.95, 95% CI 0.87 to 1.04,  $d_+ = -0.03$ ; Adj. OR = 0.96, 95% CI 0.86 to 1.06,  $d_+ = -0.02$ ).

### 4. Discussion

This large-scale randomised controlled trial aimed to investigate the influence of two theory based brief behaviour change interventions (individually and in combination) on cervical cancer screening uptake in a large sample of women from the North of England. The study used an objective measure of screening attendance and was conducted in collaboration with NHS Digital and the cervical cancer screening programme. Over 14,000 women were included in the study and an objective measure of screening uptake in the 16-weeks following the intervention mailing was used as the outcome variable. Overall screening uptake in this period was around 40%. There was no evidence of any benefit of either intervention alone or in combination.

Recent national statistics provided by NHS England show that 71.3% of women aged 25–49 and 75.0% of women aged 50–65 as having attended screening in the past 3–5 years in England in the period of time between April 2020 and March 2021, although rates are slightly lower in the Northern region (68.9%; 75.3%). The 40% uptake rate in the present study is therefore much lower than the reported national levels and also lower than the recommended rate of 85% uptake (Gianino et al., 2018).

**Table 1**  
Demographic characteristics of participants by condition.

	Usual care only	Social Norms Approach (SNA)	Volitional Help Sheet (VHS)	Volitional Help Sheet (VHS) + Social Norms Approach (SNA)	<i>p</i>
	<i>n</i> = 3590	<i>n</i> = 3583	<i>n</i> = 3674	<i>n</i> = 3616	
Characteristic <i>n</i> (%)					
<b>Age</b>					0.45
24-29	674 (18.8)	664 (18.5)	702 (19.1)	679 (18.8)	
30-40	1172 (32.6)	1161 (32.4)	1160 (31.4)	1145 (31.7)	
41-49	835 (23.3)	914 (25.5)	877 (23.9)	876 (24.2)	
50-76	909 (25.3)	844 (23.6)	935 (25.4)	916 (25.3)	
<b>Index of Multiple Deprivation quintile</b>					0.19
1 (greatest deprivation)	1215 (33.8)	1186 (33.1)	1224 (33.3)	1175 (32.5)	
2	636 (19.0)	639 (17.8)	683 (18.6)	701 (19.4)	
3	574 (16.0)	623 (17.4)	616 (16.8)	652 (18.0)	
4	608 (16.9)	595 (16.6)	661 (18.0)	589 (16.3)	
5 (lowest deprivation)	510 (14.2)	539 (15.0)	489 (13.3)	499 (13.8)	
<b>Previously invited before</b>					0.23
No (%)	981 (27.3)	951 (26.5)	1033 (28.1)	942 (26.0)	
Yes (%)	2609 (72.6)	2632 (73.4)	2641 (71.9)	2674 (73.9)	

Total *n* = 14,463.

**Table 2**  
Cervical cancer screening uptake at 16-week follow up by intervention condition.

	Usual care only	Social Norms Approach (SNA)	Volitional Help Sheet (VHS)	Volitional Help Sheet (VHS) + Social Norms Approach (SNA)
	<i>n</i> = 3590	<i>n</i> = 3583	<i>n</i> = 3674	<i>n</i> = 3616
<b>Characteristic</b>				
<b>Attended screening</b>				
Number	1469	1406 (39.2)	1482 (40.3)	1436 (39.7)
attended (%)	(40.9)			
Unadjusted odds ratios (95% CI)	1.00	0.93 (0.85, 1.02)	0.98 (0.89, 1.07)	0.95 (0.87, 1.04)
Adjusted <sup>a</sup> odds ratios (95% CI)	1.00	0.89 (0.80, 0.99)	0.99 (0.90, 1.10)	0.96 (0.86, 1.06)

<sup>a</sup> Adjusted for participants' age, index of multiple deprivation quintile, previous screening history.

The follow up period is shorter than the time period used for national statistics which may explain the lower-than-average uptake. However, recent quarterly data from England supports that around 70% of women attended screening between July and September 2021 (NHS Digital, 2022). The intervention mailing took place in early December 2021 which coincided with the time period where COVID-19 cases were increasing in the UK (UK Government, 2021) where the Omicron variant

of the virus was widespread and case numbers were at a peak high in this month. This may have discouraged individuals from making appointments for and attending screening. Avoiding or putting off screening until COVID-19 rates decreased may have been an appropriate decision taken by individuals considering the potential high risk of contracting COVID-19, compared against the relatively low immediate risk of developing cervical cancer. The two interventions were developed prior to the COVID-19 pandemic and may not have been powerful enough to overcome these potential barriers which were additional to those identified during intervention development and piloting. Therefore COVID-19 may have reduced screening rates across conditions. Nevertheless, the randomised design employed should ensure that the test of the intervention was not compromised unless COVID-19 rates had a differential effect on screening rates in different conditions. This latter possibility seems unlikely.

Alternatively, it may be the case that mailed interventions are not an effective means of increasing screening uptake. Recently, both [Wardle et al. \(2016\)](#) and [Wilding et al. \(2020a,b\)](#) have demonstrated null effects of mailed interventions in bowel cancer screening, despite previous research showing promising results to support their effectiveness (see also [Tsipa et al., 2021](#)). That said, [Wilding et al. \(2020a,b\)](#) did find that a combined VHS and SNA intervention was more effective than a control condition in a younger age group (<62.5 years), suggesting that more targeted approaches may yield more promising findings.

Screening uptake was found to be lowest in the youngest women (age <30) and those from the highest areas of deprivation. This is consistent with the literature, where both age and deprivation have been found to influence screening uptake ([Moser et al., 2009](#); [Douglas et al., 2016](#); [NHS Digital, 2022](#); [Cancer Research UK, 2021](#)). Younger women tend to report practical barriers to screening attendance, such as a lack of time or issues with childcare, while older women report attitudinal barriers to attendance (e.g., low worry or perceived risk to cervical cancer; [Waller et al., 2012](#)).

One limitation of the present study is that previous work has supported structural barriers influencing uptake, key barriers in our own work include difficulties with making and attending appointments. This may be particularly problematic at the moment with the pressures on GPs caused by COVID-19 ([Jefferson et al., 2022](#)). Strengths of the study include its large sample size and collaboration with NHS Digital and the mailing service used in routine screening, which demonstrates the ability of similar interventions to be incorporated alongside routine screening invitations. Messaging from both interventions had been pilot tested in online surveys including over 700 participants, and barriers and facilitators were taken from qualitative work ([Wilding et al., 2020a, b](#)). That the intervention was mailed out could be considered both a strength and a limitation. As a strength, it demonstrates that the intervention can be integrated easily into routine screening. However, it may be the case that the same individuals that ignore mailed invitations to screening are also likely to ignore intervention materials received by post. A further limitation of the present research was the use of a 16 week cut off for monitoring screening. This may have reduced the observed screening rates in all conditions, but seems unlikely to have biased the test of the effectiveness of the intervention conditions given the RCT design.

This large scale randomised controlled trial of two psychological interventions did not demonstrate any evidence of increased cervical cancer screening uptake after receiving either intervention alone or in combination. This supports our previous findings in relation to bowel cancer screening ([Wilding et al., 2020a,b](#)). Uptake levels were much lower than average in the study group and this may have reduced overall intervention effectiveness. Future research needs to urgently investigate the barriers to uptake following from the COVID-19 pandemic. The current research tested the effectiveness of the interventions when sent out shortly after an initial invitation to all women. Although shown to be ineffective, this trial does not address whether these or similar interventions targeted at those who initially do not attend (e.g., with the

18 week reminder currently employed in the UK) might be effective. Future research ought to explore this possibility further.

### Author contribution

Sarah Wilding - Investigation, Project administration, Methodology, Writing – original draft, Writing – review & editing. Sarah Wighton - Methodology, Writing – review & editing. Robert West - Funding acquisition, Data curation, Formal analysis, Writing – original draft, Writing – review & editing. Mark Conner - Conceptualization, Funding acquisition, Methodology, Supervision Writing – original draft, Writing – review & editing. Daryl B. O'Connor - Conceptualization, Funding acquisition, Methodology, Supervision Writing – original draft, Writing – review & editing

### Funding

The study was funded by Yorkshire Cancer Research, grant number L415. The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

### Data availability

The r script and data output files are available as supplementary materials 2-3. The data itself cannot be shared due to ethical approvals requiring data deletion following analysis.

### Acknowledgments

Data from this study is based on information collected and quality assured by the Public Health England (PHE) Population Screening Programs. Access to the data was facilitated by the PHE Office for Data Release.

### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.socscimed.2023.115800>.

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