ANZCTR
Australian New Zealand Clinical Trials Registry

Questions in **bold** text are mandatory. **(*)**

Request Number:	343044
Current Page:	Review

Trial from ANZCTR

Trial ID	ACTRN12612000723886
Trial Status:	Registered
Date Submitted:	15/06/2011
Date Registered:	6/07/2012
	Retrospectively registered

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Public title	A randomised controlled trial of an interactive decision aid for prostate cancer screening
Study title in 'Participant- Intervention- Comparator- Outcome (PICO)' format	A randomised controlled trial of an online interactive decision aid applied to prostate cancer screening for men aged 40 to 69 years, assessing decision quality
Secondary ID [1]	None
UTN	U1111-1121-9610
Trial acronym	None

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Health condition(s) or problem(s) studied:	
PSA testing for prostate cancer.	
Condition category:	**Condition code:**
Public Health	Health promotion/education
Public Health	Epidemiology
Cancer	Prostate

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Descriptions of intervention(s) / exposure	We have developed an online decision aid ('My Prostate Cancer Screening Annalisa') for men aged 40 to 69 years. The aid summarises the evidence for the benefits, potential harms and other factors associated with screening and elicits individual participant's preferences for each factor associated with the decision to screen (the benefits, potential harms and other factors). Responses to these questions are used to generate a personalised decision aid for the user. There are two arms of the trial: Control arm: Users are asked to indicate how important 5 attributes of prostate cancer screening (benefits and potential harms) are to them; these were pre-installed by researchers based on literature (RCT data) and a pilot study (i.e. the attributes are fixed). This arm is referred to as My Prostate Cancer Screening Annalisa: Fixed Attributes. Intervention arm: Users are asked to choose the attributes they would like to include in their decision aid, from a total of 10 attributes. That is, users pick their own attributes. This arm is called My Prostate Cancer Screening Annalisa: You Choose. The control decision aid takes about 15 minutes to complete. The intervention decision aid takes about 18 minutes to complete.
Intervention Code:	Early detection / Screening
Intervention Code:	Prevention
Comparator / control treatment	The comparator is the 'fixed attribute' interactive decision aid.
Control group	Active

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Primary Outcome:	Primary outcome: Decision quality as measured by "MyDecisionQuality" an eight point scale that encompasses dimensions of making a high quality health decision.
***Timepoint*:**	Baseline (after completion of interactive decision aid).

Secondary Outcome:	Secondary Outcome 1: The proportion of the intervention and control group who indicate they are more likely to visit their GP to discuss PSA testing after interacting with either the 'Pick Your Own' (PYO) or Fixed Attribute (control group) decision aids. (The PYO version is where participants choose, from a list of 10 attributes, the ones they think are important to them). This will be assessed in the online questionnaire by asking participants to indicate how likely they are to see their GP about PSA testing before and after they use the appropriate decision aid.
Timepoint:	After interaction with the decision aid.

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Key inclusion criteria	40-69 year old men living in Australia who have access to the internet and a reasonable command of the English language.
Minimum age	40 Years
Maximum age	69 Years
Gender	Males
Healthy volunteers?	Yes
Key exclusion criteria	No access to the internet, insufficient English, younger than 40 years or older than 69 years.

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Study type	Interventional
Purpose of the study	Educational / counselling / training
Allocation to intervention	Randomised controlled trial
Describe the procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	Global Market Insite, Inc. (GMI) will recruit 1,398 participants from their panel of 130,000 Australians. Eligible participants who agree to be in the study will be randomly allocated to one of the two arms of the study. This is done centrally by computer.
Describe the methods used to generate the sequence in which subjects will be randomised (sequence generation)	For each of the three age strata simple randomisation is performed using a randomisation table created by computer software (i.e. computerised sequence generation).
Masking / blinding	Open (masking not used)
Who is / are masked / blinded (choose all that apply)	
Assignment	Parallel
Other design features	
Type of endpoint (s)	Efficacy
Statistical Methods/Analysis	

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Phase	Not Applicable
Anticipated date of first participant enrolment	9/06/2011
Date of first participant enrolment	
Anticipated date last participant recruited/enrolled	
Actual date last participant recruited/enrolled	
Target sample size	1398
Recruitment status	Completed

Recruitment in Australia

Recruitment state(s)	NSW,VIC,ACT,QLD,SA,WA,NT,TAS

Recruitment outside Australia

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Funding Source:	Government body
Name:	National Health and Medical Research Council (NHMRC)
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Country:	Australia
Primary Sponsor	Individual
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Secondary Sponsor:	None
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Has the study received approval from at least one Ethics Committee?	Yes
Ethics Committee name:	University of Sydney Human Research Ethics Committee
Address:	Level 6 Jane Foss Russell Building (G02) The University of Sydney, NSW 2006
Country:	Australia
Approval Date:	02/06/2011
Submitted Date:	31/03/2011
HREC:	05-2011/13712
Brief summary	This study aims to evaluate an online interactive decision aid for prostate cancer screening. Who is it for? You can join this study if you are a male aged 40-69 years who lives in Australia. You must have access to the internet and a reasonable command of the English language. Trial details Participants in this trial will complete an online decision aid for prostate cancer screening. This easy to use interactive decision aid asks men to rate the importance of factors that are relevant to making a high quality

	decision, and to weigh up the potential benefits (e.g. avoiding the potential loss of lifetime by early detection of prostate cancer) and harms (e.g. false positive test results and unnecessary treatments) of PSA testing for prostate cancer. Participants will be randomly (by chance) assigned to one of two groups. One group will complete the 'Fixed Attributes' version of the decision aid and the other group will complete the 'You Choose' version. The usefulness of the decision aid will be assessed via a series of questions asking the respondents to rate aspects of the quality of the decision about prostate cancer screening.
Trial website	
Trial related presentations / publications	
Public Notes	

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