

BMJ Open Perceptions of overdiagnosis of breast cancer among women 70 years of age and older in the USA: a mixed-methods analysis

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ABSTRACT

Objectives Current research on the perceptions of overdiagnosis or overdiagnosis of breast cancer has largely been conducted outside of the USA and with women younger than 70 years. Therefore, we explored older women's perceptions about the concept of overdiagnosis of breast cancer and its influence on future screening intentions.

Design Mixed-methods analysis using purposive sampling based on race/ethnicity, age and educational level. Semistructured interviews, including two hypothetical scenarios illustrating benefits and harms of screening and overdiagnosis, were analysed using inductive and deductive thematic approaches. An inferential clustering technique was used to assess overall patterns in narrative content by sociodemographic characteristics, personal screening preferences or understanding of overdiagnosis.

Setting Houston/Galveston, Texas, USA.

Participants 59 English-speaking women aged 70 years and older with no prior history of breast cancer.

Results Very few women were familiar with the concept of overdiagnosis and overtreatment. After the scenarios were presented, half of the women still demonstrated a lack of understanding of the concept of overdiagnosis. Many women expressed suspicion of the concept, equating it to rationing. Women who showed understanding of overdiagnosis were more likely to express an intent to discontinue screening, although 86% of the women stated that hearing about overdiagnosis did not influence their screening decision. Themes identified did not differ by race/ethnicity, education, age or screening preferences. Differences were identified between women who understood overdiagnosis and women who did not ($r=0.23$, $p<0.001$).

Conclusions Many older women did not understand the concept of overdiagnosis, in addition to being suspicious of or resistant to the concept. Providing older women with descriptions of overdiagnosis may not be sufficient to influence screening intentions.

INTRODUCTION

Screening mammography is associated with lower mortality from breast cancer in average

Strengths and limitations of this study

- This study was unique as it qualitatively explored the perspectives of older women from diverse ethnic/racial and educational backgrounds regarding overdiagnosis of breast cancer and its influence on screening intentions.
- A novel inferential clustering technique from social network analysis was used to detect patterns in narratives by sociodemographic characteristics, personal screening preferences or understanding of the concept of overdiagnosis.
- This study was conducted in Houston and Galveston, Texas, which is the most racially/ethnically diverse large metropolitan area in the USA; therefore, the sample may not represent older women from other parts of the USA or other countries.

risk women aged 50–74 years.¹ The US Preventive Services Task Force has concluded that the evidence is insufficient to assess the net benefit of screening mammography in women aged 75 years and older (I statement).² Conversely, the American Cancer Society supports breast cancer screening for older women who are in good health and with a life expectancy of greater than 10 years.³

Overdiagnosis is an increasing concern in healthcare.⁴ Welch and Black define cancer overdiagnosis as ‘the diagnosis of a “cancer” that would otherwise not go on to cause symptoms or death’.⁵ The risk of overdiagnosis increases as life expectancy decreases.⁵ However, older women are often not well informed about the harms of mammography screening.⁶ Current qualitative research on women's understanding of overdiagnosis of breast cancer has largely been conducted outside of the USA and with minimal attention to women over the age of 70 years.^{7–9}



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A study of women aged 45–49 years in Denmark concluded that the women lacked awareness of and resisted the possible risk of breast cancer overdiagnosis.⁷ Similarly, an Australian study of women aged 40–79 years demonstrated a lack of prior awareness of the risk of breast cancer overdiagnosis.⁸ Screening intentions depended on the magnitude of overdiagnosis presented, with higher estimates (50%) resulting in the women reconsidering their future screening intentions and treatment options compared with lower estimates (1%–10% and 30%).⁸ In a London study, the majority of women aged 50–71 years lacked awareness of breast cancer overdiagnosis, and some women perceived that data supporting the risk of overdiagnosis could be used to restrict or withdraw participants from the screening programmes.⁹

Currently, no research exists on the perceptions of overdiagnosis in women from different racial/ethnic backgrounds. Women in the USA might be sceptical of information about overdiagnosis, given overall enthusiasm for cancer screening and fear of rationing.^{10 11} We conducted a mixed-methods study of the perceptions of overdiagnosis in breast cancer screening mammography and its influence on screening intentions among a triethnic sample of 59 older women aged 70 years and older. We combined qualitative narratives with a novel analytic technique to detect overall patterns or clusters in narrative content by sociodemographic characteristics, personal screening preferences or understanding of overdiagnosis.

METHODS

Study design and sample

We included 59 English-speaking women aged 70 years and older with no prior history of breast cancer to participate in the study. We used purposive sampling and sought to recruit five women from each of the 12 possible combinations,¹² based on race/ethnicity (ie, non-Hispanic black (NHB), non-Hispanic white (NHW) and Hispanic), education (ie, \leq high school (\leq HS), $>$ high school ($>$ HS)) and age (ie, 70–74 and \geq 75 years). Participants were recruited principally from senior community living facilities, community centres, churches and few from local clinics in Houston/Galveston, Texas, USA. Participants provided verbal informed consent and received a \$25 gift card for their participation. The institutional review boards of The University of Texas Medical Branch and The University of Texas MD Anderson Cancer Center approved all study procedures.

Interview guide

Interviews explored overdiagnosis in breast cancer screening, potential harms of overdiagnosis and the influence of overdiagnosis on screening intentions. We used the term *overdiagnosis* in the interview instead of *overdiagnosis*, as it is consistent with the lay understanding of the possible harms of cancer screening.^{8 9} Two hypothetical scenarios described the mortality benefit of screening and

the concept of overdiagnosis, respectively.⁸ The audiovisual presentations were originally developed by Hersch *et al*,⁸ which they published and have available online. The original presentations by Hersch *et al* uses women aged 64 years; however, we changed the ages to 74 years, given our sample was aged 70 years and older. The mortality benefit scenario uses a hypothetical 74-year-old woman named Judy to describe how a mammogram helped her live to be 86 years, since her small breast cancer was found and treated, later dying of heart disease. The overdiagnosis scenario uses a hypothetical 74-year-old woman named Barbara to describe how since she had a slow-growing cancer, whether she had the mammogram, she lived to 86 years and died of heart disease (online supplementary 1). Various published rates of the percentage of breast cancers exist that describe the risk for screening overdiagnosis. Based on published rates including older women, we used the rate of 10%–30% of breast cancers diagnosed by screening to explain overdiagnosis to the participants.^{13 14} Participants reported their age, race/ethnicity, education, personal screening preference and self-rated health status.

Data collection

A female research assistant (RA) who had no prior relationship with the participants conducted the interviews. She was trained to probe for participants' understanding and opinions while maintaining neutrality.¹⁵ Semistructured interviews lasting 60 min were conducted, with the overdiagnosis and overtreatment component lasting 10–15 min. The full interview was part of a larger study and included questions addressing three main topic areas: screening decision-making process and preferences; screening risks and benefits including overdiagnosis; and opinions regarding a decision aid for women aged 70 years and older. The interview guide regarding overdiagnosis and overtreatment is included in online supplementary 1. All interviews were conducted from May 2013 to May 2015 and were audio-recorded and transcribed verbatim.

Patient and public involvement

Internal and advisory committees, consisting of consumer, community, provider and administrative stakeholders, were formed prior to study development. Stakeholders provided feedback on the study aims and design. Interview questions were also piloted with community members fitting the study's inclusion criteria, which resulted in modifications to the recruitment strategy to promote diversity of the study sample. Participants also assisted the research coordinator with identifying potential participants meeting the inclusion criteria. Results of this study and other works from the larger project will be formally disseminated to the participants and other stakeholders at a stakeholder luncheon.

Qualitative analysis

Interview transcripts were iteratively analysed using inductive and deductive thematic analysis.¹⁶ Two coders

(SK and EJ) independently coded all interview transcripts until consensus, comparing codes within and across participants. The lead author (MRP) mediated all coding disagreements. All data were coded using NVivo, V.10.0 (QSR International).

Transcripts were reviewed to assess participants' understanding of the concept of overdetection after the two scenarios were presented. Women were classified into two categories: (1) 'understand overdetection' if their response included the concept; and (2) 'did not understand'. To establish *dependability* and *confirmability* of the data,¹⁷ all coders (SK, EJ and MRP) performed data coding audits and identified exemplary quotes. This study is reported in accordance with the Consolidated criteria for Reporting Qualitative research (COREQ) guidelines.

Statistical analysis

A matrix permutation test, used in social network analysis, compared a hypothesised cluster matrix (eg, younger vs older women) to the observed similarity of theme profiles between all pairs of participants to see if some subgroups have similar profiles or if clustering is present.^{18,19} This test was chosen because it allowed us to

compare the entire profile of themes across respondents by subgroups instead of assessing each theme one at a time (eg, χ^2 tests) inflating type I error. We converted the qualitative data into a table indicating whether each participant mentioned a theme or not. Then, the similarity between participants' profiles was assessed. We then tested for possible clustering by age, education, ethnicity, personal screening preference and understanding of overdetection. The observed correlation (r) between all pairs of respondents and the hypothesised clusters within the matrices were calculated based on 10 000 random permutations, and the p value (set at $p < 0.05$) represented the likelihood that they were matched at random.

RESULTS

A total of 59 women completed the study, and their characteristics are shown in table 1. A majority of the women (70%) reported having excellent or good health. Three of the 59 women reported that they never had a mammogram, although one described a procedure similar to a MRI. Before presenting the overdetection scenario,

Table 1 Participant characteristics

	All (n=59)	Value*	
		Understand overdetection (n=30)	Did not understand overdetection (n=29)
Age (years), mean (SD) (range)	77.5 (6.7) (70–92)	77.7 (6.6) (71–92)	77.2 (6.9) (70–92)
70–74, n (%)	28 (47)	15 (50)	13 (45)
≥75, n (%)	31 (53)	15 (50)	16 (55)
Education, n (%)			
≤HS	29 (49)	13 (43)	16 (55)
>HS	30 (51)	17 (57)	13 (45)
Race/ethnicity, n (%)			
Hispanic	14 (24)	7 (23)	7 (24)
Non-Hispanic black	21 (36)	10 (33)	11 (38)
Non-Hispanic white	24 (41)	13 (43)	11 (38)
Health status, n (%)			
Very poor	2 (3)	2 (7)	0 (0)
Fair	16 (27)	7 (23)	10 (34)
Good	34 (58)	16 (53)	17 (59)
Excellent	7 (12)	5 (17)	2 (7)
Initial screening decision, n (%)			
Continue	29 (49)	11 (37)	18 (62)
Discontinue	19 (32)	9 (30)	10 (35)
Depends on physician	6 (10)	5 (17)	1 (3)
Unsure	2 (3)	2 (6)	0 (0)
Never had a mammogram	3 (5)	3 (10)	0 (0)

*Data are presented as number (column percentage) of participants. HS, high school.

Table 2 Perceptions of overdetection themes and subthemes

Themes and subthemes	Illustrative quotations	Understand (n=30)	Did not understand (n=29)
1. Resistance to the concept, n (%)		17 (57)*	12 (41)
Negative persuasion	'It [overdetection] might encourage women not to get mammograms... and that could be a risk' (P24, age 71 years, Hispanic, ≤HS). 'This to me should not be an issue brought to the elderly because you're going to have people that are easier to persuade that they'll start thinking, "Well, this little bitty piece of cancer here's not going to bother me...I don't like the negative persuasion."' (P20, age 73 years, NHB, >HS).	5 (17)	4 (14)
How do you know?	'How do you know? I think there's no way of knowing it until you had a mammogram' (P12, age 90 years, NHW, >HS). 'How did they know she had it?' (P59, age 74 years, Hispanic, >HS).	16 (53)	9 (31)
2. Role of a physician's recommendation for screening, n (%)		8 (27)	11 (38)
Follow doctor recommendation	'I think if the doctor told me that I needed to get a mammogram, I'd go get one... I don't think you should have a closed mind at any age'. (P8, age 92 years, NHB, >HS). 'I would follow; I guess I would follow my doctor's advice on what to have done about it'. (P16, age 92 years, NHW, >HS).	8 (27)	11 (38)
Second opinion	'I am going to ask my doctor and if I like it [opinion], I'll do what she says and if I don't I'll do what I feel I need to do'. (P7, age 72 years, Hispanic, >HS). 'There's a certain thing as a second opinion too... not just take one person's word'. (P30, age 73 years, NHB, >HS).	2 (7)	0 (0)
3. Confusion with other harms of screening, n (%)		2 (7)	7 (24)
Screening harms	'Same thing happened to my daughter.... they found an abnormality in her but when she went back to take it again they found that it wasn't cancer'. (P30, age 73 years, NHW, >HS). 'I've known people to take mammograms and they didn't find them and they still ended up with cancer'. (P64, age 72 years, NHB, ≤HS).		
4. Comparison with other health conditions, n (%)		5 (17)	2 (7)
Health conditions	'Some of them, it [prostate cancer] kills and some of them go on with their life and it doesn't bother them a bit'. (P8, age 92 years, NHW, >HS). 'As long as they [thyroid nodules] are not bothering me, don't bother them'. (P25, age 74 years, NHB, >HS).		

*Data are presented as number (column percentage) of participants.
HS, high school; NHB, non-Hispanic black; NHW, non-Hispanic white.

nearly half (49%) of the women planned to continue breast cancer screening in the future.

Only a few women reported previously hearing about the concept of overdetection. After hearing the scenarios, about half (49%) of the women's comments indicated that they understood or probably understood the concept of overdetection. For example, 'It's sort of like fibroid tumors. It's not always necessary to have them removed'. The other half made comments coded as not understanding, such as 'I don't know'. Some of the women who were coded as not understanding may have understood the concept but rejected it. For example, 'Then if she gets sick and her cancer spreads all over her body, then she'll have to have another mammogram' or 'Well, a lot of machines make a lot of mistakes.'

PERCEPTIONS OF OVERDETECTION

In response to questions about overdetection, four core themes emerged: (1) resistance to the concept of

overdetection; (2) role of a physician's recommendation for screening; (3) confusion with other harms of breast cancer screening; and (4) comparison with other health conditions. Examples of these themes, along with the number of women expressing each theme, are given in [table 2](#).

Resistance to the concept

Many older women openly disagreed with the concept of overdetection and expressed suspicion of the motives behind communicating the concept:

Propaganda. (P6, age 83 years, Hispanic, >HS)

I think that's where the government is going... Don't treat them, they're going to die anyway and they are saying that and in congress. (P27, age 75 years, NHW, >HS)

It's just someone trying to do a con job on not having a mammogram done every year. (P61, age 70 years, NHW, >HS)

The women also expressed uncertainty regarding the information or questioned how a physician could know when someone has cancer without a mammogram.

Role of a physician's recommendation for screening

Several older women desired to discuss over-detection with their physician and obtain their recommendation for screening. The role of their physician was also essential to making sense of the concept of over-detection for many: 'Now that I'm seeing this, I might go back now and ask [my doctor] questions about this' (P66, age 82 years, Hispanic, >HS). However, some women, those who understood over-detection, stated that they would only listen to the physician if they liked what they heard.

Confusion with other harms of screening

Older women who had difficulty understanding over-detection perceived it as a misdiagnosis or compared it with other harms from breast cancer screening, such as false positives or negatives. For example, one woman described others receiving false-positive screenings:

I've known so many people, who have found something in their mammogram, then they go back for the second and the third and then all is fine. (P11, age 71 years, NHW, >HS)

Comparison with other health conditions

Some older women who understood over-detection of breast cancer screening compared it with other health conditions, such as high cholesterol, prostate cancer or thyroid nodules. One woman compared breast cancer over-detection to fibroid tumours: 'It's like fibroid tumors. It's not always necessary to have them removed' (P31, age 86 years, NHB, >HS). Some referred to *watchful waiting*, where time elapses before treatment is given.

OVERDETECTION IN THE CONTEXT OF SCREENING PREFERENCES

Women who did not understand over-detection were more likely to desire to continue screening (62% vs 37%, $p=0.045$). All of the women considered over-detection in the context of their own screening preferences. Three specific subthemes identified related to: (1) older women's right to mammograms; (2) a varying desire to know if cancer is present; and (3) necessity of mammograms or treatment at an older age (table 3).

A right to decide about mammograms

Several of the older women, regardless of their understanding of over-detection, emphasised that women must

Table 3 Supporting screening decisions themes and subthemes

Themes and subthemes	Illustrative quotations	Understand (n=30)	Did not understand (n=29)
1. A right to decide about mammograms, n (%)		10 (33)*	7 (24)
	'It's still left up to me what I want to do... I'm 83 right now'. (P6, age 83 years, NHW, ≤HS). 'I think the person needs to decide should I go through it?' (P59, age 74 years, Hispanic, >HS).		
2. Varying desire to know about the presence of cancer, n (%)		7 (23)	13 (45)
Better to know	'If they find something, they just find something. It's better to know than not know'. (P33, age 74 years, NHB, ≤HS) 'It's best to know what's going on in your body. This is the way I see it'. (P44, age 72 years, Hispanic, ≤HS)	2 (7)	11 (38)
Better to not know	'I feel like that's more power to her. If she doesn't know about it, it's not going to hurt her'. (P15, age 75 years, NHW, >HS) 'I know we say you shouldn't worry about these things but when you find out, you do worry. And, I don't want to worry'. (P22, age 81 years, NHB, >HS) '[There] may be a lot of things wrong with me that I don't know about'. (P28, age 87 years, NHW, ≤HS)	6 (20)	3 (10)
3. Necessity of screening older women, n (%)		28 (93)	28 (97)
No symptoms, no mammograms	'If you don't have no symptoms, then there's no reason to have the mammogram'. (P18, age 84 years, Hispanic, ≤HS) 'I don't think I need one, now that I am older and have no problems'. (P19, age 72 years, NHW, >HS)	24 (80)	10 (35)
Support regular mammograms	'Would have known if she went to get her screening'. (P17, age 71 years, NHW, ≤HS) 'Should have had a mammogram'. (P3, age 84 years, NHW, ≤HS)	6 (20)	20 (69)

*Data are presented as number (column percentage) of participants.
HS, high school; NHB, non-Hispanic black; NHW, non-Hispanic white.

make a personal decision about having a mammogram and also cancer treatment: *'It's a choice that people just have to make. Right or wrong, you make your choice'* (P64, age 72 years, NHB, \leq HS).

Varying desire to know about the presence of cancer

A clear distinction was evident between older women who chose to continue screening and those who discontinued screening on their desire to know whether cancer was present. This was consistent, regardless of their level of understanding of overdetected. For those who chose to continue screening, the importance of knowing what was wrong and stating that it is better to know than not know was emphasised. All of the women who believed it was better to not to know about the presence of cancer also understood overdetected and chose to discontinue screening. Whereas other women believed that it was *better to not know* if cancer is present, because it was *'not going to hurt her'* and *'she would not worry'*.

Necessity of screening older women

A common subtheme among those who understood overdetected and decided not to undergo additional screening mammograms was *'no symptoms, no mammograms'*. For example, one woman said, *'No symptoms, I'm not gonna go'* (P12, age 90 years, NHW, $>$ HS). Several women who did not understand overdetected believed that older women should still get mammograms to be on the *'safe side'*.

DIFFERENCES IN THEMES BY CHARACTERISTICS

Women who understood overdetected expressed a different pattern of themes than those who did not ($r=0.23$, $p<0.001$) for the overall comparison. Women who understood overdetected were more likely to question how to know when overdetected is occurring (53% vs 31%) and also stated that women should not undergo mammograms in the absence of symptoms (80% vs 35%). Women who did not understand overdetected were more likely to emphasise a physician's screening recommendation (38% vs 27%) and confused the concept of overdetected with other screening harms (24% vs 7%). They were also more likely to want to know about the presence of cancer (38% vs 7%) and support regular mammogram screenings (69% vs 20%). There were no systematic differences on theme usage by age ($r=0.02$, $p=0.19$), ethnicity ($r=0.01$, $p=0.42$), educational level ($r=-0.01$, $p=0.43$) or screening preference ($r=0.06$, $p=0.09$).

IMPACT OF OVERDETECTION ON SCREENING INTENTIONS

Only five women stated that the information about overdetected influenced their decision to receive a mammogram in the future, with all five stating they were less likely to screen. The remaining women stated that the information on overdetected would not influence their decisions about mammograms.

DISCUSSION

In this analysis of US older women's views about overdetected of breast cancer, several findings emerged. Understanding of the concept of overdetected was variable, even after a detailed overview was provided. This lack of understanding was associated with a desire to be screened and reliance on a physician's recommendation. Many women rejected the message about overdetected. They expressed concerns over undermining screening efforts, or believed the concept of overdetected was part of a strategy to deter women from screening. Scepticism and distrust of the rationale behind messages about the limits of screening mammography suggest it will be challenging to implement strategies to decrease its use among some older women.

Recent survey studies in the USA of women younger than 59 found that many women were not aware of overdetected or overtreatment,^{20 21} and statements regarding overdetected or overtreatment were not compelling enough to be factored into their screening decisions.²¹ Similar to some studies conducted in Australia and the UK, many women did not have prior awareness of the concept of overdetected, and some were resistant to information that conflicted with their personal beliefs or attitudes.^{7-9 22} Fear of rationing may be more prevalent in the USA because of the high-profile public discussions of healthcare reform, with rationing being a major criticism of reform efforts.¹¹

Some women questioned the concept of overdetected because they could not know if they had been diagnosed with a breast cancer never destined to cause harm. They demonstrated an understanding of overdetected as a concept that applies to populations rather than individuals. This finding has important implications for developing decision-making interventions and determining how risks of screening are framed.²³ It may be helpful to develop interventions that present personal, experiential harms of screening (ie, 'the harms you may experience') differently than harms that reside primarily at the population level (ie, 'the harms you will never know about'). Patients are well known to make affective forecasting errors when anticipating the outcomes of health decisions,²⁴ and hypothetical harms may be undervalued compared with other harms, such as false positives, which are more well known.²⁵

Half of the women interviewed appeared not to understand the concept of overdetected, and most (62%) of the women who did not understand also intended to continue screening. Decision aids can support women's screening decisions and help women understand the concept of overdetected. Two studies have assessed the effect of a mammography screening decision aid among older women.^{26 27} Both decision aid scenarios introduced the concept of overdetected and increased older women's knowledge. In a pretest/post-test trial in the USA with 45 NHB and NHW women aged 75-89 years with diverse educational backgrounds, the decision aid resulted in 12 fewer women desiring to be screened.²⁶

In a randomised trial in Australia of 710 women aged 70–71 years with 16% having greater than high school education,²⁷ a decision aid did not influence intentions to discontinue screening.

Shared decision-making tools have been suggested as one method to reduce medical overuse.²⁸ Given how challenging the concept of overdetection is for many patients, traditional tools such as patient decision aids might be supplemented by alternative strategies for engaging older patients in evidence about the benefits and harms of mammography.²⁹ Older women are interested in hearing about the benefits and risks of screening from their physician and other healthcare providers, and receiving this information in print material and other formats (eg, senior groups, videos and so on).³⁰ Patient narratives, or personal stories, are a potentially powerful and underused strategy in clinician–patient decision making which, in case of screening mammography, may provide a familiar vehicle to engage in discussions about trade-offs for a screening test that many patients may have not previously questioned.³¹

This mixed-method analysis has strengths and limitations. The study used an inferential clustering technique to identify similarity of theme usage by demographic characteristics and screening preferences. In addition, this study used purposive sampling, which helped to assess perspectives of older women from diverse backgrounds. All demographic subgroups were represented in the study themes. However, we could not achieve the target sample of five Hispanic participants in the 70–74 and ≥75 age groups. The sample may not generalise to women of other ethnic/racial groups or from other parts of the USA. Past mammography screening behaviours were self-reported, which may result in recall or reporting biases.^{32 33} Nearly 3 years have passed since these data were collected; therefore, it is possible that their views may now have changed given the increase in media coverage on overdetection. It is also important to note that we did not assess factors that may influence understanding of overdetection, such as cognitive function, numeracy or sociocultural factors (eg, religious beliefs, fatalism, social status and mistrust of healthcare providers).

CONCLUSIONS

This study is the first to report the views of older women in the USA on the concept of overdetection of breast cancer and its impact on their screening intentions. Findings highlight the significant challenges facing clinicians in helping older women make decisions about breast cancer screening. In the absence of a clear understanding of the concept, women remain supportive of screening. At the same time, accurate perceptions of overdetection seem to have little impact on existing screening preferences. Future work is needed to develop clear messages on how the harms of screening may outweigh the benefits for older women with limited life expectancy who are enthusiastic about screening mammography.

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Collaborators Marsja R Stearnes.

Contributors MRP designed the study, coded and quality checked the data, conducted the qualitative and statistical analysis, made substantial contributions to the interpretation of the data and drafted and critically revised the paper. RJV designed the study, made substantial contributions to the interpretation of the data and drafted and critically revised the paper. SK coded and quality checked the data, made substantial contributions to the interpretation of the data and drafted and critically revised the paper. SCW designed the study, designed and piloted data collection tools, monitored data collection, quality checked the data, wrote the statistical plan, made substantial contributions to the interpretation of the data and critically revised the paper. EJ coded and quality checked the data, made substantial contributions to the interpretation of the data and critically revised the paper. DSH, SHG and AJH made substantial contributions to the interpretation of the data and critically revised the paper. AT designed the study, designed data collection tools, monitored data collection, quality checked the data, made substantial contributions to the interpretation of the data and critically revised the paper. KMS designed the study, designed and piloted data collection tools and critically revised the paper. JSG designed the study, monitored data collection, made substantial contributions to the interpretation of the data, drafted the paper and critically revised the paper. All authors gave the final approval of the manuscript.

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