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Title Page

Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.

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Abstract

Objective Prostate-specific antigen (PSA) screening is controversial. A community jury allows presentation of complex information and may clarify how participants view screening after being well-informed of the benefits and harms. We sought to determine whether participating in a community jury had an effect on men's knowledge about and their intention to participate in PSA screening.

Design Participants were randomly allocated to either a 2-day community jury or a control group, with pre- post- and three-month follow-up.

Setting Community members from the Gold Coast (Australia) were recruited via radio, newspaper, and community meetings.

Participants Twenty-six eligible men aged 50-70 years with no previous diagnosis of prostate cancer.

Intervention The control group (n= 14) received factsheets on PSA screening. Community jury participants (n= 12) received the same factsheets and further information about screening for prostate cancer. In addition, three experts presented information on PSA screening: a neutral scientific adviser provided background information, one expert emphasised the potential benefits of screening, and another expert emphasised the potential harms. Participants discussed this information, asked questions of the experts and deliberated on personal and policy decisions.

Main Outcome and Measures Our primary outcome was change in individual intention to have a PSA screening test. We also assessed knowledge about screening for prostate cancer.

Results All analyses were conducted using intention-to-treat. Immediately after the jury, the community jury group had less intention-to-screen for prostate cancer than men in the control group (effect size = -0.6SD, $p=0.05$). This was sustained at three-month follow-up.

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3 Community jury men also answered more knowledge questions correctly and considered
4 themselves more informed (effect size 1.2SD, $p < 0.001$).
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7 **Conclusions** Evidence-informed deliberation of the harms and benefits of PSA screening
8 effects men's individual choice to be screened for prostate cancer. Community juries may be
9 a valid method for eliciting target group input to policy decisions.
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16 **Trial Registration** Australian and New Zealand Clinical Trials Registry
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18 (ACTRN12612001079831) <http://www.anzctr.org.au>
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21 22 23 **Strengths and limitations of this study**

- 24
25 • This is the first study to use scientific methods to evaluate the effect of a community
26 jury on an individual's knowledge and decisions.
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- 28
29 • Participants in community juries make value-based decisions from complex
30 information and can differentiate individual from community choices.
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34 • Expert presentations were based on large population studies that have limitations.
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37 • The sample size of this study was small, but the results were clear and sustained.
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40 • How sampling, recruitment techniques, and group processes affect community jury
41 outcomes are yet to be examined.
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Introduction

Screening for prostate cancer by prostate-specific antigen (PSA) testing is controversial¹ and the benefits and harms of screening are uncertain.² The results of two large randomised controlled trials of population screening (the ERSPC trial in Europe³ and the PLCO trial in the United States⁴) were much anticipated, but the equivocal results have led to conflicting interpretations and recommendations from expert groups.^{5,6} Given the uncertainty, most guidelines recommend that men should be fully informed of the potential advantages and disadvantages of screening prior to having a PSA test.^{5,7,8} Although individuals vary in the degree to which they want to engage with the evidence about their health concerns, a majority consistently report an interest in sharing health care decisions with their treating doctor.^{9,10} However, providing the complex information relevant to men who are interested in PSA screening remains challenging.

Citizens' deliberation methodologies, such as community juries can facilitate the communication of complex evidence and aim to elicit 'informed' community perspectives for the purpose of guiding services and public policy. A range of community jury processes have been described, but the common features are i) participants are drawn from the lay public; ii) the jury deliberates on a question requiring an ethics or values-based decision (as opposed to a problem requiring a technical solution); iii) the jury is provided with information on the relevant issues and possible positions from expert "witnesses", with the opportunity to ask them questions; and iv) the jury then engages in a deliberation phase with participants discussing their preferences, opinions, values and positions, and attempt to reach a consensus position.¹¹

Community juries have been conducted on topics such as public health priorities,¹² mammography screening,¹³ and health research.^{14,15} A recent review of deliberation methodologies found only four unique studies that compared deliberative methodologies with

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2
3 a control group; only two of these were in relation to health topics.¹¹ While theoretically
4
5 sound,¹¹ community juries are a resource-intensive process and it is uncertain whether the
6
7 views of those participating are better “informed” than those of a public provided with
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9 reading material on the same topic. It is also unclear whether and how being informed
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11 influences a jury’s conclusions. If community juries are to be used to inform screening
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13 policy, it is essential to understand the capacity of a community jury process to support
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15 better-informed conclusions by its participants.
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19 The aim of this study was to examine the degree to which participants of a community
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21 jury on PSA screening of asymptomatic men were better “informed” than other citizens and,
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23 based on the ERSPC³ and PLCO⁴ trials together with the general practice guidelines, whether
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25 evidence-informed deliberations of the benefits and harms of PSA screening impact on men’s
26
27 intention to be screen for prostate cancer. We conducted a randomised controlled trial that
28
29 compared a community jury with men allocated to receive typical information. As part of the
30
31 community jury process, men were also asked to deliberate on two community focused
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33 questions:
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36 • Should government campaigns be provided (on PSA screening) and if so, what
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38 information should be included in those campaigns?
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40 • What do you as a group of men think about a government organised invitation
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42 program for testing for prostate cancer?
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46 This is the first randomised controlled trial of a deliberative democracy process on the topic
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48 of PSA screening.
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50 51 52 **Method**

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54 We recruited men in the target age group of 50 to 70 years from the Gold Coast region
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56 (Australia) who had no previous diagnosis of prostate cancer, using media advertisements,
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3 radio interviews, and community groups. Men with a family history of prostate cancer were
4
5 not excluded from participating. Eligible and available respondents attended a session on a
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7 Friday evening to receive a full briefing on the study; all agreed to participate and completed
8
9 a consent form, before being randomly allocated to either a community jury group or a
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11 control group (Figure 1). Random allocation occurred by each man selecting a piece of paper
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13 with the name of either group from an opaque container. The research project was approved
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15 by the Bond University Human Research Ethics Committee (R01570) and the protocol
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17 registered with the Australian and New Zealand Clinical Trials Registry
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19 (ACTRN12612001079831).
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23 All men were given standard PSA fact sheets from the Cancer Council Australia and
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25 Andrology Australia.^{16,17} In addition to the factsheets, men in the community jury group also
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27 received a Cochrane Collaboration plain language statement,² information from the Royal
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29 Australian College of General Practitioners' Guidelines for "Preventive Activities in General
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31 Practice" pertaining to screening for prostate cancer,⁷ and the Executive Summary of "PSA
32
33 Testing" from the Urology Society of Australia and New Zealand.⁸ Men in both groups
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35 received \$20 gift cards as reimbursement for their time at the introductory session and for
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37 each survey. The community jury group received an \$80 gift card as reimbursement for
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39 attending the community jury weekend. Men in the control group were given a follow-up
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41 survey with a return stamped envelope to be mailed after the weekend.
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45 The community jury weekend and a qualitative analysis of the jury deliberations have
46
47 been described in detail elsewhere.¹⁸ In brief, the community jury consisted of an iterative
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49 process of education and deliberation. Three experts presented to the community jury on day
50
51 one: a neutral scientific advisor discussed medical information regarding the role of the
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53 prostate, screening tests (including PSA and Digital Rectal Examination), explanations about
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55 changes to PSA levels, how cancer is detected, and treatment options and potential outcomes
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3 (Jim Dickinson, Professor of Family Medicine, University of Calgary). Two further experts
4
5 (a urologist and expert in prostate cancer (author RG) and an expert in evidence-based
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7 medicine (author PG) presented the benefits and harms of being screened for prostate cancer.
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9 Although both speakers aimed to give balanced presentations, one emphasised the benefits of
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11 PSA screening, in particular selective screening, (RG <http://youtu.be/9vPt3NAcG8g>) and the
12
13 other the harms (PG <http://youtu.be/nifkjdZKmsU>). Both presentations focused on the
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15 evidence from the two trials of PSA population screening. However, both presenters also
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17 made reference to lower levels of evidence relating to the risks of metastases if a cancer
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19 remains undetected due to a lack of screening and the consequences of treating localised
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21 disease detected during screening. Each presentation ran for approximately 45 minutes, with
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23 15 minutes for questions. After each presentation, men were able to deliberate on the
24
25 information and could ask the experts any questions. The men reflected on the information
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27 overnight and returned on Sunday to deliberate and discuss the information presented the day
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29 before, including asking any further questions of the expert witnesses by phone.
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34 A nominal group technique was used on both days to elicit individual thoughts prior to
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36 group deliberations. After the final deliberations on Sunday, including the community level
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38 decisions, the men in the community jury completed the post-assessment survey. Men in the
39
40 control group were contacted on the Monday and either completed the post-assessment
41
42 survey by phone or mailed the survey back to researchers the same week. Three months after
43
44 the community jury weekend, all men in both groups were re-contacted and completed a
45
46 follow-up survey.
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49 **Non-protocol Extension**

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51 Because they indicated a strong desire to have the experience of the community jury
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53 weekend, after their three-month follow-up survey the control group was offered the same
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55 community jury experience. Six of the 14 men randomised to the control group participated
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3 in the second community jury (Figure 1). The two primary experts were the same as for the
4
5 original community jury group, however, the scientific advisor was changed to a female
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7 general practitioner and professor of clinical epidemiology (author JD). A final post-jury
8
9 survey was conducted with the second community jury.
10

11 **Measures**

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14 We collected demographic information, history of previous PSA testing and
15
16 information sources for PSA screening at the introductory session. In each of the three
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18 surveys, men were asked to nominate on a scale 0 to 10 (0 = *not at all*, 5 = *maybe*, and 10 =
19
20 *absolutely*), whether they intended, while symptomless, to undergo PSA screening for
21
22 prostate cancer in the future. They were also asked to nominate how informed they
23
24 considered themselves in relation to the harms and benefits of screening for prostate cancer
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26 on a scale 0 to 4 (0 = *not at all* and 4 = *very*). We asked six knowledge questions in each
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28 survey that assessed a) the men's knowledge about the recommendation on PSA screening in
29
30 the Australian general practice guidelines,⁷ b) the likelihood of being diagnosed with prostate
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32 cancer,¹⁹ c) the likelihood of dying of prostate cancer,¹⁹ d) the accuracy of the PSA test and e)
33
34 two questions about treatment options and side-effects of prostate cancer treatment (Box 1).
35
36 Australia has a primary care based system, requiring a referral from a general practitioner to
37
38 see a urologist. General practitioners are therefore responsible for the majority of the PSA
39
40 screening tests requested in Australia. For this reason, we were interested in the participants'
41
42 knowledge of current general practice guidelines.
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47 **Statistical Analyses**

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49 Pre- to post-, and post- to follow-up assessment differences between the groups were
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51 examined with ANCOVA and Fisher's exact test. It was anticipated that the number of PSA
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53 tests previously undertaken would impact on a man's future decision to be screened for
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55 prostate cancer with the PSA test.²⁰ Therefore we conducted the analyses with adjustment for
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3 baseline intention-to-screen and the number of times a man had already received a PSA test.
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5 Unadjusted post-assessment analyses were conducted using an independent t-test. All
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7 analyses were conducted on an intention-to-treat basis.
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10 11 12 **Results**

13 14 **Participant Demographics**

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16 Of the 59 men who contacted the research team, 27 respondents were available on the set
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18 date and elected to participate in the study. One man was excluded post-randomisation as his
19
20 age exceeded the limit of the study (see Figure 1). Participating men's ages ranged between
21
22 53 and 70 years (average 62 years, $SD = 4.8$). Further demographic information is described
23
24 in Table 1. There was no loss to follow up during the course of the study. The groups were
25
26 similar at baseline in age, number of times previously screened for prostate cancer, and
27
28 whether they intended to be screened for prostate cancer in the future. All but 3 men had
29
30 previously had a PSA test; 14 had been tested 2 or 3 times, 4 on one occasion, two 6 times,
31
32 and 3 men had been tested on 7, 8, and 12 occasions each. No men had undergone a biopsy.
33
34 At pre-assessment, the majority of men (16/26, 62%) agreed with the statement that routine
35
36 screening for prostate cancer saved lives, whereas 4 (15%) disagreed and 6 (23%) did not
37
38 know (Table 1). The men reported a variety of sources for how they accessed information
39
40 about prostate cancer screening, with the most common source of information being their
41
42 general practitioner (Table 2).
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47 **Changes in Intention-to-Screen and Individual Knowledge**

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49 **Pre-to post-intervention.** At post-assessment, men in the community jury group had
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51 significantly less intention-to-screen for prostate cancer on the 0 to 10 scale than men in the
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53 control group (median score 2.5 and 7.0, Effect Size= $-0.6SD$, $p=0.05$). When we adjusted
54
55 for baseline intention to be screened for prostate cancer and the number of prior PSA tests,
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3 the mean difference was 3.7 ($p=.005$, Table 3). The unadjusted mean difference between the
4
5 groups was 2.7 (Figure 2).
6

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8 After completion of the community jury weekend, men in the jury group considered
9
10 themselves more informed about screening for prostate cancer than the control group (median
11
12 score 4.0 and 2.0, mean difference = 1.7, Effect Size=1.2SD, $p<0.001$). Compared with the
13
14 control group, the community jury participants were more likely to “correctly” identify how
15
16 many men out of 1000 would be likely to die from prostate cancer as indicated in the
17
18 knowledge question from Fagerlin et al¹⁹ ($p=0.004$), but not how many would be diagnosed¹⁹
19
20 ($p=.44$). The community jury group was also more likely to correctly identify that the PSA
21
22 test was not always accurate in indicating the likelihood of prostate cancer as it had both false
23
24 positive and false negative results ($p=0.03$, Table 4).
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28 **Post-to 3 month follow-up assessment.** The influence of the community jury
29
30 experience was sustained at 3 months: men in the community jury group maintained their
31
32 intention-to-screen score at 3 months (Figure 2) whereas there was a slight increase in the
33
34 control group’s future intention-to-screen for prostate cancer. There was no further change in
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36 knowledge (Table 5).
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38 **Community Level Questions**

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40 Men in the community jury voted unanimously (12/12) against a government campaign
41
42 targeting the public about PSA screening for prostate cancer, and against a government
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44 organised invitation program. Unprompted, the jury members instead suggested the
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46 government provide a campaign that targeted general practitioners to assist them to provide
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48 better quality and more consistent information to their patients on the benefits and harms of
49
50 screening for prostate cancer using the PSA test.¹⁸
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54 **Non-protocol Extension.** Compared with their 3-month follow-up scores, the men
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56 from the control group who completed the second community jury also subsequently
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3 increased their self-report score of how informed they considered themselves (mean score
4 increased from 2.2 to 3.7), and decreased their future intention to be screened for prostate
5 cancer (mean score decreased from 8 to 2.8). There were similar pre-to-post changes in
6 knowledge among those who participated in the second community jury: 68% were able to
7 correctly identify how many men out of 1000 might die from prostate cancer and 50%
8 correctly answered how many men would be diagnosed with prostate cancer in their
9 lifetimes.
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19 Discussion

20 Compared with men who received standard information, participants in a 2-day
21 community jury considered themselves better informed about the benefits and harms of PSA
22 screening and reduced their stated intention to participate in screening in the future. Although
23 the process led to some men to changing their minds about participating in PSA screening,
24 others said they would continue to be tested; highlighting the individual nature of this
25 decision and the need for informed consent.²¹
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34 Yet despite differences in the men's individual intentions to be screened for prostate
35 cancer, the group was unanimous in opposing any government-sponsored community
36 campaign. Our findings demonstrate the capacity of a community jury to consider complex
37 information on the harms and benefits of screening, and to distinguish individual from
38 community choices. This echoes the findings of a New Zealand community jury on
39 mammography screening¹³ which also indicated that community juries are able to
40 differentiate between individual and public health needs.
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49 All deliberative democracy methods rely on engagement of those who have an interest
50 in the topic and agree to take part. The generalisability of our study findings may be limited
51 by the uncertain representativeness of a jury of volunteers from the Gold Coast, Australia,
52 who may be different in several ways to men in the wider Australian community. For
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3 example, 88% of our participants had already had at least one PSA test, implying that prior to
4
5 the community jury they were more likely to be favorably disposed to PSA screening.
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8 The authors considered PSA screening an appropriate topic for engaging middle-aged
9
10 men because the data are equivocal and guidelines differ.^{2,7,8} However, we also acknowledge
11
12 the limitations of these mass population studies. Neither the ERSPC³ nor PLCO⁴ trials has a
13
14 median follow-up long enough to reliably address prostate cancer mortality and their
15
16 respective methodologies have been criticised.²² This limitation may have impacted the
17
18 community jury decision. Nevertheless, this pilot study does illustrate the potential of the
19
20 community jury approach to instruct a cross section of men of different ages, with different
21
22 backgrounds, and educational levels.
23

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25 Whether and how sampling and recruitment techniques affect community jury
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27 outcomes are important research questions yet to be examined. Other important
28
29 methodological questions for community research include: what are the impacts on group
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31 decisions of normative (conformity to group thinking) or informational (discussion of facts)
32
33 influences?²³ and when and how in the deliberation process do community jury participants
34
35 form their conclusions?
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39 Our results have implications for clinical and public health practice. A large proportion
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41 of men have not been engaged in an evidence-informed discussion of the potential benefits
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43 and harms of screening prior to their physician ordering a PSA test^{24,25}; have not been asked
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45 about their screening preferences prior to a PSA screening test²⁶; and some doctors screen
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47 without a discussion.²⁷ Alarming, a study conducted in the theatre waiting room in men
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49 waiting to undergo a trans rectal ultrasound and prostate biopsy found 8% were unaware their
50
51 primary care provider had conducted a PSA screening test.²⁸ Current practice of PSA
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53 screening in asymptomatic men is not standardised. Our findings reinforce the importance of
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55 presenting the potential benefits and harms of PSA testing to men interested in being
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3 screened, primarily because such information will lead some men to change their mind once
4 fully informed. When practitioners are faced with the difficult situation of being asked to
5 determine such a decision on behalf of their patient, in addition to considering their
6 individual patient's history, concerns, and priorities, it may be valuable to also have available
7 information about community attitudes and concerns regarding screening.²¹
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16 **Contributors** RT led the preparations and revisions of the manuscript, had full access to all
17 of the data in the study and takes responsibility for the accuracy of the data analyses. PG and
18 JD led the conception and design of the study, contributed to the interpretation of the data,
19 and made substantial revisions to the manuscript. LR contributed to the study design and
20 made substantial revisions to the manuscript. GM and RG contributed to the study design,
21 interpretation of data and made significant revisions to the manuscript.
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44
45
46
47
48

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52
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1
2
3 funding support from a NHMRC funding grant (#1023197); no other relationships or
4
5 activities that could appear to have influenced the submitted work.
6

7 **Ethics Approval** The research project was approved by the Bond University Human
8
9 Research Ethics Committee (RO1570).
10

11 **Data Sharing Statement** Additional data is available by emailing author Rae Thomas.
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Box 1**Knowledge Questions from Surveys (answers considered correct highlighted)**

1. Is routine testing for prostate cancer recommended by RACGP Guidelines?

- Yes No Don't know

2. Out of every 1000 men, about how many do you think will be diagnosed with prostate cancer some time in their life? *

- 0 1-14 15-25 >25 Don't know

3. Out of every 1000 men, about how many do you think will die from prostate cancer? *

- 0 1-5 6-10 11-20 >20 Don't know

4. How accurate do *you* think the prostate specific antigen (PSA) blood test is for diagnosing prostate cancer?

- Reasonably accurate but some people *who do* have cancer can have a negative test result (false negative)

- Reasonably accurate but some people *who do not* have cancer can have an abnormal result (false positive)

- The PSA test is not always accurate because it can have both false positive or false negative results

- The PSA test is completely accurate

- Don't know

5. In terms of your knowledge about Prostate cancer, could you list some treatment options?

- No Yes, please list

6. Could you list some potential side effects of treatments for prostate cancer?

- No Yes, please list

* questions from Fagerlin A, Sepucha KR, Couper MP, Levin CA, Singer E Zikmund-Fisher

B. Patients' knowledge about 9 common health conditions: The DECISIONS survey. *Med Decis Making* 2010;30:35S.

Figure 1 Consort Flow-Chart of Participants

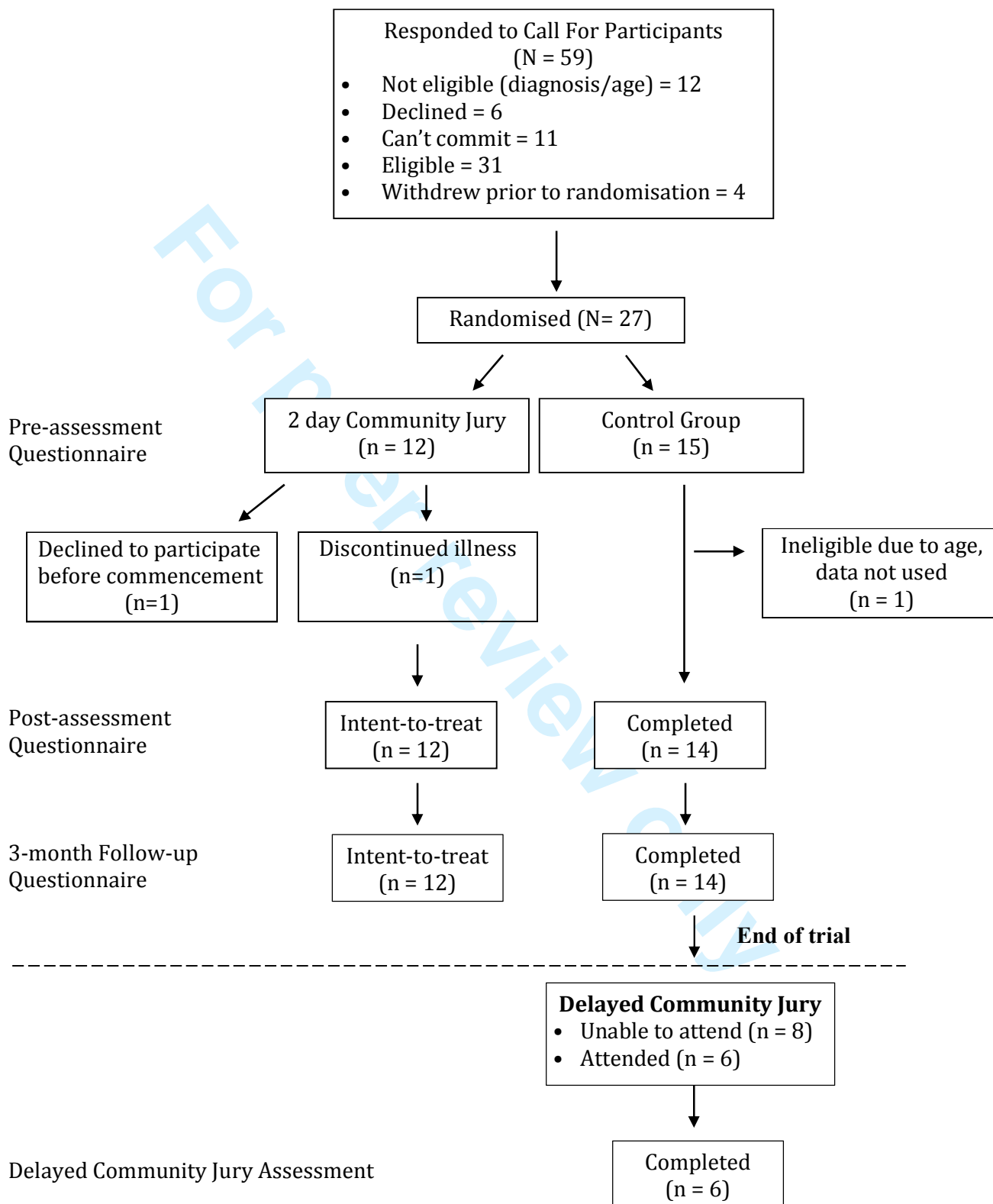
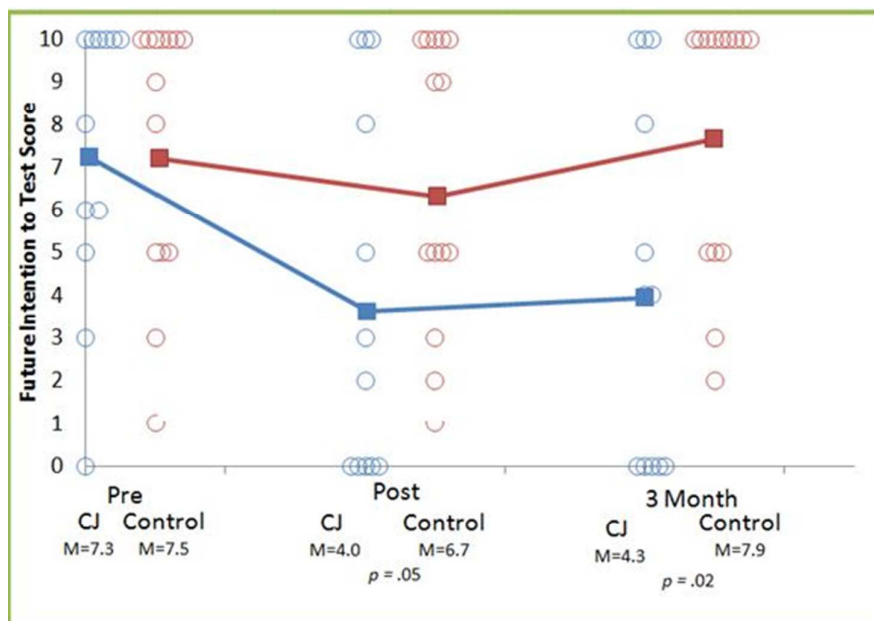


Figure 2 Future Intention-to-Screen Scores at Pre, Post, and Three Month Follow-up



Note: CJ=Community Jury group; M = mean score; p values based on ANCOVA analyses pre to post and pre to 3 month follow-up.

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		Community Jury (n=12)	(SD/%)	Control (n=14)	SD/%
<i>Age</i>					
	Mean	61	(4.8)	62	(4.9)
<i>Number previous PSA tests</i>					
	Mean	3.9	(3.6)	2.2*	(1.8)
<i>Routine PSA testing saves lives</i>					
Frequency	yes	7	(58%)	9	(64%)
	no	2	(17%)	2	(14%)
	don't know	3	(25%)	3	(21%)
<i>Education</i>					
Frequency	High school or less	2	(17%)	4	(28%)
	some uni or TAFE	4	(33%)	4	(28%)
	uni/TAFE graduate	4	(33%)	1	(7%)
	uni postgrad	2	(17%)	5	(36%)
Note. * n=13, (1 missing); TAFE = Technical and Further Education Institutions					

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	Agree	(%)
I don't look for information	3	(12)
Family and friends	11	(42)
Internet	10	(38)
Media	9	(35)
General practitioner	17	(65)
Urologist/specialist/hospital	5	(20)
Note: men could endorse more than one source		

A Community Jury and PSA Screening 22

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	<i>Coefficient</i>	<i>SE B</i>	CI Lower	CI Upper	<i>p</i>
Constant	-0.16	1.69	-3.66	3.35	0.93
Pre-assessment intention-to-screen score	0.74	0.18	0.36	1.11	0.001
Number of previous PSA tests	0.63	0.22	0.18	1.07	0.008
Group (Community Jury/Control)	-3.69	1.19	-6.16	-1.21	0.005

Note. N=25; CI= confidence interval;
These data are slightly different to Rychetnik et al (2014) analyses as they are based on intention-to-treat.

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		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community									0.08
	jury	4	(42)	3	(25)	1	(8)	3	(25)	
	control*	1	(8)	1	(8)	1	(8)	10	(77)	
out of 1000, how many men are diagnosed?	community									0.4
	jury	2	(17)	6	(50)	1	(8)	3	(25)	
	control	2	(14)	6	(43)	3	(21)	3	(21)	
out of 1000, how many men die?	community									0.004
	jury	6	(50)	2	(17)	0	(0)	4	(33)	
	control	1	(7)	0	(0)	1	(7)	12	(86)	
how accurate is the PSA test?	community									0.03
	jury	6	(50)	4	(33)	1	(8)	1	(8)	
	control	2	(14)	9	(64)	0	(0)	3	(21)	
list possible treatment options	community									0.6
	jury	2	(17)	7	(58)	0	(0)	2	(17)	
	control	3	(21)	7	(50)	0	(0)	4	(27)	
list possible side effects of treatments	community									0.6
	jury	3	(25)	7	(58)	0	(0)	2	(17)	
	control	3	(21)	7	(50)	0	(0)	4	(27)	

Note: *n=13 (1 missing)

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		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	0	(0)	7	(58)	1	(8)	4	(33)	0.7
	control*	0	(0)	1	(7)	1	(7)	11	(85)	
out of 1000, how many men are diagnosed?	community jury	1	(8)	4	(33)	4	(33)	3	(25)	0.1
	control	0	(0)	2	(14)	6	(43)	6	(43)	
out of 1000, how many men die?	community jury	2	(17)	6	(50)	2	(17)	2	(17)	0.6
	control	2	(14)	0	(0)	2	(14)	10	(71)	
how accurate is the PSA test?	community jury	0	(0)	10	(83)	0	(0)	2	(17)	0.1
	control	2	(14)	9	(64)	2	(14)	1	(7)	

Note: *n=13 (1 missing)



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

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2		assessing outcomes) and how	
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4		11b If relevant, description of the similarity of interventions	6-7
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	8-9
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	8-9
7			
8	Results		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	Figure 1
10	diagram is strongly	were analysed for the primary outcome	
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	Figure 1
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	5-7
13		14b Why the trial ended or was stopped	NA
14			
15	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	Table 1
16	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	9
17		by original assigned groups	
18			
19	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	9-11
20	estimation	precision (such as 95% confidence interval)	
21		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
22	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	10-11
23		pre-specified from exploratory	
24			
25	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
26			
27	Discussion		
28	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11-12
29	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	11-12
30	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-13
31			
32	Other information		
33	Registration	23 Registration number and name of trial registry	2
34	Protocol	24 Where the full trial protocol can be accessed, if available	2
35	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	13
36			

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.

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Title Page

Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.

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Abstract

Objective Prostate-specific antigen (PSA) screening is controversial. A community jury allows presentation of complex information and may clarify how participants view screening after being well-informed of the benefits and harms. We examined whether participating in a community jury had an effect on men's knowledge about and their intention to participate in PSA screening.

Design Random allocation to either a 2-day community jury or control group, with pre- post- and three-month follow-up.

Setting Participants from the Gold Coast (Australia) recruited via radio, newspaper, and community meetings.

Participants Twenty-six men aged 50-70 years with no previous diagnosis of prostate cancer.

Intervention The control group (n= 14) received factsheets on PSA screening. Community jury participants (n= 12) received the same factsheets and further information about screening for prostate cancer. In addition, three experts presented information on PSA screening: a neutral scientific adviser provided background information, one expert emphasised the potential benefits of screening, and another expert emphasised the potential harms.

Participants discussed information, asked questions of the experts and deliberated on personal and policy decisions.

Main Outcome and Measures Our primary outcome was change in individual intention to have a PSA screening test. We also assessed knowledge about screening for prostate cancer.

Results Analyses were conducted using intention-to-treat. Immediately after the jury, the community jury group had less intention-to-screen for prostate cancer than men in the control group (effect size = -0.6SD, $p=0.05$). This was sustained at three-month follow-up.

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3 Community jury men also correctly identified PSA test accuracy and considered themselves
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5 more informed (effect size 1.2SD, $p < 0.001$).
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7 **Conclusions** Evidence-informed deliberation of harms and benefits of PSA screening effects
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9 men's individual choice to be screened for prostate cancer. Community juries may be a valid
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11 method for eliciting target group input to policy decisions.
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16 **Trial Registration** Australian and New Zealand Clinical Trials Registry
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18 (ACTRN12612001079831)
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21 22 23 **Strengths and limitations of this study**

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25 • This is the first study to use scientific methods to evaluate the effect of a community
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27 jury on an individual's knowledge and decisions.
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30 • Participants in community juries make value-based decisions from complex
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32 information and can differentiate individual from community choices.
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35 • Expert presentations were based on large population studies that have limitations.
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38 • The sample size of this study was small, but the results were clear and sustained.
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41 • How sampling, recruitment techniques, and group processes affect community jury
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43 outcomes are yet to be examined.
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Introduction

Screening for prostate cancer by prostate-specific antigen (PSA) testing is controversial¹ and the benefits and harms of screening are uncertain.² The results of two large randomised controlled trials of population screening (the ERSPC trial in Europe³ and the PLCO trial in the United States⁴) were much anticipated, but the equivocal results have led to conflicting interpretations and recommendations from expert groups.^{5,6} Given the uncertainty, most guidelines recommend that men should be fully informed of the potential advantages and disadvantages of screening prior to having a PSA test.^{5,7,8} Although individuals vary in the degree to which they want to engage with the evidence about their health concerns, a majority consistently report an interest in sharing health care decisions with their treating doctor.^{9,10} However, providing the complex information relevant to men who are interested in PSA screening remains challenging.

Citizens' deliberation methodologies, such as community juries can facilitate the communication of complex evidence and aim to elicit 'informed' community perspectives for the purpose of guiding services and public policy. A range of community jury processes have been described, but the common features are i) participants are drawn from the lay public; ii) the jury deliberates on a question requiring an ethics or values-based decision (as opposed to a problem requiring a technical solution); iii) the jury is provided with information on the relevant issues and possible positions from expert "witnesses", with the opportunity to ask them questions; and iv) the jury then engages in a deliberation phase with participants discussing their preferences, opinions, values and positions, and attempt to reach a consensus position.¹¹

Community juries have been conducted on topics such as public health priorities,¹² mammography screening,¹³ and health research.^{14,15} A recent review of deliberation methodologies found only four unique studies that compared deliberative methodologies with

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2
3 a control group; only two of these were in relation to health topics.¹¹ While theoretically
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5 sound,¹¹ community juries are a resource-intensive process and it is uncertain whether the
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7 views of those participating are better “informed” than those of a public provided with
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9 reading material on the same topic. It is also unclear whether and how being informed
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11 influences a jury’s conclusions. If community juries are to be used to inform screening
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13 policy, it is essential to understand the capacity of a community jury process to support
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15 better-informed conclusions by its participants.
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19 The aim of this study was to examine the degree to which participants of a community
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21 jury on PSA screening of asymptomatic men were better “informed” than other citizens and,
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23 based on the ERSPC³ and PLCO⁴ trials together with the general practice guidelines, whether
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25 evidence-informed deliberations of the benefits and harms of PSA screening impact on men’s
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27 intention to be screen for prostate cancer. We conducted a randomised controlled trial that
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29 compared a community jury with men allocated to receive typical information. As part of the
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31 community jury process, men were also asked to deliberate on two community focused
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33 questions:
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- 36 • Should government campaigns be provided (on PSA screening) and if so, what
37 information should be included in those campaigns?
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- 39 • What do you as a group of men think about a government organised invitation
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41 program for testing for prostate cancer?
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45 This is the first randomised controlled trial of a deliberative democracy process on the topic
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47 of PSA screening.
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50 51 52 **Method** 53

54 We recruited men in the target age group of 50 to 70 years from the Gold Coast region
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56 (Australia) who had no previous diagnosis of prostate cancer, using media advertisements,
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3 radio interviews, and community groups. Men with a family history of prostate cancer were
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5 not excluded from participating. Eligible and available respondents attended a session on a
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7 Friday evening to receive a full briefing on the study; all agreed to participate and completed
8
9 a consent form, before being randomly allocated to either a community jury group or a
10
11 control group (Figure 1). Random allocation occurred by each man selecting a piece of paper
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13 with the name of either group from an opaque container. The research project was approved
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15 by the Bond University Human Research Ethics Committee (R01570) and the protocol
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17 registered with the Australian and New Zealand Clinical Trials Registry
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19 (ACTRN12612001079831).
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23 All men were given standard PSA fact sheets from the Cancer Council Australia and
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25 Andrology Australia.^{16,17} In addition to the factsheets, men in the community jury group also
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27 received a Cochrane Collaboration plain language statement,² information from the Royal
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29 Australian College of General Practitioners' Guidelines for "Preventive Activities in General
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31 Practice" pertaining to screening for prostate cancer,⁷ and the Executive Summary of "PSA
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33 Testing" from the Urology Society of Australia and New Zealand.⁸ Men in both groups
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35 received \$20 gift cards as reimbursement for their time at the introductory session and for
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37 each survey. The community jury group received an \$80 gift card as reimbursement for
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39 attending the community jury weekend. Men in the control group were given a follow-up
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41 survey with a return stamped envelope to be mailed after the weekend.
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45 The community jury weekend and a qualitative analysis of the jury deliberations have
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47 been described in detail elsewhere.¹⁸ In brief, the community jury consisted of an iterative
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49 process of education and deliberation. Three experts presented to the community jury on day
50
51 one: a neutral scientific advisor discussed medical information regarding the role of the
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53 prostate, screening tests (including PSA and Digital Rectal Examination), explanations about
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55 changes to PSA levels, how cancer is detected, and treatment options and potential outcomes
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3 (Jim Dickinson, Professor of Family Medicine, University of Calgary). Two further experts
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5 (a urologist and expert in prostate cancer (author RG) and an expert in evidence-based
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7 medicine (author PG) presented the benefits and harms of being screened for prostate cancer.
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9 Although both speakers aimed to give balanced presentations, one emphasised the benefits of
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11 PSA screening, in particular selective screening, (RG <http://youtu.be/9vPt3NACG8g>) and the
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13 other the harms (PG <http://youtu.be/nifkjdZKmsU>). Both presentations focused on the
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15 evidence from the two trials of PSA population screening. However, both presenters also
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17 made reference to lower levels of evidence relating to the risks of metastases if a cancer
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19 remains undetected due to a lack of screening and the consequences of treating localised
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21 disease detected during screening. After each presentation, men were able to deliberate on the
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23 information and could ask the experts any questions. The men reflected on the information
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25 overnight and returned on Sunday to deliberate and discuss the information presented the day
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27 before, including asking any further questions of the expert witnesses by phone.
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32 A nominal group technique was used on both days to elicit individual thoughts prior to
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34 group deliberations. After the final deliberations on Sunday, including the community level
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36 decisions, the men in the community jury completed the post-assessment survey. Men in the
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38 control group were contacted on the Monday and either completed the post-assessment
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40 survey by phone or mailed the survey back to researchers the same week. Three months after
41
42 the community jury weekend, all men in both groups were re-contacted and completed a
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44 follow-up survey.
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47 **Non-protocol Extension**

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49 Because they indicated a strong desire to have the experience of the community jury
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51 weekend, after their three-month follow-up survey the control group was offered the same
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53 community jury experience. Six of the 14 men randomised to the control group participated
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55 in the second community jury (Figure 1). The two primary experts were the same as for the
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3 original community jury group, however, the scientific advisor was changed to a female
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5 general practitioner and professor of clinical epidemiology (author JD). A final post-jury
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7 survey was conducted with the second community jury.
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9 10 **Measures**

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12 We collected demographic information, history of previous PSA testing and
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14 information sources for PSA screening at the introductory session. In each of the three
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16 surveys, men were asked to nominate on a scale 0 to 10 (0 = *not at all*, 5 = *maybe*, and 10 =
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18 *absolutely*), whether they intended, while symptomless, to undergo PSA screening for
19
20 prostate cancer in the future. They were also asked to nominate how informed they
21
22 considered themselves in relation to the harms and benefits of screening for prostate cancer
23
24 on a scale 0 to 4 (0 = *not at all* and 4 = *very*). We asked four knowledge questions in each
25
26 survey that assessed a) the men's knowledge about the recommendation on PSA screening in
27
28 the Australian general practice guidelines,⁷ b) the accuracy of the PSA test and c) two
29
30 questions about treatment options and side-effects of prostate cancer treatment (Box 1).
31
32 Australia has a primary care based system, requiring a referral from a general practitioner to
33
34 see a urologist. General practitioners are therefore responsible for the majority of the PSA
35
36 screening tests requested in Australia. For this reason, we were interested in the participants'
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38 knowledge of current general practice guidelines.
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43 **Statistical Analyses**

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45 Pre- to post-, and post- to follow-up assessment differences between the groups were
46
47 examined with ANCOVA and Fisher's exact test. It was anticipated that the number of PSA
48
49 tests previously undertaken would impact on a man's future decision to be screened for
50
51 prostate cancer with the PSA test.¹⁹ Therefore we conducted the analyses with adjustment for
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53 baseline intention-to-screen and the number of times a man had already received a PSA test.
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3 Unadjusted post-assessment analyses were conducted using an independent t-test. All
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5 analyses were conducted on an intention-to-treat basis.
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9 10 **Results**

11 **Participant Demographics**

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14 Of the 59 men who contacted the research team, 27 respondents were available on the set
15
16 date and elected to participate in the study. One man was excluded post-randomisation as his
17
18 age exceeded the limit of the study (see Figure 1). Participating men's ages ranged between
19
20 53 and 70 years (average 62 years, $SD = 4.8$). Further demographic information is described
21
22 in Table 1. There was no loss to follow up during the course of the study. The groups were
23
24 similar at baseline in age, number of times previously screened for prostate cancer, and
25
26 whether they intended to be screened for prostate cancer in the future. All but 3 men had
27
28 previously had a PSA test; 14 had been tested 2 or 3 times, 4 on one occasion, two 6 times,
29
30 and 3 men had been tested on 7, 8, and 12 occasions each. No men had undergone a biopsy.
31
32 At pre-assessment, the majority of men (16/26, 62%) agreed with the statement that routine
33
34 screening for prostate cancer saved lives, whereas 4 (15%) disagreed and 6 (23%) did not
35
36 know (Table 1). The men reported a variety of sources for how they accessed information
37
38 about prostate cancer screening, with the most common source of information being their
39
40 general practitioner (Table 2).
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45 **Changes in Intention-to-Screen and Individual Knowledge**

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47 **Pre-to post-intervention.** At post-assessment, men in the community jury group had
48
49 significantly less intention-to-screen for prostate cancer on the 0 to 10 scale than men in the
50
51 control group (median score 2.5 and 7.0, Effect Size= $-0.6SD$, $p=0.05$). When we adjusted
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53 for baseline intention to be screened for prostate cancer and the number of prior PSA tests,
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3 the mean difference was 3.7 ($p=.005$, Table 3). The unadjusted mean difference between the
4
5 groups was 2.7 (Figure 2).
6

7 After completion of the community jury weekend, men in the jury group considered
8 themselves more informed about screening for prostate cancer than the control group (median
9 score 4.0 and 2.0, mean difference = 1.7, Effect Size=1.2SD, $p<0.001$). Compared with the
10 control group, the community jury group was more likely to correctly identify that the PSA
11 test was not always accurate in indicating the likelihood of prostate cancer as it had both false
12 positive and false negative results ($p=0.03$, Table 4).
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20 **Post-to 3 month follow-up assessment.** The influence of the community jury
21 experience was sustained at 3 months: men in the community jury group maintained their
22 intention-to-screen score at 3 months (Figure 2) whereas there was a slight increase in the
23 control group's future intention-to-screen for prostate cancer. There was no further change in
24 knowledge (Table 5).
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31 **Community Level Questions**

32 Men in the community jury voted unanimously (12/12) against a government campaign
33 targeting the public about PSA screening for prostate cancer, and against a government
34 organised invitation program. Unprompted, the jury members instead suggested the
35 government provide a campaign that targeted general practitioners to assist them to provide
36 better quality and more consistent information to their patients on the benefits and harms of
37 screening for prostate cancer using the PSA test.¹⁸
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47 **Non-protocol Extension.** Compared with their 3-month follow-up scores, the men
48 from the control group who completed the second community jury also subsequently
49 increased their self-report score of how informed they considered themselves (mean score
50 increased from 2.2 to 3.7), and decreased their future intention to be screened for prostate
51 cancer (mean score decreased from 8 to 2.8).
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Discussion

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5 Compared with men who received standard information, participants in a 2-day
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7 community jury considered themselves better informed about the benefits and harms of PSA
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9 screening and reduced their stated intention to participate in screening in the future. Although
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11 the process led to some men changing their minds about participating in PSA screening,
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13 others said they would continue to be tested; highlighting the individual nature of this
14
15 decision and the need for informed consent.²⁰
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19 Yet despite differences in the men's individual intentions to be screened for prostate
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21 cancer, the group was unanimous in opposing any government-sponsored community
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23 campaign. Our findings demonstrate the capacity of a community jury to consider complex
24
25 information on the harms and benefits of screening, and to distinguish individual from
26
27 community choices. This echoes the findings of a New Zealand community jury on
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29 mammography screening¹³ which also indicated that community juries are able to
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31 differentiate between individual and public health needs.
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35 All deliberative democracy methods rely on engagement of those who have an interest
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37 in the topic and agree to take part. The generalisability of our study findings may be limited
38
39 by the uncertain representativeness of a jury of volunteers from the Gold Coast, Australia,
40
41 who may be different in several ways to men in the wider Australian community. For
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43 example, 88% of our participants had already had at least one PSA test, implying that prior to
44
45 the community jury they were more likely to be favorably disposed to PSA screening.
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49 The authors considered PSA screening an appropriate topic for engaging middle-aged
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51 men because the data are equivocal and guidelines differ.^{2,7,8} However, we also acknowledge
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53 the limitations of these mass population studies. Neither the ERSPC³ nor PLCO⁴ trials has a
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55 median follow-up long enough to reliably address prostate cancer mortality and their
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57 respective methodologies have been criticised.²¹ This limitation may have impacted the
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3 community jury decision. Nevertheless, this pilot study does illustrate the potential of the
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5 community jury approach to instruct a cross section of men of different ages, with different
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7 backgrounds, and educational levels.
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10 Whether and how sampling and recruitment techniques affect community jury
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12 outcomes are important research questions yet to be examined. Other important
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14 methodological questions for community research include: what are the impacts on group
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16 decisions of normative (conformity to group thinking) or informational (discussion of facts)
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18 influences?²² and when and how in the deliberation process do community jury participants
19
20 form their conclusions?
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23 Our results have implications for clinical and public health practice. A large proportion
24
25 of men have not been engaged in an evidence-informed discussion of the potential benefits
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27 and harms of screening prior to their physician ordering a PSA test^{23, 24}; have not been asked
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29 about their screening preferences prior to a PSA screening test²⁵; and some doctors screen
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31 without a discussion.²⁶ Alarming, a study conducted in the theatre waiting room in men
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33 waiting to undergo a trans rectal ultrasound and prostate biopsy found 8% were unaware their
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35 primary care provider had conducted a PSA screening test.²⁷ Current practice of PSA
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37 screening in asymptomatic men is not standardised. Our findings reinforce the importance of
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39 presenting the potential benefits and harms of PSA testing to men interested in being
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41 screened, primarily because such information will lead some men to change their mind once
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43 fully informed. When practitioners are faced with the difficult situation of being asked to
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45 determine such a decision on behalf of their patient, in addition to considering their
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47 individual patient's history, concerns, and priorities, it may be valuable to also have available
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49 information about community attitudes and concerns regarding screening.²⁰
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3 **Contributors** RT led the preparations and revisions of the manuscript, had full access to all
4 of the data in the study and takes responsibility for the accuracy of the data analyses. PG and
5
6
7 JD led the conception and design of the study, contributed to the interpretation of the data,
8
9 and made substantial revisions to the manuscript. LR contributed to the study design and
10
11 made substantial revisions to the manuscript. GM and RG contributed to the study design,
12
13 interpretation of data and made significant revisions to the manuscript.
14

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43
44 activities that could appear to have influenced the submitted work.
45

46
47 **Ethics Approval** The research project was approved by the Bond University Human
48
49 Research Ethics Committee (RO1570).
50

51
52 **Data Sharing Statement** In addition to the quantitative analysis reported in this paper, a
53
54 qualitative analysis of the jury deliberations and recommendations was conducted and
55

1
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3 reported elsewhere and cited as reference 18. Additional data is available by emailing the first
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5 author.
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9 10 **Figure Legends**

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12 Figure 1. Consort Flow-Chart of Participants (no legend)

13
14 Figure 2. Future Intention-to-Screen Scores at Pre, Post, and Three Month Follow-up

15
16 ○ — Community Jury Group;

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18 △ — Control Group
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21 Foot note for Figure 2

22 Note: CJ=Community Jury group; M = mean score; p values based on ANCOVA analyses
23 pre to post and pre to 3 month follow-up.
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Box 1.**Knowledge Questions from Surveys (answers considered correct highlighted)**

1. Is routine testing for prostate cancer recommended by RACGP Guidelines?

- Yes No Don't know

2. How accurate do *you* think the prostate specific antigen (PSA) blood test is for diagnosing prostate cancer?

- Reasonably accurate but some people *who do* have cancer can have a negative test result (false negative)

- Reasonably accurate but some people *who do not* have cancer can have an abnormal result (false positive)

- The PSA test is not always accurate because it can have both false positive or false negative results

- The PSA test is completely accurate

- Don't know

3. In terms of your knowledge about Prostate cancer, could you list some treatment options?

- No Yes, please list

4. Could you list some potential side effects of treatments for prostate cancer?

- No Yes, please list
-

Table 1. Participants Demographics

		Community Jury (n=12)	(SD/%)	Control (n=14)	SD/%
<i>Age</i>					
	Mean	61	(4.8)	62	(4.9)
<i>Number previous PSA tests</i>					
	Mean	3.9	(3.6)	2.2*	(1.8)
<i>Routine PSA testing saves lives</i>					
Frequency	yes	7	(58%)	9	(64%)
	no	2	(17%)	2	(14%)
	don't know	3	(25%)	3	(21%)
<i>Education</i>					
Frequency	High school or less	2	(17%)	4	(28%)
	some uni or TAFE	4	(33%)	4	(28%)
	uni/TAFE graduate	4	(33%)	1	(7%)
	uni postgrad	2	(17%)	5	(36%)
Note. * n=13, (1 missing); TAFE = Technical and Further Education Institutions					

Table 2. Where do Men Receive Information about Testing for Prostate Cancer? (N=26)

	Agree	(%)
I don't look for information	3	(12)
Family and friends	11	(42)
Internet	10	(38)
Media	9	(35)
General practitioner	17	(65)
Urologist/specialist/hospital	5	(20)
Note: men could endorse more than one source		

Table 3. Linear Regression Analysis Predicting Future Intention-to-Screen for Prostate Cancer

	<i>Coefficient</i>	<i>SE B</i>	CI Lower	CI Upper	<i>p</i>
Constant	-0.16	1.69	-3.66	3.35	0.93
Pre-assessment intention-to-screen score	0.74	0.18	0.36	1.11	0.001
Number of previous PSA tests	0.63	0.22	0.18	1.07	0.008
Group (Community Jury/Control)	-3.69	1.19	-6.16	-1.21	0.005

Note. N=25; CI= confidence interval;
These data are slightly different to Rychetnik et al (2014) analyses as they are based on intention-to-treat.

Table 4. Changes in Men's Knowledge Scores from Pre-to Post-assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	4	(42)	3	(25)	1	(8)	3	(25)	0.08
	control*	1	(8)	1	(8)	1	(8)	10	(77)	
how accurate is the PSA test?	community jury	6	(50)	4	(33)	1	(8)	1	(8)	0.03
	control	2	(14)	9	(64)	0	(0)	3	(21)	
list possible treatment options	community jury	2	(17)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	
list possible side effects of treatments	community jury	3	(25)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	

Note: *n=13 (1 missing)

Table 5. Changes in Men's Knowledge Scores Post- to Follow-up Assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	0	(0)	7	(58)	1	(8)	4	(33)	0.7
	control*	0	(0)	1	(7)	1	(7)	11	(85)	
how accurate is the PSA test?	community jury	0	(0)	10	(83)	0	(0)	2	(17)	0.1
	control	2	(14)	9	(64)	2	(14)	1	(7)	

Note: *n=13 (1 missing)

A Community Jury and PSA Screening 1

Title Page

Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.

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A Community Jury and PSA Screening 2

Abstract

Objective Prostate-specific antigen (PSA) screening is controversial. A community jury allows presentation of complex information and may clarify how participants view screening after being well-informed of the benefits and harms. We sought to determine whether participating in a community jury had an effect on men's knowledge about and their intention to participate in PSA screening.

Design Participants were randomly allocated to either a 2-day community jury or a control group, with pre- post- and three-month follow-up.

Setting Community members from the Gold Coast (Australia) were recruited via radio, newspaper, and community meetings.

Participants Twenty-six eligible men aged 50-70 years with no previous diagnosis of prostate cancer.

Intervention The control group (n= 14) received factsheets on PSA screening. Community jury participants (n= 12) received the same factsheets and further information about screening for prostate cancer. In addition, three experts presented information on PSA screening: a neutral scientific adviser provided background information, one expert emphasised the potential benefits of screening, and another expert emphasised the potential harms.

Participants discussed this information, asked questions of the experts and deliberated on personal and policy decisions.

Main Outcome and Measures Our primary outcome was change in individual intention to have a PSA screening test. We also assessed knowledge about screening for prostate cancer.

Results All analyses were conducted using intention-to-treat. Immediately after the jury, the community jury group had less intention-to-screen for prostate cancer than men in the control group (effect size = -0.6SD, $p=0.05$). This was sustained at three-month follow-up.

A Community Jury and PSA Screening 3

Community jury men also ~~correctly identified PSA test accuracy~~ ~~answered more knowledge questions correctly~~ and considered themselves more informed (effect size 1.2SD, $p < 0.001$).

Conclusions Evidence-informed deliberation of the harms and benefits of PSA screening effects men's individual choice to be screened for prostate cancer. Community juries may be a valid method for eliciting target group input to policy decisions.

Trial Registration Australian and New Zealand Clinical Trials Registry

(ACTRN12612001079831) <http://www.anzctr.org.au>

Strengths and limitations of this study

- This is the first study to use scientific methods to evaluate the effect of a community jury on an individual's knowledge and decisions.
- Participants in community juries make value-based decisions from complex information and can differentiate individual from community choices.
- Expert presentations were based on large population studies that have limitations.
- The sample size of this study was small, but the results were clear and sustained.
- How sampling, recruitment techniques, and group processes affect community jury outcomes are yet to be examined.

A Community Jury and PSA Screening 4

Introduction

Screening for prostate cancer by prostate-specific antigen (PSA) testing is controversial¹ and the benefits and harms of screening are uncertain.² The results of two large randomised controlled trials of population screening (the ERSPC trial in Europe³ and the PLCO trial in the United States⁴) were much anticipated, but the equivocal results have led to conflicting interpretations and recommendations from expert groups.^{5,6} Given the uncertainty, most guidelines recommend that men should be fully informed of the potential advantages and disadvantages of screening prior to having a PSA test.^{5,7,8} Although individuals vary in the degree to which they want to engage with the evidence about their health concerns, a majority consistently report an interest in sharing health care decisions with their treating doctor.^{9,10} However, providing the complex information relevant to men who are interested in PSA screening remains challenging.

Citizens' deliberation methodologies, such as community juries can facilitate the communication of complex evidence and aim to elicit 'informed' community perspectives for the purpose of guiding services and public policy. A range of community jury processes have been described, but the common features are i) participants are drawn from the lay public; ii) the jury deliberates on a question requiring an ethics or values-based decision (as opposed to a problem requiring a technical solution); iii) the jury is provided with information on the relevant issues and possible positions from expert "witnesses", with the opportunity to ask them questions; and iv) the jury then engages in a deliberation phase with participants discussing their preferences, opinions, values and positions, and attempt to reach a consensus position.¹¹

Community juries have been conducted on topics such as public health priorities,¹² mammography screening,¹³ and health research.^{14,15} A recent review of deliberation methodologies found only four unique studies that compared deliberative methodologies with

A Community Jury and PSA Screening 5

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7 a control group; only two of these were in relation to health topics.¹¹ While theoretically
8 sound,¹¹ community juries are a resource-intensive process and it is uncertain whether the
9 views of those participating are better “informed” than those of a public provided with
10 reading material on the same topic. It is also unclear whether and how being informed
11 influences a jury’s conclusions. If community juries are to be used to inform screening
12 policy, it is essential to understand the capacity of a community jury process to support
13 better-informed conclusions by its participants.
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20 The aim of this study was to examine the degree to which participants of a community
21 jury on PSA screening of asymptomatic men were better “informed” than other citizens and,
22 based on the ERSPC³ and PLCO⁴ trials together with the general practice guidelines, whether
23 evidence-informed deliberations of the benefits and harms of PSA screening impact on men’s
24 intention to be screen for prostate cancer. We conducted a randomised controlled trial that
25 compared a community jury with men allocated to receive typical information. As part of the
26 community jury process, men were also asked to deliberate on two community focused
27 questions:
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- 35 • Should government campaigns be provided (on PSA screening) and if so, what
36 information should be included in those campaigns?
37
- 38 • What do you as a group of men think about a government organised invitation
39 program for testing for prostate cancer?
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43 This is the first randomised controlled trial of a deliberative democracy process on the topic
44 of PSA screening.
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48 Method

49 We recruited men in the target age group of 50 to 70 years from the Gold Coast region
50 (Australia) who had no previous diagnosis of prostate cancer, using media advertisements,
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7 radio interviews, and community groups. Men with a family history of prostate cancer were
8
9 not excluded from participating. Eligible and available respondents attended a session on a
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11 Friday evening to receive a full briefing on the study; all agreed to participate and completed
12
13 a consent form, before being randomly allocated to either a community jury group or a
14
15 control group (Figure 1). Random allocation occurred by each man selecting a piece of paper
16
17 with the name of either group from an opaque container. The research project was approved
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19 by the Bond University Human Research Ethics Committee (R01570) and the protocol
20
21 registered with the Australian and New Zealand Clinical Trials Registry
22
23 (ACTRN12612001079831).

24
25 All men were given standard PSA fact sheets from the Cancer Council Australia and
26
27 Andrology Australia.^{16,17} In addition to the factsheets, men in the community jury group also
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29 received a Cochrane Collaboration plain language statement,² information from the Royal
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31 Australian College of General Practitioners' Guidelines for "Preventive Activities in General
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33 Practice" pertaining to screening for prostate cancer,⁷ and the Executive Summary of "PSA
34
35 Testing" from the Urology Society of Australia and New Zealand.⁸ Men in both groups
36
37 received \$20 gift cards as reimbursement for their time at the introductory session and for
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39 each survey. The community jury group received an \$80 gift card as reimbursement for
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41 attending the community jury weekend. Men in the control group were given a follow-up
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43 survey with a return stamped envelope to be mailed after the weekend.

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45 The community jury weekend and a qualitative analysis of the jury deliberations have
46
47 been described in detail elsewhere.¹⁸ In brief, the community jury consisted of an iterative
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49 process of education and deliberation. Three experts presented to the community jury on day
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51 one: a neutral scientific advisor discussed medical information regarding the role of the
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53 prostate, screening tests (including PSA and Digital Rectal Examination), explanations about
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55 changes to PSA levels, how cancer is detected, and treatment options and potential outcomes
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(Jim Dickinson, Professor of Family Medicine, University of Calgary). Two further experts (a urologist and expert in prostate cancer (author RG) and an expert in evidence-based medicine (author PG) presented the benefits and harms of being screened for prostate cancer. Although both speakers aimed to give balanced presentations, one emphasised the benefits of PSA screening, in particular selective screening, (RG <http://youtu.be/9vPt3NAcG8g>) and the other the harms (PG <http://youtu.be/nifkjdZKmsU>). Both presentations focused on the evidence from the two trials of PSA population screening. However, both presenters also made reference to lower levels of evidence relating to the risks of metastases if a cancer remains undetected due to a lack of screening and the consequences of treating localised disease detected during screening. ~~Each presentation ran for approximately 45 minutes, with 15 minutes for questions.~~ After each presentation, men were able to deliberate on the information and could ask the experts any questions. The men reflected on the information overnight and returned on Sunday to deliberate and discuss the information presented the day before, including asking any further questions of the expert witnesses by phone.

A nominal group technique was used on both days to elicit individual thoughts prior to group deliberations. After the final deliberations on Sunday, including the community level decisions, the men in the community jury completed the post-assessment survey. Men in the control group were contacted on the Monday and either completed the post-assessment survey by phone or mailed the survey back to researchers the same week. Three months after the community jury weekend, all men in both groups were re-contacted and completed a follow-up survey.

Non-protocol Extension

Because they indicated a strong desire to have the experience of the community jury weekend, after their three-month follow-up survey the control group was offered the same community jury experience. Six of the 14 men randomised to the control group participated

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in the second community jury (Figure 1). The two primary experts were the same as for the original community jury group, however, the scientific advisor was changed to a female general practitioner and professor of clinical epidemiology (author JD). A final post-jury survey was conducted with the second community jury.

Measures

We collected demographic information, history of previous PSA testing and information sources for PSA screening at the introductory session. In each of the three surveys, men were asked to nominate on a scale 0 to 10 (0 = *not at all*, 5 = *maybe*, and 10 = *absolutely*), whether they intended, while symptomless, to undergo PSA screening for prostate cancer in the future. They were also asked to nominate how informed they considered themselves in relation to the harms and benefits of screening for prostate cancer on a scale 0 to 4 (0 = *not at all* and 4 = *very*). We asked ~~six-four~~ knowledge questions in each survey that assessed a) the men's knowledge about the recommendation on PSA screening in the Australian general practice guidelines,⁷ b) ~~the likelihood of being diagnosed with prostate cancer,¹⁹~~ c) ~~the likelihood of dying of prostate cancer,¹⁹~~ d) the accuracy of the PSA test and e) two questions about treatment options and side-effects of prostate cancer treatment (Box 1). Australia has a primary care based system, requiring a referral from a general practitioner to see a urologist. General practitioners are therefore responsible for the majority of the PSA screening tests requested in Australia. For this reason, we were interested in the participants' knowledge of current general practice guidelines.

Statistical Analyses

Pre- to post-, and post- to follow-up assessment differences between the groups were examined with ANCOVA and Fisher's exact test. It was anticipated that the number of PSA tests previously undertaken would impact on a man's future decision to be screened for prostate cancer with the PSA test.²⁰⁻¹⁹ Therefore we conducted the analyses with adjustment

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for baseline intention-to-screen and the number of times a man had already received a PSA test. Unadjusted post-assessment analyses were conducted using an independent t-test. All analyses were conducted on an intention-to-treat basis.

Results

Participant Demographics

Of the 59 men who contacted the research team, 27 respondents were available on the set date and elected to participate in the study. One man was excluded post-randomisation as his age exceeded the limit of the study (see Figure 1). Participating men's ages ranged between 53 and 70 years (average 62 years, $SD = 4.8$). Further demographic information is described in Table 1. There was no loss to follow up during the course of the study. The groups were similar at baseline in age, number of times previously screened for prostate cancer, and whether they intended to be screened for prostate cancer in the future. All but 3 men had previously had a PSA test; 14 had been tested 2 or 3 times, 4 on one occasion, two 6 times, and 3 men had been tested on 7, 8, and 12 occasions each. No men had undergone a biopsy. At pre-assessment, the majority of men (16/26, 62%) agreed with the statement that routine screening for prostate cancer saved lives, whereas 4 (15%) disagreed and 6 (23%) did not know (Table 1). The men reported a variety of sources for how they accessed information about prostate cancer screening, with the most common source of information being their general practitioner (Table 2).

Changes in Intention-to-Screen and Individual Knowledge

Pre-to post-intervention. At post-assessment, men in the community jury group had significantly less intention-to-screen for prostate cancer on the 0 to 10 scale than men in the control group (median score 2.5 and 7.0, Effect Size= -0.6SD, $p=0.05$). When we adjusted for baseline intention to be screened for prostate cancer and the number of prior PSA tests,

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the mean difference was 3.7 ($p=.005$, Table 3). The unadjusted mean difference between the groups was 2.7 (Figure 2).

After completion of the community jury weekend, men in the jury group considered themselves more informed about screening for prostate cancer than the control group (median score 4.0 and 2.0, mean difference = 1.7, Effect Size=1.2SD, $p<0.001$). ~~Compared with the control group, the community jury participants were more likely to “correctly” identify how many men out of 1000 would be likely to die from prostate cancer as indicated in the knowledge question from Fagerlin et al¹⁹ ($p=0.004$), but not how many would be diagnosed¹⁹ ($p=.44$). Compared with the control group, the community jury group was also more likely to correctly identify that the PSA test was not always accurate in indicating the likelihood of prostate cancer as it had both false positive and false negative results ($p=0.03$, Table 4).~~

Post-to 3 month follow-up assessment. The influence of the community jury experience was sustained at 3 months: men in the community jury group maintained their intention-to-screen score at 3 months (Figure 2) whereas there was a slight increase in the control group’s future intention-to-screen for prostate cancer. There was no further change in knowledge (Table 5).

Community Level Questions

Men in the community jury voted unanimously (12/12) against a government campaign targeting the public about PSA screening for prostate cancer, and against a government organised invitation program. Unprompted, the jury members instead suggested the government provide a campaign that targeted general practitioners to assist them to provide better quality and more consistent information to their patients on the benefits and harms of screening for prostate cancer using the PSA test.¹⁸

Non-protocol Extension. Compared with their 3-month follow-up scores, the men from the control group who completed the second community jury also subsequently

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increased their self-report score of how informed they considered themselves (mean score increased from 2.2 to 3.7), and decreased their future intention to be screened for prostate cancer (mean score decreased from 8 to 2.8). ~~There were similar pre to post changes in knowledge among those who participated in the second community jury: 68% were able to correctly identify how many men out of 1000 might die from prostate cancer and 50% correctly answered how many men would be diagnosed with prostate cancer in their lifetimes.~~

Discussion

Compared with men who received standard information, participants in a 2-day community jury considered themselves better informed about the benefits and harms of PSA screening and reduced their stated intention to participate in screening in the future. Although the process led to some men ~~to~~ changing their minds about participating in PSA screening, others said they would continue to be tested; highlighting the individual nature of this decision and the need for informed consent.²⁴

Yet despite differences in the men's individual intentions to be screened for prostate cancer, the group was unanimous in opposing any government-sponsored community campaign. Our findings demonstrate the capacity of a community jury to consider complex information on the harms and benefits of screening, and to distinguish individual from community choices. This echoes the findings of a New Zealand community jury on mammography screening¹³ which also indicated that community juries are able to differentiate between individual and public health needs.

All deliberative democracy methods rely on engagement of those who have an interest in the topic and agree to take part. The generalisability of our study findings may be limited by the uncertain representativeness of a jury of volunteers from the Gold Coast, Australia, who may be different in several ways to men in the wider Australian community. For

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example, 88% of our participants had already had at least one PSA test, implying that prior to the community jury they were more likely to be favorably disposed to PSA screening.

The authors considered PSA screening an appropriate topic for engaging middle-aged men because the data are equivocal and guidelines differ.^{2,7,8} However, we also acknowledge the limitations of these mass population studies. Neither the ERSPC³ nor PLCO⁴ trials has a median follow-up long enough to reliably address prostate cancer mortality and their respective methodologies have been criticised.²²⁻²¹ This limitation may have impacted the community jury decision. Nevertheless, this pilot study does illustrate the potential of the community jury approach to instruct a cross section of men of different ages, with different backgrounds, and educational levels.

Whether and how sampling and recruitment techniques affect community jury outcomes are important research questions yet to be examined. Other important methodological questions for community research include: what are the impacts on group decisions of normative (conformity to group thinking) or informational (discussion of facts) influences?²³⁻²² and when and how in the deliberation process do community jury participants form their conclusions?

Our results have implications for clinical and public health practice. A large proportion of men have not been engaged in an evidence-informed discussion of the potential benefits and harms of screening prior to their physician ordering a PSA test^{23,24,25}; have not been asked about their screening preferences prior to a PSA screening test^{26,5}; and some doctors screen without a discussion.^{27,6} Alarming, a study conducted in the theatre waiting room in men waiting to undergo a trans rectal ultrasound and prostate biopsy found 8% were unaware their primary care provider had conducted a PSA screening test.^{28,7} Current practice of PSA screening in asymptomatic men is not standardised. Our findings reinforce the importance of presenting the potential benefits and harms of PSA testing to men interested in being

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7 screened, primarily because such information will lead some men to change their mind once
8 fully informed. When practitioners are faced with the difficult situation of being asked to
9 determine such a decision on behalf of their patient, in addition to considering their
10 individual patient's history, concerns, and priorities, it may be valuable to also have available
11 information about community attitudes and concerns regarding screening.²¹⁰
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18 **Contributors** RT led the preparations and revisions of the manuscript, had full access to all
19 of the data in the study and takes responsibility for the accuracy of the data analyses. PG and
20 JD led the conception and design of the study, contributed to the interpretation of the data,
21 and made substantial revisions to the manuscript. LR contributed to the study design and
22 made substantial revisions to the manuscript. GM and RG contributed to the study design,
23 interpretation of data and made significant revisions to the manuscript.
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43
44
45
46

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49 PG also received funding support from a NHMRC Program grant (#633033); LR received
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Ethics Approval The research project was approved by the Bond University Human Research Ethics Committee (RO1570).

Data Sharing Statement In addition to the quantitative analysis reported in this paper, a qualitative analysis of the jury deliberations and recommendations was conducted and reported elsewhere and cited as reference 18. Additional data is available by emailing the first author.

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Box 1

Knowledge Questions from Surveys (answers considered correct highlighted)

1. Is routine testing for prostate cancer recommended by RACGP Guidelines?

- Yes No Don't know

~~2. Out of every 1000 men, about how many do you think will be diagnosed with prostate cancer some time in their life? *~~

- ~~0 1-14 15-25 >25 Don't know~~

~~3. Out of every 1000 men, about how many do you think will die from prostate cancer? *~~

- ~~0 1-5 6-10 11-20 >20 Don't know~~

4.2. How accurate do you think the prostate specific antigen (PSA) blood test is for diagnosing prostate cancer?

- Reasonably accurate but some people *who do* have cancer can have a negative test result (false negative)
- Reasonably accurate but some people *who do not* have cancer can have an abnormal result (false positive)
- The PSA test is not always accurate because it can have both false positive or false negative results

The PSA test is completely accurate

Don't know

~~5.3. In terms of your knowledge about Prostate cancer, could you list some treatment options?~~

- ~~No Yes, please list~~

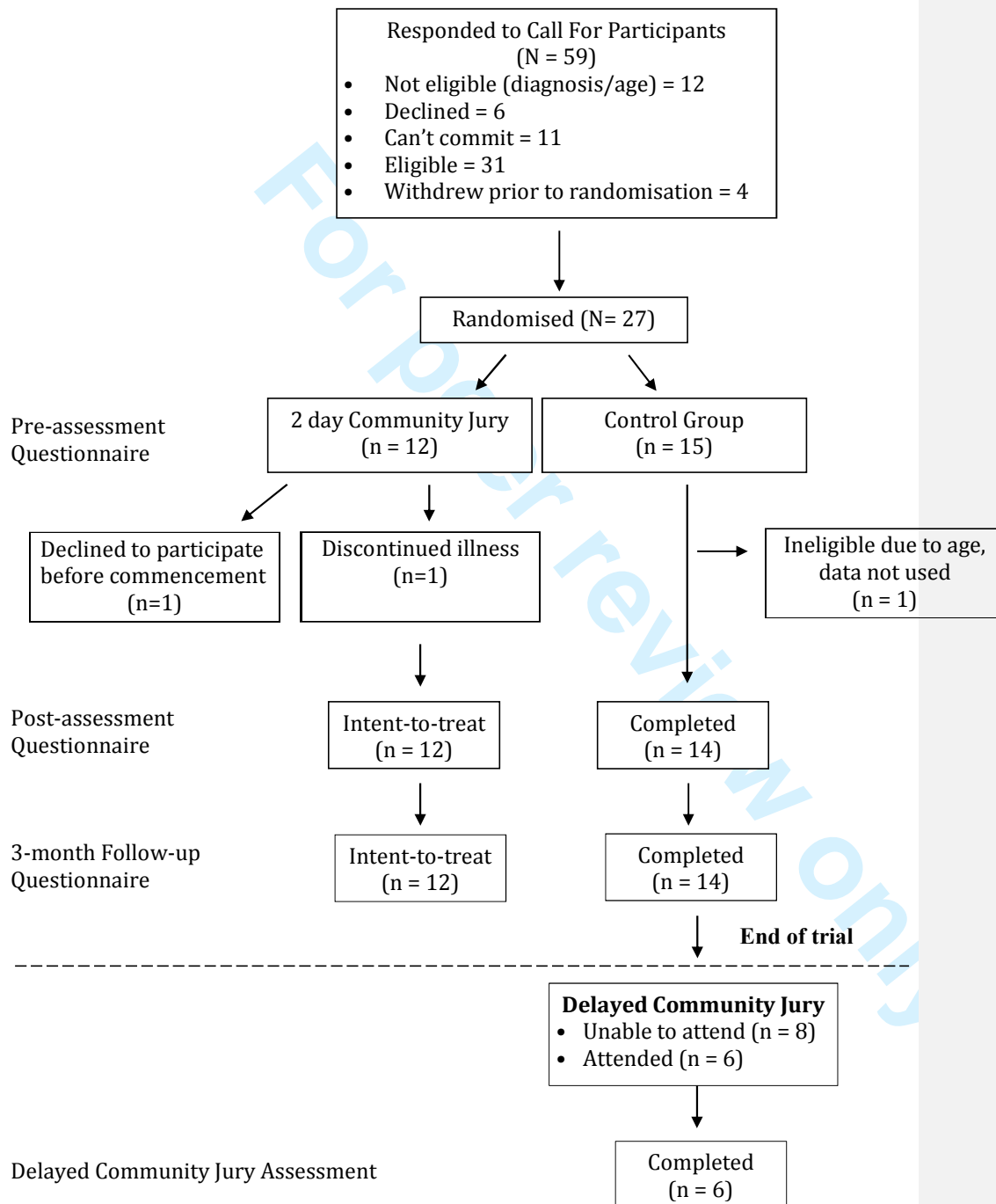
~~6.4. Could you list some potential side effects of treatments for prostate cancer?~~

- ~~No Yes, please list~~

~~* questions from Fagerlin A, Sepucha KR, Couper MP, Levin CA, Singer E Zikmund Fisher B. Patients' knowledge about 9 common health conditions: The DECISIONS survey. *Med Decis Making* 2010;30:35S.~~

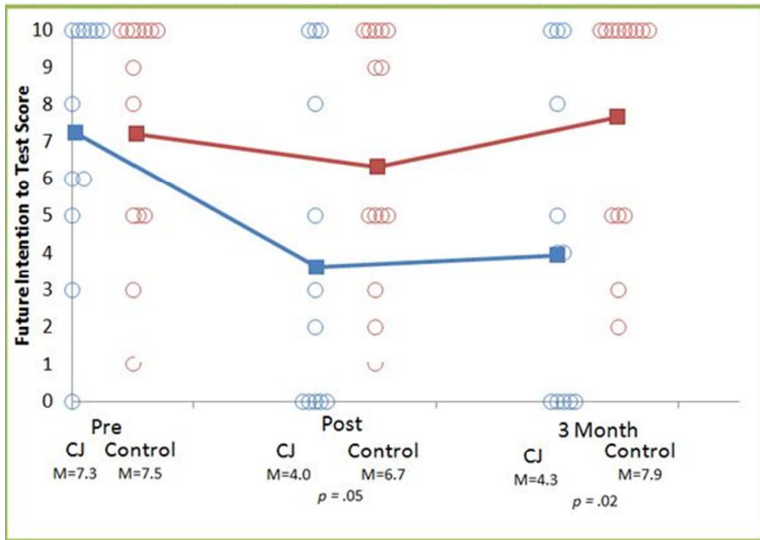
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Figure 1 Consort Flow-Chart of Participants



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Figure 2 Future Intention-to-Screen Scores at Pre, Post, and Three Month Follow-up



Note: CJ=Community Jury group; M = mean score; p values based on ANCOVA analyses pre to post and pre to 3 month follow-up.

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Table 1.
Demographics of Participants

	Community Jury (n=12)	(SD/%)	Control (n=14)	SD/%
<i>Age</i>				
Mean	61	(4.8)	62	(4.9)
<i>Number previous PSA tests</i>				
Mean	3.9	(3.6)	2.2*	(1.8)
<i>Routine PSA testing saves lives</i>				
Frequency	yes	7 (58%)	9 (64%)	
	no	2 (17%)	2 (14%)	
	don't know	3 (25%)	3 (21%)	
<i>Education</i>				
Frequency	High school or less	2 (17%)	4 (28%)	
	some uni or TAFE	4 (33%)	4 (28%)	
	uni/TAFE graduate	4 (33%)	1 (7%)	
	uni postgrad	2 (17%)	5 (36%)	

Note. * n=13, (1 missing); TAFE = Technical and Further Education Institutions

Table 2
Where do you get information about testing for prostate cancer? (N=26)

	Agree	(%)
I don't look for information	3	(12)
Family and friends	11	(42)
Internet	10	(38)
Media	9	(35)
General practitioner	17	(65)
Urologist/specialist/hospital	5	(20)

Note: men could endorse more than one source

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Table 3
Linear Regression Analysis Predicting Future Intention-to-Screen for Prostate Cancer

	<i>Coefficient</i>	<i>SE B</i>	CI		<i>p</i>
			Lower	Upper	
Constant	-0.16	1.69	-3.66	3.35	0.93
Pre-assessment intention-to-screen score	0.74	0.18	0.36	1.11	0.001
Number of previous PSA tests	0.63	0.22	0.18	1.07	0.008
Group (Community Jury/Control)	-3.69	1.19	-6.16	-1.21	0.005

Note. N=25; CI= confidence interval;
These data are slightly different to Rychetnik et al (2014) analyses as they are based on intention-to-treat.

Table 4
Changes in Men's Knowledge Scores from Pre- to Post-assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	4	(42)	3	(25)	1	(8)	3	(25)	0.08
	control*	1	(8)	1	(8)	1	(8)	10	(77)	
out of 1000, how many men are diagnosed?	community jury	2	(17)	6	(50)	1	(8)	3	(25)	0.4
	control	2	(14)	6	(43)	3	(21)	3	(21)	
- out of 1000, how many men die?	community jury	6	(50)	2	(17)	0	(0)	4	(33)	0.004
	control	1	(7)	0	(0)	1	(7)	12	(86)	
how accurate is the PSA test?	community jury	6	(50)	4	(33)	1	(8)	1	(8)	0.03
	control	2	(14)	9	(64)	0	(0)	3	(21)	
list possible treatment options	community jury	2	(17)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	
list possible side effects of treatments	community jury	3	(25)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	

Note: *n=13 (1 missing)

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Table 5
Changes to Men's Knowledge Scores Post- to Follow-up Assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	0	(0)	7	(58)	1	(8)	4	(33)	0.7
	control*	0	(0)	1	(7)	1	(7)	11	(85)	
out of 1000, how many men are diagnosed?	community jury	1	(8)	4	(33)	4	(33)	3	(25)	0.1
	control	0	(0)	2	(14)	6	(43)	6	(43)	
out of 1000, how many men die?	community jury	2	(17)	6	(50)	2	(17)	2	(17)	0.6
	control	2	(14)	0	(0)	2	(14)	10	(71)	
how accurate is the PSA test?	community jury	0	(0)	10	(83)	0	(0)	2	(17)	0.1
	control	2	(14)	9	(64)	2	(14)	1	(7)	

Note: *n=13 (1 missing)

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Figure 1. Consort Flow-Chart of Participants

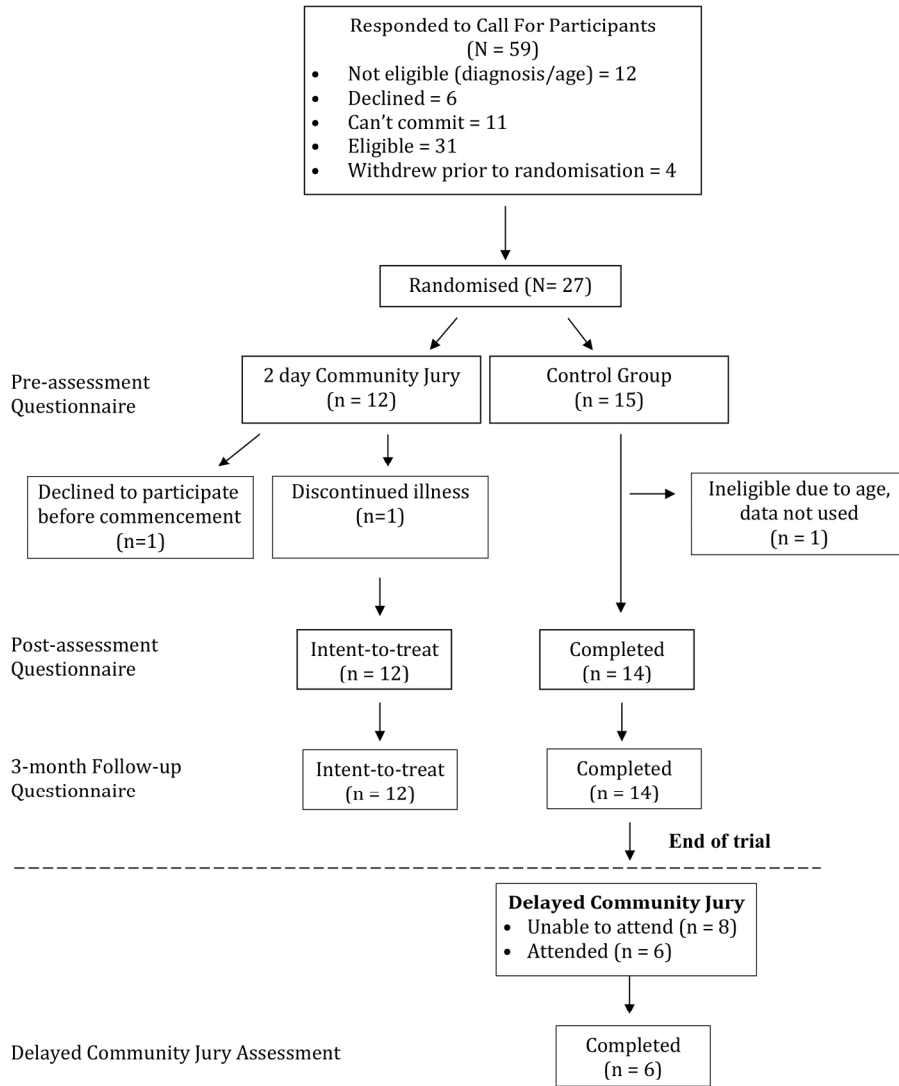
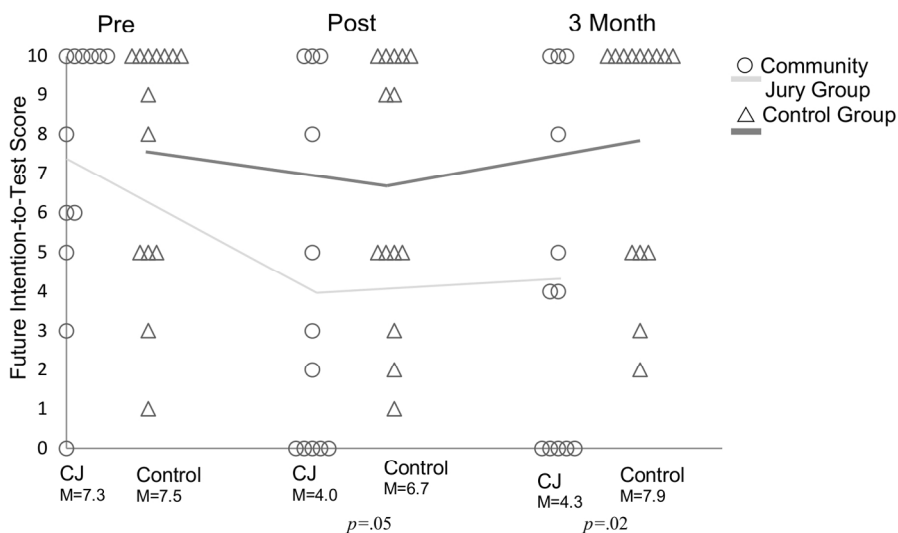


Figure 2. Future Intention-to-Screen Scores at Pre, Post, and Three Month Follow-up



Note: CJ=Community Jury group; M = mean score; p values based on ANCOVA analyses pre to post and pre to 3 month follow-up.

view only



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6-7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8-9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5-7
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	10-11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11-12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-13
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.

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Title Page

Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.

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Abstract

Objective Prostate-specific antigen (PSA) screening is controversial. A community jury allows presentation of complex information and may clarify how participants view screening after being well-informed of the benefits and harms. We examined whether participating in a community jury had an effect on men's knowledge about and their intention to participate in PSA screening.

Design Random allocation to either a 2-day community jury or control group, with pre- post- and three-month follow-up.

Setting Participants from the Gold Coast (Australia) recruited via radio, newspaper, and community meetings.

Participants Twenty-six men aged 50-70 years with no previous diagnosis of prostate cancer.

Intervention The control group (n= 14) received factsheets on PSA screening. Community jury participants (n= 12) received the same factsheets and further information about screening for prostate cancer. In addition, three experts presented information on PSA screening: a neutral scientific adviser provided background information, one expert emphasised the potential benefits of screening, and another expert emphasised the potential harms.

Participants discussed information, asked questions of the experts and deliberated on personal and policy decisions.

Main Outcome and Measures Our primary outcome was change in individual intention to have a PSA screening test. We also assessed knowledge about screening for prostate cancer.

Results Analyses were conducted using intention-to-treat. Immediately after the jury, the community jury group had less intention-to-screen for prostate cancer than men in the control group (effect size = -0.6SD, $p=0.05$). This was sustained at three-month follow-up.

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3 Community jury men also correctly identified PSA test accuracy and considered themselves
4 more informed (effect size 1.2SD, $p < 0.001$).
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7 **Conclusions** Evidence-informed deliberation of harms and benefits of PSA screening effects
8 men's individual choice to be screened for prostate cancer. Community juries may be a valid
9 method for eliciting target group input to policy decisions.
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16 **Trial Registration** Australian and New Zealand Clinical Trials Registry
17 (ACTRN12612001079831)
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20 21 22 23 **Strengths and limitations of this study**

- 24
25 • This is the first study to use scientific methods to evaluate the effect of a community
26 jury on an individual's knowledge and decisions.
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- 28
29 • Participants in community juries make value-based decisions from complex
30 information and can differentiate individual from community choices.
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- 33
34 • Expert presentations were based on large population studies that have limitations.
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37 • The sample size of this study was small, but the results were clear and sustained.
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40 • How sampling, recruitment techniques, and group processes affect community jury
41 outcomes are yet to be examined.
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Introduction

Screening for prostate cancer by prostate-specific antigen (PSA) testing is controversial¹ and the benefits and harms of screening are uncertain.² The results of two large randomised controlled trials of population screening (the ERSPC trial in Europe³ and the PLCO trial in the United States⁴) were much anticipated, but the differing methods and results have led to conflicting interpretations and recommendations from expert groups.^{5,6} Given the uncertainty, most guidelines recommend that men should be fully informed of the potential advantages and disadvantages of screening prior to having a PSA test.^{5,7,8} Although individuals vary in the degree to which they want to engage with the evidence about their health concerns, a majority consistently report an interest in sharing health care decisions with their treating doctor.^{9,10} However, providing the complex information relevant to men who are interested in PSA screening remains challenging.

Citizens' deliberation methodologies, such as community juries can facilitate the communication of complex evidence and aim to elicit 'informed' community perspectives for the purpose of guiding services and public policy. A range of community jury processes have been described, but the common features are i) participants are drawn from the lay public; ii) the jury deliberates on a question requiring an ethics or values-based decision (as opposed to a problem requiring a technical solution); iii) the jury is provided with information on the relevant issues and possible positions from expert "witnesses", with the opportunity to ask them questions; and iv) the jury then engages in a deliberation phase with participants discussing their preferences, opinions, values and positions, and attempt to reach a consensus position.¹¹

Community juries have been conducted on topics such as public health priorities,¹² mammography screening,¹³ and health research.^{14,15} A recent review of deliberation methodologies found only four unique studies that compared deliberative methodologies with

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2
3 a control group; only two of these were in relation to health topics.¹¹ While theoretically
4
5 sound,¹¹ community juries are a resource-intensive process and it is uncertain whether the
6
7 views of those participating are better “informed” than those of a public provided with
8
9 reading material on the same topic. It is also unclear whether and how being informed
10
11 influences a jury’s conclusions. If community juries are to be used to inform screening
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13 policy, it is essential to understand the capacity of a community jury process to support
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15 better-informed conclusions by its participants.
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19 The aim of this study was to examine the degree to which participants of a community
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21 jury on PSA screening of asymptomatic men were better “informed” than other citizens and,
22
23 based on the ERSPC³ and PLCO⁴ trials together with the general practice guidelines, whether
24
25 evidence-informed deliberations of the benefits and harms of PSA screening impact on men’s
26
27 intention to be screen for prostate cancer. We conducted a randomised controlled trial that
28
29 compared a community jury with men allocated to receive typical information. As part of the
30
31 community jury process, men were also asked to deliberate on two community focused
32
33 questions:
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- 36 • Should government campaigns be provided (on PSA screening) and if so, what
37 information should be included in those campaigns?
- 38 • What do you as a group of men think about a government organised invitation
39 program for testing for prostate cancer?
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45 This is the first randomised controlled trial of a deliberative democracy process on the topic
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47 of PSA screening.
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50 51 52 **Method**

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54 We recruited men in the target age group of 50 to 70 years from the Gold Coast region
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56 (Australia) who had no previous diagnosis of prostate cancer, using media advertisements,
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3 radio interviews, and community groups. Men with a family history of prostate cancer were
4
5 not excluded from participating. Eligible and available respondents attended a session on a
6
7 Friday evening to receive a full briefing on the study; all agreed to participate and completed
8
9 a consent form, before being randomly allocated to either a community jury group or a
10
11 control group (Figure 1). Random allocation occurred by each man selecting a piece of paper
12
13 with the name of either group from an opaque container. The research project was approved
14
15 by the Bond University Human Research Ethics Committee (R01570) and the protocol
16
17 registered with the Australian and New Zealand Clinical Trials Registry
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19 (ACTRN12612001079831).
20
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22

23 All men were given standard PSA fact sheets from the Cancer Council Australia and
24
25 Andrology Australia.^{16,17} In addition to the factsheets, men in the community jury group also
26
27 received a Cochrane Collaboration plain language statement,² information from the Royal
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29 Australian College of General Practitioners' Guidelines for "Preventive Activities in General
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31 Practice" pertaining to screening for prostate cancer,⁷ and the Executive Summary of "PSA
32
33 Testing" from the Urology Society of Australia and New Zealand.⁸ Men in both groups
34
35 received \$20 gift cards as reimbursement for their time at the introductory session and for
36
37 each survey. The community jury group received an \$80 gift card as reimbursement for
38
39 attending the community jury weekend. Men in the control group were given a follow-up
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41 survey with a return stamped envelope to be mailed after the weekend.
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45 The community jury weekend and a qualitative analysis of the jury deliberations have
46
47 been described in detail elsewhere.¹⁸ In brief, the community jury consisted of an iterative
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49 process of education and deliberation. Three experts presented to the community jury on day
50
51 one: a neutral scientific advisor discussed medical information regarding the role of the
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53 prostate, screening tests (including PSA and Digital Rectal Examination), explanations about
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55 changes to PSA levels, how cancer is detected, and treatment options and potential outcomes
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3 (Jim Dickinson, Professor of Family Medicine, University of Calgary). Two further experts
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5 (a urologist and expert in prostate cancer (author RG) and an expert in evidence-based
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7 medicine (author PG) presented the benefits and harms of being screened for prostate cancer.
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9 Although both speakers aimed to give balanced presentations, one emphasised the benefits of
10
11 PSA screening, in particular selective screening, (RG <http://youtu.be/9vPt3NAcG8g>) and the
12
13 other the harms (PG <http://youtu.be/nifkjdZKmsU>). Both presentations focused on the
14
15 evidence from the two trials of PSA population screening. However, both presenters also
16
17 made reference to lower levels of evidence relating to the risks of metastases if a cancer
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19 remains undetected due to a lack of screening and the consequences of treating localised
20
21 disease detected during screening. After each presentation, men were able to deliberate on the
22
23 information and could ask the experts any questions. The men reflected on the information
24
25 overnight and returned on Sunday to deliberate and discuss the information presented the day
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27 before, including asking any further questions of the expert witnesses by phone.
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32 A nominal group technique was used on both days to elicit individual thoughts prior to
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34 group deliberations. After the final deliberations on Sunday, including the community level
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36 decisions, the men in the community jury completed the post-assessment survey. Men in the
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38 control group were contacted on the Monday and either completed the post-assessment
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40 survey by phone or mailed the survey back to researchers the same week. Three months after
41
42 the community jury weekend, all men in both groups were re-contacted and completed a
43
44 follow-up survey.
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47 **Non-protocol Extension**

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49 Because they indicated a strong desire to have the experience of the community jury
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51 weekend, after their three-month follow-up survey the control group was offered the same
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53 community jury experience. Six of the 14 men randomised to the control group participated
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55 in the second community jury (Figure 1). The two primary experts were the same as for the
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3 original community jury group, however, the scientific advisor was changed to a female
4
5 general practitioner and professor of clinical epidemiology (author JD). A final post-jury
6
7 survey was conducted with the second community jury.
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9 10 **Measures**

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12 We collected demographic information, history of previous PSA testing and
13
14 information sources for PSA screening at the introductory session. In each of the three
15
16 surveys, men were asked to nominate on a scale 0 to 10 (0 = *not at all*, 5 = *maybe*, and 10 =
17
18 *absolutely*), whether they intended, while symptomless, to undergo PSA screening for
19
20 prostate cancer in the future. They were also asked to nominate how informed they
21
22 considered themselves in relation to the harms and benefits of screening for prostate cancer
23
24 on a scale 0 to 4 (0 = *not at all* and 4 = *very*). We asked four knowledge questions in each
25
26 survey that assessed a) the men's knowledge about the recommendation on PSA screening in
27
28 the Australian general practice guidelines,⁷ b) the accuracy of the PSA test and c) two
29
30 questions about treatment options and side-effects of prostate cancer treatment (Box 1).
31
32 Australia has a primary care based system, requiring a referral from a general practitioner to
33
34 see a urologist. General practitioners are therefore responsible for the majority of the PSA
35
36 screening tests requested in Australia. For this reason, we were interested in the participants'
37
38 knowledge of current general practice guidelines.
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43 **Statistical Analyses**

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45 Pre- to post-, and post- to follow-up assessment differences between the groups were
46
47 examined with ANCOVA and Fisher's exact test. It was anticipated that the number of PSA
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49 tests previously undertaken would impact on a man's future decision to be screened for
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51 prostate cancer with the PSA test.¹⁹ Therefore we conducted the analyses with adjustment for
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53 baseline intention-to-screen and the number of times a man had already received a PSA test.
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3 Unadjusted post-assessment analyses were conducted using an independent t-test. All
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5 analyses were conducted on an intention-to-treat basis.
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9 10 **Results**

11 **Participant Demographics**

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14 Of the 59 men who contacted the research team, 27 respondents were available on the set
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16 date and elected to participate in the study. One man was excluded post-randomisation as his
17
18 age exceeded the limit of the study (see Figure 1). Participating men's ages ranged between
19
20 53 and 70 years (average 62 years, $SD = 4.8$). Further demographic information is described
21
22 in Table 1. There was no loss to follow up during the course of the study. The groups were
23
24 similar at baseline in age, number of times previously screened for prostate cancer, and
25
26 whether they intended to be screened for prostate cancer in the future. All but 3 men had
27
28 previously had a PSA test; 14 had been tested 2 or 3 times, 4 on one occasion, two 6 times,
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30 and 3 men had been tested on 7, 8, and 12 occasions each. No men had undergone a biopsy.
31
32 At pre-assessment, the majority of men (16/26, 62%) agreed with the statement that routine
33
34 screening for prostate cancer saved lives, whereas 4 (15%) disagreed and 6 (23%) did not
35
36 know (Table 1). The men reported a variety of sources for how they accessed information
37
38 about prostate cancer screening, with the most common source of information being their
39
40 general practitioner (Table 2).
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45 **Changes in Intention-to-Screen and Individual Knowledge**

46
47 **Pre-to post-intervention.** At post-assessment, men in the community jury group had
48
49 significantly less intention-to-screen for prostate cancer on the 0 to 10 scale than men in the
50
51 control group (median score 2.5 and 7.0, Effect Size= $-0.6SD$, $p=0.05$). When we adjusted
52
53 for baseline intention to be screened for prostate cancer and the number of prior PSA tests,
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3 the mean difference was 3.7 ($p=.005$, Table 3). The unadjusted mean difference between the
4
5 groups was 2.7 (Figure 2).
6

7 After completion of the community jury weekend, men in the jury group considered
8 themselves more informed about screening for prostate cancer than the control group (median
9 score 4.0 and 2.0, mean difference = 1.7, Effect Size=1.2SD, $p<0.001$). Compared with the
10 control group, the community jury group was more likely to correctly identify that the PSA
11 test was not always accurate in indicating the likelihood of prostate cancer as it had both false
12 positive and false negative results ($p=0.03$, Table 4).
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20 **Post-to 3 month follow-up assessment.** The influence of the community jury
21 experience was sustained at 3 months: men in the community jury group maintained their
22 intention-to-screen score at 3 months (Figure 2) whereas there was a slight increase in the
23 control group's future intention-to-screen for prostate cancer. There was no further change in
24 knowledge (Table 5).
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31 **Community Level Questions**

32 Men in the community jury voted unanimously (12/12) against a government campaign
33 targeting the public about PSA screening for prostate cancer, and against a government
34 organised invitation program. Unprompted, the jury members instead suggested the
35 government provide a campaign that targeted general practitioners to assist them to provide
36 better quality and more consistent information to their patients on the benefits and harms of
37 screening for prostate cancer using the PSA test.¹⁸
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47 **Non-protocol Extension.** Compared with their 3-month follow-up scores, the men
48 from the control group who completed the second community jury also subsequently
49 increased their self-report score of how informed they considered themselves (mean score
50 increased from 2.2 to 3.7), and decreased their future intention to be screened for prostate
51 cancer (mean score decreased from 8 to 2.8).
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Discussion

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5 Compared with men who received standard information, participants in a 2-day
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7 community jury considered themselves better informed about the benefits and harms of PSA
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9 screening and reduced their stated intention to participate in screening in the future. Although
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11 the process led to some men changing their minds about participating in PSA screening,
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13 others said they would continue to be tested; highlighting the individual nature of this
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15 decision and the need for informed consent.²⁰
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19 Yet despite differences in the men's individual intentions to be screened for prostate
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21 cancer, the group was unanimous in opposing any government-sponsored community
22
23 campaign. Our findings demonstrate the capacity of a community jury to consider complex
24
25 information on the harms and benefits of screening, and to distinguish individual from
26
27 community choices. This echoes the findings of a New Zealand community jury on
28
29 mammography screening¹³ which also indicated that community juries are able to
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31 differentiate between individual and public health needs.
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35 All deliberative democracy methods rely on engagement of those who have an interest
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37 in the topic and agree to take part. The generalisability of our study findings may be limited
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39 by the uncertain representativeness of a jury of volunteers from the Gold Coast, Australia,
40
41 who may be different in several ways to men in the wider Australian community. For
42
43 example, 88% of our participants had already had at least one PSA test, implying that prior to
44
45 the community jury they were more likely to be favorably disposed to PSA screening.
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49 The authors considered PSA screening an appropriate topic for engaging middle-aged
50
51 men because the data are equivocal and guidelines differ.^{2,7,8} However, we also acknowledge
52
53 the limitations of these mass population studies. The median follow-ups of the ERSPC³ and
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55 PLCO⁴ trials (13 and 11 years) are not sufficient to reliably address long-term prostate cancer
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57 mortality and their respective methodologies have been criticised.²¹ This limitation may have
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3 impacted the community jury decision. Nevertheless, this pilot study does illustrate the
4
5 potential of the community jury approach to instruct a cross section of men of different ages,
6
7 with different backgrounds, and educational levels.
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10 Whether and how sampling and recruitment techniques affect community jury
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12 outcomes are important research questions yet to be examined. Other important
13
14 methodological questions for community research include: what are the impacts on group
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16 decisions of normative (conformity to group thinking) or informational (discussion of facts)
17
18 influences?²² and when and how in the deliberation process do community jury participants
19
20 form their conclusions?
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23 Our results have implications for clinical and public health practice. A large proportion
24
25 of men have not been engaged in an evidence-informed discussion of the potential benefits
26
27 and harms of screening prior to their physician ordering a PSA test^{23, 24}; have not been asked
28
29 about their screening preferences prior to a PSA screening test²⁵; and some doctors screen
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31 without a discussion.²⁶ Alarming, a study conducted in the theatre waiting room in men
32
33 waiting to undergo a trans rectal ultrasound and prostate biopsy found 8% were unaware their
34
35 primary care provider had conducted a PSA screening test.²⁷ Current practice of PSA
36
37 screening in asymptomatic men is not standardised. Our findings reinforce the importance of
38
39 presenting the potential benefits and harms of PSA testing to men interested in being
40
41 screened, primarily because such information will lead some men to change their mind once
42
43 fully informed. When practitioners are faced with the difficult situation of being asked to
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45 determine such a decision on behalf of their patient, in addition to considering their
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47 individual patient's history, concerns, and priorities, it may be valuable to also have available
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49 information about community attitudes and concerns regarding screening.²⁰
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2
3 **Contributors** RT led the preparations and revisions of the manuscript, had full access to all
4 of the data in the study and takes responsibility for the accuracy of the data analyses. PG and
5
6
7 JD led the conception and design of the study, contributed to the interpretation of the data,
8
9
10 and made substantial revisions to the manuscript. LR contributed to the study design and
11
12 made substantial revisions to the manuscript. GM and RG contributed to the study design,
13
14 interpretation of data and made significant revisions to the manuscript.
15

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17
18 Calgary, Canada for kindly providing his scientific expertise as our scientific advisor in the
19
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21
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43
44 activities that could appear to have influenced the submitted work.
45
46

47 **Ethics Approval** The research project was approved by the Bond University Human
48
49 Research Ethics Committee (RO1570).
50
51

52 **Data Sharing Statement** In addition to the quantitative analysis reported in this paper, a
53
54 qualitative analysis of the jury deliberations and recommendations was conducted and
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1
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3 reported elsewhere and cited as reference 18. Additional data is available by emailing the first
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5 author.
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9 10 **Figure Legends**

11
12 Figure 1. Consort Flow-Chart of Participants (no legend)

13
14 Figure 2. Future Intention-to-Screen Scores at Pre, Post, and Three Month Follow-up

15
16 ○ — Community Jury Group;

17
18 △ — Control Group
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20
21 Foot note for Figure 2

22 Note: CJ=Community Jury group; M = mean score; p values based on ANCOVA analyses
23 pre to post and pre to 3 month follow-up.
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Box 1.**Knowledge Questions from Surveys* (answers considered correct highlighted)**

1. Is routine testing for prostate cancer recommended by RACGP Guidelines?

- Yes No Don't know

2. How accurate do *you* think the prostate specific antigen (PSA) blood test is for diagnosing prostate cancer?

- Reasonably accurate but some people *who do* have cancer can have a negative test result (false negative)

- Reasonably accurate but some people *who do not* have cancer can have an abnormal result (false positive)

- The PSA test is not always accurate because it can have both false positive or false negative results

- The PSA test is completely accurate

- Don't know

3. In terms of your knowledge about Prostate cancer, could you list some treatment options?

- No Yes, please list

4. Could you list some potential side effects of treatments for prostate cancer?

- No Yes, please list

*There were originally six knowledge questions however the answers for two (one on prevalence and the other on mortality rates of prostate cancer) were incorrect and were deleted from analyses.

Table 1. Participants Demographics

		Community Jury (n=12)	(SD/%)	Control (n=14)	SD/%
<i>Age</i>					
	Mean	61	(4.8)	62	(4.9)
<i>Number previous PSA tests</i>					
	Mean	3.9	(3.6)	2.2*	(1.8)
<i>Routine PSA testing saves lives</i>					
Frequency	yes	7	(58%)	9	(64%)
	no	2	(17%)	2	(14%)
	don't know	3	(25%)	3	(21%)
<i>Education</i>					
Frequency	High school or less	2	(17%)	4	(28%)
	some uni or TAFE	4	(33%)	4	(28%)
	uni/TAFE graduate	4	(33%)	1	(7%)
	uni postgrad	2	(17%)	5	(36%)
Note. * n=13, (1 missing); TAFE = Technical and Further Education Institutions					

Table 2. Where do Men Receive Information about Testing for Prostate Cancer? (N=26)

	Agree	(%)
I don't look for information	3	(12)
Family and friends	11	(42)
Internet	10	(38)
Media	9	(35)
General practitioner	17	(65)
Urologist/specialist/hospital	5	(20)
Note: men could endorse more than one source		

Table 3. Linear Regression Analysis Predicting Future Intention-to-Screen for Prostate Cancer

	<i>Coefficient</i>	<i>SE B</i>	CI Lower	CI Upper	<i>p</i>
Constant	-0.16	1.69	-3.66	3.35	0.93
Pre-assessment intention-to-screen score	0.74	0.18	0.36	1.11	0.001
Number of previous PSA tests	0.63	0.22	0.18	1.07	0.008
Group (Community Jury/Control)	-3.69	1.19	-6.16	-1.21	0.005

Note. N=25; CI= confidence interval;
These data are slightly different to Rychetnik et al (2014) analyses as they are based on intention-to-treat.

Table 4. Changes in Men's Knowledge Scores from Pre-to Post-assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	4	(42)	3	(25)	1	(8)	3	(25)	0.08
	control*	1	(8)	1	(8)	1	(8)	10	(77)	
how accurate is the PSA test?	community jury	6	(50)	4	(33)	1	(8)	1	(8)	0.03
	control	2	(14)	9	(64)	0	(0)	3	(21)	
list possible treatment options	community jury	2	(17)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	
list possible side effects of treatments	community jury	3	(25)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	

Note: *n=13 (1 missing)

Table 5. Changes in Men's Knowledge Scores Post- to Follow-up Assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	0	(0)	7	(58)	1	(8)	4	(33)	0.7
	control*	0	(0)	1	(7)	1	(7)	11	(85)	
how accurate is the PSA test?	community jury	0	(0)	10	(83)	0	(0)	2	(17)	0.1
	control	2	(14)	9	(64)	2	(14)	1	(7)	

Note: *n=13 (1 missing)

Title Page

Deliberative democracy and cancer screening consent: a randomised control trial of the effect of a community jury on men's knowledge about and intentions to participate in PSA screening.

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Abstract

Objective Prostate-specific antigen (PSA) screening is controversial. A community jury allows presentation of complex information and may clarify how participants view screening after being well-informed of the benefits and harms. We examined whether participating in a community jury had an effect on men's knowledge about and their intention to participate in PSA screening.

Design Random allocation to either a 2-day community jury or control group, with pre- post- and three-month follow-up.

Setting Participants from the Gold Coast (Australia) recruited via radio, newspaper, and community meetings.

Participants Twenty-six men aged 50-70 years with no previous diagnosis of prostate cancer.

Intervention The control group (n= 14) received factsheets on PSA screening. Community jury participants (n= 12) received the same factsheets and further information about screening for prostate cancer. In addition, three experts presented information on PSA screening: a neutral scientific adviser provided background information, one expert emphasised the potential benefits of screening, and another expert emphasised the potential harms.

Participants discussed information, asked questions of the experts and deliberated on personal and policy decisions.

Main Outcome and Measures Our primary outcome was change in individual intention to have a PSA screening test. We also assessed knowledge about screening for prostate cancer.

Results Analyses were conducted using intention-to-treat. Immediately after the jury, the community jury group had less intention-to-screen for prostate cancer than men in the control group (effect size = -0.6SD, $p=0.05$). This was sustained at three-month follow-up.

Community jury men also correctly identified PSA test accuracy and considered themselves more informed (effect size 1.2SD, $p < 0.001$).

Conclusions Evidence-informed deliberation of harms and benefits of PSA screening effects men's individual choice to be screened for prostate cancer. Community juries may be a valid method for eliciting target group input to policy decisions.

Trial Registration Australian and New Zealand Clinical Trials Registry
(ACTRN12612001079831)

Strengths and limitations of this study

- This is the first study to use scientific methods to evaluate the effect of a community jury on an individual's knowledge and decisions.
- Participants in community juries make value-based decisions from complex information and can differentiate individual from community choices.
- Expert presentations were based on large population studies that have limitations.
- The sample size of this study was small, but the results were clear and sustained.
- How sampling, recruitment techniques, and group processes affect community jury outcomes are yet to be examined.

Introduction

Screening for prostate cancer by prostate-specific antigen (PSA) testing is controversial¹ and the benefits and harms of screening are uncertain.² The results of two large randomised controlled trials of population screening (the ERSPC trial in Europe³ and the PLCO trial in the United States⁴) were much anticipated, but the differing methods and results have led to conflicting interpretations and recommendations from expert groups.^{5,6} Given the uncertainty, most guidelines recommend that men should be fully informed of the potential advantages and disadvantages of screening prior to having a PSA test.^{5,7,8} Although individuals vary in the degree to which they want to engage with the evidence about their health concerns, a majority consistently report an interest in sharing health care decisions with their treating doctor.^{9,10} However, providing the complex information relevant to men who are interested in PSA screening remains challenging.

Citizens' deliberation methodologies, such as community juries can facilitate the communication of complex evidence and aim to elicit 'informed' community perspectives for the purpose of guiding services and public policy. A range of community jury processes have been described, but the common features are i) participants are drawn from the lay public; ii) the jury deliberates on a question requiring an ethics or values-based decision (as opposed to a problem requiring a technical solution); iii) the jury is provided with information on the relevant issues and possible positions from expert "witnesses", with the opportunity to ask them questions; and iv) the jury then engages in a deliberation phase with participants discussing their preferences, opinions, values and positions, and attempt to reach a consensus position.¹¹

Community juries have been conducted on topics such as public health priorities,¹² mammography screening,¹³ and health research.^{14,15} A recent review of deliberation methodologies found only four unique studies that compared deliberative methodologies with

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3 a control group; only two of these were in relation to health topics.¹¹ While theoretically
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5 sound,¹¹ community juries are a resource-intensive process and it is uncertain whether the
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7 views of those participating are better “informed” than those of a public provided with
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9 reading material on the same topic. It is also unclear whether and how being informed
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11 influences a jury’s conclusions. If community juries are to be used to inform screening
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13 policy, it is essential to understand the capacity of a community jury process to support
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15 better-informed conclusions by its participants.
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19 The aim of this study was to examine the degree to which participants of a community
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21 jury on PSA screening of asymptomatic men were better “informed” than other citizens and,
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23 based on the ERSPC³ and PLCO⁴ trials together with the general practice guidelines, whether
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25 evidence-informed deliberations of the benefits and harms of PSA screening impact on men’s
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27 intention to be screen for prostate cancer. We conducted a randomised controlled trial that
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29 compared a community jury with men allocated to receive typical information. As part of the
30
31 community jury process, men were also asked to deliberate on two community focused
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33 questions:
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36 • Should government campaigns be provided (on PSA screening) and if so, what
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38 information should be included in those campaigns?
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40 • What do you as a group of men think about a government organised invitation
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42 program for testing for prostate cancer?
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46 This is the first randomised controlled trial of a deliberative democracy process on the topic
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48 of PSA screening.
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50 51 52 **Method**

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54 We recruited men in the target age group of 50 to 70 years from the Gold Coast region
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56 (Australia) who had no previous diagnosis of prostate cancer, using media advertisements,
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3 radio interviews, and community groups. Men with a family history of prostate cancer were
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5 not excluded from participating. Eligible and available respondents attended a session on a
6
7 Friday evening to receive a full briefing on the study; all agreed to participate and completed
8
9 a consent form, before being randomly allocated to either a community jury group or a
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11 control group (Figure 1). Random allocation occurred by each man selecting a piece of paper
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13 with the name of either group from an opaque container. The research project was approved
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15 by the Bond University Human Research Ethics Committee (R01570) and the protocol
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17 registered with the Australian and New Zealand Clinical Trials Registry
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19 (ACTRN12612001079831).
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23 All men were given standard PSA fact sheets from the Cancer Council Australia and
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25 Andrology Australia.^{16,17} In addition to the factsheets, men in the community jury group also
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27 received a Cochrane Collaboration plain language statement,² information from the Royal
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29 Australian College of General Practitioners' Guidelines for "Preventive Activities in General
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31 Practice" pertaining to screening for prostate cancer,⁷ and the Executive Summary of "PSA
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33 Testing" from the Urology Society of Australia and New Zealand.⁸ Men in both groups
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35 received \$20 gift cards as reimbursement for their time at the introductory session and for
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37 each survey. The community jury group received an \$80 gift card as reimbursement for
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39 attending the community jury weekend. Men in the control group were given a follow-up
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41 survey with a return stamped envelope to be mailed after the weekend.
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45 The community jury weekend and a qualitative analysis of the jury deliberations have
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47 been described in detail elsewhere.¹⁸ In brief, the community jury consisted of an iterative
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49 process of education and deliberation. Three experts presented to the community jury on day
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51 one: a neutral scientific advisor discussed medical information regarding the role of the
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53 prostate, screening tests (including PSA and Digital Rectal Examination), explanations about
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55 changes to PSA levels, how cancer is detected, and treatment options and potential outcomes
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3 (Jim Dickinson, Professor of Family Medicine, University of Calgary). Two further experts
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5 (a urologist and expert in prostate cancer (author RG) and an expert in evidence-based
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7 medicine (author PG) presented the benefits and harms of being screened for prostate cancer.
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9 Although both speakers aimed to give balanced presentations, one emphasised the benefits of
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11 PSA screening, in particular selective screening, (RG <http://youtu.be/9vPt3NAcG8g>) and the
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13 other the harms (PG <http://youtu.be/nifkjdZKmsU>). Both presentations focused on the
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15 evidence from the two trials of PSA population screening. However, both presenters also
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17 made reference to lower levels of evidence relating to the risks of metastases if a cancer
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19 remains undetected due to a lack of screening and the consequences of treating localised
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21 disease detected during screening. After each presentation, men were able to deliberate on the
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23 information and could ask the experts any questions. The men reflected on the information
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25 overnight and returned on Sunday to deliberate and discuss the information presented the day
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27 before, including asking any further questions of the expert witnesses by phone.
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32 A nominal group technique was used on both days to elicit individual thoughts prior to
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34 group deliberations. After the final deliberations on Sunday, including the community level
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36 decisions, the men in the community jury completed the post-assessment survey. Men in the
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38 control group were contacted on the Monday and either completed the post-assessment
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40 survey by phone or mailed the survey back to researchers the same week. Three months after
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42 the community jury weekend, all men in both groups were re-contacted and completed a
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44 follow-up survey.
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47 **Non-protocol Extension**

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49 Because they indicated a strong desire to have the experience of the community jury
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51 weekend, after their three-month follow-up survey the control group was offered the same
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53 community jury experience. Six of the 14 men randomised to the control group participated
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55 in the second community jury (Figure 1). The two primary experts were the same as for the
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3 original community jury group, however, the scientific advisor was changed to a female
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5 general practitioner and professor of clinical epidemiology (author JD). A final post-jury
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7 survey was conducted with the second community jury.
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9 10 **Measures**

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12 We collected demographic information, history of previous PSA testing and
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14 information sources for PSA screening at the introductory session. In each of the three
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16 surveys, men were asked to nominate on a scale 0 to 10 (0 = *not at all*, 5 = *maybe*, and 10 =
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18 *absolutely*), whether they intended, while symptomless, to undergo PSA screening for
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20 prostate cancer in the future. They were also asked to nominate how informed they
21
22 considered themselves in relation to the harms and benefits of screening for prostate cancer
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24 on a scale 0 to 4 (0 = *not at all* and 4 = *very*). We asked four knowledge questions in each
25
26 survey that assessed a) the men's knowledge about the recommendation on PSA screening in
27
28 the Australian general practice guidelines,⁷ b) the accuracy of the PSA test and c) two
29
30 questions about treatment options and side-effects of prostate cancer treatment (Box 1).
31
32 Australia has a primary care based system, requiring a referral from a general practitioner to
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34 see a urologist. General practitioners are therefore responsible for the majority of the PSA
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36 screening tests requested in Australia. For this reason, we were interested in the participants'
37
38 knowledge of current general practice guidelines.
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43 **Statistical Analyses**

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45 Pre- to post-, and post- to follow-up assessment differences between the groups were
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47 examined with ANCOVA and Fisher's exact test. It was anticipated that the number of PSA
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49 tests previously undertaken would impact on a man's future decision to be screened for
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51 prostate cancer with the PSA test.¹⁹ Therefore we conducted the analyses with adjustment for
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53 baseline intention-to-screen and the number of times a man had already received a PSA test.
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3 Unadjusted post-assessment analyses were conducted using an independent t-test. All
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5 analyses were conducted on an intention-to-treat basis.
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9 10 **Results**

11 **Participant Demographics**

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14 Of the 59 men who contacted the research team, 27 respondents were available on the set
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16 date and elected to participate in the study. One man was excluded post-randomisation as his
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18 age exceeded the limit of the study (see Figure 1). Participating men's ages ranged between
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20 53 and 70 years (average 62 years, $SD = 4.8$). Further demographic information is described
21
22 in Table 1. There was no loss to follow up during the course of the study. The groups were
23
24 similar at baseline in age, number of times previously screened for prostate cancer, and
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26 whether they intended to be screened for prostate cancer in the future. All but 3 men had
27
28 previously had a PSA test; 14 had been tested 2 or 3 times, 4 on one occasion, two 6 times,
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30 and 3 men had been tested on 7, 8, and 12 occasions each. No men had undergone a biopsy.
31
32 At pre-assessment, the majority of men (16/26, 62%) agreed with the statement that routine
33
34 screening for prostate cancer saved lives, whereas 4 (15%) disagreed and 6 (23%) did not
35
36 know (Table 1). The men reported a variety of sources for how they accessed information
37
38 about prostate cancer screening, with the most common source of information being their
39
40 general practitioner (Table 2).
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45 **Changes in Intention-to-Screen and Individual Knowledge**

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47 **Pre-to post-intervention.** At post-assessment, men in the community jury group had
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49 significantly less intention-to-screen for prostate cancer on the 0 to 10 scale than men in the
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51 control group (median score 2.5 and 7.0, Effect Size= $-0.6SD$, $p=0.05$). When we adjusted
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53 for baseline intention to be screened for prostate cancer and the number of prior PSA tests,
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3 the mean difference was 3.7 ($p=.005$, Table 3). The unadjusted mean difference between the
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5 groups was 2.7 (Figure 2).
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7 After completion of the community jury weekend, men in the jury group considered
8 themselves more informed about screening for prostate cancer than the control group (median
9 score 4.0 and 2.0, mean difference = 1.7, Effect Size=1.2SD, $p<0.001$). Compared with the
10 control group, the community jury group was more likely to correctly identify that the PSA
11 test was not always accurate in indicating the likelihood of prostate cancer as it had both false
12 positive and false negative results ($p=0.03$, Table 4).
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20 **Post-to 3 month follow-up assessment.** The influence of the community jury
21 experience was sustained at 3 months: men in the community jury group maintained their
22 intention-to-screen score at 3 months (Figure 2) whereas there was a slight increase in the
23 control group's future intention-to-screen for prostate cancer. There was no further change in
24 knowledge (Table 5).
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31 **Community Level Questions**

32 Men in the community jury voted unanimously (12/12) against a government campaign
33 targeting the public about PSA screening for prostate cancer, and against a government
34 organised invitation program. Unprompted, the jury members instead suggested the
35 government provide a campaign that targeted general practitioners to assist them to provide
36 better quality and more consistent information to their patients on the benefits and harms of
37 screening for prostate cancer using the PSA test.¹⁸
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47 **Non-protocol Extension.** Compared with their 3-month follow-up scores, the men
48 from the control group who completed the second community jury also subsequently
49 increased their self-report score of how informed they considered themselves (mean score
50 increased from 2.2 to 3.7), and decreased their future intention to be screened for prostate
51 cancer (mean score decreased from 8 to 2.8).
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Discussion

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5 Compared with men who received standard information, participants in a 2-day
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7 community jury considered themselves better informed about the benefits and harms of PSA
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9 screening and reduced their stated intention to participate in screening in the future. Although
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11 the process led to some men changing their minds about participating in PSA screening,
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13 others said they would continue to be tested; highlighting the individual nature of this
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15 decision and the need for informed consent.²⁰
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19 Yet despite differences in the men's individual intentions to be screened for prostate
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21 cancer, the group was unanimous in opposing any government-sponsored community
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23 campaign. Our findings demonstrate the capacity of a community jury to consider complex
24
25 information on the harms and benefits of screening, and to distinguish individual from
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27 community choices. This echoes the findings of a New Zealand community jury on
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29 mammography screening¹³ which also indicated that community juries are able to
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31 differentiate between individual and public health needs.
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35 All deliberative democracy methods rely on engagement of those who have an interest
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37 in the topic and agree to take part. The generalisability of our study findings may be limited
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39 by the uncertain representativeness of a jury of volunteers from the Gold Coast, Australia,
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41 who may be different in several ways to men in the wider Australian community. For
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43 example, 88% of our participants had already had at least one PSA test, implying that prior to
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45 the community jury they were more likely to be favorably disposed to PSA screening.
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49 The authors considered PSA screening an appropriate topic for engaging middle-aged
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51 men because the data are equivocal and guidelines differ.^{2,7,8} However, we also acknowledge
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53 the limitations of these mass population studies. The median follow-ups of the ERSPC³ and
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55 PLCO⁴ trials (13 and 11 years) are not sufficient to reliably address long-term prostate cancer
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57 mortality and their respective methodologies have been criticised.²¹ This limitation may have
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3 impacted the community jury decision. Nevertheless, this pilot study does illustrate the
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5 potential of the community jury approach to instruct a cross section of men of different ages,
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7 with different backgrounds, and educational levels.
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10 Whether and how sampling and recruitment techniques affect community jury
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12 outcomes are important research questions yet to be examined. Other important
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14 methodological questions for community research include: what are the impacts on group
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16 decisions of normative (conformity to group thinking) or informational (discussion of facts)
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18 influences?²² and when and how in the deliberation process do community jury participants
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20 form their conclusions?
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24 Our results have implications for clinical and public health practice. A large proportion
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26 of men have not been engaged in an evidence-informed discussion of the potential benefits
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28 and harms of screening prior to their physician ordering a PSA test^{23, 24}; have not been asked
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30 about their screening preferences prior to a PSA screening test²⁵; and some doctors screen
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32 without a discussion.²⁶ Alarming, a study conducted in the theatre waiting room in men
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34 waiting to undergo a trans rectal ultrasound and prostate biopsy found 8% were unaware their
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36 primary care provider had conducted a PSA screening test.²⁷ Current practice of PSA
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38 screening in asymptomatic men is not standardised. Our findings reinforce the importance of
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40 presenting the potential benefits and harms of PSA testing to men interested in being
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42 screened, primarily because such information will lead some men to change their mind once
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44 fully informed. When practitioners are faced with the difficult situation of being asked to
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46 determine such a decision on behalf of their patient, in addition to considering their
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48 individual patient's history, concerns, and priorities, it may be valuable to also have available
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50 information about community attitudes and concerns regarding screening.²⁰
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3 **Contributors** RT led the preparations and revisions of the manuscript, had full access to all
4 of the data in the study and takes responsibility for the accuracy of the data analyses. PG and
5
6
7 JD led the conception and design of the study, contributed to the interpretation of the data,
8
9
10 and made substantial revisions to the manuscript. LR contributed to the study design and
11
12 made substantial revisions to the manuscript. GM and RG contributed to the study design,
13
14 interpretation of data and made significant revisions to the manuscript.
15

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17
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25
26

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34
35

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37
38 declare: RT, JD, PG, and GM received funding support from Bond University; RT, JD and
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41
42 funding support from a NHMRC funding grant (#1023197); no other relationships or
43
44 activities that could appear to have influenced the submitted work.
45
46

47 **Ethics Approval** The research project was approved by the Bond University Human
48
49 Research Ethics Committee (RO1570).
50
51

52 **Data Sharing Statement** In addition to the quantitative analysis reported in this paper, a
53
54 qualitative analysis of the jury deliberations and recommendations was conducted and
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3 reported elsewhere and cited as reference 18. Additional data is available by emailing the first
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5 author.
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9 10 **Figure Legends**

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12 Figure 1. Consort Flow-Chart of Participants (no legend)

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14 Figure 2. Future Intention-to-Screen Scores at Pre, Post, and Three Month Follow-up

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16 ○ — Community Jury Group;
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18 △ — Control Group
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21 Foot note for Figure 2

22 Note: CJ=Community Jury group; M = mean score; p values based on ANCOVA analyses
23 pre to post and pre to 3 month follow-up.
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Box 1.**Knowledge Questions from Surveys* (answers considered correct highlighted)**

1. Is routine testing for prostate cancer recommended by RACGP Guidelines?

- Yes No Don't know

2. How accurate do *you* think the prostate specific antigen (PSA) blood test is for diagnosing prostate cancer?

- Reasonably accurate but some people *who do* have cancer can have a negative test result (false negative)
- Reasonably accurate but some people *who do not* have cancer can have an abnormal result (false positive)
- The PSA test is not always accurate because it can have both false positive or false negative results
- The PSA test is completely accurate
- Don't know

3. In terms of your knowledge about Prostate cancer, could you list some treatment options?

- No Yes, please list

4. Could you list some potential side effects of treatments for prostate cancer?

- No Yes, please list

*There were originally six knowledge questions however the answers for two (one on prevalence and the other on mortality rates of prostate cancer) were incorrect and were deleted from analyses.

Table 1. Participants Demographics

		Community Jury (n=12)	(SD/%)	Control (n=14)	SD/%
<i>Age</i>					
	Mean	61	(4.8)	62	(4.9)
<i>Number previous PSA tests</i>					
	Mean	3.9	(3.6)	2.2*	(1.8)
<i>Routine PSA testing saves lives</i>					
Frequency	yes	7	(58%)	9	(64%)
	no	2	(17%)	2	(14%)
	don't know	3	(25%)	3	(21%)
<i>Education</i>					
Frequency	High school or less	2	(17%)	4	(28%)
	some uni or TAFE	4	(33%)	4	(28%)
	uni/TAFE graduate	4	(33%)	1	(7%)
	uni postgrad	2	(17%)	5	(36%)
Note. * n=13, (1 missing); TAFE = Technical and Further Education Institutions					

Table 2. Where do Men Receive Information about Testing for Prostate Cancer? (N=26)

	Agree	(%)
I don't look for information	3	(12)
Family and friends	11	(42)
Internet	10	(38)
Media	9	(35)
General practitioner	17	(65)
Urologist/specialist/hospital	5	(20)
Note: men could endorse more than one source		

Table 3. Linear Regression Analysis Predicting Future Intention-to-Screen for Prostate Cancer

	<i>Coefficient</i>	<i>SE B</i>	CI Lower	CI Upper	<i>p</i>
Constant	-0.16	1.69	-3.66	3.35	0.93
Pre-assessment intention-to-screen score	0.74	0.18	0.36	1.11	0.001
Number of previous PSA tests	0.63	0.22	0.18	1.07	0.008
Group (Community Jury/Control)	-3.69	1.19	-6.16	-1.21	0.005

Note. N=25; CI= confidence interval;
These data are slightly different to Rychetnik et al (2014) analyses as they are based on intention-to-treat.

Table 4. Changes in Men's Knowledge Scores from Pre-to Post-assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	4	(42)	3	(25)	1	(8)	3	(25)	0.08
	control*	1	(8)	1	(8)	1	(8)	10	(77)	
how accurate is the PSA test?	community jury	6	(50)	4	(33)	1	(8)	1	(8)	0.03
	control	2	(14)	9	(64)	0	(0)	3	(21)	
list possible treatment options	community jury	2	(17)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	
list possible side effects of treatments	community jury	3	(25)	7	(58)	0	(0)	2	(17)	0.6
	control	3	(21)	7	(50)	0	(0)	4	(27)	

Note: *n=13 (1 missing)

Table 5. Changes in Men's Knowledge Scores Post- to Follow-up Assessment

		Wrong to Right		Right to Right		Right to Wrong		Wrong to Wrong		<i>p</i>
		n	(%)	n	(%)	n	(%)	n	(%)	
Recommended by guidelines?	community jury	0	(0)	7	(58)	1	(8)	4	(33)	0.7
	control*	0	(0)	1	(7)	1	(7)	11	(85)	
how accurate is the PSA test?	community jury	0	(0)	10	(83)	0	(0)	2	(17)	0.1
	control	2	(14)	9	(64)	2	(14)	1	(7)	

Note: *n=13 (1 missing)

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Figure 1. Consort Flow-Chart of Participants

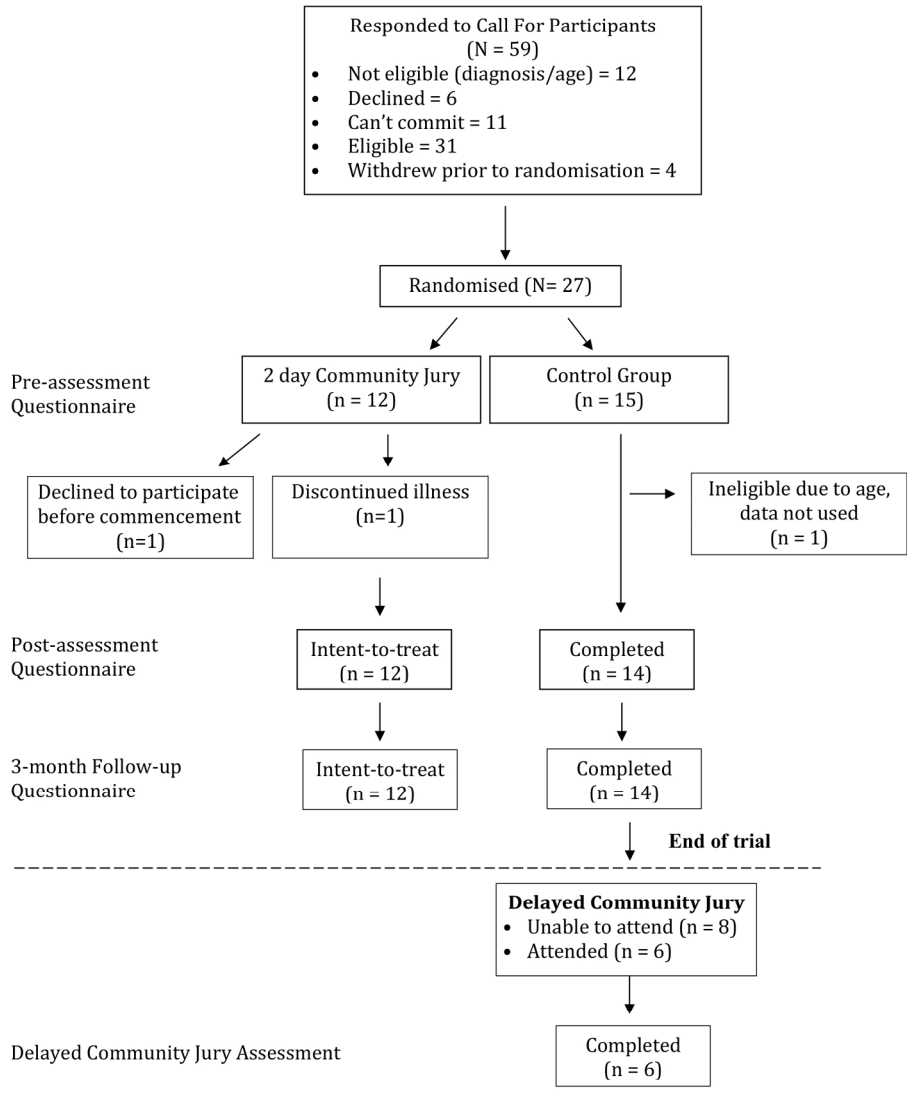
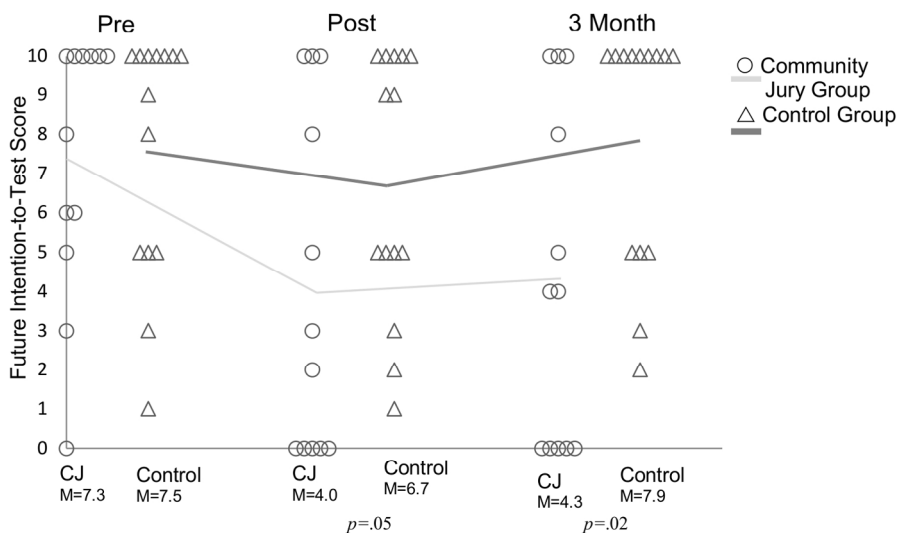


Figure 2. Future Intention-to-Screen Scores at Pre, Post, and Three Month Follow-up



Note: CJ=Community Jury group; M = mean score; p values based on ANCOVA analyses pre to post and pre to 3 month follow-up.

view only



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6-7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8-9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5-7
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	10-11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11-12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-13
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.