Benefits and harms of 'Hypertension' and 'High Normal' labels: a randomised experiment

Muscat & Morris – Benefits and harms of Hypertension labels

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Abstract (305 words)

Background

Recent US guidelines lowered the threshold for diagnosing 'hypertension' while other international guidelines use alternative/no labels for the same group (blood pressure [BP]<140/90mmHg). We investigated potential benefits and harms of 'hypertension' and 'high normal BP' labels, compared to control, among people at lower risk of cardiovascular disease (CVD).

Methods

We conducted a randomised experiment using a national sample of Australians (*n*=1,318) 40-50 years recruited from an online panel. Participants were randomised to one of three hypothetical scenarios where a GP told them they had a BP reading of 135/85mmHg, using either: 'hypertension' / 'high normal BP' / control (general BP description) labels. Participants were then randomised to receive an additional absolute risk description, or nothing. Primary outcomes were willingness to change diet and worry. Secondary outcomes included exercise/medication intentions, risk perceptions and other psychosocial outcomes.

Results

There was no difference in willingness to change diet across label groups (p=0.22). The 'hypertension' label (MD=0.74, 95%CI:0.41,1.06; p<0.001) and 'high normal BP' label (MD=0.45, 95%CI:0.12,0.78; p=0.008) had increased worry about CVD risk compared to control. There was no evidence that either label increased willingness to exercise (p=0.80). However, the 'hypertension' (MD=0.20, 95%CI:0.04,0.36; p=0.014), but not 'high normal' label (MD=0.06, 95%CI:-0.10,0.21; p=0.49), increased willingness to accept BP lowering medication compared to control. Psychosocial differences including lower control, higher risk perceptions, and more negative affect were found for the hypertension and high normal

labels compared to control. Providing absolute risk information decreased willingness to change diet (MD=0.25, 95%CI:0.10,0.41; p=0.001) and increase exercise (MD=0.28, 95%CI:0.11,0.45; p=0.001) in the 'hypertension' group.

Conclusions

Neither 'hypertension' nor 'high normal' labels motivated participants to change their diet or exercise more than control, but both labels had adverse psychosocial outcomes. Labelling people who have systolic BP 130-140mmHg, who are otherwise at low risk of CVD, may cause harms that outweigh benefit.

Registration

Australian New Zealand Clinical Trials Register Number: ACTRN12618001700224.

Keywords

Guideline, outcomes research, clinical trial, evidence-based medicine

Non-standard Abbreviations and Acronyms

American College of Cardiology and the American Heart Association (ACC/AHA)

European Society of Cardiology/European Society of Hypertension (ESC/ESH)

National Institute for Health and Care Excellence (NICE) guidelines

Cardiovascular disease (CVD)

Systolic or diastolic blood pressure (SBP/DBP)

Newest Vital Sign (NVS)

Introduction

High blood pressure is a key modifiable risk factor for cardiovascular disease (CVD), and better control has contributed to declining CVD rates over the last four decades.[1] Clinical guidelines have progressively lowered the threshold for diagnosing and treating 'hypertension' based on systolic or diastolic blood pressure (SBP/DBP) of 160/85 mmHg in the 1970s, to 140/90 mmHg in the 2000s.[2] In 2017, the American College Of Cardiology and the American Heart Association (ACC/AHA) hypertension guidelines lowered the diagnostic threshold still further, to 130/80 mmHg.[3] Concerns have been expressed about potential harms of such a move, particularly for people at lower risk of CVD.[4-6] Meanwhile, both the 2018 European Society of Cardiology/European Society of Hypertension (ESC/ESH) guidelines,[7] and the 2019 National Institute for Health and Care Excellence (NICE) guidelines have not lowered the diagnostic threshold for 'hypertension' (Table 1).[8] The ESC/ESH guideline recommends using the label 'high normal BP' for people with SBP 130–139 mmHg and/or DBP 85–89, whereas the NICE guideline does not recommend any label for BP <140/90 mmHg. Guidelines, recommended diagnostic thresholds, and treatments are summarised in Table 1.

--- Table 1 ---

For people at low risk with SBP 130-140 mmHg, there are minimal expected benefits from BP lowering drug treatment, but potential harms from adverse drug effects.[4] This is because the expected benefits of drug treatment depend on the baseline risk of CVD, with diminishing returns the lower the baseline risk, with the same risk of adverse drug effects. In fact, randomised trials in lower risk people have found no evidence that drug treatment

prevented CVD for people with SBP<140 mmHg, but there was evidence of major adverse drug events.[9, 10]

The apparent premise for lowering the diagnostic threshold while not recommending drug treatment for lower risk people (80% of people with SBP 130-140mmHg) is that the 'hypertension' label itself may have beneficial effects by increasing adherence with lifestyle interventions such as a healthier diet and more exercise. But the evidence from trials is that even highly personalized risk information does not change health-related behaviors.[11] Further, there is evidence of potential harms from disease labels: they increase patients' perceived severity of the condition and make them more likely to choose invasive tests and/or treatments.[12-14] The 'hypertension' label is associated with anxiety and depression,[15] work absenteeism,[16, 17] and increased BP levels observed after diagnosis.[18] Although these studies suggest potential negative impacts, no randomised studies have explored the 'hypertension' label specifically.

Two factors may moderate the impact of blood pressure labels. Absolute CVD risk is increasingly used to inform treatment decisions in international guidelines,[3, 19] to target medication to those at higher risk who are most likely to benefit.[20] Providing this information has been shown to improve patient understanding and prevention intentions.[21-23] Lower health literacy can negatively influence these outcomes for CVD[24] but has rarely been considered in disease label research.

Aims

The aim of this study was to investigate the potential benefits and harms of the 'hypertension' label, and the 'high normal BP' label, compared to control, among people at low risk of CVD. We also investigated whether absolute risk information or health literacy had any modifying effects on the 'hypertension' label.

Methods

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Study population

Australian adults aged 40-50 years were recruited online through a market research company's (Dynata) panel of 600,000 members. In order to mimic the low risk profile used in the scenarios, participants were excluded from the study if they self-reported the following risk factors: current smoker, diagnosis of heart disease, diabetes, kidney disease, hypercholesterolaemia (total cholesterol reading of 7+ mmol/L (mg/DL)), or hypertension (in Australia hypertension is only diagnosed for people with BP ≥140/90) .

Demographic information collected included age in years, gender, country of birth, language spoken at home, identification as an Aboriginal person or as a Torres Strait Islander, and the educational level attained. Health literacy was measured using the Newest Vital Sign (NVS), a validated tool for health literacy assessment converted for online use.[25] Participants were categorized as having inadequate (score 0-3 on NVS) or adequate health literacy (score 4-6 on NVS).

Design

Participants were randomly assigned to one of three study arms; 'hypertension label' arm, 'high normal blood pressure' arm, or 'control' arm where only a general description of BP was given (allocation ratio 1:1:1). Within each arm participants were then randomised to receive subsequent information about their absolute risk of heart attack or stroke in the next 10 years, or no further information (absolute risk described vs not described 1:1).

Intervention

Hypothetical scenario

Participants were asked to imagine that they were having a check-up and the doctor had taken their blood pressure a "few times recently" (as per guidelines).[3, 7, 8]

Labelling condition

Each participant was given the same blood pressure reading (135/ 85) with only the label description ('hypertension' / 'high normal blood pressure' / control) changing across each study arm (see Figure 1).

We used a blood pressure reading of 135/85 mmHg as this would be classified as 'hypertension' according to the 2017 US guideline, as 'high normal' according to the 2018 European guideline, and have no specific label according to the 2019 NICE guideline. According to all three guidelines, this patient would be recommended to make lifestyle modifications as the first step to managing their blood pressure.[3, 26]

--- Figure 1 ---

Absolute risk description condition

Participants either received no further information, or an 'absolute risk description' in addition to Figure 1: "*Hypertension/higher blood pressure can increase your risk of heart disease. Combining your current blood pressure reading with your other risk factors means your overall risk of a heart attack or stroke in the next 10 years is low (that is, you have less than 10% risk of a heart attack or stroke)*". The 10% risk was described as it is the recommended threshold for offering blood pressure lowering medication in guidelines.[3]

Procedure

The questionnaire and randomization were created using Qualtrics, which utilizes the Mersenne Twister pseudorandom number generator to randomize participants. Participants and researchers were blinded to the allocation sequence until completion of data collection. After screening, consent and demographic questions, participants were randomised, read the hypothetical scenario, and completed outcomes.

Outcome measures

Table 2 provides an overview of primary and secondary outcome measures.

--- Table 2 ---

Analysis

Multivariable linear regression models were used to analyse all study outcomes, with the label and absolute risk condition included as categorical explanatory variables. Potential effect modification was considered by adding an interaction term between label and absolute risk into regression models for all outcomes. Health literacy adequacy and the interaction of health literacy adequacy and label condition were entered for primary outcomes only. A p-value<0.05 for main effects, and p<0.025 for pairwise comparisons was considered statistically significant. All analyses were carried out using Stata/IC v15.1 (College

Station, Texas, USA). The study statistician was blinded to the label and absolute risk groups until completion of the primary analysis.

Open text explanations for the behavioural intentions were coded inductively by two authors (DM, CB), who read through all responses, developed a framework, and applied this to a random sample of 11% (n=150). Discrepancies were discussed and themes were analysed descriptively to identify any unique issues that arose in specific label conditions.

Sample size calculation

Sample size estimates were calculated to address the primary research questions, with estimates of effect sizes based on published[27] and preliminary data. A total sample size of 1272 participants (212 per arm) was estimated to provide ~80% power to detect pairwise differences for each labelling condition (compared to control) as small as 0.3 standard deviations on continuous outcome measures (worry, intentions) at an adjusted alpha level of 0.025 (allowing for multiple comparisons between the control group and each label condition). This also allowed detection of effect sizes for absolute risk condition as small as 0.2 standard deviations with 80% power.

Ethics/trial registration

Ethical approval was obtained from the University of Sydney Human Research Ethics Committee (protocol number: 2018/828). All participants gave informed consent. This trial was registered with the Australian New Zealand Clinical Trials Register (ACTRN12618001700224).

Results

Sample characteristics

Recruitment took place from February 5th to April 1st, 2019. The sample comprised 1318 individuals (see Figure 2 for Flow of Participants), with well-balanced characteristics across randomised label conditions (see Table 3). The trial ended once the target sample size was reached.

--- Figure 2 ---

--- Table 3 ---

Label effects

The effects of the 'hypertension' and 'high normal' labels on all outcomes are shown in Table 4. Willingness to change diet was relatively high across all three label conditions, with no evidence of a difference. However, there was very strong evidence that both labels increased worry (mean difference (MD) compared to control: 'hypertension' label=0.74, 95% CI:0.41 to 1.06; 'high normal' label=0.45, 95% CI:0.12 to 0.78).

For secondary outcomes, willingness to exercise was also relatively high across all study arms, with no evidence that label condition affected this. There was evidence that the 'hypertension' label, but not the 'high normal' label, increased willingness to accept medication (MD compared to control: 'hypertension' label=0.20, 95% CI:0.04 to 0.36; 'high normal' label=0.06, 95% CI:-0.10 to 0.21).

There was strong evidence that both labels increased perceived severity (MD compared to control: 'hypertension' label=0.44, 95% CI:0.23 to 0.65; 'high normal' label=0.34, 95% CI:0.14 to 0.55). There was also strong evidence that the labels impacted risk perceptions,

with label arms viewing the condition as less controllable and more serious with greater consequences compared to control (MD in composite score compared to control: 'hypertension' label=1.50, 95% CI:0.68 to 2.33; 'high normal' label=1.45, 95% CI:0.63 to 2.28). The labels increased negative affect (MD compared to control: 'hypertension' label=0.59, 95% CI: 0.33 to 0.84; 'high normal' label=0.34; 95% CI:0.08 to 0.60) but not positive affect.

Compared to control, the 'hypertension' label led participants to report it would be more difficult to obtain insurance products (MD=0.31, 95% CI:0.14 to 0.48), engage in work (MD=0.24, 95% CI:0.10 to 0.37), and to experience overall happiness (MD=0.43, 95% CI:0.27 to 0.58). The 'high normal' label also resulted in individuals believing it would be more difficult to obtain insurance products (MD=0.21, 95% CI:0.04 to 0.39) and feel overall happiness (MD=0.22, 95% CI:0.06 to 0.37) compared to control. The label condition showed no statistically significant effects on the other life impacts, or on motivation to eat well or exercise.

Qualitative themes identified in the analysis of open text explanations for willingness to change health behaviour are provided in Supplemental Table I. Overall themes were present in all randomised groups and including preferences, goals, risk perception, behavior change and information seeking. No unique issues were identified for specific label conditions.

--- Table 4 ---

Effect of describing absolute risk information

Table 5 shows the effect of describing absolute risk for all study outcomes. When absolute risk information was described, participants indicated a reduced willingness to change diet (MD=-0.11, 95% CI:-0.20 to -0.02) compared to when no such information was described. No effect of describing absolute risk was observed for worry about CVD risk.

For secondary outcomes, there was weak statistical evidence that describing absolute risk reduced willingness to exercise (MD=-0.09, 95% CI:-0.19 to 0.01, p=0.08), lowered illness perceptions and beliefs (MD=-0.58, 95% CI:-1.26 to 0.09), and decreased motivation to eat well (MD=-0.12, 95% CI:-0.24 to 0.01) compared to when no absolute risk information was given. There was also statistical evidence of decreased motivation to exercise (MD=-0.13, 95% CI:-0.26 to -0.002) when absolute risk information was described. No evidence of an effect of absolute risk description was observed for any other secondary outcomes (see Table 5).

--- Table 5 ---

Effect modification: absolute risk

Potential effect modification of the labelling effects by absolute risk was explored for all study outcomes. Descriptive statistics stratified by label and absolute risk, with p-values for the label × absolute risk interaction, are provided in Supplemental Table II. There was weak statistical evidence that describing absolute risk modified the label effect for willingness to change diet (p=0.08); when no absolute risk information was described, those who received the hypertension label reported an increased willingness to change diet (MD=0.21, 95% CI:0.06 to 0.37, p=0.008) compared to control. No difference between the hypertension and control group was observed when absolute risk information was described. Within the

215 'hypertension' label, providing absolute risk decreased willingness to change diet (MD: 0.25,
216 95% CI:0.10 to 0.41, p=0.001). No differences were observed across the other label
217 conditions (Table 6).
218
219 There was evidence that the effect of the disease labels on willingness to exercise was
220 modified by absolute risk information (p=0.03). When absolute risk information was
221 provided, there was weak evidence of lower exercise intentions when the hypertension
222 label was used (MD=-0.15, 95% CI:-0.32 to 0.03, p=0.09) compared to control; whereas the
223 effect was in the opposite direction when no absolute risk description was given (MD:
224 hypertension label compared to control=0.14, 95% CI:-0.04 to 0.31, p=0.12). When the
225 'hypertension' label was used, lower exercise intentions were observed when absolute risk
226 information was provided compared to when it was not (MD:0.28, 95%CI:0.11 to 0.45,
227 p=0.001). No differences were observed across the other label conditions (Table 6).
228
229 There was no statistical evidence of effect modification for any other outcomes (see
230 Supplemental Table II).
231
232 **--- Table 6 ---**
233
234 ***Health literacy effects and effect modification***
235 There was strong evidence that individuals with adequate health literacy would be more
236 willing to change their diet than individuals with inadequate health literacy (MD=0.28, 95%
237 CI:0.18 to 0.37, p<0.001), but no difference on worry about risk of CVD (MD=0.00, 95% CI:-
238 0.29 to 0.28, p=0.99). There was no statistical evidence that the effect of disease label was

modified by health literacy for willingness to change diet (p=0.94), or for worry about risk of CVD (p=0.25). Descriptive statistics for primary outcomes stratified by label, risk, and health literacy adequacy are provided in Supplemental Table III.

Discussion

This is the first randomised investigation comparing the effect of different guideline labels for high blood pressure (hypertension vs high normal blood pressure vs control) on psychosocial and behavioral outcomes. We found no difference between labelling conditions on people's willingness to change their diet or to exercise more; with high levels across all conditions. However, 'hypertension' and 'high normal' labels appeared to increase worry and risk perceptions (severity, seriousness, consequences), lowered perceived control, and increased negative emotions (depressed, upset, angry, anxious). These labels also resulted in individuals perceiving it would be more difficult to obtain insurance products, and to experience overall happiness. The 'hypertension' label had additional effects on work perceptions and willingness to use medication, which the 2017 ACC/AHA guideline recommends as an option for low risk people with SBP 130-140 mmHg *only if* measures to change diet and exercise fail to lower blood pressure, reflecting the lack of robust evidence to support using BP lowering medication in this patient population. These findings suggest that labelling low risk people based on SBP readings that are 130-140 mmHg may be more likely to harm than to benefit.

Our findings showed increased risk perceptions, worry, negative affect and perceived negative impacts on life (e.g. obtaining health and travel insurance) when both 'hypertension' and the 'high normal' were used. While these findings are novel for the 'high

normal label', they are consistent with a longstanding body of work examining the potential harmful impacts of the hypertension label. This includes a number of studies which found higher rates of absenteeism and lower psychological well-being among people who were aware that they had hypertension compared to those who were unaware, and studies reporting negative psychological outcomes among patients misdiagnosed with hypertension.[16, 17, 30] Our finding that those labelled felt less likely to work is consistent with previous research showing increased absenteeism from work after detection and labelling.[16, 17] This may relate to illness anxiety and hypervigilance, with participant concern that going to work might make their hypertension worse in some way. It could also reflect a general feeling of needing to look after health and rest if feeling even slightly unwell. Hypertension labelling has also been linked to reduced quality or satisfaction with marital life, higher levels of psychological distress and increased illness.[15, 18, 31-36] Labelling studies in different clinical contexts have similarly found that disease labels result in various emotional, cognitive and physical consequences, and can influence medical decision-making by shifting preferences towards more invasive management and making a condition appear more severe.[12, 32, 37, 38] To provide context to our findings that those who were labelled reported greater difficulty in their ability to get health or travel insurance, hypertension is considered a pre-existing condition by insurers, but policies in Australia and other countries vary considerably. Even in circumstances where hypertension is under control and there are no other comorbidities it may be necessary to pay an additional premium for cover/reimbursement.

In this study, label effects were not modified by health literacy level or providing absolute risk information, except that absolute risk decreased willingness to change diet and increase

exercise only when the 'hypertension' label was used. In contrast, a systematic review exploring the effect of providing absolute risk information alone or with accompanying education found it increased both psychological (risk perception accuracy) and behavioural (prevention intentions) outcomes.[21] We hypothesise that participants may have perceived the absolute risk information as smaller than anticipated, which may have modestly decreased motivation to change diet and exercise. A similar mismatch between "high" risk and subjective perceptions of risk has been identified in qualitative work.[39] However, it is important to put this into the context of the overall high willingness of the participants in our study to have a healthy diet and exercise.

Strengths and limitations

The randomised design of this study provides a powerful opportunity to investigate causal associations between different guideline labels for high blood pressure (hypertension vs high normal blood pressure vs control) and diet, exercise and treatment decision-making and psychosocial outcomes. The experimental design enabled us to isolate the effects of the labels and investigate their impact on a wide range of positive and negative outcomes, and examine the impact of absolute risk information and health literacy. This contributes much needed high quality evidence to the body of research investigating hypertension labelling which has largely relied on cross-sectional or cohort studies of those who have previously been labelled as hypertensive or otherwise.[15-17, 30, 33-35] Of note, this is the first study to examine the impact of a new label for this BP group 'high normal' which is recommended in ESC/ESH clinical guidelines.

A further strength of this study is that a range of potential positive effects of using different labels for high blood pressure were carefully investigated, such as feeling more alert, determined, active, motivated and reassured, in addition to potential negative effects which has not previously been systematically examined. This study sample was large and socio-economically diverse, and the study was powered to detect small effect sizes, based on previous labelling studies. Where effects were not observed, it is unlikely due to insufficient statistical power.

However, the online experimental design of the study does introduce limitations. People presented with labels and risk information for high blood pressure in real clinical contexts may respond differently or with greater engagement than those receiving a written hypothetical diagnosis. This warrants further empirical investigation through randomised trials to test how different labels influence decision-making and psychosocial outcomes, both initially and over time, within a clinical sample. This study was also conducted only among those aged 40-50 with no clinical risk factors (e.g. diabetes) and was administered in English. Our findings may not be generalizable to other populations. Additionally, small effect sizes for psychosocial outcomes were evident and require further investigation to understand their clinical importance. However, given the hypothetical nature of this study, there is also potential that these effects underestimate how a real patient would respond. Given some psychosocial outcomes measured in our study were adapted from existing scales, we acknowledge that this limits the ability to compare effects with other studies. We also acknowledge the potential for multiplicity issues as a limitation of this study; several (planned) comparisons across multiple outcomes were conducted potentially inflating the type I error rate. Finally, we used self-report measures (including willingness to change

behavior) and were unable to assess the impact of labels on actual behavior. This is an important direction for future research given that longitudinal studies in other clinical contexts have shown that disease diagnoses and risk labels may not improve actual health behavior,[40] and that there is likely to be a gap between intention and behavior. Notably, previous research has shown an increase in illness behaviors among those labelled as hypertensive, such as work absenteeism and increased visits to primary care physicians. Further work to explore behavior changes over time is needed.

Conclusion

Findings from this study suggest that labelling low risk people on the basis of SBP readings that are 130-140 mmHg may be more likely to harm than to benefit, supporting concerns raised after the US guidelines were published.[41] Using the 'hypertension' diagnosis label does not appear to increase willingness to change diet or increase exercise when compared to a control, however, it could potentially increase the likelihood of medication use (with unfavourable benefit: harm ratio), reduce perceived control and negatively affect psychological wellbeing. Importantly, the 'high normal' label had similar negative effects as the 'hypertension' label. We therefore urge guideline bodies to carefully consider the use of medical labels for people with elevated blood pressure at low CVD risk and apply these only when evidence indicates the benefits outweigh harms.[42]

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Disclosures

None.

Supplemental Materials:

Supplemental Tables I-III

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Figure legends

Figure 1. Hypothetical Blood Pressure Descriptions used in each Labelling Study Arm

Figure 2. Study design and Flow of Participants

Tables

Table 1. Summary of guidelines for detection and management of high blood pressure

Guideline and year	Diagnostic threshold (SBP/DBP mm Hg)* and label	Recommended treatment
ACC/AHA 2017[3]	130/80: *'Hypertension'*	*Lower absolute risk*: lifestyle interventions (e.g. diet, exercise), consider blood pressure lowering drug therapy if SBP <130 mm Hg not achieved *Higher absolute risk*: drug therapy†
ESC/ESH 2018[7]	SBP 130-139 and/or DBP 85-89: '*High normal blood pressure'* 140/90: '*Hypertension'*	Do not recommend drug therapy to people with SBP 130-140 mm Hg, regardless of absolute risk
NICE 2019[8]	<140/90: No label 140/90: '*Hypertension'*	Do not recommend drug therapy to people with SBP 130-140 mm Hg, regardless of absolute risk

ACC/AHA: American College of Cardiology & the American Heart Association; ESC/ESH: European Society of Cardiology/European Society of Hypertension; NICE: National Institute for Health and Care Excellence

*Systolic blood pressure/diastolic blood pressure

†Lower absolute risk = <10% 10-year absolute risk (80% of people in this category), higher absolute risk = ≥10% 10-year risk

Table 2. Outcomes Measures

Outcome	Measure
Primary outcomes	
Willingness to change diet	'Would you change your diet in the way your doctor has recommended?' rated on five-point scale 1 (no, definitely not) to 5 (yes, definitely), adapted from [27].
Worry about CVD risk	'How worried would you be about your risk of heart attack or stroke?' rated from 0 (not worried at all) to 10 (extremely worried), adapted from [12].
Secondary outcomes	
Willingness to increase exercise	'Would you do more exercise like your doctor has recommended?' rated on five-point scale 1 (no, definitely not) to 5 (yes, definitely).
Willingness to accept medication	'Would you take the medication if your doctor offered it?' rated on five-point scale 1 (no, definitely not) to 5 (yes, definitely).
Open text explanation for willingness to change health behavior	Open-ended optional question 'Please tell us why you feel this way about what you would do', asking about willingness to change diet, exercise and medications altogether (to identify any unique issues for label conditions).
Perceived severity	'I feel that my *[label]* is a serious condition for me to have', rated from 1 (Strongly Disagree) to 7 (Strongly Agree).[13]
Illness perceptions and beliefs	Nine items adapted from the Brief Illness Perception Questionnaire (IPQ)[28] rated from 0 (lowest impact) to 10 (highest impact). A total illness perception score (out of 70) was generated by summing item responses; higher values indicate a greater negative impact on illness perceptions and beliefs. Treatment control questions (i.e., belief that diet, exercise, or

	medication could control the disease) were assessed separately and averaged.
Positive and negative affect	Ten items assessed; 'How likely is it you would feel […]?' for positive (alert, active, determined, motivated, reassured) and negative (depressed, upset, angry, worried, anxious) affect, rated a scale of 0 (not at all likely) to 10 (extremely likely) adapted from [29]. As this was an adapted measure, principal components analysis (with orthogonal varimax rotation) was applied to responses to derive negative and positive affect component scores.
Impacts on life	On a scale of -3 to +3 five items assessed; 'How much do you think that knowing you have *[label]* would impact: • Your ability to get health or travel insurance • Your ability to work • Your ability to be employed • Your overall happiness • Support from friends and family Negative values reflected reduced ability, happiness, or support.
Impacts on motivation	Two items assessed motivation to exercise and eat well using the same -3/+3 format as above. Negative values reflected reduced motivation.

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Table 3. Descriptive Characteristics of the Analysis Sample (N=1318), by Randomised Labelling Condition. Data are presented as n (%) unless otherwise specified.

	Labelling condition			
Characteristic	**Hypertension (n=450)**	**High normal (n=448)**	**Control (n=420)**	***Total (N=1318)***
Age [years; mean (SD)]	44.7 (3.2)	44.7 (3.3)	44.8 (3.2)	44.7 (3.2)
Gender				
Female	270 (60.0)	273 (60.9)	246 (58.6)	789 (59.9)
Male	179 (39.8)	174 (38.8)	174 (41.4)	527 (40.0)
Other	1 (0.2)	1 (0.2)	0	2 (0.2)
Language spoken at home				
English	428 (95.1)	433 (96.7)	401 (95.5)	1262 (95.8)
Country of birth				
Australia	323 (71.8)	341 (76.1)	326 (77.6)	990 (75.1)
United Kingdom	28 (6.2)	16 (3.6)	16 (3.8)	60 (4.6)
New Zealand	10 (2.2)	14 (3.1)	6 (1.4)	30 (2.3)
Identifies as an Aboriginal Australian or Torres Strait Islander	3 (0.7)	4 (0.9)	6 (1.4)	13 (1.0)
Education				
High school or less	171 (38.0)	191 (42.6)	176 (41.9)	538 (40.8)
Diploma or greater	279 (62.0)	257 (57.4)	244 (58.1)	780 (59.2)
Health literacy†				
Adequate	311 (69.1)	297 (66.3)	282 (67.1)	890 (67.5)
Inadequate	139 (30.9)	151 (33.7)	138 (32.9)	428 (32.5)
Previous diagnosis of cancer	16 (3.6)	19 (4.2)	25 (6.0)	60 (4.6)
Previous diagnosis of asthma	58 (12.9)	60 (13.4)	62 (14.8)	180 (13.7)
Family history of chronic condition*	289 (64.2)	281 (62.7)	274 (65.2)	844 (64.0)

*chronic conditions included at least one of cancer, heart disease, hypertension, asthma, hypercholesterolaemia, diabetes, or kidney disease. †as measured by the Newest Vital Sign (NVS).

Table 4. Descriptive statistics for outcome measures [displayed as mean (SD)] and pairwise comparisons of marginal means to control [displayed as mean difference (95% confidence interval); p-value], stratified by label condition.

	Label condition					Main
	Control	Hypertension		High Normal		effect
Outcome measure	**M (SD)**	**M (SD)**	**MD (95% CI) compared to control; p-value**	**M (SD)**	**MD (95% CI) compared to control; p-value**	**p-value**
Primary outcomes						
Willingness to change diet (1 to 5)*	4.16 (0.84)	4.26 (0.83)	0.09 (-0.02, 0.20); p=.11	4.24 (0.85)	0.08 (-0.03, 0.19); p=.16	.21
Worry about CVD risk (0 to 10)	5.76 (2.60)	6.50 (2.36)	0.74 (0.41, 1.06); p<.001	6.21 (2.41)	0.45 (0.12, 0.78); p=.008	<.001
Secondary outcomes						
Willingness to increase exercise (1 to 5)*	4.18 (0.85)	4.18 (0.99)	0.00 (-0.13, 0.12); p=.95	4.21 (0.93)	0.03 (-0.09, 0.16); p=.60	.80
Willingness to accept medication (1 to 5)	3.40 (1.22)	3.60 (1.17)	0.20 (0.04, 0.36); p=.014	3.45 (1.18)	0.06 (-0.10, 0.21); p=.49	.04
Perceived Severity (1 to 7)	4.55 (1.68)	4.99 (1.49)	0.44 (0.23, 0.64); p<.001	4.89 (1.44)	0.34 (0.13, 0.55); p=.001	<.001
Affect (standard deviation units)†						
Negative affect	-0.31 (1.98)	0.27 (1.85)	0.59 (0.33, 0.84); p<.001	0.02 (1.93)	0.34 (0.08, 0.59); p=.01	<.001
Positive affect	-0.08 (1.96)	0.02 (1.74)	0.09 (-0.15, 0.34); p=.45	0.05 (1.84)	0.13 (-0.12, 0.38); p=.31	.57
Illness perceptions and beliefs (0 to 70)	31.66 (6.46)	33.17 (6.21)	1.50 (0.68, 2.33); p<.001	33.12 (5.94)	1.45 (0.63, 2.28); p=.001	<.001
Impacts on life (-3 to 3)‡						

Ability to obtain insurance products	-0.19 (1.19)	-0.50 (1.38)	-0.31 (-0.48, -0.14); p<.001	-0.40 (1.30)	-0.21 (-0.39, -0.04); p=.02	.002
Ability to work	0.07 (0.86)	-0.17 (1.05)	-0.24 (-0.37, -0.10); p<.001	0.02 (1.03)	-0.05 (-0.18, 0.08); p=.47	.001
Overall happiness	-0.09 (1.12)	-0.51 (1.19)	-0.43 (-0.58, -0.27); p<.001	-0.31 (1.22)	-0.22 (-0.37, -0.06); p=.007	<.001
Impacts on motivation (-3 to 3) ‡						
Motivation to eat well	1.46 (1.12)	1.62 (1.13)	0.16 (0.00, 0.31); p=.048	1.56 (1.23)	0.10 (-0.06, 0.25); p=.23	.14
Motivation to exercise	1.44 (1.17)	1.52 (1.23)	0.08 (-0.08, 0.24); p=.34	1.55 (1.22)	0.11 (-0.05, 0.27); p=.18	.39

*These outcomes showed some evidence of effect modification, see Table 5 for stratified estimates;.†derived by principal components analysis; ‡negative values indicate reduced ability, motivation, happiness or support.

Table 5. Descriptive statistics for outcome measures [displayed as mean (SD)], stratified by absolute risk description, with marginal mean differences (with 95% confidence intervals) and corresponding p-values.

Outcome measure	Absolute risk		MD (95% CI)	p-value
	Not described	Described		
Primary outcomes				
Willingness to change diet (1 to 5)*	4.28 (0.84)	4.17 (0.85)	-0.11 (-0.20, -0.02)	.017
Worry about CVD risk (0 to 10)	6.22 (2.49)	6.10 (2.46)	-0.12 (-0.39, 0.15)	.37
Secondary outcomes				
Willingness to increase exercise (1 to 5)*	4.24 (0.90)	4.15 (0.95)	-0.09 (-0.19, 0.01)	.08
Willingness to accept medication (1 to 5)	3.43 (1.19)	3.54 (1.19)	0.11 (-0.02, 0.24)	.10
Perceived Severity (1 to 7)	4.88 (1.52)	4.75 (1.57)	-0.13 (-0.29, 0.04)	.13
Affect (standard deviation units)†				
Negative affect	0.00 (1.96)	0.00 (1.91)	0.00 (-0.21, 0.21)	.98
Positive affect	0.00 (1.91)	0.00 (1.77)	0.00 (-0.20, 0.20)	.98
Illness perceptions and beliefs (0 to 70)	32.96 (6.20)	32.37 (6.26)	-0.58 (-1.26, 0.09)	.09
Impacts on life (-3 to 3)‡				
Ability to obtain insurance products	-0.31 (1.29)	-0.42 (1.30)	-0.11 (-0.25, 0.03)	.14
Ability to work	-0.06 (0.99)	0.00 (0.99)	0.07 (-0.04, 0.18)	.21
Overall happiness	-0.33 (1.19)	-0.28 (1.18)	0.04 (-0.08, 0.17)	.51
Impacts on motivation (-3 to 3)‡				
Motivation to eat well	1.61 (1.18)	1.49 (1.14)	-0.12 (-0.24, 0.01)	.07
Motivation to exercise	1.57 (1.18)	1.44 (1.23)	-0.13 (-0.26, -0.002)	.047

* These outcomes showed some evidence of effect modification, see Table 5 for stratified estimates; †derived by principal components analysis; ‡ negative values indicate reduced ability, motivation, happiness or support.

Table 6. Descriptive statistics for outcome measures [displayed as mean (SD)], stratified by label and absolute risk description. Marginal mean differences (with 95% confidence intervals and corresponding p-values) are provided for each label condition compared to control within each absolute risk condition, and comparing absolute risk conditions within each label condition. P-values are provided for the effect modification of label by absolute risk.

	Label Condition					Label x Risk
	Control	Hypertension		High Normal		
Absolute Risk Condition	**M (SD)**	**M (SD)**	**MD (95% CI); p-value**	**M (SD)**	**MD (95%CI); p-value**	**p-value**
Willingness to change diet (1 to 5)						.08
Absolute Risk Not Described	4.17 (0.88)	4.38 (0.75)	0.21 (0.06, 0.37); p=.008	4.27 (0.86)	0.11 (-0.05, 0.67); p=.18	
Absolute Risk Described	4.16 (0.81)	4.13 (0.89)	-0.03 (-0.19, 0.13); p=.71	4.21 (0.85)	0.05 (-0.10, 0.21); p=.50	
MD (95% CI)	-0.01 (-0.17, 0.15)	-0.25 (-0.41, -0.10)		-0.06 (-0.22, 0.09)		
p-value	.91	.001		.43		
Willingness to increase exercise (1 to 5)						.03
Absolute Risk Not Described	4.18 (0.84)	4.31 (0.88)	0.14 (-0.04, 0.31); p=.12	4.21 (0.97)	0.04 (-0.14, 0.21); p=.68	
Absolute Risk Described	4.19 (0.86)	4.04 (1.08)	-0.15 (-0.32, 0.03); p=.09	4.22 (0.90)	0.03 (-0.14, 0.21); p=.73	
MD (95% CI)	0.01 (-0.17, 0.19)	-0.28 (-0.45, -0.11)		0.00 (-0.17, 0.18)		
p-value	.92	.001		.97		