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# BMJ Open

## Multimedia for delivering participant informed consent

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# 1 **Multimedia for delivering participant informed consent**

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23  
24 **Key words:** personal autonomy, bioethics, research conduct, participant decision-making,  
25 participant comprehension.

## 26 **Abstract**

27 **Objective.** Obtaining informed consent is a cornerstone requirement of conducting ethical  
28 research. Traditional paper-based consent is often excessively lengthy, legalistic in character,  
29 and may fail to achieve desired participant understanding of study requirements. Multimedia  
30 tools including video and audio may be a useful alternative. This study aimed to determine  
31 the efficacy, usability and acceptability of stand-alone multimedia delivery of participant  
32 consent.

33 **Design.** A single-centre, randomised, prospective study to determine the efficacy, usability  
34 and acceptability of a multimedia consent process (intervention) compared with the  
35 traditional paper-based approach (control). Intervention was free of research staff and  
36 included short audio-visual explanations, with computer-based finger-signed consent.

37 **Setting.** Pathology blood collection services in Hobart, Tasmania, Australia.

38 **Participants.** 298 participants (63±8 years; 51% female) referred from general practice to  
39 pathology services were randomised to intervention (n=146) and control (n=152). Outcome  
40 measures.

41 Outcome measures. Efficacy, usability and acceptability of the allocated consent process  
42 were assessed by questionnaire.

43 **Results.** All participants successfully completed allocated interventions. Efficacy parameters  
44 were significantly higher among intervention participants, including better understanding of  
45 study requirements compared with controls ( $P<0.05$  all). Intervention participants were also  
46 significantly more likely to engage with the study information and spend more time on the  
47 consent process ( $P=0.038$  and  $P=0.007$ , respectively). Both groups reported similar levels of  
48 acceptability of the consent process, although more control participants reported that the  
49 study information was too long (24% versus 14%;  $P=0.020$ ).

50 **Conclusion.** A standalone multimedia consent process is effective for achieving participant  
51 understanding and obtaining consent in a clinical research setting free of research staff. Thus,  
52 multimedia represents a viable method to reduce the burden on researchers, meet participant  
53 needs, and achieve informed consent in clinical research.

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6 56 **Article summary**  
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8 57 **Strengths and limitations of this study:**  
9  
10 58 • This is the largest randomised evaluation of a standalone multimedia consent process.  
11 59 • Multimedia consent tools were developed in collaboration with community members.  
12  
13 60 • Multimedia was an acceptable, efficient and effective alternative to traditional consent  
14  
15 61 processes in medical research.  
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17 62 Generalisability of the findings will need to be confirmed in further studies.  
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## Article summary

### Strengths and limitations of this study:

- This is the largest randomised evaluation of a standalone multimedia consent process.
- Multimedia consent tools were developed in collaboration with community members.
- Multimedia was an acceptable, efficient and effective alternative to traditional consent processes in medical research.

Generalisability of the findings will need to be confirmed in further studies.

## 64 **Introduction**

65 Informed consent is a cornerstone procedure of ethically conducted medical research.  
66 Consent processes aim to ensure potential participants are fully informed prior to deciding to  
67 take part in research. Guidelines emphasise the need for full disclosure of study information  
68 including the aims, requirements, risks, benefits, funding and conflicts of interest, with the  
69 view that more information facilitates better informed decision-making. [1–3] However, this  
70 has resulted in lengthy consent processes that are burdensome for both researchers and  
71 participants, while often failing to achieve the desired level of participant understanding. [4–  
72 11] Indeed, as few as 50% of participants understand study information, including associated  
73 risks and that participation is voluntary.[5] These shortcomings, as well as the emergence of  
74 complex contemporary methods, including biobanking, gene sequencing, linked data, remote  
75 research and large-scale trials often spanning multiple countries, have led to calls to update  
76 consent guidelines to more appropriately reflect the modern research landscape.[12–15]  
77 Multimedia delivery of information via video and audio platforms may offer an effective  
78 alternative or complementary tool to traditional consent processes. Previous reviews  
79 evaluating the efficacy of multimedia tools in the consent process have been  
80 inconclusive.[4,16,17] This ambiguity may be due to heterogeneous study designs and  
81 population characteristics. Moreover, previous research focused on using multimedia to  
82 augment traditional research consent processes rather than multimedia as a standalone  
83 process making it difficult to discern the generalisability and utility of multimedia for  
84 consent. In any case, there appears to be good acceptability and usability of multimedia tools  
85 used within the consent process with respect to participant satisfaction and facilitating  
86 recruitment, but also for understanding information in a non-research (clinical) setting.[16–  
87 18] As far as we are aware, there has never been a study to determine if consent for  
88 participation in research can be appropriately delivered in the absence of research staff using  
89 a standalone multimedia process compared to the traditional paper-based approach in the  
90 presence of research staff. This study sought to determine this during the consent process for  
91 people being recruited to participate in a clinical research project that focused on  
92 cardiovascular risk assessment.

## 93 **Methods**

### 94 **STUDY PROTOCOL**

1  
2  
3 95 This research was undertaken in the context of a study testing the use of a computer-based  
4 96 application (app) to gather information for the assessment of absolute cardiovascular disease  
5 97 risk within a clinical setting. The study was performed in concordance with ethical approval  
6 98 obtained from Tasmanian Human Research Ethics Committee [H0015648]. Participants  
7 99 referred by a general practitioner to pathology services were approached for involvement in  
8 100 the cardiovascular risk assessment study by the pathology services receptionist. Inclusion  
9 101 criteria for participation included those with a referral for a full lipid profile aged between 45  
10 102 and 74 in accordance with absolute cardiovascular risk assessment guidelines. [19]  
11 103 Participants who were interested in involvement in the cardiovascular risk assessment study  
12 104 were randomised to receive standalone multimedia consent (intervention) or traditional  
13 105 paper-based consent with a researcher (control) (Figure 1). Due to the setting of the study  
14 106 field notes were used to collect data on why participants did not take part after initial  
15 107 eligibility screening.

16 108 Both groups received a short demonstration on how to use the app. The demonstration was  
17 109 quick with rudimentary instructions provided as it was intended to be delivered by pathology  
18 110 staff in under a minute who would then resume normal clinical duties. The intervention group  
19 111 were shown how to play the study video and audio and advised to engage with the  
20 112 information until they had decided if they wanted to take part, at which point they could  
21 113 provide their consent or leave without taking part. The control group were provided with the  
22 114 paper-based information sheet by a researcher, advised to read and asked if they needed  
23 115 assistance or had any questions as per conventional consent processes. Both groups provided  
24 116 signed consent using their finger on a touchscreen monitor via the app to proceed to the  
25 117 cardiovascular assessment. Immediately after the app cardiovascular risk assessment, each  
26 118 participant was asked to complete a questionnaire to evaluate the efficacy, usability and  
27 119 acceptability of the consent process they had undertaken.

## 28 120 RANDOMISATION

29 121 Referred patients that met the criteria for participation received a postcard that contained  
30 122 basic information about the study (Supp 1, Study Postcard). A total of 831 participants were  
31 123 identified as eligible for participation in the cardiovascular risk assessment study, from these,  
32 124 303 were randomised to participate (Figure 2). Randomisation was determined by computer  
33 125 program on a 1:1 ratio prior to recruitment. It was not possible to blind participants to their  
34 126 allocated interventions because multimedia was obviously different to paper-based consent.



## 127 DELIVERY OF PAPER-BASED CONSENT PROCESS AS THE STUDY CONTROL

128 Control participants received a two-page paper-based study participant information sheet  
129 compliant with the requirements of the National Health and Medical Research Council and  
130 Australian Research Council, National Statement on Ethical Conduct in Human Research.[1]  
131 The first page provided information on the aims, participation requirements and why  
132 participants were invited to take part. The second page detailed the risks, benefits, funding  
133 sources, ethical approval and privacy protections. The control consent process involved the  
134 participant being asked to read the information sheet in the presence of a researcher who  
135 provided further information and answered questions as requested (as per usual practice).

## 136 DELIVERY OF MULTIMEDIA CONSENT PROCESS AS THE STUDY 137 INTERVENTION

138 Intervention participants received study participation information via multimedia approach  
139 using a three-minute animated video and additional audio content using the same terminology  
140 and content as the paper-based study participant information sheet. The study video was  
141 congruent with the first page of the information sheet and focused on the aims and  
142 requirements of the study (Supp 2. Study Video). The additional audio content, which was  
143 optional for participants to engage with, was congruent with the second page of the  
144 information sheet and provided information on study funding, ethical approval, risks and  
145 benefits associated with participation and privacy protection.

146 A multidisciplinary team of research staff, graphic designers and communications staff  
147 developed the study video through an iterative approach including feedback from community  
148 members typical of the target demographic.

## 149 PATIENT AND PUBLIC INVOLVEMENT

150 Community members reviewed and contributed to all aspects of study materials including the  
151 questionnaires, multimedia and paper-based study information and advised on the content  
152 that was included in the final version.

## 153 SETTING AND CONSENT ENVIRONMENT

154 All study procedures took place on the premises of pathology services. A purpose-built booth  
155 was designed for the study (Figure 1). The study booth provided a private environment for

1  
2  
3 156 the consent process and clinical data collection. The booth contained a bench with the  
4  
5 157 computer that delivered the study app, a chair and a curtain for privacy.  
6

## 7 158 ASSESSMENT OF CONSENT PROCESS

9  
10 159 The evaluation questionnaire was delivered by a researcher at a separate work station after  
11  
12 160 participants completed all study processes in the booth. A 12-item questionnaire was used to  
13  
14 161 assess efficacy, usability and acceptability of the consent process. The questionnaire was  
15  
16 162 mixed methods with dichotomous and multiple-choice questions, each with a comment box  
17  
18 163 for open-ended responses.

### 19 164 *Efficacy and usability of the consent process.*

21  
22 165 The effectiveness of the allocated consent processes to inform participants about the study  
23  
24 166 was assessed via two measures: 1) the extent to which participants understood participation  
25  
26 167 was voluntary and 2) participant understanding of specific aspects of study participation by  
27  
28 168 true or false questions. Four measures denoting user-friendliness of the allocated consent  
29  
30 169 processes were used to indicate usability: 1) participant engagement with the study  
31  
32 170 information, 2) participant perceived understanding of the study, 3) successful completion of  
33  
34 171 the consent process and 4) the time taken to complete the consent process. The app  
35  
36 172 automatically recorded the time for both groups as the app set-up and demonstration took  
37  
38 173 place before the consent process. The time included the set-up, the consent process and the  
39  
40 174 cardiovascular assessment questionnaire.

### 41 175 *Acceptability of the consent process.*

42  
43 176 Three indicators of acceptability of the consent process were used: 1) was there sufficient  
44  
45 177 information available to give consent 2) were participants satisfied with the length of the  
46  
47 178 study information; and 3) what was the preferred method of information delivery for deciding  
48  
49 179 to take part in research.

## 50 180 DATA ANALYSIS

51  
52 181 Data are presented as mean and standard deviation or percentage of the total sample. For  
53  
54 182 comparison of categorical variables, percentage differences were tested using Chi<sup>2</sup> tests; *t* test  
55  
56 183 was used for continuous variables. For all statistical tests, a *P* value of <0.05 was considered  
57  
58 184 significant. Analysis was conducted by a researcher blinded to allocation. Analyses were  
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2  
3 185 performed using R statistical software version 3.5.3 (R Foundation for Statistical Computing,  
4 186 Vienna, Austria).

## 187 **Results**

### 188 PARTICIPANT CHARACTERISTICS

189 There were no differences in sociodemographic characteristics between the intervention and  
190 control groups (Table 1). Participants were predominantly white and middle-older aged. Half  
191 of participants had completed an undergraduate degree or higher, and a quarter were in full-  
192 time employment. From field notes, the main reason participants did not progress from  
193 eligibility screening to study participation was due to time constraints as many were attending  
194 pathology services before going to work.

### 195 EFFICACY AND USABILITY OF MULTIMEDIA INTERVENTION VERSUS 196 CONTROL

197 Intervention participants demonstrated better understanding of the follow-up requirements  
198 and data sharing practices of the study compared with control participants (Table 2,  $P < 0.001$   
199 and 0.025, respectively). Intervention participants were more likely to engage with the study  
200 information and spend more time on the consent process and study questionnaire (Table 2,  $P$   
201 = 0.038 and 0.006, respectively)).

202 Thirty-seven participants (15 intervention, 22 control) commented on ways to improve their  
203 understanding of the study. The themes of these comments focused on simplifying the study  
204 information sheet, adding more information to the study postcard, providing a variety of  
205 information delivery options for participants to choose from and providing participants with  
206 updates on the research outcomes of the study. Four participants in the control group  
207 requested assistance with the consent process as they did not have their reading glasses to  
208 read the information sheet. No participants in the intervention group requested assistance.

### 209 ACCEPTABILITY OF MULTIMEDIA INTERVENTION VERSUS CONTROL

210 Both groups reported similar levels of acceptability (Table 3), although more control  
211 participants reported that the study information was too long and had a greater preference for  
212 paper-based information delivery ( $P = 0.020$ ). On average only 4% of participants reported a  
213 preference for a researcher to be present and there was no difference between groups.

## 214 **Discussion**

1  
2  
3 215 The key finding from this study is that a multimedia consent process free from research staff  
4 216 was a suitable mode for delivering study information and obtaining informed consent for a  
5 217 clinical research study. Additionally, multimedia delivery of study information improved  
6 218 participant understanding of aspects of study involvement. High acceptability of both consent  
7 219 processes was reported in this population of middle-to-older aged, community dwelling  
8 220 adults. These findings suggest that multimedia is an acceptable, efficient and effective  
9 221 alternative to traditional consent processes in medical research.

16 222 The evidence on using multimedia to enhance the traditional consent process has  
17 223 concentrated on participants with special needs such as low literacy, mental health issues or  
18 224 children.[20–23] Moreover, previous work focused on augmenting the traditional consent  
19 225 approach with multimedia tools, rather than comparing a truly standalone multimedia consent  
20 226 process, as we have done in this current study. Our study design fulfils an identified research  
21 227 gap on the need for high-quality comparisons of multimedia delivery of consent compared  
22 228 with the traditional approach for research.[17] One small study assessed the effectiveness of  
23 229 standalone multimedia information delivery, but this was in the setting of consent for surgery  
24 230 rather than research participation. In that study, they found that 98% of multimedia  
25 231 participants understood the information provided compared to 88% that received  
26 232 conventional verbal consent. [18] Our findings further develop this knowledge beyond a  
27 233 special population and in a much larger sample to confirm that a standalone multimedia  
28 234 platform should be generalisable for use among populations without special needs, such as  
29 235 community dwelling, older adults (i.e. average age 63 years). With the potential to enhance  
30 236 current consent processes, further work is needed in diverse populations from other  
31 237 institutions to investigate the generalisability of multimedia consent processes.

44 238 Ethical conduct is paramount in medical research, and consent processes need to adapt to  
45 239 adequately reflect modern attitudes and contemporary research practices.[13–15] This current  
46 240 study is relevant to the calls to update consent guidelines to better support participant  
47 241 autonomy and move away from an unwieldy approach of full-disclosure, to one that supports  
48 242 values-based decision making for participants.[13,24,25] Our findings indicate as few as 4%  
49 243 of participants would prefer research staff to be present during the consent process  
50 244 Importantly, we observed starkly different levels of participant engagement with study  
51 245 information, with only 9% of participants in the multimedia group choosing to listen to  
52 246 additional audio segments on the more technical aspects of research governance. This  
53 247 indicates that participant engagement with study information is highly individual and

248 engaging with all study information is not necessarily a priority for making an autonomous  
249 choice for most participants. Accordingly, consent processes, such as we have provided using  
250 multimedia, should support participant autonomy by providing options to engage with study  
251 information relevant to their values to aid decision-making processes.

## 252 IMPLICATIONS FOR RESEARCH AND PRACTICE

253 A key benefit of the standalone consent process evaluated in this research is its potential to  
254 improve participant understanding of study information while reducing the burden of consent  
255 for research staff. Another key advantage is the possible health economic benefit. Current  
256 healthcare consumers are highly 'information-savvy' and may seek the delivery of  
257 information from different platforms, including consumer-informatics platforms.[26] We  
258 suggest that the societal health economics benefits that are realised through better delivery of  
259 consent information will drive cost savings both in the short and longer terms. Short term  
260 health economics savings include the cost of time and the uptake of information that is more  
261 beneficial (and better understood) by the consumer. Longer term health economics savings  
262 could include cost savings to the healthcare system through improved understanding of both  
263 benefits and risks to participation, improved health literacy, and perhaps positive healthy  
264 ageing lifestyle modifications during and after participation.

265 Although attempts at standardisation of conventional paper-based consent processes have  
266 been made, achieving standardised consent delivery by study personnel is  
267 challenging.[1,2,27] Multimedia tools offer an inherently standardised method of information  
268 delivery, as the delivery is predetermined, that would otherwise be difficult to achieve in  
269 standard consent processes undertaken in multi-site research projects with large staff teams.  
270 Several software packages that support the development and/or delivery of multimedia  
271 consent processes are publicly available, and many can also be used to collect data as we did  
272 in this study (e.g. Research Electronic Data Capture; REDCap). This is an attractive  
273 alternative to current consent processes.[28]. The findings of this present study highlight that  
274 multimedia information delivery achieves desired levels of participant understanding and is  
275 as appropriate as the traditional paper-based approach for obtaining participant consent.  
276 Indeed, in a number of settings it may be more desirable, such as large-scale multisite clinical  
277 trials.[29,30]

## 278 STRENGTHS AND LIMITATIONS

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3 279 A key strength of this work is the randomised evaluation design among a sizeable study  
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5 280 sample, conducted in a real clinical setting, and demonstrates the value of this approach in a  
6  
7 281 minimal or low risk research protocol. Further work is needed to explore the acceptability  
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9 282 and appropriateness of consent processes independent of research staff before it is  
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11 283 implemented for more complex research with higher levels of participant risk. Potential  
12  
13 284 limitations include the possibility of selection bias as participation was by self-selection after  
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15 285 the initial eligibility screening in people attending a pathology service with a cholesterol  
16  
17 286 referral. We cannot be sure whether the findings will be generalisable beyond our study  
18  
19 287 population and this will need to be tested in future. Additionally, it was not possible to use  
20  
21 288 validated evaluation tools to assess the efficacy, usability and acceptability of the consent  
22  
23 289 process due to time constraints of undertaking a research protocol within a pathology services  
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25 290 setting. It was not feasible to notify participants about the research prior to presenting at  
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27 291 pathology services and all participants had to take part on the same day their blood sample  
28  
29 292 was collected. For this reason, the entire process had to be shorter than 20 minutes to  
30  
31 293 minimise disruption to participants and pathology services.

## 32 294 CONCLUSION

33 295 A standalone, multimedia consent process free from research staff is an effective and  
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35 296 acceptable approach to appropriately deliver participant information and receive informed  
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37 297 consent for minimal and low risk research. Our findings imply that multimedia consent  
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39 298 processes are suitable for reducing the burden on research staff and improving the delivery of  
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41 299 consent for research.  
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12 306 acquisition of data. NC, RM, and JS interpreted the data, drafted the article and revised it  
13 307 critically for intellectual content. All authors contributed to drafts of the article and provided  
14 308 final approval of the version to be published and accept accountability for article integrity.  
15  
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21

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27 313 author.  
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Table 1. Sociodemographic and clinical characteristics of study participants randomised to multimedia intervention or control delivery of study information and informed consent.

Variable	Control (n=152)	Intervention (n=146)
<b>Age (years)</b>	63±8	63±7
<b>Male (%)</b>	50	48
<b>Education (%)</b>		
High school	24	21
Certificate, diploma or apprenticeship	16	21
University degree or higher	53	52
<b>Employment (%)</b>		
Employed	44	44
Retired	37	37
Other	12	9
<b>Ethnicity (%)</b>		
White	86	90
Aboriginal or Torres Strait Islander	1	1
Asian	2	3
Other	1	1

Data are expressed as percentage of the total the sample size or mean ± standard deviation. Response rates varied from 135 - 152 for Control and 133 - 146 for Intervention. No significant differences were observed between the groups.

Table 2. Efficacy and usability of informed consent process of study participants randomised to multimedia intervention or control delivery of study information and informed consent.

Variable	Control (n = 152)	Intervention (n = 146)	P Value
<b>Efficacy</b>			
Taking part was completely voluntary (% yes)	99	99	0.17
The right to withdraw from the study at any time. (% correct)	94	93	0.89
Baseline participation requirements. (% correct)	98	99	0.09
Follow-up participation requirements. (% correct)	54	87	<0.001
Data sharing with referring practitioner. (% correct)	87	93	0.025
<b>Usability:</b>			
Engaged with the study information. (%)	70	80	0.038
Perceived understanding of the study could be improved. (%)	18	11	0.075
Successfully completed the consent process (%)	100	100	1
Total duration (minutes (range))	8.4 (2.1 – 30.5)	9.6 (3.3 – 17.3)	0.006

Data are expressed as percentages of the group total.

Table 3. Acceptability of participant information and informed consent process of study participants randomised to multimedia intervention or control delivery of participant information and informed consent.

Variable	Control (n = 152)	Intervention (n = 146)	P value
Sufficient information was available to provide consent: (%)			
Yes	95	95	0.73
There was too much	1	1	0.97
There was not enough	3	3	0.69
Not sure	1	0	0.16
The study information was too long. (%)	24	14	0.020
Preferred method of information delivery: (%)			
Paper-based written document	58	41	0.004
Multimedia	18	28	0.048
A researcher must be present	5	3	0.39
No preference	16	21	0.29

Data are expressed as percentages of the group total.

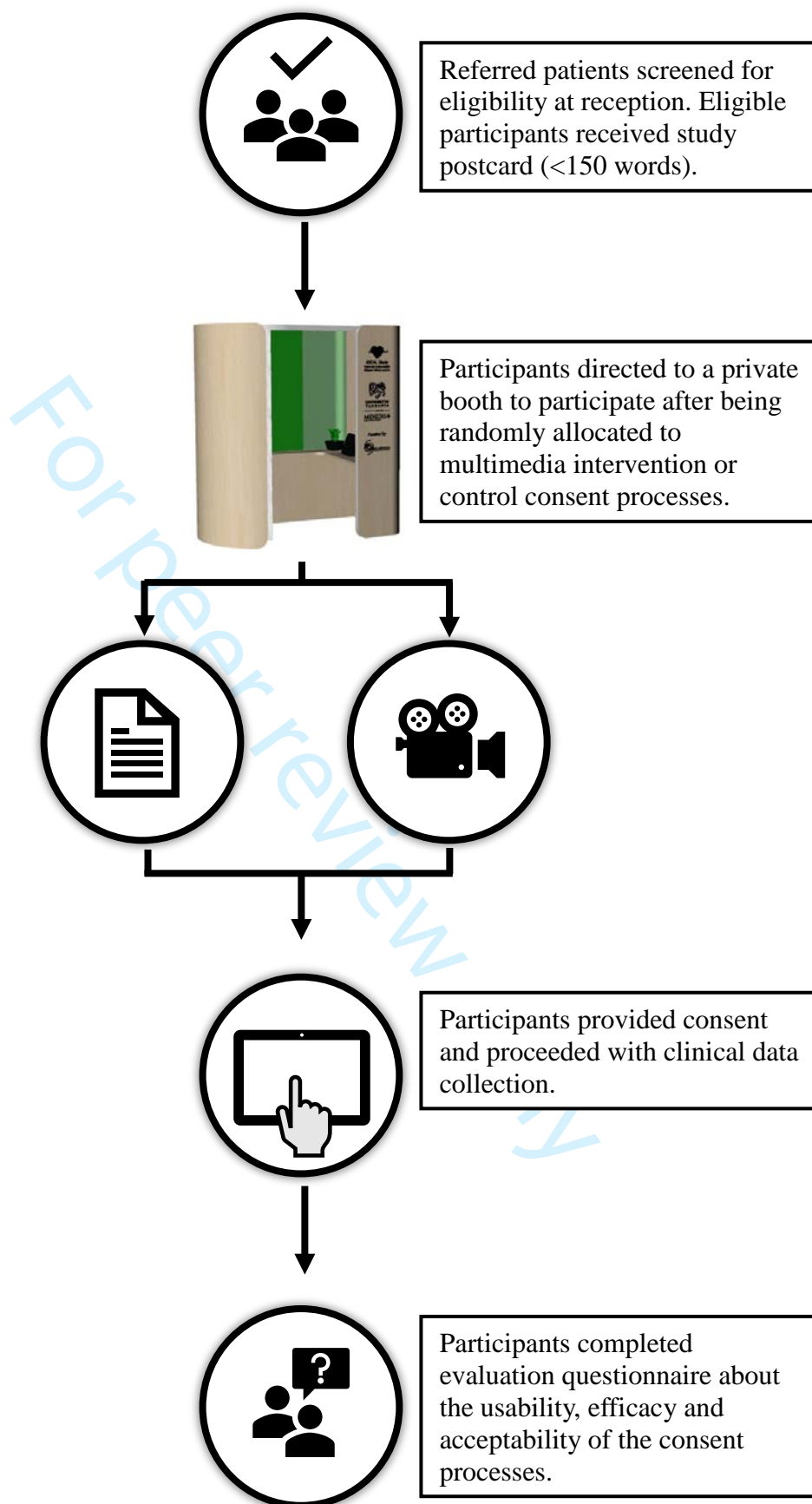


Figure 1. Flow diagram of study protocol.

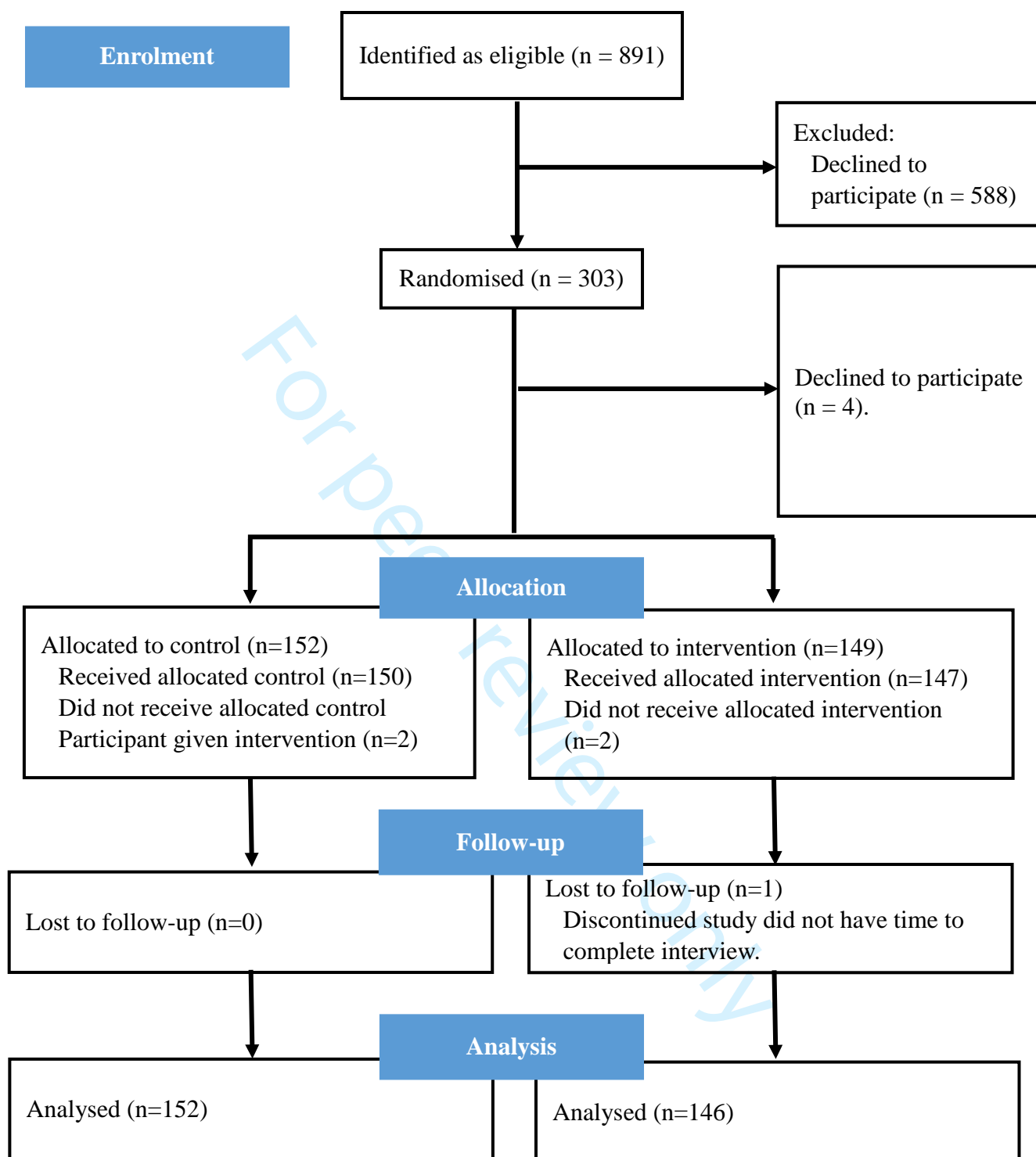


Figure 2. Participant flow diagram.

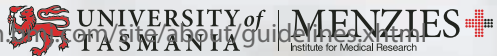


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## IDEAL Study

Improved cardiovascular  
Disease hEALth service  
delivery in Australia

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# IDEAL Study

The IDEAL study aims to lower the risk of people developing cardiovascular disease, including heart attack and stroke.

Patients attending Hobart Pathology, 20-22 Gregory St, Sandy Bay, for a cholesterol test may be eligible to participate.

If you wish to participate, medical health information and blood pressure will be recorded in a specially built booth.

A risk score on the chances of having a cardiovascular event in the next five years will be calculated and sent to your GP.

This risk score is based on best-practice medicine and is designed to help doctors

make better-informed decisions to manage the risk of cardiovascular disease.

You may also be invited to attend optional follow-up studies, which include a full cardiovascular assessment or attending a focus group on cardiovascular disease and primary healthcare.

## For further information

Email: [menzies.ideal@utas.edu.au](mailto:menzies.ideal@utas.edu.au)

Phone: (03) 6226 7700

For peer review only - [http://www.menzies.utas.edu.au/research/ideal\\_study](http://www.menzies.utas.edu.au/research/ideal_study)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract <b>Study title.</b> (b) Provide in the abstract an informative and balanced summary of what was done and what was found <b>Abstract submitted.</b>
<b>Introduction</b>		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported <b>Page 3, lines 64-90.</b>
Objectives	3	State specific objectives, including any prespecified hypotheses <b>Page 3, lines 90-92.</b>
<b>Methods</b>		
Study design	4	Present key elements of study design early in the paper <b>Page 5, lines 95-119.</b>
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection <b>Page 5, line 95-97.</b>
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants <b>Page 5, line 100-105.</b>
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable <b>Page 7, lines 158-179.</b>
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group <b>Page 7, lines 158-179.</b>
Bias	9	Describe any efforts to address potential sources of bias <b>Page 5, line 120.</b>
Study size	10	Explain how the study size was arrived at <b>Page 5, line 100-105., sample size was derived based on a separate study.</b>
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why <b>Page 7, lines 158-179.</b>
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding <b>Page 7, lines 180-186.</b> (b) Describe any methods used to examine subgroups and interactions <b>Page 7, lines 180-186.</b> (c) Explain how missing data were addressed NA (d) If applicable, describe analytical methods taking account of sampling strategy NA

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(e) Describe any sensitivity analyses

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**Results**

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed <b>Page 8, lines 188-194 and Figure 1.</b> (b) Give reasons for non-participation at each stage <b>Figure 1.</b> (c) Consider use of a flow diagram <b>Figures 1 and 2.</b>
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders <b>Page 8, lines 188-194 and Table 1.</b> (b) Indicate number of participants with missing data for each variable of interest NA
Outcome data	15*	Report numbers of outcome events or summary measures <b>Page 8, lines 195-213.</b>
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included NA (b) Report category boundaries when continuous variables were categorized NA (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses NA
<b>Discussion</b>		
Key results	18	Summarise key results with reference to study objectives <b>Page 9, lines 215-221.</b>
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias <b>Page 11, lines 279-293.</b>
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence <b>Page 9-10, lines 222-251.</b>
Generalisability	21	Discuss the generalisability (external validity) of the study results <b>Page 10, lines 253-277.</b>
<b>Other information</b>		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based <b>Provided under funding section, page 12, lines 310-311.</b>

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2 \*Give information separately for exposed and unexposed groups.  
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# BMJ Open

## A self-directed multimedia process for delivering participant informed consent

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Secondary Subject Heading:	Research methods
Keywords:	ETHICS (see Medical Ethics), Clinical trials < THERAPEUTICS, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT
Note: The following files were submitted by the author for peer review, but cannot be converted to PDF. You must view these files (e.g. movies) online.	
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3 1 **A self-directed multimedia process for delivering participant informed**  
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5 2 **consent**  
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19 **Word count:** abstract: 250 text: 3,003

20 **References:** 31

21 **Figures:** 2

22 **Tables:** 3

23 **Supplementary files:** 2

24  
25 **Key words:** personal autonomy, bioethics, research conduct, participant decision-making,  
26 participant comprehension.

## 27 **Abstract**

28 **Objective.** Obtaining informed consent is a cornerstone requirement of conducting ethical  
29 research. Traditional paper-based consent is often excessively lengthy and may fail to achieve  
30 desired participant understanding of study requirements. Multimedia tools including video  
31 and audio may be a useful alternative. This study aimed to determine the efficacy, usability  
32 and acceptability of self-directed multimedia delivery of participant consent.

33 **Design.** A single-centre, randomised, prospective study to determine the efficacy, usability  
34 and acceptability of a self-directed multimedia consent process (intervention) compared with  
35 the traditional paper-based approach (control). Intervention was free of research staff, with  
36 computer-based finger-signed consent.

37 **Setting.** Pathology blood collection services in Tasmania, Australia.

38 **Participants.** 298 participants (63±8 years; 51% female) referred from general practice were  
39 randomised to intervention (n=146) and control (n=152).

40 **Outcome measures.** Efficacy, usability and acceptability of the allocated consent process  
41 were assessed by questionnaire.

42 **Results.** All participants successfully completed allocated interventions. Efficacy parameters  
43 were higher among intervention participants, including better understanding of study  
44 requirements compared with controls ( $P<0.05$  all). Intervention participants were more likely  
45 to engage with the study information and spend more time on the consent process ( $P=0.038$   
46 and  $P=0.007$ , respectively). Both groups reported similar levels of acceptability, although  
47 more control participants reported that the study information was too long (24% versus 14%;  
48  $P=0.020$ ).

49 **Conclusion.** A self-directed multimedia consent process is effective for achieving participant  
50 understanding and obtaining consent free of research staff. Thus, multimedia represents a  
51 viable method to reduce the burden on researchers, meet participant needs, and achieve  
52 informed consent in clinical research.

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4 54 **Article summary**

5 55 **Strengths and limitations of this study:**

- 6  
7 56 • This is the largest randomised evaluation of a self-directed multimedia consent process.  
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9 57 • Multimedia consent tools were developed in collaboration with community members.  
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11 58 • Self-directed multimedia was an acceptable, efficient and effective alternative to  
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13 59 traditional consent processes in medical research.  
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15 60 • Generalisability of the findings will need to be confirmed in further studies.  
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## 62 **Introduction**

63 Informed consent is a cornerstone procedure of ethically conducted medical research.  
64 Consent processes aim to ensure potential participants are fully informed prior to deciding to  
65 take part in research. Guidelines emphasise the need for full disclosure of study information  
66 including the aims, requirements, risks, benefits, funding and conflicts of interest, with the  
67 view that more information facilitates better informed decision-making. [1–3] However, this  
68 has resulted in lengthy consent processes that are burdensome for both researchers and  
69 participants, while often failing to achieve the desired level of participant understanding. [4–  
70 11] Indeed, as few as 50% of participants understand study information, including associated  
71 risks and that participation is voluntary.[5] These shortcomings, as well as the emergence of  
72 complex contemporary methods, including biobanking, gene sequencing, linked data, remote  
73 research and large-scale trials often spanning multiple countries, have led to calls to update  
74 consent guidelines to more appropriately reflect the modern research landscape.[12–15]

75 Self-directed multimedia delivery of information via video and audio platforms may offer an  
76 effective alternative or complementary tool to traditional consent processes. Previous reviews  
77 evaluating the efficacy of multimedia tools in the consent process have been  
78 inconclusive.[4,16,17] This ambiguity may be due to heterogeneous study designs and  
79 population characteristics. Moreover, previous research focused on using multimedia to  
80 augment traditional research consent processes, with a researcher present, rather than  
81 multimedia as a standalone and self-directed process, making it difficult to discern the  
82 generalisability and utility of a self-directed multimedia process for consent. In any case,  
83 there appears to be good acceptability and usability of multimedia tools used within the  
84 consent process with respect to participant satisfaction and facilitating recruitment, but also  
85 for understanding information in a non-research (clinical) setting.[16–18]

86 As far as we are aware, there has never been a study to determine if consent for participation  
87 in research can be appropriately delivered in the absence of research staff using a self-  
88 directed multimedia process compared to the traditional paper-based approach in the presence  
89 of research staff. This study sought to determine this during the consent process for people  
90 being recruited to participate in a clinical research project that focused on cardiovascular risk  
91 assessment.

## 92 **Methods**

### 93 **STUDY PROTOCOL**

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3 94 This research was undertaken in the context of a study testing the use of a computer-based  
4 95 application (app) to gather information for the assessment of absolute cardiovascular disease  
5 96 risk within a clinical setting.[19] The study was performed in concordance with ethical  
6 97 approval obtained from Tasmanian Human Research Ethics Committee [H0015648].  
7 98 Participants referred by a general practitioner to pathology services were approached for  
8 99 involvement in the cardiovascular risk assessment study by the pathology services  
9 100 receptionist. Inclusion criteria for participation included those with a referral for a full lipid  
10 101 profile aged between 45 and 74 years in accordance with absolute cardiovascular risk  
11 102 assessment guidelines. [20] Participants who were interested in involvement in the  
12 103 cardiovascular risk assessment study were randomised to receive self-directed multimedia  
13 104 consent (intervention) or traditional paper-based consent with a researcher (control) (Figure  
14 105 1). Due to the setting of the study, field notes were used to collect data on why participants  
15 106 did not take part after initial eligibility screening.

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17 107 Both groups received a short demonstration on how to use the app. The demonstration was  
18 108 quick with rudimentary instructions provided as it was intended to be delivered by pathology  
19 109 staff in under a minute who would then resume normal clinical duties. The intervention group  
20 110 were shown how to play the study video and audio and advised to engage with the  
21 111 information until they had decided if they wanted to take part, at which point they could  
22 112 provide their consent or leave without taking part. The control group were provided with the  
23 113 paper-based information sheet by a researcher, advised to read and asked if they needed  
24 114 assistance or had any questions as per conventional consent processes. Both groups provided  
25 115 signed consent using their finger on a touchscreen monitor via the app to proceed to the  
26 116 cardiovascular assessment. Immediately after the app cardiovascular risk assessment, each  
27 117 participant was asked to complete a questionnaire to evaluate the efficacy, usability and  
28 118 acceptability of the consent process they had undertaken.

## 119 RANDOMISATION

120 Referred patients that met the criteria for participation received a postcard that contained  
121 basic information about the study and contact details for more information (Supp 1, Study  
122 Postcard). A total of 831 participants were identified as eligible for participation in the  
123 cardiovascular risk assessment study, from these, 303 were randomised to participate (Figure  
124 2). Randomisation was determined by computer program on a 1:1 ratio prior to recruitment. It

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3 125 was not possible to blind participants to their allocated interventions because multimedia was  
4 126 obviously different to paper-based consent.

#### 7 127 DELIVERY OF PAPER-BASED CONSENT PROCESS AS THE STUDY CONTROL

9 128 Control participants received a two-page paper-based study participant information sheet  
11 129 compliant with the requirements of the National Health and Medical Research Council and  
12 130 Australian Research Council, National Statement on Ethical Conduct in Human Research.[1]  
13 131 The first page provided information on the aims, participation requirements and why  
14 132 participants were invited to take part. The second page detailed the risks, benefits, funding  
15 133 sources, ethical approval and privacy protections. The control consent process involved the  
16 134 participant being asked to read the information sheet in the presence of a researcher who  
17 135 provided further information and answered questions as requested (as per usual practice).

#### 24 136 DELIVERY OF MULTIMEDIA CONSENT PROCESS AS THE STUDY 25 137 INTERVENTION

28 138 Intervention participants received study participation information via multimedia approach  
29 139 using a three-minute animated video and separate audio content using the same terminology  
30 140 and content as the paper-based study participant information sheet. The study video was  
31 141 congruent with the first page of the information sheet and focused on the aims and  
32 142 requirements of the study (Supp 2. Study Video). The separate audio content was congruent  
33 143 with the second page of the information sheet and provided information on study funding,  
34 144 ethical approval, risks and benefits associated with participation and privacy protection,  
35 145 which was clearly labelled. Each audio segment was approximately 30 seconds in duration.  
36 146 Participants were shown how to play the audio content as part of the app demonstration. A  
37 147 multidisciplinary team of research staff, graphic designers and communications staff  
38 148 developed the study video through an iterative approach including feedback from community  
39 149 members typical of the target demographic.

#### 49 150 PATIENT AND PUBLIC INVOLVEMENT

51 151 Community members reviewed and contributed to all aspects of study materials including the  
52 152 questionnaires, multimedia and paper-based study information and advised on the content  
53 153 that was included in the final version. An iterative process was undertaken with community  
54 154 advisors to develop consent materials, with initial drafts completed by researchers.

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3 155 Community advisors provided several rounds of feedback (and final approval) on all consent  
4 156 materials, including the information sheet, postcard, video and audio recordings.

## 7 157 SETTING AND CONSENT ENVIRONMENT

9 158 All study procedures took place on the premises of pathology services. A purpose-built booth  
11 159 was designed for the study (Figure 1). The study booth provided a private environment for  
12 160 the consent process and clinical data collection. The booth contained a bench with the  
14 161 computer that delivered the study app, a chair and a curtain for privacy.

## 17 162 ASSESSMENT OF CONSENT PROCESS

19 163 The evaluation questionnaire was delivered by a researcher at a separate workstation after  
21 164 participants completed all study processes in the booth. A 12-item questionnaire was used to  
22 165 assess efficacy, usability and acceptability of the consent process. The questionnaire was  
23 166 mixed methods with dichotomous and multiple-choice questions, each with a comment box  
24 167 for open-ended responses.

### 29 168 *Efficacy and usability of the consent process.*

31 169 The effectiveness of the allocated consent processes to inform participants about the study  
32 170 was assessed via two measures: 1) the extent to which participants understood participation  
33 171 was voluntary and 2) participant understanding of specific aspects of study participation by  
34 172 true or false questions. Four measures denoting user-friendliness of the allocated consent  
35 173 processes were used to indicate usability: 1) participant engagement with the study  
36 174 information by reading, watching or listening, 2) participant perceived understanding of the  
37 175 study, 3) successful completion of the consent process and 4) the time taken to complete the  
38 176 consent process. The app automatically recorded the time for both groups as the app set-up  
39 177 and demonstration took place before the consent process. The time included the set-up, the  
40 178 consent process and the cardiovascular assessment questionnaire. All other parameters were  
41 179 measured by self-report questionnaire.

### 51 180 *Acceptability of the consent process.*

53 181 Three indicators of acceptability of the consent process were used: 1) was there sufficient  
54 182 information available to give consent 2) were participants satisfied with the length of the  
55 183 study information; and 3) what was the preferred method of information delivery for deciding  
56 184 to take part in research.

## 185 DATA ANALYSIS

186 Data are presented as mean and standard deviation or percentage of the total sample. For  
187 comparison of categorical variables, percentage differences were tested using the Chi-squared  
188 test; *t* test was used for continuous variables. For all statistical tests, a *P* value of <0.05 was  
189 considered significant. Analysis was conducted by a researcher blinded to allocation.  
190 Analyses were performed using Stata version 16.1 (StataCorp, USA).

## 191 Results

### 192 PARTICIPANT CHARACTERISTICS

193 There were no differences in sociodemographic characteristics between the intervention and  
194 control groups (Table 1). Participants were predominantly white and middle-older aged. Half  
195 of participants had completed an undergraduate degree or higher, and a quarter were in full-  
196 time employment. From field notes, the main reason participants did not progress from  
197 eligibility screening to study participation was due to time constraints as many were attending  
198 pathology services before going to work.

### 199 EFFICACY AND USABILITY OF MULTIMEDIA INTERVENTION VERSUS 200 CONTROL

201 Intervention participants demonstrated better understanding of the follow-up requirements  
202 and data sharing practices of the study compared with control participants (Table 2,  $P < 0.001$   
203 and  $P = 0.025$ , respectively). Intervention participants were more likely to spend more time  
204 on the consent process and study questionnaire ( $P = 0.006$ ). Altogether, more intervention  
205 participants engaged with any form of study information compared to control participants.  
206 However, when the section of the information sheet that was congruent with the audio  
207 component were compared, only 9% of intervention participants listened to the separate  
208 audio and 35% of control participants read the second page of the information sheet.

209 Thirty-seven participants (15 intervention, 22 control) commented on ways to improve their  
210 understanding of the study. The themes of these comments focused on simplifying the study  
211 information sheet, adding more information to the study postcard, providing a variety of  
212 information delivery options for participants to choose from and providing participants with  
213 updates on the research outcomes of the study. Four participants in the control group  
214 requested assistance with the consent process as they did not have their reading glasses to  
215 read the information sheet. No participants in the intervention group requested assistance.

## 216 ACCEPTABILITY OF MULTIMEDIA INTERVENTION VERSUS CONTROL

217 Both groups reported similar levels of acceptability (Table 3), although more control  
218 participants reported the study information was too long and had a greater preference for  
219 paper-based information delivery ( $P = 0.020$  for both). Only 4% of participants reported that  
220 a researcher must be present for the consent process and there was no difference between  
221 groups.

## 222 Discussion

223 The key finding from this study is that a self-directed multimedia consent process free from  
224 research staff was a suitable mode for delivering study information and obtaining informed  
225 consent for a clinical research study. Additionally, multimedia delivery of study information  
226 improved participant understanding of aspects of study involvement. High acceptability of  
227 both consent processes was reported in this population of middle-to-older aged, community  
228 dwelling adults. These findings suggest that multimedia is an acceptable, efficient and  
229 effective alternative to traditional consent processes in medical research.

230 The evidence on using multimedia to enhance the traditional consent process has  
231 concentrated on participants with additional support needs such as low literacy, mental health  
232 issues or children.[21–24] Moreover, previous work focused on augmenting the traditional  
233 consent approach with multimedia tools, rather than comparing a truly self-directed,  
234 multimedia consent process, as we have done in this current study. Our study design fulfils an  
235 identified research gap on the need for high-quality comparisons of self-directed multimedia  
236 delivery of consent compared with the traditional approach for research.[17] One small study  
237 assessed the effectiveness of self-directed multimedia information delivery, but this was in  
238 the setting of consent for surgery rather than research participation. In that study, they found  
239 that 98% of multimedia participants understood the information provided compared to 88%  
240 that received conventional verbal consent. [18] Our findings, in a middle-to-older population  
241 without specific support needs, further develop this knowledge beyond a special population  
242 and in a larger sample to confirm that a self-directed multimedia platform may be useful  
243 among populations without special needs, such as community dwelling, older adults (i.e.  
244 average age 63 years). With the potential to enhance current consent processes, further work  
245 is needed in diverse populations to investigate the generalisability of multimedia consent  
246 processes.



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3 247 Ethical conduct is paramount in medical research, and consent processes need to adapt to  
4 248 adequately reflect modern attitudes and contemporary research practices.[13–15] This current  
5 249 study is relevant to the calls to update consent guidelines to better support participant  
6 250 autonomy and move away from an unwieldy approach of full-disclosure, to one that supports  
7 251 values-based decision making for participants.[13,25,26] As few as 4% of participants  
8 252 reported research staff must be present during the consent process. Importantly, we observed  
9 253 starkly different levels of participant engagement with study information, with only 9% of  
10 254 participants in the multimedia group choosing to listen to the separate audio segments on the  
11 255 more technical aspects of research governance. This indicates engaging with all study  
12 256 information, by reading, watching or listening, is not necessarily a priority for making an  
13 257 autonomous choice for most participants and is highly individual. Accordingly, consent  
14 258 processes, such as we have provided, using self-directed multimedia, should support  
15 259 participant autonomy by providing options to engage with study information relevant to their  
16 260 values to aid decision-making processes.

## 27 261 IMPLICATIONS FOR RESEARCH AND PRACTICE

28 262 A key benefit of the self-directed consent process evaluated in this research, is its potential to  
29 263 improve participant understanding of study information while reducing the burden of consent  
30 264 for research staff. Another key advantage is the possible economic benefit. Current healthcare  
31 265 consumers and research participants are highly ‘information-savvy’ and may seek the  
32 266 delivery of information from different platforms or prefer diverse options for information  
33 267 delivery such as multimedia.[27] We suggest that the benefits of better delivery of consent  
34 268 information will drive cost savings both in the short and longer terms. Short term savings  
35 269 include the cost of time and the uptake of information that is more beneficial (and better  
36 270 understood) by the participant including understanding participation requirements. Longer  
37 271 term savings could include cost savings through widespread uptake of self-directed  
38 272 multimedia consent processes to reduce staff burden (noting that only 4 participants asked for  
39 273 staff assistance in our study).

40 274 Although attempts at standardisation of conventional paper-based consent processes have  
41 275 been made, achieving standardised consent delivery by study personnel is  
42 276 challenging.[1,2,28] Multimedia tools offer an inherently standardised method of information  
43 277 delivery, as the delivery is predetermined, that would otherwise be difficult to achieve in  
44 278 standard consent processes undertaken in multi-site research projects with large staff teams.



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3 279 As demonstrated in this study, a self-directed multimedia consent process allows flexibility to  
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5 280 engage with study information relevant to support participant decision making while also  
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7 281 ensuring the delivery of that information is standardised for each participant. Several publicly  
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9 282 available software packages support the development and/or delivery of self-directed  
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11 283 multimedia consent processes and many can also be used to collect data as we did in this  
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13 284 study (e.g. Research Electronic Data Capture; REDCap). [29] Posing an attractive alternative  
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15 285 to current consent processes. The findings of this present study highlight that self-directed  
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17 286 multimedia information delivery achieves desired levels of participant understanding and is  
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19 287 as appropriate as the traditional paper-based approach for obtaining participant consent.  
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21 288 Indeed, in a number of settings it may be more desirable, such as large-scale multisite clinical  
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23 289 trials.[30,31]

## 23 290 STRENGTHS AND LIMITATIONS

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25 291 A key strength of this work is the randomised evaluation design among a sizeable study  
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27 292 sample, conducted in a real clinical setting, and demonstrates the value of this approach in a  
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29 293 minimal or low risk research protocol. Further work is needed to explore the acceptability  
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31 294 and appropriateness of consent processes independent of research staff before it is  
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33 295 implemented for more complex research with higher levels of participant risk. Potential  
34  
35 296 limitations include the possibility of selection bias as participation was by self-selection after  
36  
37 297 initial eligibility screening. We cannot be sure whether the findings will be generalisable  
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39 298 beyond our study population of middle-to-older aged, mostly white adults with high levels of  
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41 299 education attainment, and this will need to be tested in future. Additionally, it was not  
42  
43 300 possible to use validated evaluation tools to assess the efficacy, usability and acceptability of  
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45 301 the consent process due to time constraints of undertaking a research protocol within a  
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47 302 pathology services setting. It was not feasible to notify participants about the research prior to  
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49 303 presenting at pathology services and all participants had to take part on the same day their  
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51 304 blood sample was collected. For this reason, the entire process had to be shorter than 20  
52  
53 305 minutes to minimise disruption to participants and pathology services. Efficacy, usability and  
54  
55 306 acceptability were assessed of the consent process as a whole and not specifically of the  
56  
57 307 information provided on the second page of the information sheet or the separate audio in the  
58  
59 308 multimedia consent process. Consequently, we cannot draw definitive conclusions on these  
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309 different aspects of the consent process. Additionally, the duration of video and audio content  
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311 was not visible to participants before selection, which may have deterred some participants  
from engaging with this information and should be rectified in the future.

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3 312 CONCLUSION  
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5 313 A self-directed, multimedia consent process free from research staff was effective and  
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7 314 acceptable to deliver participant information and receive informed consent in a middle-to-  
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9 315 older age population. Our findings suggest that multimedia consent processes may be suitable  
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11 316 for reducing the burden on research staff and improving the delivery of consent for research.  
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For peer review only

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3 317 **Figure legends:**  
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6 318 Figure 1. Flow diagram of study protocol.  
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8 319 Figure 2. Participant flow diagram.  
9

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Table 1. Sociodemographic and clinical characteristics of study participants randomised to multimedia intervention or control delivery of study information and informed consent.

Variable	Control (n=152)	Intervention (n=146)
<b>Age (years)</b>	63±8	63±7
<b>Male n (%)</b>	76 (50)	70 (48)
<b>Education n (%)</b>		
High school	37 (24)	31 (21)
Certificate, diploma or apprenticeship	24 (16)	31 (21)
University degree or higher	81 (53)	76 (52)
<b>Employment n (%)</b>		
Employed	67 (44)	64 (44)
Retired	56 (37)	58 (37)
Other	18 (12)	13 (9)
<b>Ethnicity n (%)</b>		
White	131 (86)	131 (90)
Aboriginal or Torres Strait Islander	1 (1)	2 (1)
Asian	3 (2)	4 (3)
Other	3 (1)	1 (1)

Data are expressed as percentage of the total the sample size or mean ± standard deviation. Response rates varied from 135 - 152 for Control and 133 - 146 for Intervention. No significant differences were observed between the groups.

Table 2. Efficacy and usability of informed consent process of study participants randomised to multimedia intervention or control delivery of study information and informed consent.

Variable	Control (n = 152)	Intervention (n = 146)	P value
<b>Efficacy, participants understood:</b>			
Taking part was completely voluntary n (% yes)	150 (99)	(144) 99	0.167
The right to withdraw from the study at any time n (% correct)	143 (94)	136 (93)	0.893
Baseline participation requirements n (% correct)	149 (98)	144 (99)	0.090
Follow-up participation requirements n (% correct)	82 (54)	118 (87)	<0.001
Data sharing with referring practitioner n (% correct)	132 (87)	136 (93)	0.025
<b>Usability:</b>			
Engaged with the study information n (%)	106 (70)	117 (80)	<0.001
Perceived understanding of the study could be improved n (%)	28 (18)	16 (11)	0.077
Successfully completed the consent process n (%)	152 (100)	146 (100)	1
Total duration (minutes (range))	8.4 (2.1 – 30.5)	9.6 (3.3 – 17.3)	0.006

Data are expressed as percentages of the group total. P values relate to the chi-squared test used for comparison of categorical variables and *t* test was used for continuous variables.



Table 3. Acceptability of participant information and informed consent process of study participants randomised to multimedia intervention or control delivery of participant information and informed consent.

Variable	Control (n = 152)	Intervention (n = 146)	P value
Sufficient information was available to provide consent: n (%)			0.558
Yes	145 (95)	138 (95)	
There was too much	1 (1)	1 (1)	
There was not enough	4 (3)	5 (3)	
Not sure	2 (1)	0	
The study information was too long n (%)	37 (24)	21 (14)	0.020
Preferred method of information delivery: n (%)			0.020
Paper-based written document	88 (58)	60 (41)	
Multimedia	31 (18)	47 (28)	
A researcher must be present	7 (5)	4 (3)	
No preference	24 (16)	30 (21)	

Data are expressed as percentages of the group total. The chi-squared test was used for comparison of categorical variables.

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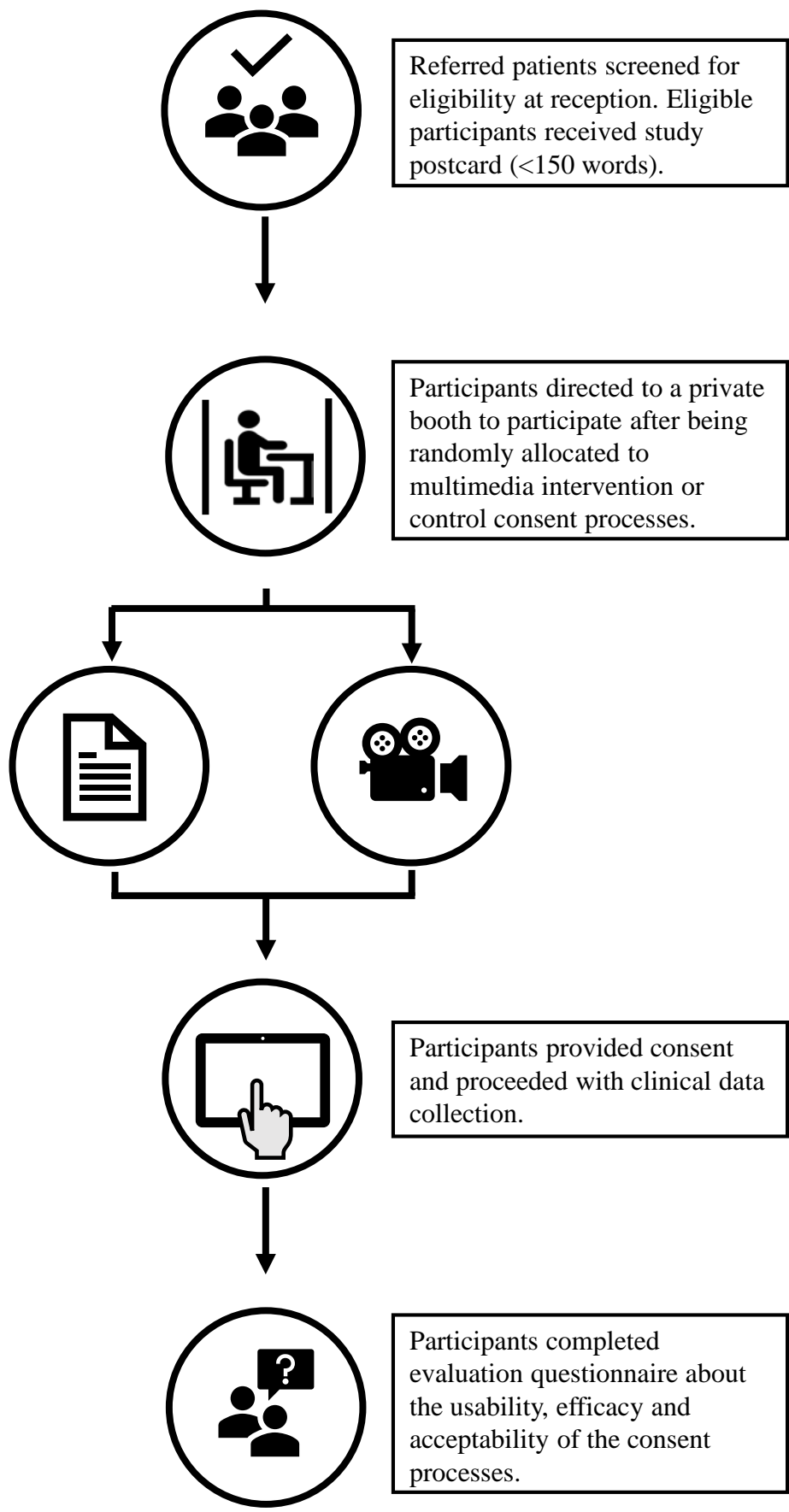


Figure 1. Flow diagram of study protocol.

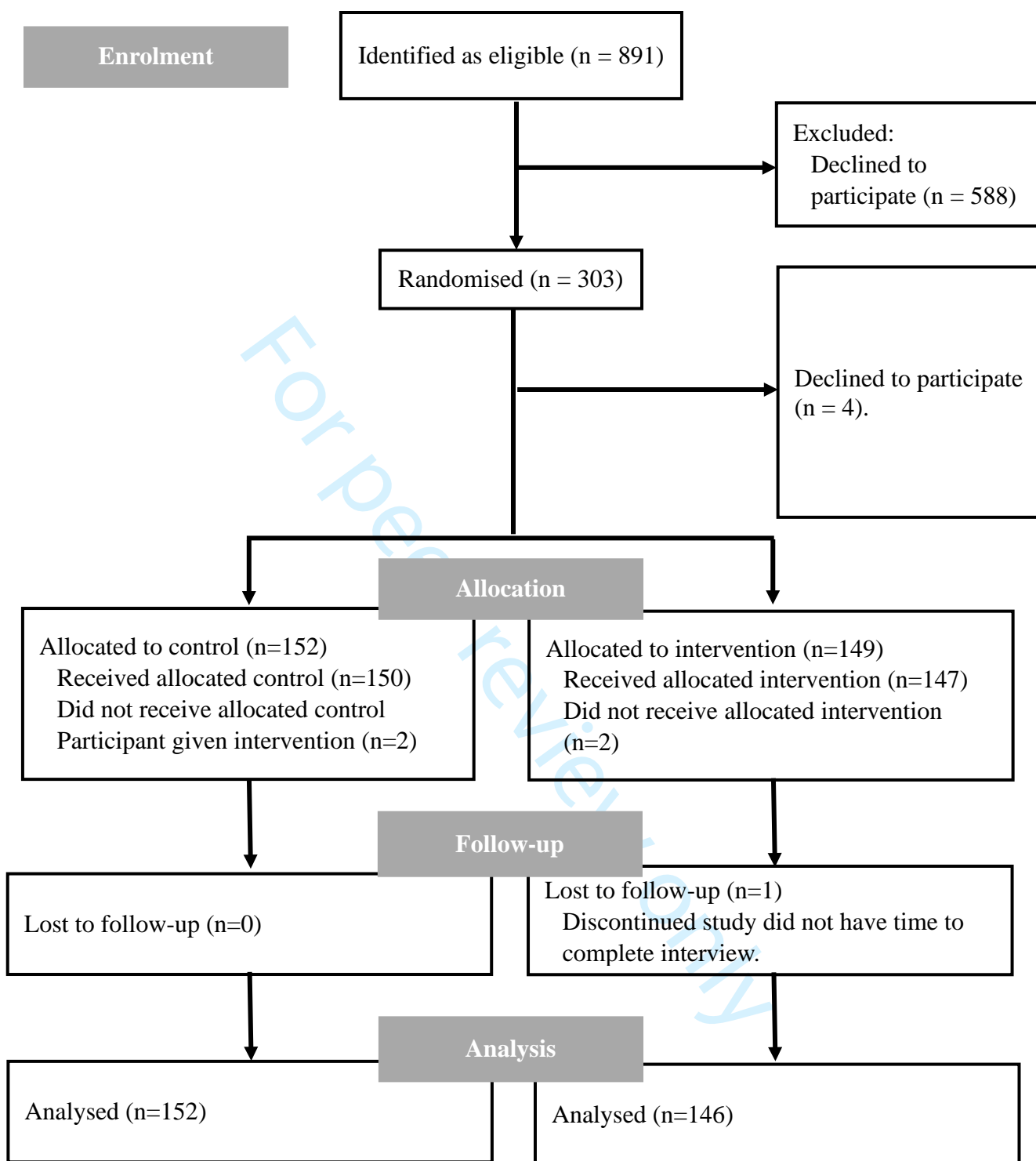


Figure 2. Participant flow diagram.



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## IDEAL Study

Improved cardiovascular  
Disease hEALTH service  
delivery in Australia

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

# IDEAL Study

The IDEAL study aims to lower the risk of people developing cardiovascular disease, including heart attack and stroke.

Patients attending Hobart Pathology, 20-22 Gregory St, Sandy Bay, for a cholesterol test may be eligible to participate.

If you wish to participate, medical health information and blood pressure will be recorded in a specially built booth.

A risk score on the chances of having a cardiovascular event in the next five years will be calculated and sent to your GP.

This risk score is based on best-practice medicine and is designed to help doctors

make better-informed decisions to manage the risk of cardiovascular disease.

You may also be invited to attend optional follow-up studies, which include a full cardiovascular assessment or attending a focus group on cardiovascular disease and primary healthcare.

## **For further information**

Email: [menzies.ideal@utas.edu.au](mailto:menzies.ideal@utas.edu.au)

Phone: (03) 6226 7700

For peer review only - [http://www.menzies.utas.edu.au/research/ideal\\_study](http://www.menzies.utas.edu.au/research/ideal_study)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	<b>Item No</b>	<b>Recommendation</b>
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract <b>Study title.</b> (b) Provide in the abstract an informative and balanced summary of what was done and what was found <b>Abstract submitted.</b>
<b>Introduction</b>		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported <b>Page 3, lines 64-90.</b>
Objectives	3	State specific objectives, including any prespecified hypotheses <b>Page 3, lines 90-92.</b>
<b>Methods</b>		
Study design	4	Present key elements of study design early in the paper <b>Page 5, lines 95-119.</b>
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection <b>Page 5, line 95-97.</b>
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants <b>Page 5, line 100-105.</b>
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable <b>Page 7, lines 158-179.</b>
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group <b>Page 7, lines 158-179.</b>
Bias	9	Describe any efforts to address potential sources of bias <b>Page 5, line 120.</b>
Study size	10	Explain how the study size was arrived at <b>Page 5, line 100-105., sample size was derived based on a separate study.</b>
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why <b>Page 7, lines 158-179.</b>
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding <b>Page 7, lines 180-186.</b> (b) Describe any methods used to examine subgroups and interactions <b>Page 7, lines 180-186.</b> (c) Explain how missing data were addressed NA (d) If applicable, describe analytical methods taking account of sampling strategy NA

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(e) Describe any sensitivity analyses

NA

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**Results**

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed <b>Page 8, lines 188-194 and Figure 1.</b> (b) Give reasons for non-participation at each stage <b>Figure 1.</b> (c) Consider use of a flow diagram <b>Figures 1 and 2.</b>
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders <b>Page 8, lines 188-194 and Table 1.</b> (b) Indicate number of participants with missing data for each variable of interest NA
Outcome data	15*	Report numbers of outcome events or summary measures <b>Page 8, lines 195-213.</b>
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included NA (b) Report category boundaries when continuous variables were categorized NA (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses NA
<b>Discussion</b>		
Key results	18	Summarise key results with reference to study objectives <b>Page 9, lines 215-221.</b>
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias <b>Page 11, lines 279-293.</b>
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence <b>Page 9-10, lines 222-251.</b>
Generalisability	21	Discuss the generalisability (external validity) of the study results <b>Page 10, lines 253-277.</b>
<b>Other information</b>		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based <b>Provided under funding section, page 12, lines 310-311.</b>

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\*Give information separately for exposed and unexposed groups.

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