


# Should I take aspirin? A qualitative study on the implementation of a decision aid on taking aspirin for bowel cancer prevention

Shakira Onwuka <sup>1,2,3</sup>, Jennifer McIntosh,<sup>2,4</sup> Lucy Boyd,<sup>1,2</sup> Napin Karnchanachari,<sup>2</sup> Finlay Macrae,<sup>5,6</sup> George Fishman,<sup>7</sup> Jon Emery<sup>2,3</sup>

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## ABSTRACT

**Objectives** Australian guidelines recommend 50–70 years consider taking aspirin to reduce their bowel cancer risk. We trialled a decision aid in general practice to facilitate the implementation of these guidelines into clinical practice. This publication reports on the qualitative results from the process evaluation of the trial. We aimed to explore general practitioners' (GPs) and their patients' approach to shared decision-making (SDM) about taking aspirin to prevent bowel cancer and how the decision aids were used in practice.

**Methods** Semistructured interviews were conducted with 17 participants who received the decision aid and 12 GPs who participated in the trial between June and November 2021. The interviews were coded inductively, and emerging themes were mapped onto the Revised Programme Theory for SDM.

**Results** The study highlighted the dynamics of SDM for taking aspirin to prevent bowel cancer. Some participants discussed the decision aid with their GPs as advised prior to taking aspirin, others either took aspirin or dismissed it outright without discussing it with their GPs. Notably, participants' trust in their GPs, and participants' diverse worldviews played pivotal roles in their decisions. Although the decision aid supported SDM for some, it was not always prioritised in a consultation. This was likely impacted during the trial period as the COVID-19 pandemic was the focus for general practice.

**Conclusion** In summary, this study illustrated the complexities of SDM through using a decision aid in general practice to implement the guidelines for low-dose aspirin to prevent bowel cancer. While the decision aid prompted some participants to speak to their GPs, they were also heavily influenced by their unwavering trust in the GPs and their different worldviews. In the face of the COVID-19 pandemic, SDM was not highly prioritised. This study provides insights into the implementation of guidelines into clinical practice and highlights the need for ongoing support and prioritisation of cancer prevention in general practice consultations.

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## INTRODUCTION

In Australia, in 2022, bowel cancer was a leading cause of mortality among cancers,

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Existing research has demonstrated the positive impact of decision aids on shared decision-making in clinical care, but their specific application in the context of general practice for health decisions such as aspirin use for bowel cancer prevention remains a gap in knowledge.

### WHAT THIS STUDY ADDS

⇒ This study contributes to our understanding by revealing how participants in the Should I Take Aspirin trial engaged with a decision aid to make informed choices about aspirin, shedding light on the factors influencing their engagement, barriers they faced and the potential of decision aids in promoting shared decision-making.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The implications of this study span research, clinical practice and healthcare policy, emphasising the feasibility of decision aid use in general practice, the influence of general practitioners on patient decisions, and the need for accessible decision aids, with future research exploring diverse strategies and real-world implementation.

second only to lung cancer.<sup>1</sup> In as early as 1991, evidence emerged that aspirin could help reduce the risk of and mortality from bowel cancer.<sup>2,3</sup>

Aspirin has been shown to reduce the incidence, and mortality of bowel cancer by up to 25% and 33%, respectively, based on findings of several systematic reviews and meta-analyses.<sup>4,5</sup> Australian guidelines recommend that all Australians aged 50–70 years, without a contraindication to aspirin, consider taking low-dose aspirin (100–300 mg) daily for 2.5–5 years to reduce risk of bowel cancer.<sup>6</sup>

As the decision to take aspirin is a personal one where potential benefits and harms need to be considered, we designed and trialled a



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### Correspondence to

Shakira Onwuka;  
shakira.onwuka@unimelb.edu.au

decision aid to implement these aspirin guidelines into general practice to facilitate shared decision-making (SDM).

The decision aid included three key components: (1) an expected frequency tree (EFT) to communicate the risks and benefits associated with taking aspirin, including effects on the incidence of bowel cancer, cardiovascular disease, gastrointestinal bleeding and all-cause mortality; (2) a reminder to patients that they should speak to their general practitioner (GP) before commencing aspirin and (3) information about who should not take aspirin due to contraindications.

Details about the methods for the SITA (Should I Take Aspirin?) trial are published elsewhere,<sup>7</sup> as are papers describing how we developed the decision aid.<sup>8</sup>

To date, one other decision aid has been developed for the use of aspirin to reduce bowel cancer risk, but not for Australians and an educational leaflet was developed for people at increased risk of developing bowel cancer, but none have been trialled in general practice.<sup>9 10</sup> The UK decision aid underwent usertesting, where 11 people in the community provided feedback on the prototype of their decision aid, in one-on-one interviews but this user-testing was not conducted with clinicians.<sup>9</sup> The SITA trial follow-up was completed in May 2022. The aim of this process evaluation of the SITA trial was to explore the effectiveness of a decision aid on facilitating SDM between GPs and their patients about taking aspirin to reduce their risk of developing bowel cancer and other chronic illnesses. We further sought to understand how the decision aid was used and received to provide insights that could inform future efforts to implement guidelines into clinical practice using decision aids. Furthermore, the aim was to explore the feasibility of implementing the decision aid into routine practice.

## METHODS

### SITA trial participation

Details of the SITA trial methods have been published in a protocol.<sup>7</sup> The SITA trial, an individually randomised trial, invited individuals aged 50–70 who were not currently taking aspirin and had a scheduled GP appointment to participate. Participants were randomised into either the intervention or control group. Participants in the intervention group attended a consultation with a trained research assistant where the decision aid was used to discuss taking aspirin for disease prevention. In 2020, we developed a second brochure alongside the decision aids, which presented general ways to reduce bowel cancer risk and served as the control brochure. This brochure was also presented to intervention participants.

The sex-specific decision aids and control brochure can be found in online supplemental files A-C

### Approach

A qualitative process evaluation was conducted using semistructured interviews with SITA trial intervention

participants and with GPs who participated in the trial. The approach used was based on a constructivist paradigm, which assumes that individuals create their own understanding and perspective of the world.<sup>11</sup> This means that people are active learners who construct their knowledge rather than passive recipients of information.

### Setting and sampling strategy

During the trial, as participants were consented to participate, they indicated if they were happy to be approached, for a subsequent interview about their experience in the trial. Trial participants randomised to the intervention group, were purposively sampled to ensure a diverse group were recruited based on recruitment site. Using a sampling matrix, we invited participants based on their age, gender, education, socioeconomic status based on postcode and their decision to take aspirin or not, including starting and subsequently stopping aspirin.

During the 6-month follow-up medical record audits for trial participants, a researcher (SO) invited the trial GPs to be interviewed. The interviews could take place in person that day, or over the phone or via Zoom<sup>12</sup> at a later scheduled time.

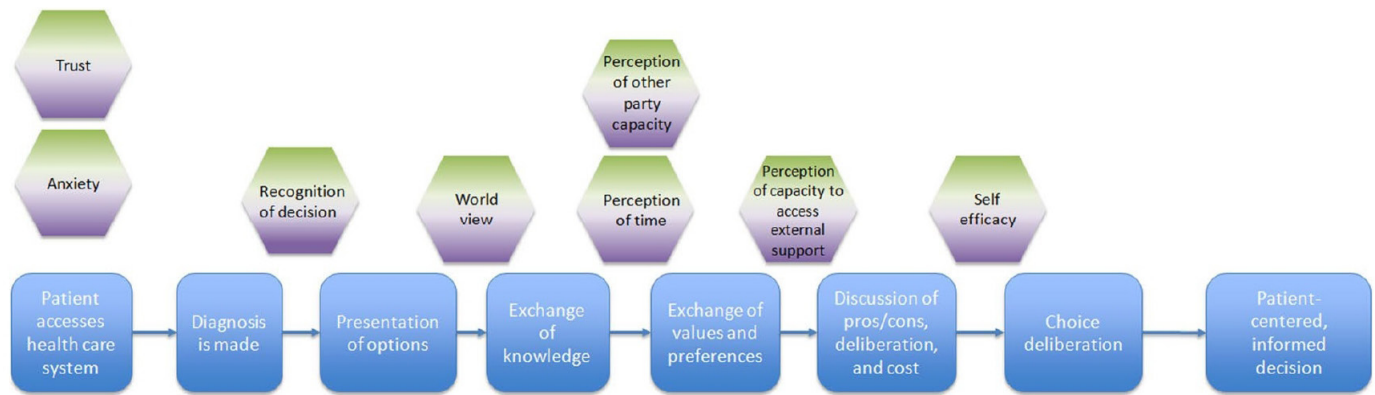
Recruitment for all participants and GPs were conducted between June and November 2021. Before commencing the interviews, researchers provided copies of the decision aid to participants. All participants provided written or e-consent. GPs were reimbursed US\$100 for their time.

### Data collection techniques

The authors developed separate semistructured interview guides for participants and GPs. These guides were created by the trial steering group committee (online supplemental files D-E).

Trial intervention participants were interviewed by researchers LB and NK after the completion of the trial, including the follow-up after 6 months. LB and NK, both university educated, served as research assistants responsible for delivering the trial intervention. They were not part of the participant age group. LB and NK interviewed participants who they did not recruit in order to reduce biasing participants' responses to the interview questions. All participant interviews were conducted over the phone or via Zoom<sup>12</sup> videoconferencing software according to the participant's preference and/or because of COVID-19-related state-wide restrictions and Victorian lockdowns. All GPs were interviewed by researcher SO. SO was a PhD candidate, leading the trial coordination and this process evaluation.

Throughout the data collection process, we assessed data saturation through peer debriefing sessions among the authors, until no new themes or insights emerged, or we had no more participants left to interview. We reached data saturation for participants who decided not to take aspirin but ran out of participants to interview for those who decided to take aspirin and those who started then stopped taking aspirin. This was due to a limited number



**Figure 1** Revised focused IP-SDM mechanism map. This figure overlays the IP-SDM steps (blue) with the identified key mechanisms of the process. Here, mechanisms are aligned with the area they are thought to first manifest in the process. This figure was copied directly from the manuscript by Waldron *et al* and shows the Revised Programme Theory for shared decision-making. The manuscript was published under the terms of the Creative Commons Attribution 4.0 International Licence (<http://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution and reproduction in any medium, no changes were made to the figure. IP-SDM, interprofessional shared decision-making.

of eligible participants within the trial cohort. We further reached data saturation for GP participants.

### Analysis

All audio-recordings were deidentified and assigned unique ID numbers before being professionally transcribed. The completed transcripts were uploaded into NVivo V.12 (QSR International released 2020), which was used to organise the qualitative data for coding.

Interview transcripts were inductively analysed into codes which were organised into emerging themes. A second researcher (JM) who was not involved in the data collection checked the coding. The themes that emerged from the data were mapped onto the Revised Programme Theory for SDM, a framework developed to understand the underlying mechanisms and the contextual factors which impact on SDM. Figure 1 shows the Revised Programme Theory for SDM, revised focused interprofessional-SDM mechanism map, which will be referred to as the ‘IP-SDM mechanism map’. The IP-SDM mechanism map shows when each of the mechanisms would appear before, during and after a SDM health practitioner consultation where a decision about an individual’s health is made. The wider framework ‘Revised Programme Theory for SDM’ includes contextual factors that impact on the mechanisms, including the difficulty of a healthcare decision, the pre-existing relationship between healthcare professionals and patients, and system support<sup>13</sup> (figure 2). We present the results for all the contextual factors except for pre-existing relationship which we’ve incorporated into the trust mechanism. As themes emerged, these were discussed and refined in meetings with the core research team (SO, JM, JE and FM). Tong and colleagues’ Consolidated criteria for Reporting Qualitative checklist was used to ensure enhanced interpretive rigour.<sup>14</sup>

### Patient and public involvement

The trial had two patient and public involvement (PPI) representatives on the SITA trial and one, author GF was

involved in this process evaluation. The PPI representatives served on the trial’s steering group committee. They actively participated in the development of the trial and provided valuable feedback and input on its activities. GF provided input on the process evaluation design and this manuscript.

### RESULTS

Thirty-five trial participants were invited, 18 refused and 17 were ultimately interviewed for this study. The participants were diverse with varying levels of education and a range of socioeconomic backgrounds (table 1). After being shown the decision aid, most of the participants interviewed in this process evaluation decided not to take aspirin (58.8%), some had started and then stopped taking aspirin (17.7%) and 23.5% started and continued to take aspirin. Participants were invited to be interviewed after the trial follow-up complete.

Twelve GPs were interviewed including GPs from both rural and urban settings with a range of years of clinical experience (table 2). The interviews lasted between 15 and 40 min.

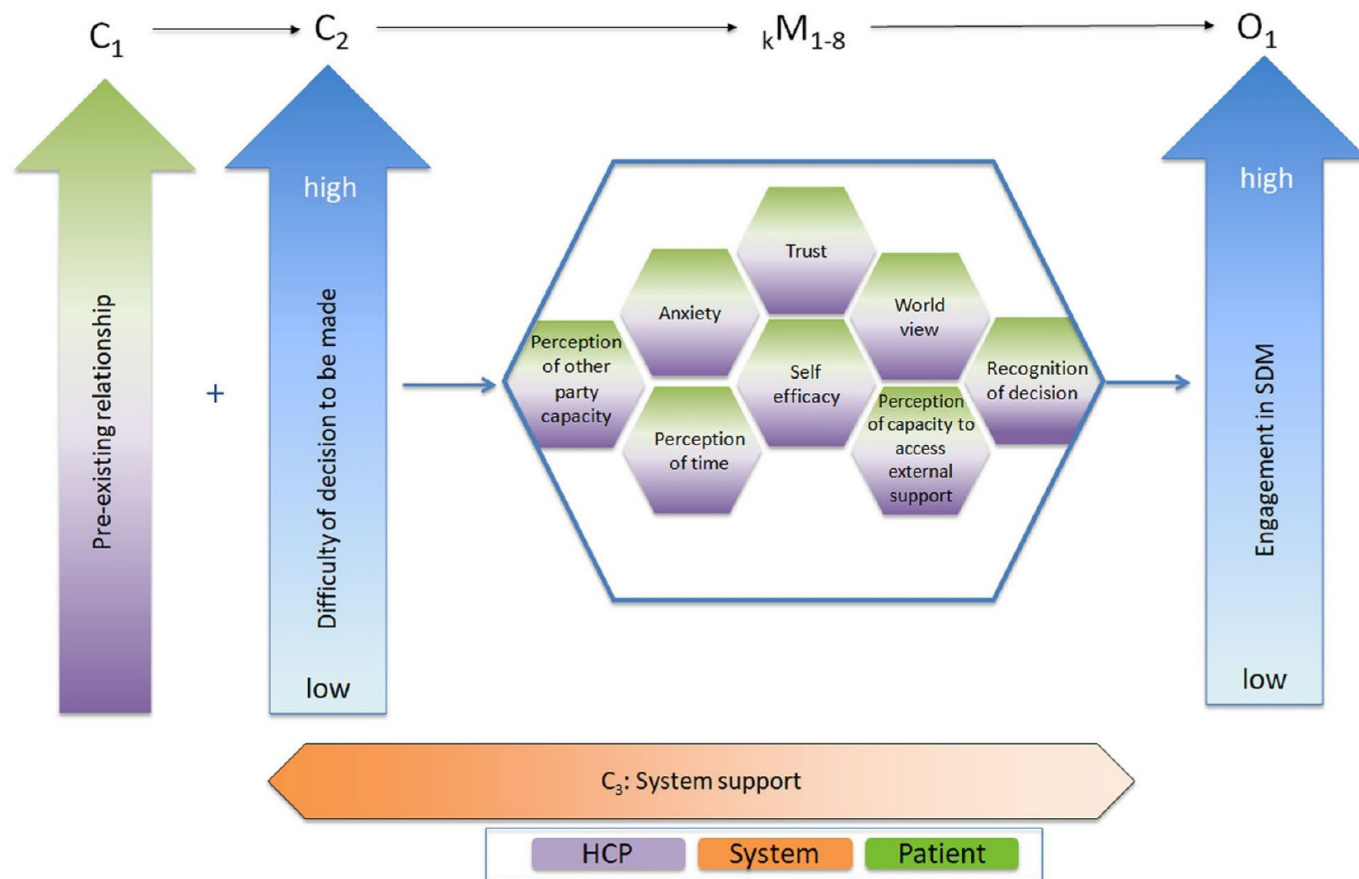
All quotations corresponding to the results can be found in tables 3 and 4.

#### Eight key mechanisms which impact on SDM

The qualitative results followed the IP-SDM mechanism map where the mechanisms were aligned to the area they were thought to arise in an SDM consultation (figure 1).

#### Trust (including a pre-existing relationship between participant and GP)

Patients reported that they generally trusted what their GPs advised them about their health. Patients mentioned unquestioningly following their GPs’ instructions with little contemplation. Patients wanted a degree of SDM, as after being presented with decision aid, they discussed it with their GPs before deciding to take aspirin (quotation



**Figure 2** Revised Programme Theory. This figure represents our Revised Programme Theory, beginning with the nature of any pre-existing relationship and difficulty of decision to be made. These interact with the key mechanisms ( $kM_{1-8}$ ), while the context of system support ( $C_3$ ) continues throughout process. Together, the contexts ( $C_1$  and  $C_2$ ) and mechanisms ( $kM_{1-8}$ ) form the outcome of level of engagement within SDM ( $O_1$ ). This figure was copied directly from the manuscript by Waldron *et al* and shows the Revised Programme Theory for shared decision-making. The manuscript was published under the terms of the Creative Commons Attribution 4.0 International Licence (<http://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution and reproduction in any medium, no changes were made to the figure. SDM, shared decision-making; HCP, healthcare professional.

1A, 1B and 1C). Some GPs also spoke of the ease of incorporating SDM into a consultation if their patients' trust them; noting that if they discussed taking aspirin to prevent bowel cancer and showed them the decision aid, most did not hesitate to take aspirin (quotation 1D).

#### Anxiety

Participants did not speak of any feelings of anxiety associated with taking aspirin; they were familiar with aspirin and thought it was safe (quotation 2).

#### GPs' recognition of decision

GPs understood that if their patients came into an appointment with a decision aid, and asked questions, they were looking for their GPs to help them decide whether taking aspirin was right for them (quotation 3).

#### Worldview

A few participants mentioned that they were sceptical about medical advice because it often changes over time (quotation 4A).

Participants also thought that having a healthy diet and weight, and screening for bowel cancer was enough to reduce their bowel cancer risk. They did not believe that they were at increased risk of developing bowel cancer and therefore did not feel that they needed to take aspirin to prevent it (quotations 4B, 4C and 4D).

A few participants believed that it was not worth trying to prevent cancer as they thought they were all going to get cancer someday so did not see the point in taking aspirin (quotation 4E). Some individuals had a distinct perception of their cancer risk, understanding the potential benefits of aspirin, and thus, chose to include aspirin in their regimen (quotations 4F and 4G).

#### Perception of capacity of other party

GPs found that due to the COVID-19 pandemic, patients were more aware of their health, and were more confident about asking questions. This perception led GPs to believe that patients would ask questions about the decision aid (quotation 5A).

**Table 1** Characteristics of participants (N=17)

Characteristics	%
Mean age (years)	59.1
Sex, female	52.9
Mode of trial delivery	
Face to face	76.5
Teletrial	23.5
Education	
Never completed high school	23.5
Completed high school only	0
TAFE qualification or similar	23.5
University degree or higher	53.0
Aspirin use after study participation	
No, I haven't taken aspirin	58.8
I started then stopped taking aspirin	17.7
Yes, I am currently taking aspirin	23.5
**IRSAD socioeconomic status	
Disadvantaged 1	11.8
2	0
3	47.1
4	0
Advantaged 5	41.1

\*The IRSAD: The IRSAD considers economic and social conditions to rank relative advantage and disadvantage in an area by postcode. Low scores indicate relatively greater disadvantage and a lack of advantage, while high scores indicate relatively lack of disadvantage and greater advantage.  
 IRSAD, Index of Relative Socio-economic Advantage and Disadvantage; TAFE, Technical and Further Education.

Some GPs, who worked in areas of high social deprivation, where patients present with multiple comorbidities, thought their patient population would not have the capacity for a SDM discussion about taking aspirin. GPs thought the decision aid was better suited for more affluent populations (quotation 5B).

#### Perception of time and clinician capacity

GPs acknowledged that they did not have time to talk about the decision aid due to patients coming in with competing health demands (quotations 6A and 6B).

For patients living in regional areas, the COVID-19 pandemic increasingly hindered access to their GPs, therefore, when they were able to see their GPs, the decision aid was not prioritised as they perceived that discussing aspirin would impede their GPs more 'important' work (quotation 6C and 6D).

#### Access to external support

GPs spoke of using the internet to search up the bowel cancer guidelines and because they could be easily found through conducting a Google Search and found on reputable websites, the guidelines were sufficiently supported.

**Table 2** Characteristics of general practitioner participants (N=12)

Characteristics	
Mean age (years)	52.5
Sex, female (n)	41.2
Mean years working as a GP (years)	23.8
Years in general practice (n)	
<10	4
10–19	0
20–29	2
30+	7
Mean hours worked per week	50.2
Mean percentage telehealth appointments	17.4
Work setting	
General practice (%)	
Mixed billing	35.3
Bulk-billing clinic	29.4
Private	11.8
Clinic *IRSAD socioeconomic status	
Disadvantaged 1	1
2	1
3	3
4	0
Advantaged 5	2

\*The IRSAD: The IRSAD considers economic and social conditions to rank relative advantage and disadvantage in an area by postcode. Low scores indicate relatively greater disadvantage and a lack of advantage, while high scores indicate relatively lack of disadvantage and greater advantage.  
 GP, general practitioner; IRSAD, Index of Relative Socio-economic Advantage and Disadvantage.

On Googling 'bowel cancer prevention', a GP tried to see if aspirin guidelines would come up early (quotation 7A).

GPs also mentioned that the Australian government is in support of SDM, which encouraged them to support their patients proactively approaching them with new medical advice, such as the decision aid for aspirin chemoprevention (quotation 7B).

#### Self-efficacy

Participants approached the decision-making process as if they were external to the decision to take aspirin. They did not speak of participating much in the decision-making process. Participants relied on the belief and support of their GPs to decide whether to take aspirin (quotations 8A and 8B).

Most participants perceived aspirin as beneficial for preventing bowel cancer after seeing the decision aids, but this did not translate into action or much participation in the decision-making if their GPs did not support the evidence (quotation 8C).

**Table 3** The quotations organised by the eight key mechanisms which impact on shared decision-making from the revised focused interprofessional-SDM mechanism map<sup>13</sup>

Eight key mechanisms which impact on SDM		
	Quote #	Quotation
Trust (including a pre-existing relationship)	1A	<i>“At the time, because they got me before I was going to a doctor’s consultation so I asked, should I take aspirin and she said yeah, it’s good for you. The GP didn’t try to talk me out of it.” -Male participant, 51 years I would take it. Yeah, because I trust her.” -Female participant, 65 years</i>
	1B	<i>“When I spoke with my GP and he was quite supportive of it, I was happy to take it.” -Female, participant, 66 years</i>
	1C	<i>“Not to say that I wouldn’t take it in the future. If the doctor suggested that I take it, I would. -Female participant, 65 years</i>
	1D	<i>“So, I think that, if a patient trusts you as a GP, and your present information, certainly in the demographic that I work with up north [mostly socially disadvantaged populations], they—it’s very rare that people question sources.” -Female GP, 35 years</i>
Anxiety	2A	<i>“Yeah. It was sort of what—it didn’t come as a big surprise. You know, wow, aspirin. I mean, I know aspirin’s used in—I used to drive tow trucks, and often the ambos would just—somebody had a busted leg or something, they’d just give them the aspirin straight away, and that was to help not get clots and stuff like that as well. So, it’s fairly handy for a lot of things.”—Male participant, 51 years</i>
General practitioners recognition of decision	3A	<i>“I think it does because they’ve read it in the room, in the off—out the front and they’d say, oh yeah, well, I had a look at this. I think most of them just say, oh, because it reduces risk of this so what do I need to do?” -Male GP 67 years</i>
Worldview	4A	<i>“Life is a continuum of listening to and accepting or rejecting advice. This one wasn’t worth accepting.” Male participant, 62 years.</i>
	4B	<i>“I looked at the other components what was recommended and thought, well, most of that is not dissimilar to my current diet, et cetera.”—Female participant, 66 years</i>
	4C	<i>“Well, I think the thing is to have a sensible diet—which I’ve always eaten really well, I’m not overweight—I think that has a lot to do with it.”—Female participant, 67 years</i>
	4D	<i>“I’ve had two colonoscopies in the last 2 months, so I’m not particularly worried about bowel cancer at the moment”—Female participant, 65 years</i>
	4E	<i>“There is an old song that you may not know called ‘Everything Gives You Cancer’. It’s not a particularly down song, it’s just a sort of factual song by someone called Joe Jackson from way back. I think that we’re all going to die, weigh up their risks, all that sort of thing.” Male participant, 62 years</i>
	4F	<i>“Just taking aspirin is probably—when you get to a certain age it’s better for you, rather than not”—Male participant, 51 years</i>
	4G	<i>“Well, I think it’s such a simple way of increasing your prevention and it has other benefits as well, which that brochure identified. Heart attack, stroke, deaths from other causes. So there didn’t seem to be a reason not to”—Female participant, 66 years</i>
Perception of capacity of other party	5A	<i>“I think the COVID’s done one thing, it’s raised people’s awareness of how to ask questions and how to ask very sophisticated questions about their health and what treatments are.”—Male GP, 67 years</i>
	5B	<i>“Yeah, I mean some affluent suburbs, yeah, I think that would be ideal for this decision aid.”—Male GP, 55 years</i>
Perception of time and clinician capacity	6A	<i>“Yeah, people who want to discussion preventive activities are very healthy and then they have nothing else to talk with the doctor and then they will come and say oh, what do you think that I might do to improve my health? Yeah, then we can talk preventative, but here it’s just yeah, it’s more of issues already bothering them and there are so many that you don’t have time to talk about preventative.”—Male GP, 55 years</i>
	6B	<i>“Why would I bring it up in the first place when there’s so many other things, they talk about that are totally unrelated.” Male GP, 69 years</i>
	6C	<i>“Yep. It wasn’t like an urgent medical issue that I thought I must make an appointment, because I think he was snowed under during telehealth appointments over COVID.”—Female participant, 65 years</i>

Continued

**Table 3** Continued

Eight key mechanisms which impact on SDM		
	6D	<i>"I mean, the doctors in this - you know, we're only in a little town, and they're that under-the-pump, I just—it's hard to get a booking"</i> —Male participant, 51 years
Access to external support	7A	<i>"I suppose in Australia, Bowelcanceraustralia.org would be considered to be the peak organisation for advice, and that [the aspirin guidelines] came up second, which is pretty good. Yeah, taking aspirin every day for at least five years decreased risk of bowel cancer, discuss it with your GP. So that's actually quite a nice one too, there's lots of pictures."</i> —Male GP, 55 years
	7B	<i>"So, at the moment the Department of Health and all the politicians are saying, go to see your GP because they'll help you decide."</i> —Male GP, 60 years
Self-efficacy	8A	<i>"Straight after I talked to you guys, I talked to my GP, yes."</i> Facilitator: <i>"What did they say about it?"</i> <i>"It wouldn't be a good idea for me."</i> —Male participant, 52 years
	8B	<i>"So, I didn't have a lot of contact with him [my GP] till finally I got to see him. I said, now, I got this brochure, and I sort of joined the study, but then I stopped taking it. He goes, no, no, take it. It's really good."</i> —Female participant, 65 years
	8C	<i>"It encouraged me to talk to my doctor because, of course, I would want to. I didn't want to, but I did mention to the doctor who wasn't particularly interested in it."</i> Male participant, 62 years
	8D	<i>"It's incredibly cheap stuff."</i> —Male participant, 55 years
	8E	<i>"I have a problem, you know, just I have five kids, my wife and myself, so little bit during the lockdown, lots of problems. You know, we are from overseas, and my family are arriving for three years, almost three years now. So, it's hard, life is hard, you know. It's not an easy thing. Yeah, it's a little bit harder for me to get that one but if I get, I'll take every day. If I get a chance—if there is a possibility to get aspirin, it's good for myself and for my wife. Yeah. So that's why on one of the (reasons I'm not taking it is) I don't have enough money to buy that one"</i> —Male participant, 51 years

SDM, shared decision-making.

Participants further commented on the price of aspirin. Though many thought it was affordable, cheap and easy to access, one participant who started then stopped taking aspirin explained it was due to financial difficulties they were experiencing due to the COVID-19 pandemic and recently migrating to Australia with a large family (quotations 8D and 8E).

### Three contextual components that impact on the above key mechanisms

#### System support

As GPs already discuss preventive health activities, they found that advising aspirin for bowel cancer prevention suited their existing practice (quotation 9A). GPs also recognised that care plans presented a great opportunity to talk through the decision aid, and other preventive health activities (quotation 9B).

#### Engagement in SDM

Participants spoke about how the decision aid prompted them to speak to their GP and helped them become aware of their contraindications to aspirin. Prompting SDM conversations and discussing contraindications to aspirin are clear purposes of the decision aids and the logic model within the SITA trial (Quotation 10A). Although the decision aid was designed to prompt a discussion between participants and their GPs, a few participants decided to bypass having a discussion (quotation 10B).

Some of the dialogues between patients and their GPs regarding aspirin were characterised by brevity and lack of depth, as they were simple and it was the GPs' goal to ensure their patients did not have any contraindications to taking aspirin. Multiple patients conveyed a sense of feeling underwhelmed with respect to aspirin, and although many discussed aspirin and the decision aid, it did not reach a high level of engagement (quotation 10C).

According to the GPs, patients who were provided with the decision aids about aspirin expressed a high level of satisfaction with the discussion. Patient satisfaction suggested that engaging in such a discussion was likely to be perceived as valuable by potential patients (quotation 10D).

#### Difficulty of decision to be made

Participants generally thought the decision aids were clear and easy to understand but struggled to correctly interpret the statistics or risks and benefits of taking aspirin from the EFTs (quotation 11A). Many were unable to see the relevance of taking aspirin for themselves as the numbers of people required to take aspirin for it to have an effect seemed very large (quotation 11B).

Participants understood from the EFTs that aspirin was beneficial for reducing the risk of bowel cancer and other chronic illnesses. Although they could clearly see the benefit, they did not always believe that it was worth

**Table 4** The quotations organised by the three contextual components which impact shared decision-making from the revised focused interprofessional-SDM mechanism<sup>13</sup>

Three contextual components that impact on the above key mechanisms		
System support	9A	<i>“So, I’m looking at cardiovascular disease prevention, musculoskeletal issue prevention, and now, since, obviously, meeting you, I’ve then added this into my little kind of speech that I normally do about, you know, the other things that they need to be looking at.”</i> —Male GP, 34 years
	9B	<i>“So, healthcare plans if they’re done properly, should address all of this stuff. But we know that the majority of healthcare plans in Australia are done purely because people want to get the discounted visits to the podiatrist or the physio, yes.”</i> —Male GP, 55 years
Engagement in shared decision-making	10A	<i>“Well, when I read about the aspirin, I asked my doctor about it, and she said that because of the medication I’m on that I can’t have aspirin. So, yeah, I was interested enough to ask my doctor about it.”</i> —Female participant, 67 years
	10B	<i>“Couple of weeks, and then I sort of stopped and thought about it. Then I had an interview and I said, oh, look, I’m not taking it, because I have to speak to my doctor (laughs).”</i> —Female participant, 65 years
	10C	<i>“It was good stuff I guess but—and they talked about the side-effects of aspirin which was good. It was all quite fair, but it just didn’t seem quite compelling. I might be better, for example, eating a lot of celery than taking aspirin for the rest of my life.”</i> —Male participant, 62 years
	10D	<i>“So, he definitely started it, and he was really happy with the conversation we’d had.”</i> Female GP, 35 years
Difficulty of decision to be made	11A	<i>“I thought the information in the brochures was clear and easy to understand.”</i> —Female participant, 56 years
	11B	<i>Yeah, it’s a reduction but it’s not a massive reduction, but it’s better than nothing, isn’t it?”</i> —Male participant, 51 years
	11C	<i>“Well, my thoughts were that it communicated well to me. I know statistically there are fewer deaths from stroke or for fewer strokes, it is not really significant. But I suppose it reinforced that it was most beneficial in the bowel cancer space, but it had other advantages as well.”</i> —Female participant, 66 years
	11D	<i>“Yeah, just that I bleed a lot, bleed easily so that would have been an issue sometimes.”</i> —Male participant, 70 years
	11E	<i>“So, that—I found that probably the most interesting and easiest way to engage the patients through looking through that.”</i> —Female GP, 35 years

SDM, shared decision-making.

taking aspirin. Participants also overestimated the risks and due to existing contraindications decided against taking aspirin (quotations 11C and 11D).

Decision aids are interventions designed to facilitate a discussion between patients and their healthcare practitioners, GPs understood this and felt that the decision aid would make it easier to engage their patients in a discussion (quotation 11E).

## DISCUSSION

### Principal findings

This study highlights how participants in the SITA trial used a decision aid to come to a shared decision to take aspirin to prevent bowel cancer in the context of a consultation in general practice. Participant engagement in SDM varied, although most participants actively engaged in SDM due to their trust in their GPs, low levels of anxiety about the thought of taking aspirin and having a perceived risk of developing bowel cancer. Consequently, after being shown the decision aid and speaking to their

GPs, some participants decided to take aspirin. Most participants also found that aspirin was affordable and easily accessible, although one participant expressed that due to their financial difficulties, they could not afford to buy it. GPs also thought the decision aid made it easier to engage in SDM, since they already discuss preventive strategies with their patients, and have government support for SDM. SDM has been increasing in Australian healthcare since 2017, with government support to back it up.<sup>15</sup> GPs also liked that the guidelines were easily accessible on the internet and were supported by reputable organisations, such as the Cancer Council Australia, and the Royal Australian College of General Practitioners, which are guideline publishing bodies in Australia, regularly used by GPs.

Participants and GPs expressed several barriers to engaging in SDM which led to many not discussing the decision aid and ultimately deciding against taking aspirin. Participants perceived aspirin as not being compelling or interesting and they had low levels of anxiety about



aspirin, which could have prevented them from participating in SDM. They often misunderstood the benefits of taking aspirin and thought that the absolute benefits at an individual level were relatively small. Additionally, participants perceived their GPs as being too busy with more important activities due to the COVID-19 pandemic, resulting in them deprioritising engaging in SDM about the decision aid. A few participants bypassed the discussion and decided to take aspirin anyway or decided against it due to their fatalistic and sceptical attitudes. One study identified several factors that impact patients' engagement in SDM, including socioeconomic status and ethnicity.<sup>16</sup> Additionally, the study found that individuals with higher levels of numeracy are better equipped to participate in SDM. This study supported our finding by additionally concluding that, those with lower numeracy skills, may struggle to comprehend the risks and benefits of treatments for cancer.<sup>16</sup> Some participants in our study decided against taking aspirin due to their perceived low risk of ever developing bowel cancer. Similarly, a qualitative study concluded that patients who misperceive their cancer risk as lower than it actually is, are less likely to engage in behaviours that reduce their cancer risk.<sup>17</sup>

A few GPs also believed that the decision aid was better suited for higher socioeconomic status populations, who are already in better health, further suggesting that they do not have enough time to address preventive health strategies with patients who are unwell. This view is contrary to what is found in the literature. In one systematic review of 11 randomised controlled trials on the use of decision aids in disadvantaged populations, more than half reported improved knowledge and informed choice, and high patient engagement in SDM.<sup>18</sup>

For some, the decision aid prompted discussions between GPs and their patients, while others deprioritised discussing the decision aid with their GP due to it not being seen as urgent, especially regional participants in the context of the COVID-19 pandemic. Although some discussions were had, participants discussed that they were brief, and pending their GPs opinion they either decided for or against taking aspirin. GPs conversely understood that a decision was to be made, helped their patients decide, and reported a high level of patient satisfaction with the consultations.

Such findings underline the decision aid's potential in promoting SDM and enabling constructive patient-GP dialogue, although it was not useful for everyone. Our findings are consistent with a qualitative study of a decision aid for prostate cancer screening in supporting SDM between GPs and male patients.<sup>19</sup> In our study, the decision aid was not universally accepted, and participants' worldviews, socioeconomic status, self-efficacy, their general practice readiness for implementation and the timing of advice impacted on SDM.

### Strengths and limitations

The results of this qualitative process evaluation should be interpreted in the context of some limitations. First,

GPs and participants were interviewed after their initial researcher consultations, about 6–8 months later, consequently, the findings must be interpreted with regard for the possible influence of recall bias and social desirability bias, given the role of the interviewers in the trial.

We included a diverse group of participants and GPs who practised in both metropolitan and regional locations. Participants were also diverse in socioeconomic status and educational attainment, which further shows that SDM via a decision aid was feasible for them.

Other limitations include the relatively small number of participants interviewed in terms of their different behavioural responses to the decision aid, whether they decided to take aspirin or started then stopped taking it.

### Context in relation to other studies

It is well documented in the literature that decision aids are beneficial for implementing evidence into clinical care.<sup>20</sup> Decision aids support SDM between patients and clinicians, in a systematic review of decisions aids for complex healthcare decisions, decision aids were beneficial for communicating the risks and benefits of healthcare decisions.<sup>21</sup> In our study, the decision aid possibly supported SDM for some participants through facilitating discussions between participants and their GP. In contrast, if GPs supported the decision to take aspirin, no further discussion was had, and patients took it because they trusted their GP.

This study is a process evaluation of an efficacy trial where trained research assistants delivered the decision aid in a controlled way, thus the results do not reflect patient and GP engagement in SDM if the decision aid were implemented in the real-world. We do not know the impact of the decision aid if the GPs discussed it vs it being discussed by a research assistant. A few implementation strategies were discussed, as GPs thought the decision aid would fit well with their current practice, during care plan appointments, and with government support of SDM. Barriers to real-world implementation include the limited time GPs have to successfully participate in SDM consultations, which is a well-documented barrier in the literature.<sup>22</sup>

### Possible explanations and implications for clinicians and policy-makers

This study shows that a decision aid about taking aspirin for bowel cancer prevention is feasible for use in general practice, even though some patients and GPs might overestimate the risks of potential harms from taking aspirin. In Lloyd *et al's* review they found that the general public and patients generally had positive attitudes towards aspirin use for cancer prevention, including for bowel cancer prevention.<sup>23</sup>

This process evaluation shows that the use of decision aids is effective in encouraging a discussion with a GP about cancer prevention. If GPs agree with what the decision aid presents, then it can be a powerful tool for communicating the harms or benefits of different

healthcare decisions. In our previous research, input from 64 clinicians, including GPs, was obtained in an iterative process to refine the EFT used to communicate the benefits and risks of taking aspirin as part of the decision aid.<sup>8</sup> The clinician consultation or developing the decision aid with clinicians did not convince all GPs participating in the SITA trial to support the aspirin guidelines. While involving consumers in the intervention development process was crucial it does not guarantee that it will be acceptable by all end-users. In a qualitative study, where Australian GPs were interviewed about the primary prevention of cardiovascular disease, they found that if GPs thought taking aspirin was a good idea, patients were more likely to initiate taking it.<sup>24</sup> This study further supports our findings, that patients are influenced by what their GP recommends.

Although the aspirin guidelines are still in existence in Australia, due to the changing evidence about taking aspirin for the primary prevention of bowel cancer and cardiovascular disease in the USA<sup>25 26</sup> during this study, GPs may find the decision aids to be confusing. Australia's largest run randomised controlled trial, the ASPREE trial,<sup>27</sup> a trial of aspirin in healthy elderly people aged 50–70 years showed that aspirin is not beneficial for people over 70 years. The ASPREE trial, a widely publicised study, may have caused some confusion around whether aspirin is safe even for those aged 50–70 years. Largely as a result of ASPREE, the US Preventative Services Task Force have also recently updated their guidelines and removed the recommendation of aspirin for the prevention of bowel cancer.<sup>28</sup> The benefits of aspirin are seen only after 10 years, and with the US guidelines being based on cardiovascular studies with short-term follow-up, the USPTF may have prematurely downgraded the beneficial effects of aspirin, even in the elderly.<sup>29</sup>

### Unanswered questions and future research

This process evaluation shows that even though some participants and clinicians supported using the decision aids and participated in a degree of SDM, it may not be useful for all. It may be beneficial to communicate risk in several different ways, in a single decision aid or have decision aids developed for disadvantaged populations.

We also do not know how the results of this study would have been different if it were conducted outside of the COVID-19 pandemic.

This is a process evaluation of a randomised controlled trial, the SITA trial, and will help interpret the results. The SITA trial results publication is underway.

### Author affiliations

<sup>1</sup>Evaluation and Implementation Science Unit, Centre for Health Policy, Melbourne School of Population and Global Health, The University of Melbourne, Parkville, Victoria, Australia

<sup>2</sup>Department of General Practice, Faculty of Medicine Dentistry and Health Sciences, The University of Melbourne, Parkville, Victoria, Australia

<sup>3</sup>Centre for Cancer Research, Faculty of Medicine Dentistry and Health Sciences, University of Melbourne, Parkville, Victoria, Australia

<sup>4</sup>Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, The University of Melbourne, Melbourne, Parkville, Australia

<sup>5</sup>Colorectal Medicine and Genetics, The Royal Melbourne Hospital, Parkville, Victoria, Australia

<sup>6</sup>Department of Medicine, Faculty of Medicine Dentistry and Health Sciences, The University of Melbourne, Parkville, Victoria, Australia

<sup>7</sup>PC4 Joint Community Advisory Group, University of Melbourne VCCC, Parkville, Victoria, Australia

**Twitter** Shakira Onwuka @ShakiraOnwuka

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**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and ethics approval granted in 2020 by the University of Melbourne Human Research Ethics Committee in 2020 (approval ID: 2056513). Participants gave informed consent to participate in the study before taking part.

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### ORCID ID

Shakira Onwuka <http://orcid.org/0000-0002-8510-6351>

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Supplementary files for *What did participants and GPs think of the decision aid about taking aspirin to prevent cancer? : A process evaluation of a RCT in general practice*

Supplementary file A. Female decision aid and video

**Aspirin can reduce your risk of bowel cancer BY UP TO 25%**

Cancer Council Australia recommends that, if you are between the ages of 50 and 70, speak to your GP about taking low dose aspirin (100-300 mg every day) to prevent bowel cancer.

**Aspirin may not be appropriate if you have...**

- ✗ Indigestion
- ✗ Untreated high blood pressure
- ✗ Stomach ulcers
- ✗ Blood thinning medication e.g. Warfarin
- ✗ Kidney impairment
- ✗ Untreated H. pylori
- ✗ A bleeding disorder

**ARE YOU A WOMAN BETWEEN THE AGES OF 50 - 70?**

Reduce your **bowel cancer** risk by taking **aspirin**

**Speak to your GP today**

Information to support your decision

**This brochure will help you**

- ✓ Understand the benefits and side-effects of taking low dose aspirin.
- ✓ Decide whether taking aspirin is the right decision for you.

**How much aspirin should I take?**

- ✓ 100 – 300 mg (e.g. one baby aspirin per day).
- ✓ For a minimum of 2½ to 5 years.

**Remember to:**

- ✓ Talk to your GP before taking aspirin.
- ✓ Continue regular screening with the poo test (aka FOBT kit) that you receive in the post from the National Bowel Cancer Screening Program.

**Aspirin can reduce your risk of bowel cancer, heart disease and stroke but can increase your risk of bleeding from the stomach and gut.**

This figure shows **10,000 Australian women between the ages of 50 to 70** after 10 years if they did or did not take aspirin.

INCIDENCES OF THE FOLLOWING

	BOWEL CANCER	HEART ATTACK	STROKE	DEATH FROM ALL CAUSES	BLEEDING FROM GUT & STOMACH
NO ASPIRIN	126	311	374	675	53
ASPIRIN	95	298	370	651	65
DIFFERENCE	31 FEWER	13 FEWER	4 FEWER	24 FEWER	12 MORE

Video decision aid for females: [https://youtu.be/cDf\\_3mIJRoU](https://youtu.be/cDf_3mIJRoU)

Supplementary file B. Male decision aid and video



**Aspirin can reduce your risk of bowel cancer BY UP TO 25%**

Cancer Council Australia recommends that, if you are between the ages of 50 and 70, speak to your GP about taking low dose aspirin (100-300 mg every day) to prevent bowel cancer.



**Aspirin may not be appropriate if you have...**

- ✗ Indigestion
- ✗ Untreated high blood pressure
- ✗ Stomach ulcers
- ✗ Blood thinning medication e.g. Warfarin
- ✗ Kidney impairment
- ✗ Untreated H. pylori
- ✗ A bleeding disorder

**ARE YOU A MAN BETWEEN THE AGES OF 50 - 70?**

Reduce your **bowel cancer** risk by taking **aspirin**



Speak to your GP today

Information to support your decision

**This brochure will help you**

- ✓ Understand the benefits and side-effects of taking low dose aspirin.
- ✓ Decide whether taking aspirin is the right decision for you.

**How much aspirin should I take?**

- ✓ 100 - 300 mg (e.g. one baby aspirin per day).
- ✓ For a minimum of 2½ to 5 years.

**Remember to:**

- ✓ Talk to your GP before taking aspirin.
- ✓ Continue regular screening with the poo test (aka FOBT kit) that you receive in the post from the National Bowel Cancer Screening Program.

**Aspirin can reduce your risk of bowel cancer, heart disease and stroke but can increase your risk of bleeding from the stomach and gut.**

This figure shows what would happen to **10,000 Australian men between the ages of 50 to 70** after 10 years if they did or did not take aspirin.

	INCIDENCES OF THE FOLLOWING				
	BOWEL CANCER	HEART ATTACK	STROKE	DEATH FROM ALL CAUSES	BLEEDING FROM GUT & STOMACH
NO ASPIRIN	178	743	596	1075	104
ASPIRIN	134	707	591	1027	129
DIFFERENCE	<b>44 FEWER</b>	<b>36 FEWER</b>	<b>5 FEWER</b>	<b>48 FEWER</b>	<b>25 MORE</b>

Video decision aid for males: [https://youtu.be/p\\_Ey908EApe](https://youtu.be/p_Ey908EApe)

Supplementary file C. General reduce your bowel cancer risk brochure and video

### Drink less & live more

**Key tips!**

- ✓ Drink no more than two standard drinks per day

**One standard drink equals**

 <b>ONE GLASS OF BEER</b> 285 ml of beer	 <b>ONE SMALL GLASS OF WINE</b> 100 ml of wine	 <b>ONE MEASURE OF SPIRITS</b> 30 ml of spirits
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If you choose to drink alcoholic drinks, limit to special occasions

**DID YOU KNOW**  
Almost 1 in 5 Australian adults (18%) consume more than 2 standard drinks per day

### Speak to your GP about taking aspirin

*Taking a low dose of aspirin every day for at least 2 1/2 years decreases your risk of developing bowel cancer as well as dying from bowel cancer*

Please note: the possible harms of aspirin use include a higher than normal risk of bleeding in the stomach or brain. Please discuss with your GP before taking aspirin.

### Be physically active!

**Key tips!**

- ✓ Be physically active and elevate your heart rate every day in any way for 30 minutes or more.
- ✓ Walk or cycle instead of driving to the shops or work
- ✓ Use the stairs
- ✓ Meet a friend and play a sport together
- ✓ Take regular breaks at work

## Reduce your bowel cancer risk



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### Maintain a healthy weight

**Key tips!**

- ✓ Reduce your waistline to under 94cm for men and 80cm for women
- ✗ Avoid food and drinks that are high in fats and sugars
- ✓ Limit alcoholic drinks
- ✓ Choose fish, poultry or vegetarian options instead of red meat for some meals



**DID YOU KNOW**  
Nearly 2 in 3 Australian adults (63%) are overweight or obese

### Eat a healthy diet, limit red & processed meat

**Key tips!**

- ✓ Aim to eat 2 serves of fruit and 5 serves of vegetables daily
- ✗ Avoid eating processed meats such as bacon, ham, salami and sausages
- ✓ If you eat red meat, limit the amount to 500 grams cooked per week



**DID YOU KNOW**  
Eating 3 servings of wholegrains a day, (brown rice or wholemeal bread) can reduce your risk of bowel cancer

### Eat dairy products & take calcium supplements

**Key tips!**

- ✓ Include dairy products like low-fat milk, yoghurt and cheese in your diet
- ✓ Speak to your GP if you are lactose intolerant about what calcium supplement to take



**DID YOU KNOW**  
Having 400 grams of dairy products per day decreases your bowel cancer risk by 13% and having 200 grams of milk or 200mg of dietary calcium per day decreases risk by 6%

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### Check for unusual bowel habits & screen

**Key tips!**

- ✓ Complete the FOBT poo kit when it is delivered to you every two years from the age of 50 years



### Quit smoking

**Key tips!**

- ✓ Quit smoking
- ✗ Avoid exposure to tobacco smoke



**DID YOU KNOW**  
Eating too much red meat has been linked with an increased risk of bowel cancer

**DID YOU KNOW**  
Smoking 40 cigarettes (two packs) per day increases your risk of bowel cancer by around 40% and nearly doubles the risk of bowel cancer death

Call Quitline on **13 78 48** or visit [www.quit.org.au](http://www.quit.org.au)



Control video: <https://youtu.be/BzGHxV4-Yw0>

## Supplementary file D. Interview Schedule for Participants

- To start, tell me a little about your experience with the trial, how did you find it?
  - Did anything stand out to you? Is there anything that surprised you or anything new you learned?
  - Were you confused or unsure about anything?
- **\*\*If approached via phone\*\***
  - When you were first invited into the study, how did you feel to be contacted by a researcher over the phone?
    - Did it surprise or confuse you?
    - Would you have preferred to be approached in person or via other methods e.g. email, post?
  - Would you be happy to be contacted again over the phone for other research projects?
- Zoom: I will now share my screen with you and show you the brochures we gave you when you started in the study
- **\*\*share screen\*\***
- Telephone: do you have the brochures from the study in front of you?
- **\*\*if they say yes, continue\*\***
- Do you remember receiving this brochure, what we call a decision aid?
  - What did you think about it at the time?
  - Is there anything additional you wished the researcher had discussed? Or anything the brochure doesn't cover?
- Had you ever heard about aspirin being used to prevent bowel cancer?
- What are your perceptions of aspirin being used to prevent bowel cancer?
- What did you think of the brochures and the information in it? Was it clear?
- What did you think of the diagram?
  - Could you understand the diagram?
  - Did the information surprise you at all?
  - How did it make you feel about taking aspirin?
  - Did you show it to your GP?
    - If yes, do you remember what your GP said?
  - Did you show it anyone else? (Specialist, pharmacist, family member, friend?)
    - What did they say about it?
  - What is the biggest thing you learned from the brochure and discussion with our researchers (or with GP/pharmacist/friend etc)
- Are you taking aspirin now? Have you taken it in the last 6-7 months?
  - Can you tell me a bit about why you made that decision?
    - If yes, how did you get your aspirin?
      - Did your GP prescribe it?
      - Did you talk to your pharmacist?
      - Where did you buy it?

- How much did you pay for it? Was cost an issue?
- Was it easy to work out which one to buy?

Did you start then stop taking aspirin?

- Why did you stop taking aspirin?
- What dose are you taking?
- If taking it, did you get any side effects?
  - What kind of side effects did you experience? How did you deal with these side effects?
  - Did you talk to your GP about your side effects or symptoms? What did they do?
- Have you recommended taking aspirin to anyone else?
- Telehealth

**\*\*the following questions are only for participants who had the intervention delivered via Zoom\*\***

- I know we conducted your appointment via zoom, is this something you have used in the past?
- How did you find the telehealth consultation?
  - What did you like or not like about it?
  - There are a range of situations throughout the trial that have meant we needed to use telehealth, especially with all the changes we have had in Victoria. What were your reasons for choosing telehealth?
  - In the future, would you participate in another telehealth consultation over video?
- Did you have any technical issues? If so, how were these solved?
- How would you compare telehealth vs in-person consultations? Is there one you prefer?

**\*\*ask all participants the following questions, regardless of whether their consultation was delivered F2F or via telehealth\*\***

- Does your GP currently offer telehealth? Do you think you would use it if they did offer it in the future?/have you used it?
- How do you feel about general practice's shift to telehealth and phone consultations due to the COVID-19 pandemic?
- You met with my team over zoom which meant you could see the researcher and they could share resources with you. At the moment, most GPs only do telehealth by telephone, do you think you would feel more comfortable/prefer with video? If so/if not, why?
- Is there anything else you'd like to talk about?



## Supplementary file E. Interview Schedule for General Practitioners

- Capture **GP Demographics**
  - Age, sex, full-time/part-time (hours worked per week), bulk billing, or private clinic, rural or urban practice, volume of telehealth consults, specialties
- Can you tell me what you remember about the trial?
- Overview of Trial (*show this to the GP*)
  - Can you recall a patient who's come to talk to you about aspirin following participation in the study?
    - How did it go? Can you recall what happened in the consult?
    - Do you remember if they decided to take aspirin?
    - If a patient asked you about the study, did it significantly affect your practice e.g. did it take too long?
    - Do you routinely talk about preventative medicine with your patients over 50 years old?
  - Show the decision aids
    - Do you remember these?
    - What do you think about it?
    - Do you think it was helpful? And did it influence the way you talked to your patient about taking aspirin?
- What do you think about using aspirin to prevent bowel cancer?
  - Were you aware of the potential benefits and harms of using aspirin to prevent bowel cancer before the trial?
  - Were you aware of the updated RACGP Redbook guidelines regarding aspirin?
  - Has your involvement in the trial affected the way you think about aspirin and talk to you patients about it?
- Did any of your patients experience side effects from taking aspirin?
  - If yes, what symptoms?
  - How did you respond? (PPIs?)
- When would you find the decision aid to be useful for your patients in the future?
  - How would you like to have access to it?
  - Would you ever give it to your patients?
  - Do you currently use any decision aids? Can you tell me about how you use them?
  - Has it changed your attitude about taking aspirin for you or your family?
- Telehealth
  - How would you compare telehealth vs in-person consultations? Is there one you prefer?
  - How do you feel about general practice's shift to telehealth and phone consultations due to the COVID-19 pandemic?
  - Do you remember any patients asking you about the trial over the phone? How did the consultation go?
- Is there anything else you'd like to talk about?