BMJ Open

Accuracy of perceptions of fracture risk and osteoporosis treatment benefits: a randomised trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-013703
Article Type:	Research
Date Submitted by the Author:	31-Jul-2016
Complete List of Authors:	Kalluru, Ramanamma; University of Auckland, Department of Medicine; Auckland District Health Board, Department of Rheumatology Petrie, Keith; University of Auckland Grey, Andrew; University of Auckland Nisa, Zaynah; University of Auckland, Department of Medicine Horne, Anne; University of Auckland Gamble, Greg; University of Auckland Bolland, Mark; University of Auckland, Department of Medicine
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Communication
Keywords:	Fracture, Risk, Osteoporosis, Medication, Communication

Title: Accuracy of perceptions of fracture risk and osteoporosis treatment benefits: a randomised trial

Authors:

Rama Kalluru, FRACP [1,2]
Keith J Petrie, PhD [3]
Andrew Grey, MD,[1]
Zaynah Nisa, BSc,[1]
Anne M Horne, MBChB,[1]
Greg D Gamble, MSc,[1]
Mark J Bolland, MBChB, PhD,[1]

Affiliation:

[1]Department of Medicine, University of Auckland, Private Bag 92 019, Auckland 1142, New Zealand; [2]Department of Rheumatology, Private Bag 92189, Greenlane clinical centre, Auckland 1142; [3]Department of Psychological Medicine, University of Auckland, Private Bag 92 019, Auckland 1142, New Zealand

Address for correspondence/reprints:

Mark Bolland
Bone and Joint Research Group,
Department of Medicine, University of Auckland
Private Bag 92 019, Auckland 1142, New Zealand
Email: m.bolland@auckland.ac.nz
Ph 64 9 373 7999
Fax 64 9 373 7677

Word counts:

Text only: 3430
Abstract: 292
Figures: 2
Tables: 4

Key words: Fracture, Risk, Osteoporosis, Medication, Communication

Abstract:

Objectives:

The accuracy of patients' perception of risk is important for decisions about treatment in many diseases. We framed the risk of fracture and benefits of treatment in different ways and assessed the impact on patients' perception of fracture risk and intentions to take medication.

Design:

Randomised trial of four different presentations of fracture risk and likely benefits from osteoporosis treatment.

Setting:

Academic centre

Participants:

200 patients undergoing bone densitometry.

Intervention:

Presentation that framed the patient's absolute fracture risk either as the chance of having or not having an event, with their likely benefits from osteoporosis treatment in natural frequencies or numbers needed to treat.

Outcomes

Participants' views about their fracture risk and the need for osteoporosis treatment

Results:

The median 5y fracture risk threshold participants regarded as high enough to consider preventative medication was 50-60%, and did not change substantially after the presentation. The median (Q1,Q3) 5y risk initially estimated by participants was 20% (10,50) for any fracture and 19% (10,40) for hip fracture. 61% considered their fracture risk was low or very low, and 59-67% considered their fracture risk was lower than average. These participant estimates were 2-3 times higher than Garvan calculator estimates for any fracture, and 10-20 times higher for hip fracture. Participant estimates of fracture risk halved after the presentation, but remained higher than the Garvan estimates (1.5-2 times for any fracture, 5-10 times for hip fracture). There was no difference in these outcomes between the randomised groups. Participants' intentions about taking medication to prevent fractures were not substantially affected by receiving information about fracture risk and treatment benefits.

Conclusions:

Altering the framing of estimated fracture risks and treatment benefits had little effect on participants' perception of the need to take treatment or their individual fracture risk.

Trial registration:

Australian New Zealand Clinical Trials Registry (www.anzctr.org.au). Registration number is ACTRN12613001081707, date of registration 26/9/2013.

Article Summary

Strengths and Limitations

- A novel, randomised trial assessing different methods of risk communication by investigating the effects of framing of the risk of fracture and benefits of osteoporosis treatments.
- Participants were undergoing standard clinical care, so the results may be broadly generalizable.
- Fracture risk was the only risk measurement studied. It is not known whether similar results might be seen in other chronic conditions in which indications for treatment are based upon absolute risk such as cardiovascular disease.
- The study cohort was moderately sized and had a relatively low fracture risk.

Introduction

Accurate perception of risk is critical for the rational adoption of preventative treatment. People may make decisions about their health based upon their perceived risk of future events. Health care professionals try to predict the risks of these future events and present this information to patients to assist in making decisions about their treatment. Predictive models have been developed for many conditions, and calculators that integrate data on risk factors to estimate absolute risk for individuals are frequently used. These tools can lead to substantial shifts in disease management. Thus, management of cardiovascular risk has moved from individual risk factors such as blood pressure to become based on absolute cardiovascular risk.[1] Likewise, fracture risk calculators that integrate bone density measurements with clinical risk factors have shifted management of osteoporosis from an exclusive focus on bone density results to recommendations that incorporate absolute fracture risk.[2,3]

Communicating risk to patients is therefore fundamental to allow informed and shared decision making.[4] Problems that might arise when using estimates of the risk of a future event include misunderstanding numeric data and statistical concepts of risk and probability, both by the health care professional and the patient, and limited patient health literacy.[5,6] Research on communicating risks, benefits and harms to patients[5-11] has generated evidence-based recommendations for communicating risk.[6] They suggest that risks should be expressed as percentages or natural frequencies with benefits and harms expressed in absolute terms, supplemented by icon arrays,[6] which can be presented using a decision aid.[4]

The framing of risk is influential in patient decision-making. Risk that is framed positively by description of benefits or gains is associated with less perception of harm and increased

acceptance of therapies than when risk is framed negatively by use of harms or losses,[6] but these differences may not greatly influence behaviour.[9] Few trials have explored different approaches to communicating risk to patients for chronic conditions in which indications for treatment are based upon the absolute risk of an event within a set time frame, such as cardiovascular disease and osteoporosis.

We set out to investigate the impact of communicating absolute risk in different ways to patients, using fracture as the model health event. We investigated the effects of framing of the risk of fracture and benefits of osteoporosis treatments, and whether this influences patients' beliefs about the need for osteoporosis treatment. In particular, we assessed the effect of presenting risk and treatment benefits in terms of percentages, numbers need to treat, or natural frequencies, and of framing risk differently (for example: a 5% chance of having a hip fracture versus a 95% chance of not having a hip fracture).

Methods:

We invited consecutive patients >60y of age referred to a public hospital clinic for bone density measurement (Oct 2013-July 2014) who were not taking any specific osteoporosis treatments to take part. Prior to their bone density measurement, consenting participants completed a questionnaire exploring their beliefs about their risk of fracture and the benefits they might obtain from treatment. Following the bone density measurement, the absolute risk of fracture within 5y was calculated with the Garvan fracture risk calculator (http://www.garvan.org.au/promotions/bone-fracture-risk/calculator/). Participants were then randomised to receive one of four different written and pictorial presentations of their absolute fracture risk and the likely benefits they could expect from osteoporosis treatment. Group allocations were assigned by the study statistician using block randomisation with a

variable block size schedule, based on computer-generated random numbers. Allocation concealment occurred through centralized randomisation. After reading the presentation, participants completed a second questionnaire about the risks of fracture and benefits of treatment. The bone density scan was reported in accordance with standard practice, including management recommendations based upon the individual's absolute risk of fracture, and all participants were encouraged to discuss the report with their family doctor. We contacted all participants 3 months after their bone density scan to complete a third questionnaire exploring their beliefs about risk of fracture and the benefits of treatment. This study was approved by the Northern A Health and Disability Ethics Committee and was registered at ANZCTR (ACTRN12613001081707).

Questionnaires:

The three questionnaires are available in the Appendix. Briefly, we asked participants to rate their 5y risks of having any fracture and having a hip fracture on a scale of 0 (no chance) to 100% (definitely) and a scale of none to very high, and the 5y total fracture and hip fracture risks of the average man or woman of the same age on a scale of 0-100%. We asked participants whether they thought they should take osteoporosis medication, questions exploring their reasons for taking medication or not, and to rate the effectiveness of osteoporosis treatments on a scale of 0-100%.

Presentation of Risk:

Table 1 shows the four presentations of absolute risk of fracture and treatment benefits, which were provided to the participants in writing. The first 3 sentences were identical for each group, and stated the participant's calculated 5y risk of osteoporotic and hip fracture. Each randomised group then received text that framed risk either as the chance of having an

event or not having an event within 5y and with treatment benefits or the lack of treatment benefits (depending on the framing) in natural frequencies or presented as numbers needed to treat. All four options were accompanied by icon arrays depicting both the fracture risk and the treatment benefit (Appendix).

Statistics:

The pre-specified primary analysis was a comparison between the four randomised groups of the perceived risks of total fracture and hip fracture at which treatment would be considered. Secondary endpoints were the perceived risk of fracture, and the perceived need for osteoporosis treatment. As this was a novel study, it was difficult to estimate what effect sizes would be observed. Therefore we pragmatically aimed to recruit 200 patients, on the basis that this was feasible within a timely period, and with 50 patients per group, the largest confidence interval for a percentage result is 14% (for a proportion of 50%). A difference of approximately 20% could be detected in a pairwise comparison between two groups in this scenario. If the proportions were closer to 100% or 0%, the confidence intervals become narrower and the detectable differences become smaller. Because most data were non-normally distributed, we used non-parametric tests throughout, including the Kruskal-Wallis one-way ANOVA test for comparisons between the four groups, and the Signed Rank test for comparisons within groups. Spearman correlation analysis was used to test for significant associations between participant and calculator estimates of fracture risk. All tests were two-tailed and hypothesis tests were deemed significant for $P<0.05$. All statistical analyses were carried out using the SAS software package (SAS Institute, Cary, NC version 9.4)

Patient involvement:

Patients were not involved in the design of this study.

Results

200 people undergoing bone densitometry agreed to participate (Appendix Figure 1). Their baseline characteristics are shown in Table 2 and were similar in the four randomised groups. The cohort is broadly representative of patients seen in clinical practice for bone densitometry- the average age was 69y, 81% were female, 33% had a fracture after 50y, and the average femoral neck bone density T score was in the osteopenic range.

At baseline, the median (Q1,Q3) 5y risk threshold participants regarded as high enough to consider taking medication to prevent any fracture was 50% (25,70) for oral tablets and 60% (30,80) for intravenous medication (Table 3). For hip fracture, the respective 5y risk thresholds were 50% (30,75) and 60% (40,80). The thresholds were similar in the four randomised groups. Figure 1 shows that providing the written estimates of fracture risk and treatment benefits led to no or very small changes in these risk thresholds (a decrease of 10% or less in all groups). There were no between-groups differences in these changes (P>0.6). At baseline, 46% of participants estimated that their hip or total fracture risk was equal to or greater than one of the thresholds they considered high enough to take preventative medication. After written information on fracture risk and treatment benefits was provided, 37% of participants estimated that their hip or total fracture risk was equal to or greater than one of the thresholds they considered high enough to take preventative medication.

At baseline, the median (Q1,Q3) 5y risk of any fracture estimated by the participant was 20% (10,50), and for hip fracture was 19% (10,40) (Table 3). 61% considered that their risk of any fracture was low or very low. The median 5y risk of any fracture estimated by the participants for an average man or woman of the same age was 40% (20,50) and for hip

fracture was 30% (20,50). 59% of participants estimated that their individual risk of any fracture was lower than that of the average person, and 67% estimated their hip fracture risk as lower than average. Table 3 and Figure 2 show that the estimated risks of fracture by the participants and from the Garvan calculator were similar for the randomised groups. For the entire cohort and for each randomised group, the 5y risk of total fracture estimated by the participants was 2-3 times higher than the calculator estimates (P<0.001 for all groups). For hip fracture, the participant estimates were only slightly lower than the estimates for any fracture and were 10-20 times higher than the calculator estimates (P<0.001 for all groups). The correlation between participant and calculator risk estimates was modest: r=0.33, P<0.001 for any fracture and r=0.22, P=0.002 for hip fracture.

Table 3 and Figure 2 show the influence of providing information on the individual participant's fracture risk from the Garvan calculator on participants' estimates of their own fracture risk. There were small (0-10%) reductions in participants' perceptions of their total and hip fracture risk that were not different between groups (P>0.4). In all groups, the participant estimates remained much higher than the calculator estimates after these estimates were provided to the participants (P<0.001 for all groups).

Prior to their bone density scan, 15% of participants felt they should take medication to prevent fractures, 34% felt they should not take medication and 51% were unsure (Table 4, Appendix Table 1). The proportions did not change substantially after the calculator estimates and treatment benefits were provided- the respective proportions were 19%, 51% and 30%. At 3 months after the bone density scan, 34% of participants indicated that they had started medication or were intending to. A similar proportion (43-48%) of participants who felt they should or should not take osteoporosis medication or did not know at baseline,

estimated their hip or total fracture risk was equal to or greater than one of the thresholds they considered high enough to take preventative medication (Appendix Table 1).

Table 4 shows that one third of those who believed they should take osteoporosis medication before their bone density measurement changed their views after receiving the information on fracture risk and treatment benefits, and a similar proportion had not started or did not intend to start osteoporosis medication at the 3 month follow-up. Of those who initially believed they should not take osteoporosis medication, 80% persisted with that belief after receiving the information on fracture risk and treatment benefits, and a similar proportion had not started or did not intend to start osteoporosis medication at the 3 month follow-up. Of the group who were undecided initially, about half remained undecided after receiving the information on fracture risk and treatment benefits, but one third had started or intended to start medication at the 3 month follow-up.

Discussion

In this study, providing estimated absolute risks of fracture and benefits of treatment in four different ways had little effect on participants' perception of their need to take treatment or their individual risk of fracture. Previous research and trials on risk communication have generally reported important differences between presentations of natural frequencies or numbers needed to treat and between different framing styles, but these studies mainly focussed on understanding of risk rather than need for intervention.[5,6,8-10] Before their bone density scan, the average 5y fracture risk threshold at which participants would consider treatment was 50-60%. These thresholds changed little after information on fracture risk and treatment benefits was provided. Prior to receiving this information, participants overestimated their risk of any fracture by 2-3 times and of hip fracture by 10-20 times. After

receiving a written description of their fracture risk, participants' estimates of their risk of fracture halved but remained 1.5-2 times higher than the Garvan estimates for any fracture, and 5-10 times higher for hip fracture. Framing the presentation of risk as the chance of having a fracture did not produce different results from framing the presentation as the chance of not having a fracture.

Strengths and limitations

The strengths of the study are its novelty, randomized allocation to different methods of risk communication, and relevance to clinical practice. Although there is a large body of research into risk communication,[5-11] we are not aware of similar trials that have explored the impact of risk framing on risk perception and treatment benefits, either where the absolute risk of an event forms the basis for treatment recommendations or in the field of osteoporosis. Participants were patients undergoing standard clinical care, so the results may be generalisable to similar outpatient populations. There are limitations to our results. Our cohort was of moderate size and had a relatively low fracture risk. Whether the findings would be similar in cohorts at higher or lower risk of fracture or in other conditions, such as cardiovascular disease, is worth exploring. The questionnaires, presentation of results and icon arrays were designed for this study, and different results might be obtained using different text or icon arrays, or if similar information is discussed within the context of a clinical consultation. The results at 3 months will likely be influenced by the bone density report and the views of the primary care doctor.

Comparison to other studies

Previously, we reported that a group of patients surveyed prior to bone density measurement substantially overestimated their individual risk of fracture,[12] findings similar to those from

the current study. Other studies that have reported participants' views on their fracture risk found that older women generally consider themselves to be at lower risk of fracture than their peers, as we found in the current study. The GLOW study reported that 43-49% of women (mean age 69y) felt their fracture risk was below average, with only 12-15% considering themselves above average risk.[13] Likewise in the ROSE study, 42% of women (mean age 71y) considered their risk was below average, and only 5% considered their risk was above average.[14] There was a poor correlation between participants' own estimate of their 10y fracture risk and the estimate from the FRAX calculator.[14] However, participants were invited to classify their risk into 5 categories (<10%, 10-14%, 15-19%, 20-24% and ≥25%) and by providing these values, the investigators may have introduced an anchoring bias into participant estimates. Collectively, the results suggest that people have an optimistic bias about their personal risk,[15] generally considering themselves healthier and at lower risk than the average person. Nevertheless, their numeric estimates of their risk are substantial overestimates.

One previous trial[16] randomised participants with low bone density to receive standard care or a decision aid that contained written descriptions of fracture risk and treatment benefits: the aid improved understanding of these concepts. However, consistent with the findings from our study, 51% of women who used the aid and 72% of women receiving standard care were unable to correctly identify their fracture risk from 3 categories (<10%, 10-30%, and >30%). Taken together, the results of these studies suggest that patients have difficulty understanding information about risk presented in written and pictorial formats and that research is required into what patients think an absolute risk of fracture represents.

More broadly, previous studies on framing of risk reported that positive framing led to better understanding of the message, and higher ratings of perceived effectiveness of therapies than negative framing.[9] However, other studies reported that framing did not appear to affect hypothetical decisions or intentions to adopt interventions, or actual behaviour.[9] In our study, framing of risk had little effect on patients' perceived fracture risk or views about treatment, consistent with the latter studies. Previous studies reported that the use of absolute risk reductions is better understood than the use of numbers needed to treat, is associated with higher ratings of perceived effectiveness, but is not associated with differences in effects on hypothetical decisions or intentions to adopt interventions.[8] In our study, the use of absolute risk reductions presented with natural frequencies did not alter patients' perceived fracture risk or views about treatment compared to the use of numbers needed to treat.

Study meaning and interpretation

Some of our findings are surprising. We anticipated participants overestimating their risk of fracture at baseline.[12] However, we expected that after being provided with an explicit description of their estimated fracture risks, participants would align their personal estimates of fracture risk with the provided values. The failure to do so suggests that the participants either did not understand the concept of risk or the presentation of results, or they did not believe the estimates provided.

The results highlight some interesting features of risk perceptions among participants undergoing bone densitometry. At baseline, the median 5y risk of any fracture estimated by participants was 20%, and for hip fracture was 19%. It is not clear whether participants therefore believe that non-hip fractures are extremely rare, or that they misunderstood the question or answer. Both of these levels of risk would be categorised as high by most

osteoporosis guidelines,[2,3] yet only 7-8% of participants viewed their risk as high or very high and 61% considered their risk as low or very low. The median thresholds of 5y fracture risk at which participants considered they would take preventative medication were 40-60% and 46% of participants' own estimates of fracture risk were equal to or greater than these thresholds. However, this seemed unrelated to the decision to take treatment: similar proportions (43-48%) of people whose own estimates of fracture risk were greater than or equal to their own treatment thresholds believed they should or should not take osteoporosis medication or did not know. Similar to the findings of our previous survey,[12] these contradictions highlight large and important discrepancies between patients' and health care professionals' perception of fracture risk, and intervention thresholds.

Undertaking a bone density scan tended to reinforce rather than change patients' views about the need for treatment. Thus, only 35% of people who believed that they should take osteoporosis medication before the scan and 19% of people who believed that they should not take osteoporosis medication changed their views 3 months after the scan. The small differences between these two groups in bone density, participants' estimated fracture risk, and Garvan risk estimates are unlikely to explain the differing perceptions about the perceived need for medication. For the majority of people with a view about the need for osteoporosis medication before having a bone density scan, the results of the scan appear to have confirmed their pre-existing beliefs, regardless of the result. This may represent a confirmation bias, whereby attention is focussed on aspects of the results that support the pre-existing beliefs while aspects that challenge the beliefs are downplayed or ignored.[17]

The majority of participants in the study considered that they were at lower risk of fracture than average, a consistent finding in many studies termed the "better than average effect".

Providing comparisons of risk to the average person can change risk perception.[18] Individuals who believe they are at lower risk than average may consider they do not need to take treatment without actually considering the benefits of the treatment.

In summary, we found that patients referred for bone densitometry have a high threshold of fracture risk before they would consider taking treatment to prevent fractures, and this does not change after written information on fracture risk and treatment benefits is provided. These patients also substantially overestimate their risk of fracture, even after fracture risk estimates are provided to them explicitly in writing. We identified a number of logical contradictions in patients' views about fracture risk that present challenges for health care practitioners trying to accurately communicate fracture risk to patients as the first step in allowing informed, shared decision-making. It seems unwise to assume that simply providing absolute risks of fracture and treatment benefits to patients is adequate to allow this to occur. It is important to explore whether these findings are specific to fracture risk, or are a more general feature of conditions where absolute risk estimates of health events are a fundamental component, such as cardiovascular disease.

What this paper adds Box

What is already known on this subject

- Framing of risk affects patient understanding and acceptance of treatments.
- There is limited research on communicating risk to patients for conditions where treatment indications are based upon the absolute risk of an event, such as fracture.

What this study adds

- Altering the framing of estimated fracture risks and treatment benefits had little effect on participants' perceived need to take treatment or their individual fracture risk.
- Despite generally considering themselves at lower-than-average fracture risk, patients substantially overestimated their risk of fracture, even after receiving a written description of their fracture risk.
- Simply providing absolute risks of fracture and treatment benefits to patients is unlikely to be sufficient to allow informed and shared decision making.

Acknowledgements:

Conflicts of Interest:

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: the study was funded by the Health Research Council (HRC) of New Zealand. Andrew Grey is a shareholder in Auckland Bone Density, an organisation that provides bone densitometry services. All other authors have no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work

Contributorship:

RK, KP, AG, GG, and MB designed the research. RK, ZN, AH, and MB ran the trial. MB and GG performed the analyses. MB drafted the paper. All authors critically reviewed and improved it. MB is the guarantor for the article. All authors had access to all the data and take responsibility for the integrity of the data and the accuracy of the data analysis.

Funding:

Funded by the Health Research Council (HRC) of New Zealand. The authors are independent of the HRC. The HRC had no role in study design, the collection, analysis, and interpretation of data, the writing of the article, or the decision to submit it for publication.

Transparency statement

MB affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

Data sharing: Patient level data available from the corresponding author upon reasonable request. Patient consent was not obtained but the presented data are anonymised and risk of identification is low.

References

1. Jackson R. Guidelines on preventing cardiovascular disease in clinical practice. *BMJ.* 2000;320(7236):659-661.
2. Dawson-Hughes B. A revised clinician's guide to the prevention and treatment of osteoporosis. *J Clin Endocrinol Metab.* 2008;93(7):2463-2465.
3. Compston J, Cooper A, Cooper C, et al. Guidelines for the diagnosis and management of osteoporosis in postmenopausal women and men from the age of 50 years in the UK. *Maturitas.* 2009;62(2):105-108.
4. McCartney M, Treadwell J, Maskrey N, Lehman R. Making evidence based medicine work for individual patients. *BMJ.* 2016;353:i2452.
5. Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. *BMJ.* 2003;327(7417):741-744.
6. Zipkin DA, Umscheid CA, Keating NL, et al. Evidence-based risk communication: a systematic review. *Ann Intern Med.* 2014;161(4):270-280.
7. Ancker JS, Senathirajah Y, Kukafka R, Starren JB. Design features of graphs in health risk communication: a systematic review. *J Am Med Inform Assoc.* 2006;13(6):608-618.
8. Akl EA, Oxman AD, Herrin J, et al. Using alternative statistical formats for presenting risks and risk reductions. *Cochrane Database Syst Rev.* 2011(3):CD006776.
9. Akl EA, Oxman AD, Herrin J, et al. Framing of health information messages. *Cochrane Database Syst Rev.* 2011(12):CD006777.
10. Ahmed H, Naik G, Willoughby H, Edwards AG. Communicating risk. *BMJ.* 2012;344:e3996.

11. Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2014;1:CD001431.

12. Douglas F, Petrie KJ, Cundy T, Horne A, Gamble G, Grey A. Differing perceptions of intervention thresholds for fracture risk: a survey of patients and doctors. *Osteoporos Int.* 2012;23(8):2135-2140.

13. Jones SM, Gell NM, Roth JA, Scholes D, LaCroix AZ. The Relationship of Perceived Risk and Biases in Perceived Risk to Fracture Prevention Behavior in Older Women. *Ann Behav Med.* 2015;49(5):696-703.

14. Rothmann MJ, Ammentorp J, Bech M, et al. Self-perceived facture risk: factors underlying women's perception of risk for osteoporotic fractures: the Risk-Stratified Osteoporosis Strategy Evaluation study (ROSE). *Osteoporos Int.* 2015;26(2):689-697.

15. Weinstein ND. Optimistic biases about personal risks. *Science.* 1989;246(4935):1232-1233.

16. Montori VM, Shah ND, Pencille LJ, et al. Use of a decision aid to improve treatment decisions in osteoporosis: the osteoporosis choice randomized trial. *Am J Med.* 2011;124(6):549-556.

17. Nickerson RS. Confirmation bias: A ubiquitous phenomenon in many guises. *Rev Gen Psychol.* 1998;2(2):175-220.

18. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. "If I'm better than average, then I'm ok?": Comparative information influences beliefs about risk and benefits. *Patient Educ Couns.* 2007;69(1-3):140-144.

Table 1: Text received by participants in each randomised group

Common text	• Based on the information in your questionnaire and your bone density: • Your estimated risk of osteoporotic fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next 5 years is: 20% • Your estimated risk of hip fracture in the next 5 years is: 5%
Group 1: Framed as chance of having an event and treatment benefits in natural frequencies	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 20 would have an osteoporotic fracture within the next 5 years, and 5 would have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that if all these 100 people took osteoporosis medication for 5 years, the number of people who would have an osteoporotic fracture within those 5 years would decrease from 20 to 13. The number who would have a hip fracture within those 5 years would decrease from 5 to 3.
Group 2: Framed as chance of not having an event and treatment benefits in natural frequencies	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 80 will **not** have an osteoporotic fracture within the next 5 years, and 95 will **not** have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that if all these 100 people took osteoporosis treatments for 5 years, the number of people who would **not** have an osteoporotic fracture within those 5 years would increase from 80 to 87. The number of people who would **not** have a hip fracture within those 5 years would increase from 95 to 97.

Group 3: Framed as chance of having an event and treatment benefits as number needed to treat	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 20 would have an osteoporotic fracture within the next 5 years, and 5 would have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that 15 people like you would need to be treated with osteoporosis medications for 5 years to prevent 1 osteoporotic fracture. 50 people like you would need to be treated for 5 years to prevent 1 hip fracture.
Group 4: Framed as chance of not having an event and treatment benefits as number needed to treat	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 80 will **not** have an osteoporotic fracture within the next 5 years, and 95 will **not** have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that if 15 people like you were treated with osteoporosis medications for 5 years, 14 would receive no benefit in terms of osteoporotic fracture prevention, and in 1 person a fracture would be prevented. If 50 people like you were treated for 5 years, 49 would receive no benefit in terms of hip fracture prevention, and in 1 person a hip fracture would be prevented.

For illustrative purposes, all options use a 5 year 20% risk of osteoporotic fracture and 5% risk of hip fracture.

Table 2: Baseline characteristics by randomised group

	Group 1	Group 2	Group 3	Group 4
n	51	49	51	49
Age (y)	69.1 (7.4)	68.3 (5.7)	70.3 (6.3)	68.9 (6.0)
Body mass index (kg/m^2)	26.7 (5.1)	27.1 (4.7)	26.4 (4.4)	26.5 (5.4)
Female (%)	86	71	75	90
European descent (%)	92	98	94	96
Fracture after 50 years (%)	41	31	35	22
Bone mineral density T-score				
Lumbar spine	-0.5 (1.6)	-0.3 (1.8)	-0.4 (2.0)	-0.1 (1.6)
Total hip	-1.2 (1.1)	-0.9 (1.3)	-1.1 (1.2)	-1.1 (2.3)
Femoral neck	-1.6 (0.9)	-1.3 (1.1)	-1.5 (1.0)	-1.3 (0.9)

Data are %, or mean (SD). Group 1: framed as chance of having an event and treatment benefits in natural frequencies; Group 2: framed as chance of not having an event and treatment benefits in natural frequencies; Group 3: framed as chance of having an event and treatment benefits as number needed to treat; Group 4: framed as chance of not having an event and treatment benefits as number needed to treat.

Table 3: Influence of providing information communicating risk of fracture and treatment benefits

	Group 1 (n=51)	Group 2 (n=49)	Group 3 (n=51)	Group 4 (n=49)	Entire cohort
Participant estimates at baseline					
5y fracture risk high enough to consider taking medications (tablet/intravenous) to prevent fracture (any/hip) (%)					
Any fracture/ tablets (%)	50 (23, 75)	50 (28, 60)	50 (35, 80)	50 (20, 60)	50 (25, 70)
Any fracture/ intravenous (%)	53 (40, 80)	55 (20, 72)	60 (50, 80)	60 (30, 80)	60 (30, 80)
Hip fracture/ tablets (%)	50 (30, 80)	50 (35, 73)	55 (50, 80)	48 (20, 60)	50 (30, 75)
Hip fracture/ intravenous (%)	60 (45, 80)	55 (30, 80)	60 (40, 80)	65 (30, 80)	60 (40, 80)
Risk of any fracture in next 5y (%)	25 (10, 50)	25 (10, 50)	20 (10, 50)	15 (10, 40)	20 (10, 50)
None/ very low risk	14	17	16	24	18
Low risk	44	38	45	47	43
Moderate risk	30	42	29	24	31
High risk	12	4	10	2	7
Very high risk	0	0	0	2	1
Risk of hip fracture in next 5y (%)	15 (10, 50)	20 (10, 45)	20 (10, 40)	10 (5, 30)	19 (10, 40)
Garvan fracture risk calculator estimates					
5y Osteoporotic fracture risk	7.9 (5.8, 12.3)	7.3 (4.4, 9.9)	8.5 (5.6, 14.6)	7.1 (5.0, 9.6)	7.4 (5.5, 12.0)
5y Hip fracture risk	1.6 (0.8, 3.4)	1.2 (0.7, 2.4)	1.8 (0.8, 4.1)	1.3 (0.6, 2.0)	1.4 (0.8, 3.0)
Participant estimates after information on fracture risk and treatment benefits provided					
Risk of any fracture in next 5y (%)	14 (9, 30)	19 (10, 27)	15 (7, 30)	10 (8, 20)	12 (8, 30)
None/ very low risk	20	29	27	33	27
Low risk	45	47	47	47	47
Moderate risk	31	18	20	10	20
High risk	4	6	4	8	6
Very high risk	0	0	2	2	1
Risk of hip fracture in next 5y (%)	8 (2, 20)	10 (2, 20)	10 (2, 20)	10 (2, 15)	10 (2, 20)

Data are percent or median (Q1,Q3). Group 1: framed as chance of having an event and treatment benefits in natural frequencies; Group 2: framed as chance of not having an event and treatment benefits in natural frequencies; Group 3: framed as chance of having an event

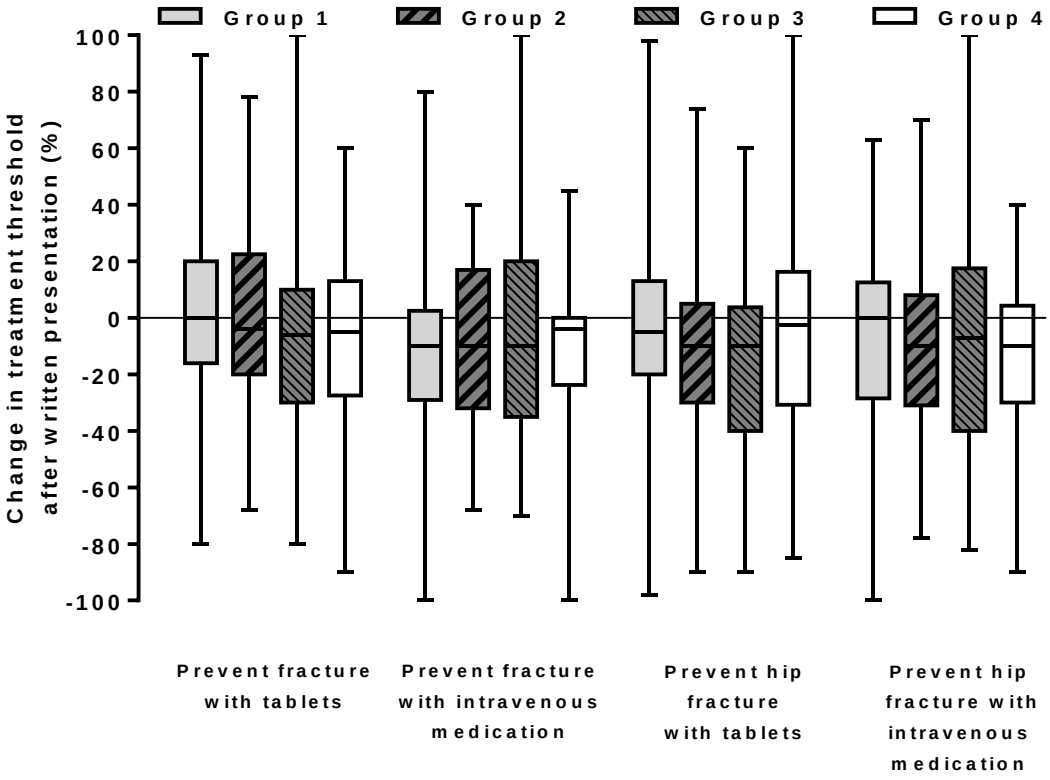
and treatment benefits with number needed to treat; Group 4: framed as chance of not having an event and treatment benefits with number needed to treat.

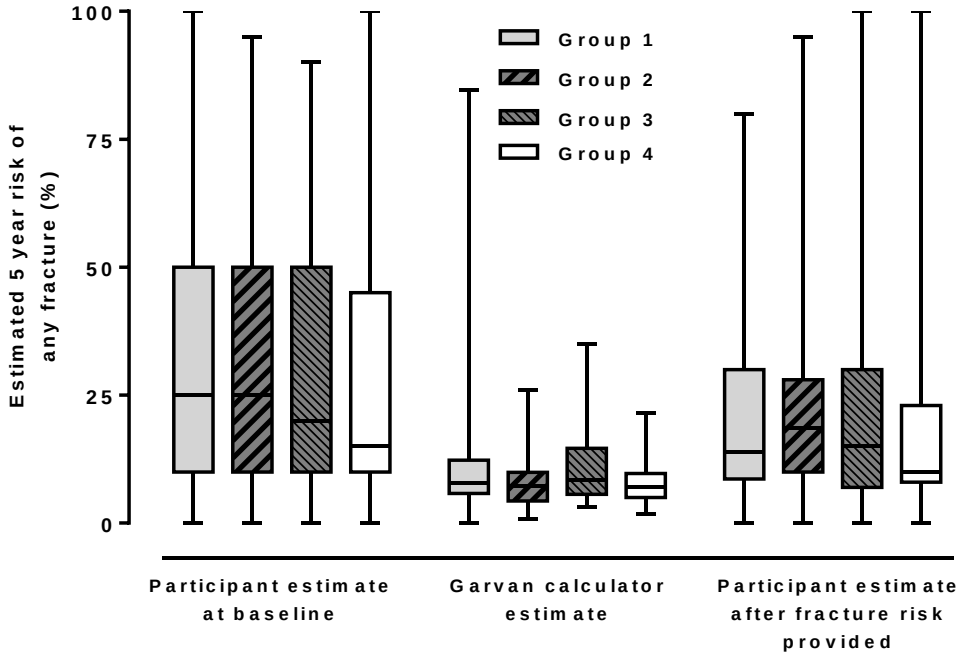
Table 4: Participant views about taking osteoporosis medicine grouped by their initial views

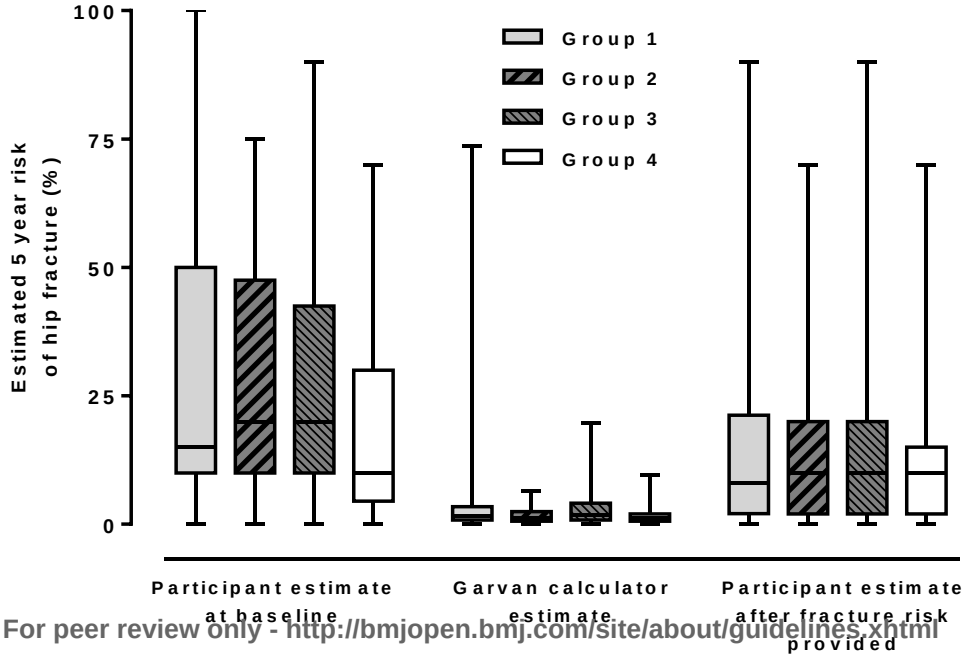
	Participants' initial view on whether they should take osteoporosis medication		
	Yes	**No**	**Don't know**
Prior to bone density scan			
n (%)	30 (15)	67 (34)	101 (51)
After information on fracture risk and treatment benefits provided			
Should you take osteoporosis medication?			
Yes (%)	20 (67)	3 (4)	14 (14)
No (%)	8 (27)	54 (81)	39 (39)
Don't know (%)	2 (7)	10 (15)	48 (48)
At 3m follow-up			
Started/intend to start osteoporosis medication			
Yes (%)	17 (65)	12 (19)	34 (35)
No (%)	9 (35)	51 (81)	62 (65)

Figure 1: Box and Whisker plots of the changes in the 5y risk thresholds participants considered high enough to take treatment, either by tablets or by intravenous infusion, to prevent any fracture or hip fracture after written information on fracture risk and treatment benefits was provided by treatment group. Group 1 (n=51): framed as chance of having an event and treatment benefits in natural frequencies; Group 2 (n=49): framed as chance of not having an event and treatment benefits in natural frequencies; Group 3 (n=51): framed as chance of having an event and treatment benefits as number needed to treat; Group 4 (n=49): framed as chance of not having an event and treatment benefits as number needed to treat.

Figure 2: Box and Whisker plots of the estimated 5y risk of osteoporotic and hip fracture before and after the provision of fracture risk estimates from the Garvan calculator. Group 1 (n=51): framed as chance of having an event and treatment benefits in natural frequencies; Group 2 (n=49): framed as chance of not having an event and treatment benefits in natural frequencies; Group 3 (n=51): framed as chance of having an event and treatment benefits as number needed to treat; Group 4 (n=49): framed as chance of not having an event and treatment benefits as number needed to treat.





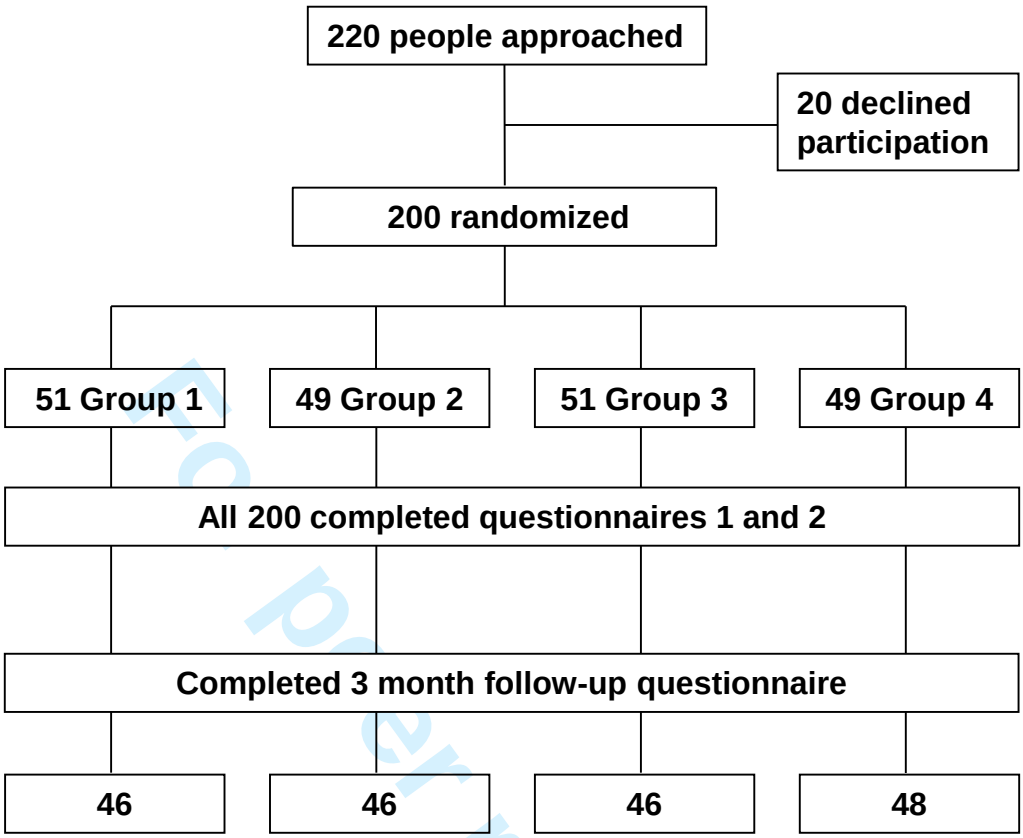


Appendix:

Table 1: characteristics and results for participants grouped by their initial views about taking osteoporosis medicine

	Participant believed they should take osteoporosis medication prior to bone density measurement		
	Yes	**No**	**Don't know**
n (%)	30 (15)	67 (34)	101 (51)
Age (y)	69.6 (8.0)	68.2 (5.4)	69.8 (6.5)
Body mass index (kg/m^2)	25.9 (4.5)	26.5 (5.1)	26.9 (4.8)
Female (%)	77	87	78
European descent (%)	90	99	94
Fracture after 50y (%)	40	31	32
Bone mineral density T-score			
Lumbar spine	-0.2 (-1.6, 0.6)	-0.8 (-1.4, 0.6)	-0.6 (-1.5, 0.8)
Total hip	-1.4 (-2.6, -0.4)	-1.0 (-1.5, -0.3)	-1.1 (-2.0, -0.3)
Femoral neck	-1.8 (-2.5, -1.5)	-1.5 (-2.0, -0.8)	-1.6 (-2.1, -0.9)
Participant estimates at baseline			
5y risk high enough to consider taking medications (tablet/intravenous) to prevent fracture (any/hip) (%)			
Any fracture/ tablets (%)	50 (30, 70)	40 (15, 70)	50 (40, 70)
Any fracture/ intravenous (%)	64 (40, 80)	50 (20, 80)	60 (40, 80)
Hip fracture/ tablets (%)	35 (10, 60)	20 (10, 25)	30 (10, 50)
Hip fracture/ intravenous (%)	28 (10, 50)	10 (5, 25)	20 (10, 50)
Estimated risk ≥ treatment threshold (%)	47	43	48
Garvan fracture risk calculator estimates			
5y Osteoporotic fracture risk	8.8 (5.6, 14.9)	6.6 (5.3, 10.2)	7.7 (5.6, 11.9)
5y Hip fracture risk	2.1 (0.9, 4.1)	1.1 (0.7, 2.5)	1.5 (0.8, 3.0)
Participant estimates and views after information on fracture risk and treatment benefits provided			
5y risk high enough to consider taking medications (tablet/intravenous) to prevent fracture (any/hip) (%)			
Any fracture/ tablets (%)	50 (20, 80)	48 (20, 70)	50 (22, 60)
Any fracture/ intravenous (%)	45 (20, 80)	40 (20, 68)	50 (23, 70)
Hip fracture/ tablets (%)	14 (10, 35)	10 (8, 20)	15 (9, 30)
Hip fracture/ intravenous (%)	10 (4, 30)	10 (0, 15)	10 (3, 20)
Estimated risk ≥ treatment threshold (%)	33	30	43

Figure 1:



Flow of participants

Questionnaires 1-3

Written information sheets on fracture risk and treatment benefits provided to participants in each randomised group, with 20% 5y osteoporotic fracture and 5% 5y hip fracture risk used for illustrative purposes.

Questionnaire 1:

As explained in the information sheet, this study is designed to gather information about your perceptions of your bone health.

The questionnaire asks about your views of your bone health and your perceptions of treatments that influence bone health.

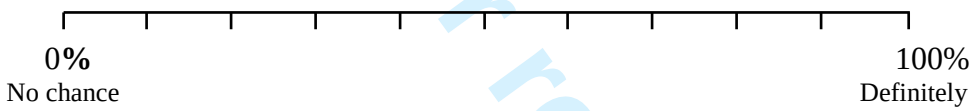
All of the information you provide is strictly *confidential* to the researchers, and will only be used for this study. This research will not affect your ongoing healthcare.

Please remember that there are no right or wrong answers to the questions – an answer is correct if it is true for you. We are interested in your experience and perception, as well as the way you evaluate risk. Please choose the responses that feel right for you.

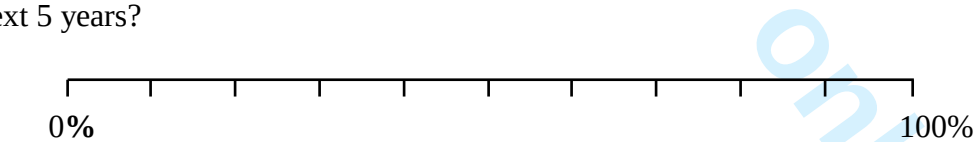
Your risk of fracture (breaking a bone):

1. How would you rate your risk of having any fracture in the next 5 years on a scale from 0% to 100%? (0% means no chance of fracture, 100% means you will definitely have a fracture)?

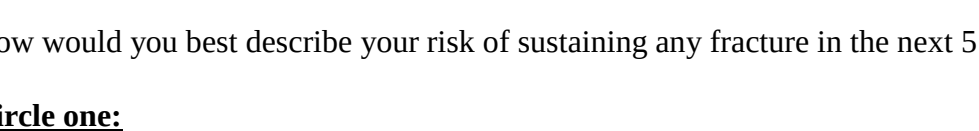
   Mark on the line to indicate your risk



2. How would you rate your risk of having a *hip* fracture in the next 5 years?



3. How would you rate the risk of the average woman/man your age of having any fracture in the next 5 years?



4. On the same scale, how would you rate the risk of the average woman/man your age having a *hip* fracture in the next 5 years?

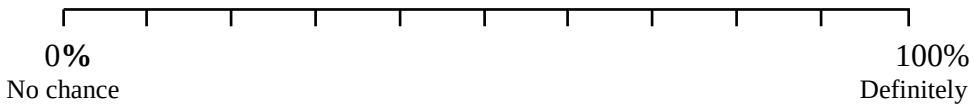
5. How would you best describe your risk of sustaining any fracture in the next 5 years?

   Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

How effective are osteoporosis treatments?

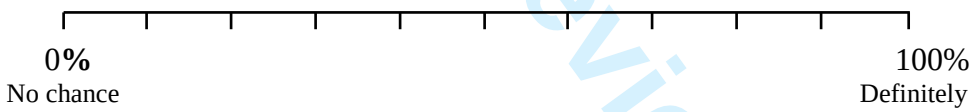
6. By how much do you think medications for osteoporosis are able to reduce the chance of fracture on a scale of 0% to 100%? (0% means not at all- the treatment prevents no fractures, 50% means that half of fractures would be prevented, and 100% means completely effective- all fractures are prevented)?



7. What risk of breaking a bone in the next 5 years, on a scale from 0% (no chance) to 100% (definitely will have a fracture), would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.

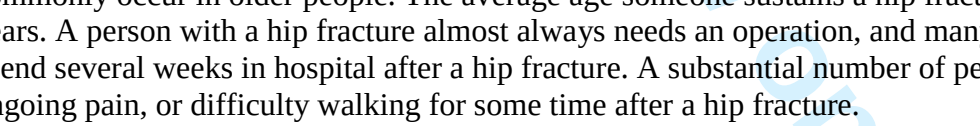
   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.



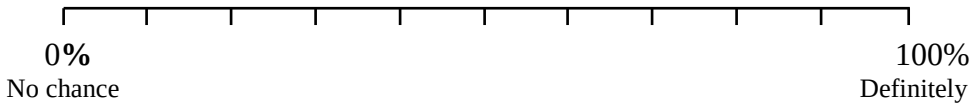
8. Hip fractures are the generally regarded as the most serious type of broken bone. They most commonly occur in older people. The average age someone sustains a hip fracture is 75-80 years. A person with a hip fracture almost always needs an operation, and many people will spend several weeks in hospital after a hip fracture. A substantial number of people will have ongoing pain, or difficulty walking for some time after a hip fracture.

   What risk of *hip* fracture in the next 5 years would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.



b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.



9. Do you think osteoporosis treatments are better at preventing hip fractures than other types of fractures?

Circle one:

Yes - osteoporosis medications are better at preventing hip fractures

No difference - osteoporosis medications prevent hip fractures as well as other types of fractures

No- osteoporosis medications are better at preventing fractures other than hip fractures

The National Osteoporosis Foundation in the United States recommends that individuals should take osteoporosis medications if their risk of a fracture over 5 years is greater than 10% (more than 10 people out of 100 will suffer a fracture in the next 5 years) **or** their risk of hip fracture over 5 years is greater than 2% (more than 2 people out of 100 will suffer a hip fracture in the next 5 years). We are interested in your views of these recommendations.

10. Do you think these thresholds (10% for osteoporotic fracture and 2% for hip fracture) are:

Circle one:

Too high (People at lower risk of fracture should be advised to take medication)

About right

Too low (People should not be treated until their risk of fracture is higher)

Please turn over the page for Question 11

Osteoporosis medications:

11. Do you think that **you** should take osteoporosis medication?

Circle one:

Yes **No** **Don't know**

12. What factors influenced your answer to question 11? Circle the number that best represents your views

My risk of breaking bones in the near future is:

1	2	3	4	5
None/Very low	Low	Moderate	High	Very High

My bone density is probably

1	2	3	4	5
None/Very low	Low	Moderate	High	Very High

I don't think that I need to take osteoporosis medications

1	2	3	4	5
Strongly disagree				Strongly agree

I am concerned about taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				Strongly agree

I am worried about side-effects of taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				Strongly agree

Osteoporosis medications stop people breaking bones

1	2	3	4	5
Strongly disagree				Strongly agree

Osteoporosis medications increase bone density

1	2	3	4	5
Strongly disagree				Strongly agree

13. Which statements do you think most accurately describes osteoporosis medications.

Circle one:

1. Osteoporosis medications are **highly** effective in preventing fractures

2. Osteoporosis medications are **moderately** effective in preventing fractures

3. Osteoporosis medications are **not very** effective in preventing fractures.

Circle one:

1. In New Zealand, osteoporosis medications are prescribed **too often**

2. In New Zealand, osteoporosis medications are prescribed **about right (not too much and not too little)**

3. In New Zealand, osteoporosis medications are **not prescribed often enough**

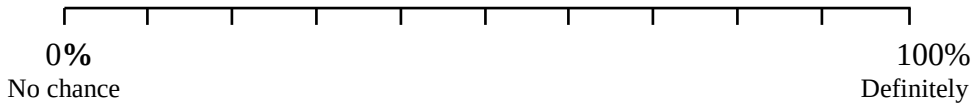
Questionnaire 2:

Option 1, 2, 3, or 4 for written information on fracture risk and treatment benefits and icon arrays.

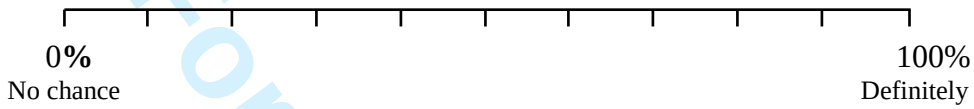
Based on this information:

Your risk of fracture (breaking a bone):

1. How would you rate your risk of having any fracture in the next 5 years on a scale from 0%- 100%? (0% means no chance of fracture, 100% means you will definitely have a fracture)?



2. How would you rate your risk of having a *hip* fracture in the next 5 years?



3. How would you best describe your risk of sustaining any fracture in the next 5 years?

Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

4. Do you think that you should take osteoporosis medication?

Circle one:

Yes	No	Don't know

5. What factors influenced your answer to question 4? Circle the number that best represents your views

My risk of breaking bones in the near future is:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

My bone density is probably

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

I don't think that I need to take osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am concerned about taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am worried about side-effects of taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications stop people breaking bones

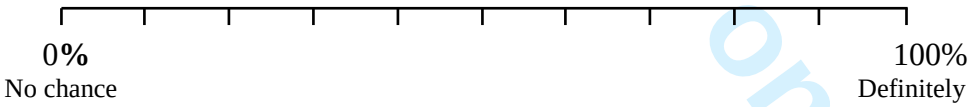
1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications increase bone density

1	2	3	4	5
Strongly disagree				**Strongly agree**

6. What risk of breaking a bone in the next 5 years, on a scale from 0% (no chance) to 100% (definitely will have a fracture), would you regard as high enough to consider taking a preventative medicine?

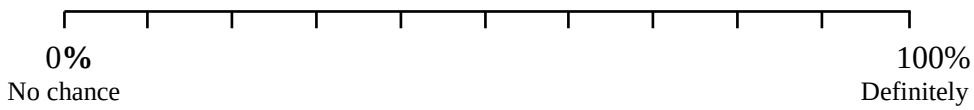
   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.



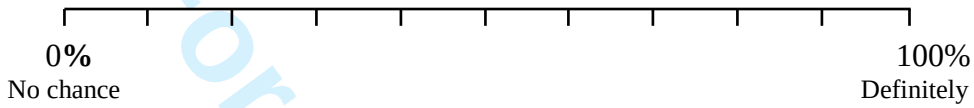
   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.

7. What risk of *hip* fracture in the next 5 years would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.



   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.



The National Osteoporosis Foundation in the United States recommends that individuals should take osteoporosis medications if their risk of a fracture over 5 years is greater than 10% or their risk of hip fracture over 5 years is greater than 2%.

8. Do you think these thresholds (10% for osteoporotic fracture and 2% for hip fracture) are:

   Circle one:

   Too high (People at lower risk of fracture should be advised to take medication)

   About right

   Too low (People should not be treated until their risk of fracture is higher)

Questionnaire 3:

About 3 months ago you had a bone density scan and answered several questions about risk of fracture (breaking bones) and effectiveness of osteoporosis treatments. This is a short series of follow-up questions.

1. Have you discussed your bone density result with your GP/specialist?

   Circle one:

   Yes **No**

2. Have you started taking osteoporosis medication (or do you intend to start medication in the near future)?

   Circle one:

   Yes **No**

3. Who made the decision to start or not to start osteoporosis medication?

   Circle one:

   Myself

   My GP/Specialist

   Joint decision between myself and my GP/specialist

   Other- please explain _____

4. How would you best describe your risk of sustaining a fracture in the next 5 years?

   Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

5. Which statements do you think most accurately describes osteoporosis medications.

   Circle one:

   Osteoporosis medications are **highly** effective in preventing fractures

   Osteoporosis medications are **moderately** effective in preventing fractures

   Osteoporosis medications are **not very** effective in preventing fractures.

   Circle one:

   In New Zealand, osteoporosis medications are prescribed **too often**

   In New Zealand, osteoporosis medications are prescribed **about right (not too much and not too little)**

   In New Zealand, osteoporosis medications are **not prescribed often enough**

Group 1

Based on the information in your questionnaire and your bone density: Participant Number 1

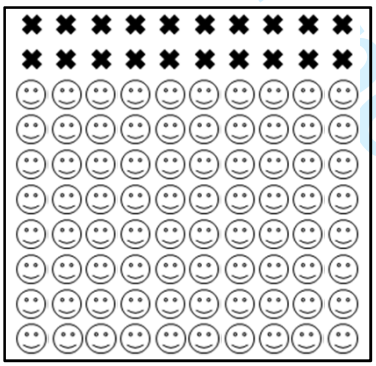
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

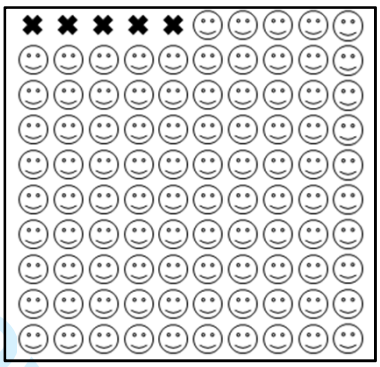
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **20** would have an **osteoporotic** fracture within the next **5** years, and **5** would have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the crosses indicate those who have a fracture within **5** years.
The smiley faces indicate those who do not have a fracture.

Osteoporotic fracture



Hip fracture

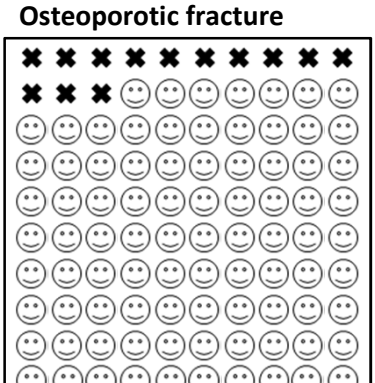


Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

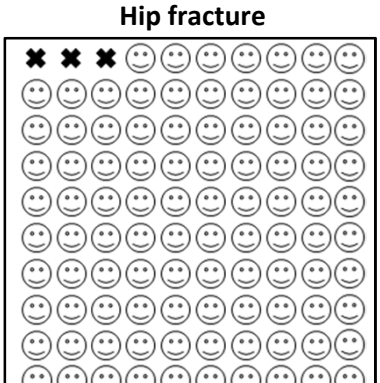
This means that if all these **100** people took osteoporosis medication for **5** years, the number of people who would have an **osteoporotic** fracture within those **5** years would decrease from **20** to **13**
The number who would have a **hip** fracture within those **5** years would decrease from **5** to **3**
(Note: sometimes these numbers are the same because of rounding.)

The crosses indicate those **with** a fracture, if **100** people took osteoporosis medication for **5** years

Osteoporotic fracture



Hip fracture



Group 2

Based on the information in your questionnaire and your bone density: Participant Number 1

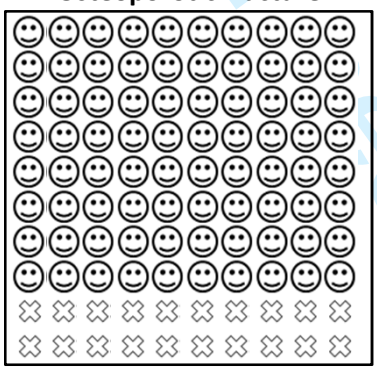
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

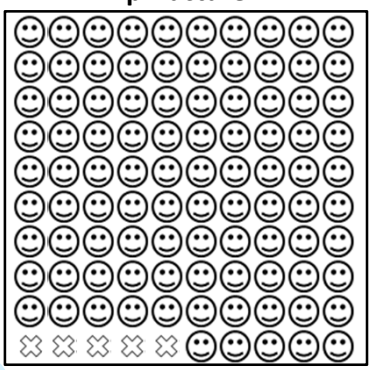
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **80** will **NOT** have an **osteoporotic** fracture within the next 5 years, and **95** will **NOT** have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the smiley faces indicate those who do **NOT** have a fracture within **5** years.
The crosses indicate those who have a fracture.

Osteoporotic fracture



Hip fracture

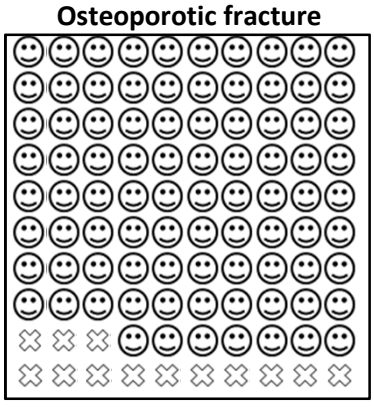


Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

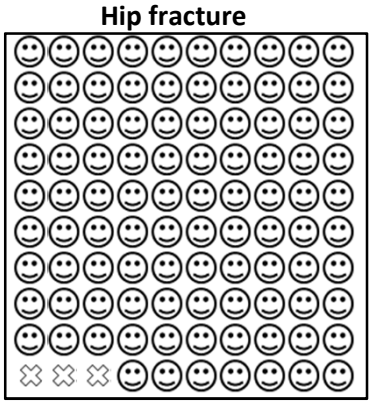
This means that if all these **100** people took osteoporosis medication for **5** years, the number of people who would **NOT** have an **osteoporotic** fracture within those **5** years would increase from **80** to **87**
The number who would **NOT** have a **hip** fracture within those **5** years would increase from **95** to **97**
(Note: sometimes these numbers are the same because of rounding.)

The smiley faces indicate those **without** a fracture, if **100** people took osteoporosis medication for **5** years

Osteoporotic fracture



Hip fracture



Group 3

Based on the information in your questionnaire and your bone density: Participant Number 1

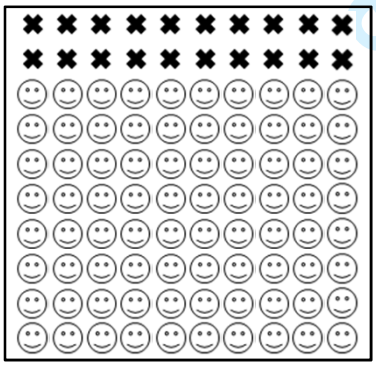
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

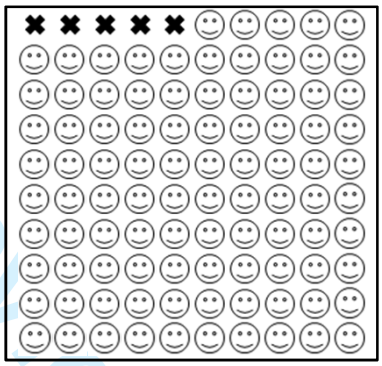
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **20** would have an **osteoporotic** fracture within the next **5** years, and **5** would have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the crosses indicate those who have a fracture within **5** years.
The smiley faces indicate those who do not have a fracture.

Osteoporotic fracture



Hip fracture



Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

This means that **15** people like you would need to be treated with osteoporosis medications for **5** years to prevent **1 osteoporotic** fracture.
50 people like you would need to be treated for 5 years to prevent 1 **hip** fracture.

These pictures show the benefits of treatment visually.
The smiley faces indicate those who benefited from treatment (by having an **osteoporotic** fracture prevented). The shaded faces indicate those who did not benefit from treatment.

The smiley faces indicate those who benefited from treatment (by having a **hip** fracture prevented). The shaded faces indicate those who did not benefit from treatment.

Group 4

Based on the information in your questionnaire and your bone density: Participant Number 1

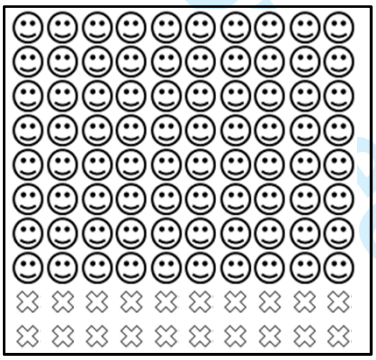
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

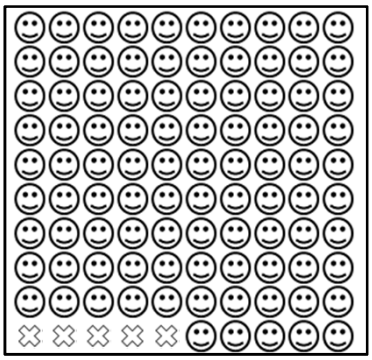
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **80** will **NOT** have an **osteoporotic** fracture within the next 5 years, and **95** will **NOT** have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the smiley faces indicate those who do **NOT** have a fracture within **5** years.
The crosses indicate those who have a fracture.

Osteoporotic fracture



Hip fracture



Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

This means that if **15** people like you were treated with osteoporosis medications for **5** years,
14 people would receive no benefit in terms of **osteoporotic** fracture prevention,
and in **1** person, a fracture would be prevented.

If **50** people like you were treated for 5 years, **49** would receive no benefit
in terms of **hip** fracture prevention, and in **1** person a **hip** fracture would be prevented.

These pictures show the benefits of treatment visually.
The shaded faces indicate those who did **NOT** benefit from treatment (ie. they did **NOT** have an **osteoporotic** fracture prevented). The smiley faces indicate those who benefited from treatment.

The shaded faces indicate those who did **NOT** benefit from treatment (ie. they did **NOT** have a **hip** fracture prevented). The smiley faces indicate those who benefited from treatment.

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

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6/7, Table 1, Appendix
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5-6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5-6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Not applicable

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Appendix Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Appendix Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1, 2 Table 3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Figure 1,2 Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	Supp file
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

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

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	2,6	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	4,5,6	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	6,7 Table 1, Appendix	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	6,7 Table 1, Appendix	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Not applicable	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	5,6,7	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	5	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	5,6,7	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Not applicable	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Not applicable	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Protocol: Exploring the effects of different approaches to communicating fracture risk to patients.

Investigators:

Rama Kalluru

Mark Bolland

Keith Petrie

Andrew Grey

1. Background:

Previously, we surveyed a group of patients prior to bone density measurement about their perceptions of risk of fracture, intervention thresholds and benefits of treatment [1]. There were three key findings: 1. Patients substantially overestimated their individual risk of fracture; 2. Patients believe that pharmacologic treatments to prevent fracture should begin at a risk of fracture that is much higher than is recommended in treatment guidelines for osteoporosis; 3. Patients want much greater risk reductions for fracture from pharmacologic interventions than occur with currently available treatments.

Communicating absolute risk to patients has been standard practice for many years for cardiovascular disease, and treatment guidelines incorporating absolute risk of cardiovascular events have been developed. For example, a 15% 5-year risk of cardiovascular events is often considered a suitable threshold for treatment intervention. Calculators that estimate the absolute risk of fracture have only become widely available within the last 5 years, and communication of absolute fracture risks to patients is now beginning to become established in clinical practice.

It is known that risk is poorly understood by patients and that presentation of risk using different methods can influence patient beliefs and responses. In particular, risk can be framed positively (eg you have a 5% chance of hip fracture within 5 years) or negatively (eg you have a 95% chance of not having a hip fracture within 5 years), and risk can be presented in terms of percentages, numbers need to treat, or natural frequencies.

We plan to extend our previous research by exploring (a) the effects of communicating absolute risk of fracture in different ways to patients and (b) how knowledge of their individual fracture risk influences patient's beliefs about osteoporosis treatment.

2. Aim

1. To determine whether the means by which risk is communicated influences patients' views about their risk of fracture.

2. To determine whether the method of presenting treatment benefits influences patients' views about whether osteoporosis treatment should be taken.

3. Research design:

200 consecutive patients >60y of age referred to a public hospital clinic for bone density measurement who are not taking any specific osteoporosis treatments will be recruited. They will complete a standard questionnaire used for all patients undergoing bone density measurement (Bone density questionnaire) and have their bone density measured. They will then complete a short questionnaire (Questionnaire 1) exploring their beliefs about their risk of fracture and the benefits they might obtain from treatment. Their absolute risk of fracture within the next 5y will be calculated using information from their bone density questionnaire and their bone density result. Participants will then be randomised to receive one of four different presentations of their absolute risk, and the likely benefits they could expect from osteoporosis treatment. Participants will then complete a short questionnaire (Questionnaire 2) exploring whether the knowledge of their absolute risk of fracture has influenced their beliefs about their personal risk of fracture, their willingness to take treatment, and the

benefits of treatment. The participant's bone density scan will be reported by a physician with a report sent to the GP (in accordance with standard practice). All participants will be encouraged to discuss the report with their GP. We will contact all participants 3 months after their bone density scan, and they will again complete a short questionnaire exploring their beliefs about their risk of fracture and the benefits they might obtain from treatment (Questionnaire 3).

3.1 Participants:

200 consecutive patients attending the University of Auckland bone densitometry service will be recruited

3.1.1 Inclusion criteria:

Age >60y (because the Garvan absolute fracture risk calculator does not estimate fracture risk for younger participants).

3.1.2 Exclusion criteria:

Patients taking antiresorptive treatment for osteoporosis.
Unable to complete the questionnaires, for language or cognitive reasons

3.2 Randomisation

The option for presentation of absolute risk of fracture and treatment benefits will be randomly assigned

3.3 Options for presentation of absolute risk of fracture

There are four different presentations of the same information. Of note, all participants will receive the same first 3 sentences. (For these examples the risk of osteoporotic fracture of 20% and hip fracture of 5% have been used, however these will be individualised in the study)

<u>Option 1: Framing as chance of having an event</u>

Based on the information in your questionnaire and your bone density:

> Your estimated risk of osteoporotic fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next 5 years is: 20%
>
> Your estimated risk of hip fracture in the next 5 years is: 5%

This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 20 would have an osteoporotic fracture within the next 5 years, and 5 would have a hip fracture within the next 5 years.

Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%.

This means that if all these 100 people took osteoporosis medication for 5 years, the number of people who would have an osteoporotic fracture within those 5 years would decrease from 20 to 13. The number who would have a hip fracture within those 5 years would decrease from 5 to 3.

Option 2: Framing as chance of not having an event

Based on the information in your questionnaire and your bone density:

> Your estimated risk of osteoporotic fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next 5 years is: 20%
>
> Your estimated risk of hip fracture in the next 5 years is: 5%

This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 80 will **not** have an osteoporotic fracture within the next 5 years, and 95 will **not** have a hip fracture within the next 5 years.

Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%.

This means that if all these 100 people took osteoporosis treatments for 5 years, the number of people who would **not** have an osteoporotic fracture within those 5 years would increase from 80 to 87. The number of people who would **not** have a hip fracture within those 5 years would increase from 95 to 97.

Option 3: Number needed to treat to prevent an event

Based on the information in your questionnaire and your bone density:

> Your estimated risk of osteoporotic fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next 5 years is: 20%
>
> Your estimated risk of hip fracture in the next 5 years is: 5%

This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 20 would have an osteoporotic fracture within the next 5 years, and 5 would have a hip fracture within the next 5 years.

Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%.

This means that 15 people like you would need to be treated with osteoporosis medications for 5 years to prevent 1 osteoporotic fracture. 50 people like you would need to be treated for 5 years to prevent 1 hip fracture.

Option 4: Number needed to treat to prevent an event, with presentation of number treated without benefit

Based on the information in your questionnaire and your bone density:

Your estimated risk of osteoporotic fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next 5 years is: 20%

Your estimated risk of hip fracture in the next 5 years is: 5%

This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 80 will **not** have an osteoporotic fracture within the next 5 years, and 95 will **not** have a hip fracture within the next 5 years.

Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%.

This means that if 15 people like you were treated with osteoporosis medications for 5 years, 14 would receive no benefit in terms of osteoporotic fracture prevention, and in 1 person a fracture would be prevented. If 50 people like you were treated for 5 years, 49 would receive no benefit in terms of hip fracture prevention, and in 1 person a hip fracture would be prevented.

Statistics

The primary analysis will be a comparison between the four randomised groups for the perceived risks of total fracture and hip fracture at which treatment would be considered. Secondary analyses will be comparisons between the four groups for the perceived risk of fracture, the perceived need for treatment, the perceived thresholds for risk of fracture, and comparisons between the baseline data and the data post provision of the participant's risk of fracture will be undertaken for all of these variables. Differences in continuous variables will be tested with one way ANOVA or t-tests as appropriate, and differences in categorical tests tested using chi-square tests or McNemar's test.

This is a novel study and it is difficult to estimate what effect sizes we will observe. Therefore a power calculation is problematic. We estimate that recruiting 200 patients is feasible and can be achieved in a timely period (< 3 months). With 50 patients per group, the largest confidence interval for a percentage result is 14% (when the result is 50%). Thus, a difference of approximately 20% could be detected in a pairwise comparison between 2 groups in this scenario. If the result was closer to 100% or 0%, the detectable difference becomes smaller.

Ethics

This study has been approved by the Northern A Health and Disability Ethics Committee

References:

1. Douglas F, Petrie KJ, Cundy T, Horne A, Gamble G, Grey A. Differing perceptions of intervention thresholds for fracture risk: a survey of patients and doctors. Osteoporos Int 2012;23:2135-40.

Bone density questionnaire:

BONE DENSITY QUESTIONNAIRE

Please **CIRCLE** correct answer. Provide other information as accurately as possible.

NAME:_____ NHI _____ Date of Birth:_____

PERSONAL HISTORY			**MEDICATION**			Years Used
Prior diagnosis of osteoporosis	Yes	No	Steroid (Prednisone)	Yes	No	_____ to _____
Height Loss	Yes	No	- Current daily dose ?			_____
Overactive thyroid gland	Yes	No	- Average daily dose past year?			_____
Rheumatoid arthritis or SLE	Yes	No	- Past prednisone > 5mg/day	Yes	No	_____ to _____
Other chronic Illness	Yes	No	Didronel/Etidronate	Yes	No	_____ to _____
eg. coeliac or liver disease, Type 1 diabetes			Alendronate (Fosamax)	Yes	No	_____ to _____
Specify: _____			Zoledronate (intravenous)	Yes	No	_____ to _____
_____			--------- Total number of infusions?			_____
Smoking (current)	Yes	No	Calcium supplements	Yes	No	
Alcohol 3 or more drinks/day	Yes	No	Monthly calciferol	Yes	No	
Number of falls in the past year			Multivitamins	Yes	No	
Hip replacements	Yes	No	Thyroxine	Yes	No	
Lower Spine surgery	Yes	No	Anticonvulsants	Yes	No	
MRI, CT scan or barium	Yes	No	Pioglitazone/Actos	Yes	No	
meal (in past 2 wks)						
FRACTURE HISTORY			**FOR WOMEN ONLY**			
Fracture of any bone/s	Yes	No	Current Pregnancy	Yes	No	
Which bone/s _____			Hysterectomy	Yes	No	
When _____			Depo Provera	Yes	No	_____ to _____
			Hormone Replacement	Yes	No	_____ to _____
HAVE YOU EVER HAD?			Age at menopause _____			
A bone density scan			***Breast Cancer Treatments:***			
If yes, when _____			Arimidex, Femara	Yes	No	_____ to _____
where _____			Tamoxifen	Yes	No	_____ to _____
FAMILY HISTORY ***(immediate family only)***			**FOR MEN ONLY**			
Diagnosis of Osteoporosis	Yes	No	Androgen Deprivation Therapy	Yes	No	_____ to _____
Spine, hip wrist or arm fracture	Yes	No	(e.g., Zoladex, Flutamide for prostate cancer)			
A parent with hip fracture	Yes	No				

- Are you interested in taking part in bone research Y / N
- A positive response does not commit you to participating in a study.

Technician use only

Any additional information: _____

_____

_____

Questionnaire 1:

As explained in the information sheet, this study is designed to gather information about your perceptions of your bone health.

The questionnaire asks about your views of your bone health and your perceptions of treatments that influence bone health.

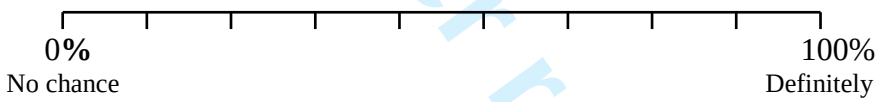
All of the information you provide is strictly *confidential* to the researchers, and will only be used for this study. This research will not affect your ongoing healthcare.

Please remember that there are no right or wrong answers to the questions – an answer is correct if it is true for you. We are interested in your experience and perception, as well as the way you evaluate risk. Please choose the responses that feel right for you.

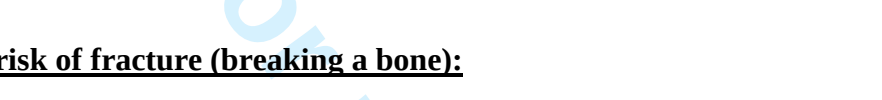
Your risk of fracture (breaking a bone):

1. How would you rate your risk of having any fracture in the next 5 years on a scale from 0% to 100%? (0% means no chance of fracture, 100% means you will definitely have a fracture)?

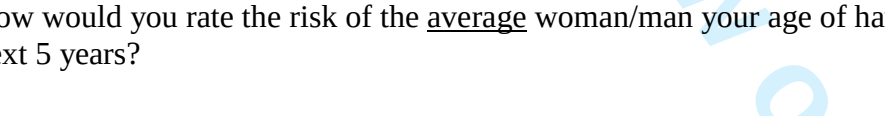
   Mark on the line to indicate your risk



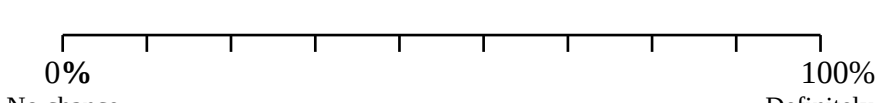
2. How would you rate your risk of having a *hip* fracture in the next 5 years?



3. How would you rate the risk of the average woman/man your age of having any fracture in the next 5 years?



4. On the same scale, how would you rate the risk of the average woman/man your age having a *hip* fracture in the next 5 years?



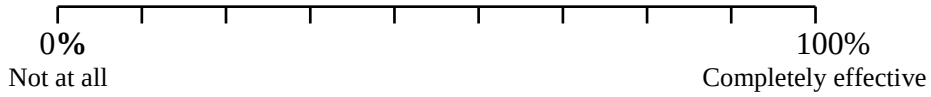
5. How would you best describe your risk of sustaining any fracture in the next 5 years?

   Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

How effective are osteoporosis treatments?

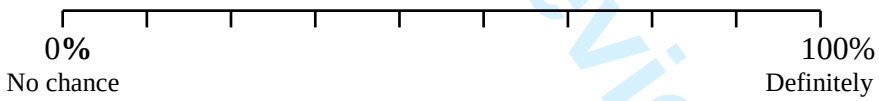
6. By how much do you think medications for osteoporosis are able to reduce the chance of fracture on a scale of 0% to 100%? (0% means not at all- the treatment prevents no fractures, 50% means that half of fractures would be prevented, and 100% means completely effective- all fractures are prevented)?



7. What risk of breaking a bone in the next 5 years, on a scale from 0% (no chance) to 100% (definitely will have a fracture), would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.

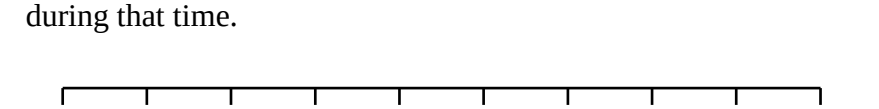
   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.



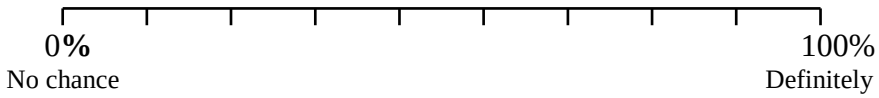
8. Hip fractures are the generally regarded as the most serious type of broken bone. They most commonly occur in older people. The average age someone sustains a hip fracture is 75-80 years. A person with a hip fracture almost always needs an operation, and many people will spend several weeks in hospital after a hip fracture. A substantial number of people will have ongoing pain, or difficulty walking for some time after a hip fracture.

   What risk of *hip* fracture in the next 5 years would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.



b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.



9. Do you think osteoporosis treatments are better at preventing hip fractures than other types of fractures?

Circle one:

Yes - osteoporosis medications are better at preventing hip fractures

No difference - osteoporosis medications prevent hip fractures as well as other types of fractures

No- osteoporosis medications are better at preventing fractures other than hip fractures

The National Osteoporosis Foundation in the United States recommends that individuals should take osteoporosis medications if their risk of a fracture over 5 years is greater than 10% (more than 10 people out of 100 will suffer a fracture in the next 5 years) **or** their risk of hip fracture over 5 years is greater than 2% (more than 2 people out of 100 will suffer a hip fracture in the next 5 years). We are interested in your views of these recommendations.

10. Do you think these thresholds (10% for osteoporotic fracture and 2% for hip fracture) are:

Circle one:

Too high (People at lower risk of fracture should be advised to take medication)

About right

Too low (People should not be treated until their risk of fracture is higher)

Please turn over the page for Question 11

Osteoporosis medications:

11. Do you think that **you** should take osteoporosis medication?

Circle one:

Yes **No** **Don't know**

12. What factors influenced your answer to question 11? Circle the number that best represents your views

My risk of breaking bones in the near future is:

1	2	3	4	5
None/Very low	Low	Moderate	High	Very High

My bone density is probably

1	2	3	4	5
None/Very low	Low	Moderate	High	Very High

I don't think that I need to take osteoporosis medications

1	2	3	4	5
Strongly disagree				Strongly agree

I am concerned about taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				Strongly agree

I am worried about side-effects of taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				Strongly agree

Osteoporosis medications stop people breaking bones

1	2	3	4	5
Strongly disagree				Strongly agree

Osteoporosis medications increase bone density

1	2	3	4	5
Strongly disagree				Strongly agree

13. Which statements do you think most accurately describes osteoporosis medications.

Circle one:

1. Osteoporosis medications are **highly** effective in preventing fractures

2. Osteoporosis medications are **moderately** effective in preventing fractures

3. Osteoporosis medications are **not very** effective in preventing fractures.

Circle one:

1. In New Zealand, osteoporosis medications are prescribed **too often**

2. In New Zealand, osteoporosis medications are prescribed **about right (not too much and not too little)**

3. In New Zealand, osteoporosis medications are **not prescribed often enough**

Questionnaire 2:

Option 1

Based on the information in your questionnaire and your bone density: Participant Number 1

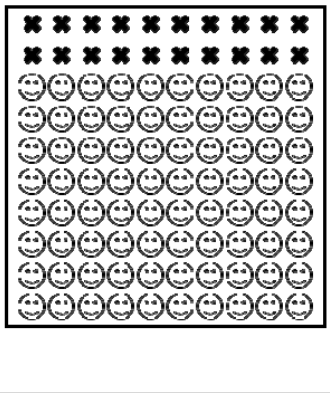
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

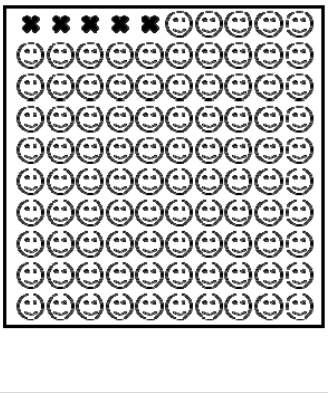
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **20** would have an **osteoporotic** fracture within the next **5** years, and **5** would have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the crosses indicate those who have a fracture within **5** years.
The smiley faces indicate those who do not have a fracture.

Osteoporotic fracture



Hip fracture

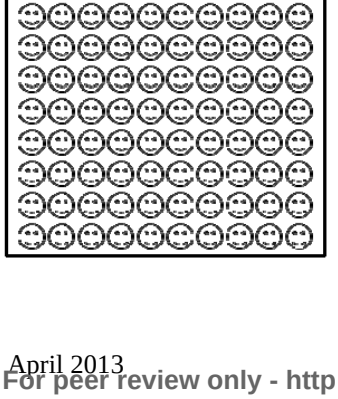


Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

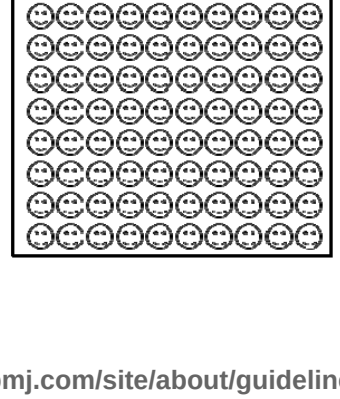
This means that if all these **100** people took osteoporosis medication for **5** years, the number of people who would have an **osteoporotic** fracture within those **5** years would decrease from **20** to **13**
The number who would have a **hip** fracture within those **5** years would decrease from **5** to **3**
(Note: sometimes these numbers are the same because of rounding.)

The crosses indicate those **with** a fracture, if **100** people took osteoporosis medication for **5** years

Osteoporotic fracture



Hip fracture



or Option 2

Based on the information in your questionnaire and your bone density: Participant Number 1

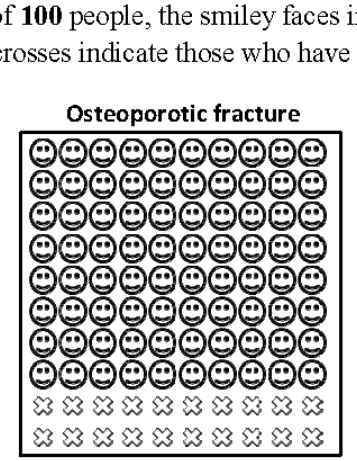
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

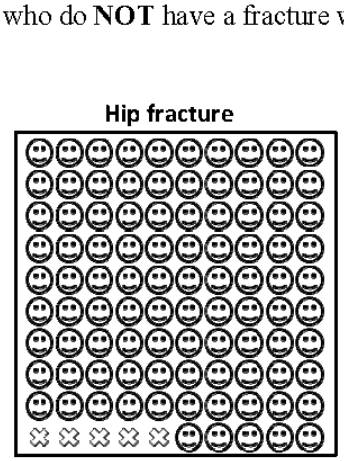
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **80** will **NOT** have an **osteoporotic** fracture within the next 5 years, and **95** will **NOT** have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the smiley faces indicate those who do **NOT** have a fracture within **5** years.
The crosses indicate those who have a fracture.

Osteoporotic fracture



Hip fracture

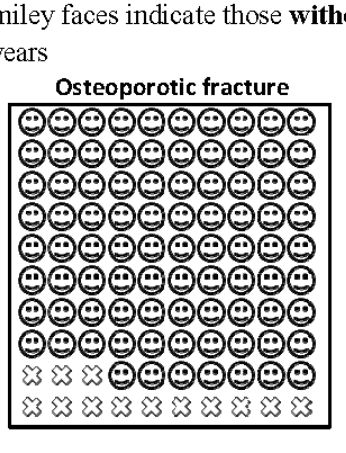


Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

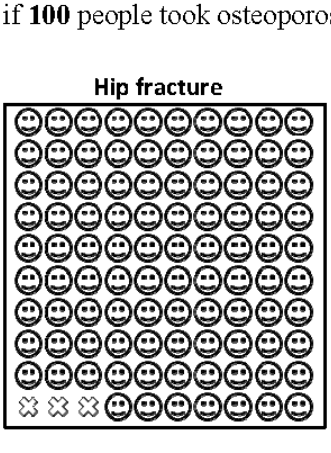
This means that if all these **100** people took osteoporosis medication for **5** years, the number of people who would **NOT** have an **osteoporotic** fracture within those **5** years would increase from **80** to **87**
The number who would **NOT** have a **hip** fracture within those **5** years would increase from **95** to **97**
(Note: sometimes these numbers are the same because of rounding.)

The smiley faces indicate those **without** a fracture, if **100** people took osteoporosis medication for **5** years

Osteoporotic fracture



Hip fracture



or Option 3

Based on the information in your questionnaire and your bone density: Participant Number 1

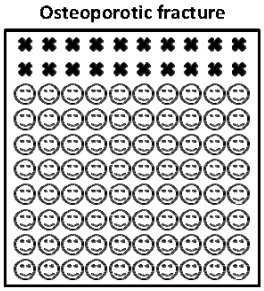
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

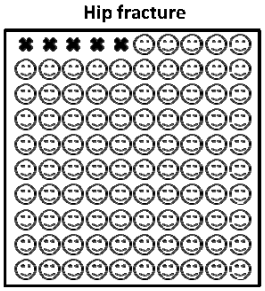
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **20** would have an **osteoporotic** fracture within the next **5** years, and **5** would have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the crosses indicate those who have a fracture within **5** years.
The smiley faces indicate those who do not have a fracture.

Osteoporotic fracture



Hip fracture



Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

This means that **15** people like you would need to be treated with osteoporosis medications for **5** years to prevent **1 osteoporotic** fracture.
50 people like you would need to be treated for 5 years to prevent 1 **hip** fracture.

These pictures show the benefits of treatment visually.
The smiley faces indicate those who benefited from treatment (by having an **osteoporotic** fracture prevented). The shaded faces indicate those who did not benefit from treatment.

The smiley faces indicate those who benefited from treatment (by having a **hip** fracture prevented). The shaded faces indicate those who did not benefit from treatment.

or Option 4

Based on the information in your questionnaire and your bone density: Participant Number 1

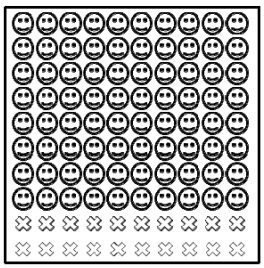
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

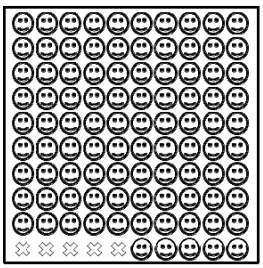
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **80** will **NOT** have an **osteoporotic** fracture within the next 5 years, and **95** will **NOT** have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the smiley faces indicate those who do **NOT** have a fracture within **5** years.
The crosses indicate those who have a fracture.

Osteoporotic fracture



Hip fracture

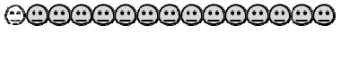


Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

This means that if **15** people like you were treated with osteoporosis medications for **5** years, **14** people would receive no benefit in terms of **osteoporotic** fracture prevention, and in **1** person, a fracture would be prevented.

If **50** people like you were treated for 5 years, **49** would receive no benefit in terms of **hip** fracture prevention, and in **1** person a **hip** fracture would be prevented.

These pictures show the benefits of treatment visually.
The shaded faces indicate those who did **NOT** benefit from treatment (ie. they did **NOT** have an **osteoporotic** fracture prevented). The smiley faces indicate those who benefited from treatment.

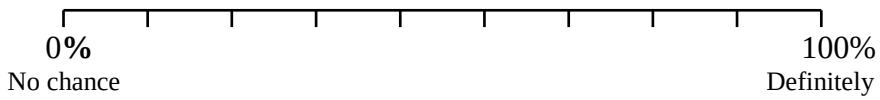


The shaded faces indicate those who did **NOT** benefit from treatment (ie. they did **NOT** have a **hip** fracture prevented). The smiley faces indicate those who benefited from treatment.

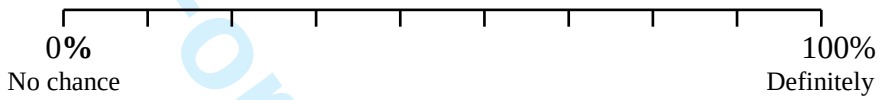
Based on this information:

Your risk of fracture (breaking a bone):

1. How would you rate your risk of having any fracture in the next 5 years on a scale from 0%- 100%? (0% means no chance of fracture, 100% means you will definitely have a fracture)?



2. How would you rate your risk of having a *hip* fracture in the next 5 years?



3. How would you best describe your risk of sustaining any fracture in the next 5 years?

Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

4. Do you think that you should take osteoporosis medication?

Circle one:

Yes	No	Don't know

5. What factors influenced your answer to question 4? Circle the number that best represents your views

My risk of breaking bones in the near future is:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

My bone density is probably

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

I don't think that I need to take osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am concerned about taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am worried about side-effects of taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications stop people breaking bones

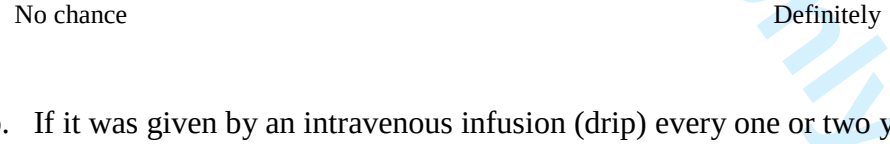
1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications increase bone density

1	2	3	4	5
Strongly disagree				**Strongly agree**

6. What risk of breaking a bone in the next 5 years, on a scale from 0% (no chance) to 100% (definitely will have a fracture), would you regard as high enough to consider taking a preventative medicine?

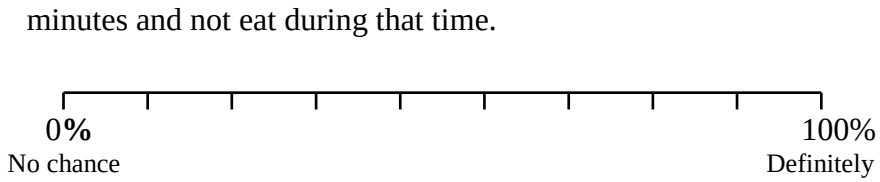
   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.



   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.

7. What risk of *hip* fracture in the next 5 years would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.



   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.

The National Osteoporosis Foundation in the United States recommends that individuals should take osteoporosis medications if their risk of a fracture over 5 years is greater than 10% or their risk of hip fracture over 5 years is greater than 2%.

8. Do you think these thresholds (10% for osteoporotic fracture and 2% for hip fracture) are:

   Circle one:

   Too high (People at lower risk of fracture should be advised to take medication)

   About right

   Too low (People should not be treated until their risk of fracture is higher)

Questionnaire 3:

About 3 months ago you had a bone density scan and answered several questions about risk of fracture (breaking bones) and effectiveness of osteoporosis treatments. This is a short series of follow-up questions.

1. Have you discussed your bone density result with your GP/specialist?

   Circle one:

   Yes **No**

2. Have you started taking osteoporosis medication (or do you intend to start medication in the near future)?

   Circle one:

   Yes **No**

3. Who made the decision to start or not to start osteoporosis medication?

   Circle one:

   Myself

   My GP/Specialist

   Joint decision between myself and my GP/specialist

   Other- please explain _____

4. How would you best describe your risk of sustaining a fracture in the next 5 years?

   Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

5. Which statements do you think most accurately describes osteoporosis medications.

   Circle one:

   Osteoporosis medications are **highly** effective in preventing fractures

   Osteoporosis medications are **moderately** effective in preventing fractures

   Osteoporosis medications are **not very** effective in preventing fractures.

   Circle one:

   In New Zealand, osteoporosis medications are prescribed **too often**

   In New Zealand, osteoporosis medications are prescribed **about right (not too much and not too little)**

   In New Zealand, osteoporosis medications are **not prescribed often enough**

BMJ Open

A randomised trial assessing the impact of framing of fracture risk and osteoporosis treatment benefits in patients undergoing bone densitometry

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-013703.R1
Article Type:	Research
Date Submitted by the Author:	05-Dec-2016
Complete List of Authors:	Kalluru, Ramanamma; University of Auckland, Department of Medicine; Auckland District Health Board, Department of Rheumatology Petrie, Keith; University of Auckland Grey, Andrew; University of Auckland Nisa, Zaynah; University of Auckland, Department of Medicine Horne, Anne; University of Auckland Gamble, Greg; University of Auckland Bolland, Mark; University of Auckland, Department of Medicine
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Communication
Keywords:	Fracture, Risk, Osteoporosis, Medication, Communication

Title:
A randomised trial assessing the impact of framing of fracture risk and osteoporosis treatment benefits in patients undergoing bone densitometry

Authors:
Rama Kalluru, FRACP [1,2]
Keith J Petrie, PhD [3]
Andrew Grey, MD,[1]
Zaynah Nisa, BSc,[1]
Anne M Horne, MBChB,[1]
Greg D Gamble, MSc,[1]
Mark J Bolland, MBChB, PhD,[1]

Affiliation:
[1]Department of Medicine, University of Auckland, Private Bag 92 019, Auckland 1142, New Zealand; [2]Department of Rheumatology, Private Bag 92189, Greenlane clinical centre, Auckland 1142; [3]Department of Psychological Medicine, University of Auckland, Private Bag 92 019, Auckland 1142, New Zealand

Address for correspondence/reprints:
Mark Bolland
Bone and Joint Research Group,
Department of Medicine, University of Auckland
Private Bag 92 019, Auckland 1142, New Zealand
Email: m.bolland@auckland.ac.nz
Ph 64 9 373 7999
Fax 64 9 373 7677

Word counts:
Text only: 3447
Abstract: 292
Figures: 2
Tables: 4

Key words: Fracture, Risk, Osteoporosis, Medication, Communication

Abstract:

Objectives:

The accuracy of patients' perception of risk is important for decisions about treatment in many diseases. We framed the risk of fracture and benefits of treatment in different ways and assessed the impact on patients' perception of fracture risk and intentions to take medication.

Design:

Randomised trial of four different presentations of fracture risk and likely benefits from osteoporosis treatment.

Setting:

Academic centre

Participants:

200 patients undergoing bone densitometry.

Intervention:

Presentation that framed the patient's absolute fracture risk either as the chance of having or not having an event, with their likely benefits from osteoporosis treatment in natural frequencies or numbers needed to treat.

Outcomes

Participants' views about their fracture risk and the need for osteoporosis treatment

Results:

The median 5y fracture risk threshold participants regarded as high enough to consider preventative medication was 50-60%, and did not change substantially after the presentation. The median (Q1,Q3) 5y risk initially estimated by participants was 20% (10,50) for any fracture and 19% (10,40) for hip fracture. 61% considered their fracture risk was low or very low, and 59-67% considered their fracture risk was lower than average. These participant estimates were 2-3 times higher than Garvan calculator estimates for any fracture, and 10-20 times higher for hip fracture. Participant estimates of fracture risk halved after the presentation, but remained higher than the Garvan estimates (1.5-2 times for any fracture, 5-10 times for hip fracture). There was no difference in these outcomes between the randomised groups. Participants' intentions about taking medication to prevent fractures were not substantially affected by receiving information about fracture risk and treatment benefits.

Conclusions:

Altering the framing of estimated fracture risks and treatment benefits had little effect on participants' perception of the need to take treatment or their individual fracture risk.

Trial registration:

Australian New Zealand Clinical Trials Registry (www.anzctr.org.au). Registration number is ACTRN12613001081707, date of registration 26/9/2013.

Article Summary

Strengths and Limitations

- A randomised trial assessing different methods of risk communication by investigating the effects of framing of the risk of fracture and benefits of osteoporosis treatments.
- Participants were undergoing standard clinical care, so the results may be broadly generalizable.
- Fracture risk was the only risk measurement studied. It is not known whether similar results might be seen in other chronic conditions in which indications for treatment are based upon absolute risk such as cardiovascular disease.
- The study cohort was moderately sized and had a relatively low fracture risk.

Introduction

Accurate perception of risk is critical for the rational adoption of preventative treatment. People may make decisions about their health based upon their perceived risk of future events. Health care professionals try to predict the risks of these future events and present this information to patients to assist in making decisions about their treatment. Predictive models have been developed for many conditions, and calculators that integrate data on risk factors to estimate absolute risk for individuals are frequently used. These tools can lead to substantial shifts in disease management. Thus, management of cardiovascular risk has moved from individual risk factors such as blood pressure to become based on absolute cardiovascular risk.[1] Likewise, fracture risk calculators that integrate bone density measurements with clinical risk factors have shifted management of osteoporosis from an exclusive focus on bone density results to recommendations that incorporate absolute fracture risk.[2,3]

Communicating risk to patients is therefore fundamental to allow informed and shared decision making.[4] Problems that might arise when using estimates of the risk of a future event include misunderstanding numeric data and statistical concepts of risk and probability, both by the health care professional and the patient, and limited patient health literacy.[5,6] Research on communicating risks, benefits and harms to patients[5-11] has generated evidence-based recommendations for communicating risk.[6] They suggest that risks should be expressed as percentages or natural frequencies with benefits and harms expressed in absolute terms, supplemented by icon arrays,[6] which can be presented using a decision aid.[4]

The framing of risk is influential in patient decision-making. Risk that is framed positively by description of benefits or gains is associated with less perception of harm and increased

acceptance of therapies than when risk is framed negatively by use of harms or losses,[6] but these differences may not greatly influence behaviour.[9] Few trials have explored different approaches to communicating risk to patients for chronic conditions in which indications for treatment are based upon the absolute risk of an event within a set time frame, such as cardiovascular disease and osteoporosis.

We set out to investigate the impact of communicating absolute risk in different ways to patients, using fracture as the model health event. We investigated the effects of framing of the risk of fracture and benefits of osteoporosis treatments, and whether this influences patients' beliefs about the need for osteoporosis treatment. In particular, we assessed the effect of presenting risk and treatment benefits in terms of percentages, numbers need to treat, or natural frequencies, and of framing risk differently (for example: a 5% chance of having a hip fracture versus a 95% chance of not having a hip fracture).

Methods:

We invited consecutive patients >60y of age referred to a public hospital clinic for bone density measurement (Oct 2013-July 2014) who were not taking any specific osteoporosis treatments to take part. Prior to their bone density measurement, consenting participants completed a questionnaire exploring their beliefs about their risk of fracture and the benefits they might obtain from treatment. Following the bone density measurement, the absolute risk of fracture within 5y was calculated with the Garvan fracture risk calculator (http://www.garvan.org.au/promotions/bone-fracture-risk/calculator/). Participants were then randomised to receive one of four different written and pictorial presentations of their absolute fracture risk and the likely benefits they could expect from osteoporosis treatment. Group allocations were assigned by the study statistician using block randomisation with a

variable block size schedule, based on computer-generated random numbers. Allocation concealment occurred through centralized randomisation. After reading the presentation, participants completed a second questionnaire about the risks of fracture and benefits of treatment. The bone density scan was reported in accordance with standard practice, including management recommendations based upon the individual's absolute risk of fracture, and all participants were encouraged to discuss the report with their family doctor. We contacted all participants 3 months after their bone density scan to complete a third questionnaire exploring their beliefs about risk of fracture and the benefits of treatment. This study was approved by the Northern A Health and Disability Ethics Committee and was registered at ANZCTR (ACTRN12613001081707).

Questionnaires:

The three questionnaires are available in the Appendix. Briefly, we asked participants to rate their 5y risks of having any fracture and having a hip fracture on a visual analogue scale of 0 (no chance) to 100% (definitely) and a scale of none to very high, and the 5y total fracture and hip fracture risks of the average man or woman of the same age on a visual analogue scale of 0-100%. We asked participants whether they thought they should take osteoporosis medication, questions exploring their reasons for taking medication or not, and to rate the effectiveness of osteoporosis treatments on a visual analogue scale of 0-100%.

Presentation of Risk:

Table 1 shows the four presentations of absolute risk of fracture and treatment benefits, which were provided to the participants in writing. The first 3 sentences were identical for each group, and stated the participant's calculated 5y risk of osteoporotic and hip fracture. Each randomised group then received text that framed risk either as the chance of having an

event or not having an event within 5y and with treatment benefits or the lack of treatment benefits (depending on the framing) in natural frequencies or presented as numbers needed to treat. All four options were accompanied by icon arrays depicting both the fracture risk and the treatment benefit (Appendix).

Statistics:

The pre-specified primary analysis was a comparison between the four randomised groups of the perceived risks of total fracture and hip fracture at which treatment would be considered. Secondary endpoints were the perceived risk of fracture, and the perceived need for osteoporosis treatment. As this was a novel study, it was difficult to estimate what effect sizes would be observed. Therefore we pragmatically aimed to recruit 200 patients, on the basis that this was feasible within a timely period, and with 50 patients per group, the largest confidence interval for a percentage result is 14% (for a proportion of 50%). A difference of approximately 20% could be detected in a pairwise comparison between two groups in this scenario. If the proportions were closer to 100% or 0%, the confidence intervals become narrower and the detectable differences become smaller. Because most data were non-normally distributed, we used non-parametric tests throughout, including the Kruskal-Wallis one-way ANOVA test for comparisons between the four groups, and the Signed Rank test for comparisons within groups. Spearman correlation analysis was used to test for significant associations between participant and calculator estimates of fracture risk. All tests were two-tailed and hypothesis tests were deemed significant for $P<0.05$. P-values were not adjusted for multiple comparisons. All statistical analyses were carried out using the SAS software package (SAS Institute, Cary, NC version 9.4)

Results

200 people undergoing bone densitometry agreed to participate (Appendix Figure 1). Their baseline characteristics are shown in Table 2 and were similar in the four randomised groups. The cohort is broadly representative of patients seen in clinical practice for bone densitometry- the average age was 69y, 81% were female, 33% had a fracture after 50y, and the average femoral neck bone density T score was in the osteopenic range.

At baseline, the median (Q1,Q3) 5y risk threshold participants regarded as high enough to consider taking medication to prevent any fracture was 50% (25,70) for oral tablets and 60% (30,80) for intravenous medication (Table 3). For hip fracture, the respective 5y risk thresholds were 50% (30,75) and 60% (40,80). The thresholds were similar in the four randomised groups. Figure 1 shows that providing the written estimates of fracture risk and treatment benefits led to no or very small changes in these risk thresholds (a decrease of 10% or less in all groups). There were no between-groups differences in these changes (P>0.6). At baseline, 46% of participants estimated that their hip or total fracture risk was equal to or greater than one of the thresholds they considered high enough to take preventative medication. After written information on fracture risk and treatment benefits was provided, 37% of participants estimated that their hip or total fracture risk was equal to or greater than one of the thresholds they considered high enough to take preventative medication.

At baseline, the median (Q1,Q3) 5y risk of any fracture estimated by the participant was 20% (10,50), and for hip fracture was 19% (10,40) (Table 3). 61% considered that their risk of any fracture was low or very low. The median 5y risk of any fracture estimated by the participants for an average man or woman of the same age was 40% (20,50) and for hip fracture was 30% (20,50). 59% of participants estimated that their individual risk of any

fracture was lower than that of the average person, and 67% estimated their hip fracture risk as lower than average. Table 3 and Figure 2 show that the estimated risks of fracture by the participants and from the Garvan calculator were similar for the randomised groups. For the entire cohort and for each randomised group, the 5y risk of total fracture estimated by the participants was 2-3 times higher than the calculator estimates (P<0.001 for all groups). For hip fracture, the participant estimates were only slightly lower than the estimates for any fracture and were 10-20 times higher than the calculator estimates (P<0.001 for all groups). The correlation between participant and calculator risk estimates was modest: r=0.33, P<0.001 for any fracture and r=0.22, P=0.002 for hip fracture.

Table 3 and Figure 2 show the influence of providing information on the individual participant's fracture risk from the Garvan calculator on participants' estimates of their own fracture risk. There were small (0-10%) reductions in participants' perceptions of their total and hip fracture risk that were not different between groups (P=0.50 for total fracture risk, P=0.42 for hip fracture risk). In all groups, the participant estimates remained much higher than the calculator estimates after these estimates were provided to the participants (P<0.001 for all groups).

Prior to their bone density scan, 15% of participants felt they should take medication to prevent fractures, 34% felt they should not take medication and 51% were unsure (Table 4, Appendix Table 1). The proportions did not change substantially after the calculator estimates and treatment benefits were provided- the respective proportions were 19%, 51% and 30%. At 3 months after the bone density scan, 34% of participants indicated that they had started medication or were intending to. A similar proportion (43-48%) of participants who felt they should or should not take osteoporosis medication or did not know at baseline,

estimated their hip or total fracture risk was equal to or greater than one of the thresholds they considered high enough to take preventative medication (Appendix Table 1).

Table 4 shows that one third of those who believed they should take osteoporosis medication before their bone density measurement changed their views after receiving the information on fracture risk and treatment benefits, and a similar proportion had not started or did not intend to start osteoporosis medication at the 3 month follow-up. Of those who initially believed they should not take osteoporosis medication, 80% persisted with that belief after receiving the information on fracture risk and treatment benefits, and a similar proportion had not started or did not intend to start osteoporosis medication at the 3 month follow-up. Of the group who were undecided initially, about half remained undecided after receiving the information on fracture risk and treatment benefits, but one third had started or intended to start medication at the 3 month follow-up.

Discussion

In this study, providing estimated absolute risks of fracture and benefits of treatment in four different ways had little effect on participants' perception of their need to take treatment or their individual risk of fracture. Previous research and trials on risk communication have generally reported important differences between presentations of natural frequencies or numbers needed to treat and between different framing styles, but these studies mainly focussed on understanding of risk rather than need for intervention.[5,6,8-10] Before their bone density scan, the average 5y fracture risk threshold at which participants would consider treatment was 50-60%. These thresholds changed little after information on fracture risk and treatment benefits was provided. Prior to receiving this information, participants overestimated their risk of any fracture by 2-3 times and of hip fracture by 10-20 times. After

receiving a written description of their fracture risk, participants' estimates of their risk of fracture halved but remained 1.5-2 times higher than the Garvan estimates for any fracture, and 5-10 times higher for hip fracture. Framing the presentation of risk as the chance of having a fracture did not produce different results from framing the presentation as the chance of not having a fracture.

Strengths and limitations

The strengths of the study are its randomized allocation to different methods of risk communication, and relevance to clinical practice. Although there is a large body of research into risk communication,[5-11] we are not aware of similar trials that have explored the impact of risk framing on risk perception and treatment benefits, either where the absolute risk of an event forms the basis for treatment recommendations or in the field of osteoporosis. Participants were patients undergoing standard clinical care, so the results may be generalisable to similar outpatient populations. There are limitations to our results. Our cohort was of moderate size and had a relatively low fracture risk. Whether the findings would be similar in cohorts at higher or lower risk of fracture, in cohorts who were not undergoing bone densitometry, or in other conditions, such as cardiovascular disease, is worth exploring. The questionnaires, presentation of results and icon arrays were designed for this study, and different results might be obtained using different text or icon arrays, or if similar information is discussed within the context of a clinical consultation. The results at 3 months will likely be influenced by the bone density report and the views of the primary care doctor.

Comparison to other studies

Previously, we reported that a group of patients surveyed prior to bone density measurement substantially overestimated their individual risk of fracture,[12] findings similar to those from the current study. Other studies that have reported participants' views on their fracture risk found that older women generally consider themselves to be at lower risk of fracture than their peers, as we found in the current study. The GLOW study reported that 43-49% of women (mean age 69y) felt their fracture risk was below average, with only 12-15% considering themselves above average risk.[13] Likewise in the ROSE study, 42% of women (mean age 71y) considered their risk was below average, and only 5% considered their risk was above average.[14] There was a poor correlation between participants' own estimate of their 10y fracture risk and the estimate from the FRAX calculator.[14] However, participants were invited to classify their risk into 5 categories (<10%, 10-14%, 15-19%, 20-24% and ≥25%) and by providing these values, the investigators may have introduced an anchoring bias into participant estimates. Collectively, the results suggest that people have an optimistic bias about their personal risk,[15] generally considering themselves healthier and at lower risk than the average person. Nevertheless, their numeric estimates of their risk are substantial overestimates.

One previous trial[16] randomised participants with low bone density to receive standard care or a decision aid that contained written descriptions of fracture risk and treatment benefits: the aid improved understanding of these concepts. However, consistent with the findings from our study, 51% of women who used the aid and 72% of women receiving standard care were unable to correctly identify their fracture risk from 3 categories (<10%, 10-30%, and >30%). Taken together, the results of these studies suggest that patients have difficulty understanding information about risk presented in written and pictorial formats and that research is required into what patients think an absolute risk of fracture represents.

More broadly, previous studies on framing of risk reported that positive framing led to better understanding of the message, and higher ratings of perceived effectiveness of therapies than negative framing.[9] However, other studies reported that framing did not appear to affect hypothetical decisions or intentions to adopt interventions, or actual behaviour.[9] In our study, framing of risk had little effect on patients' perceived fracture risk or views about treatment, consistent with the latter studies. Previous studies reported that the use of absolute risk reductions is better understood than the use of numbers needed to treat, is associated with higher ratings of perceived effectiveness, but is not associated with differences in effects on hypothetical decisions or intentions to adopt interventions.[8] In our study, the use of absolute risk reductions presented with natural frequencies did not alter patients' perceived fracture risk or views about treatment compared to the use of numbers needed to treat.

Study meaning and interpretation

Some of our findings are surprising. We anticipated participants overestimating their risk of fracture at baseline.[12] However, we expected that after being provided with an explicit description of their estimated fracture risks, participants would align their personal estimates of fracture risk with the provided values. The failure to do so suggests that the participants either did not understand the concept of risk or the presentation of results, or they did not believe the estimates provided.

The results highlight some interesting features of risk perceptions among participants undergoing bone densitometry. At baseline, the median 5y risk of any fracture estimated by participants was 20%, and for hip fracture was 19%. It is not clear whether participants therefore believe that non-hip fractures are extremely rare, or that they misunderstood the

question or answer. Both of these levels of risk would be categorised as high by most osteoporosis guidelines,[2,3] yet only 7-8% of participants viewed their risk as high or very high and 61% considered their risk as low or very low. The median thresholds of 5y fracture risk at which participants considered they would take preventative medication were 40-60% and 46% of participants' own estimates of fracture risk were equal to or greater than these thresholds. However, this seemed unrelated to the decision to take treatment: similar proportions (43-48%) of people whose own estimates of fracture risk were greater than or equal to their own treatment thresholds believed they should or should not take osteoporosis medication or did not know. Similar to the findings of our previous survey,[12] these contradictions highlight large and important discrepancies between patients' and health care professionals' perception of fracture risk, and intervention thresholds.

Undertaking a bone density scan tended to reinforce rather than change patients' views about the need for treatment. Thus, only 35% of people who believed that they should take osteoporosis medication before the scan and 19% of people who believed that they should not take osteoporosis medication changed their views 3 months after the scan. The small differences between these two groups in bone density, participants' estimated fracture risk, and Garvan risk estimates are unlikely to explain the differing perceptions about the perceived need for medication. For the majority of people with a view about the need for osteoporosis medication before having a bone density scan, the results of the scan appear to have confirmed their pre-existing beliefs, regardless of the result. This may represent a confirmation bias, whereby attention is focussed on aspects of the results that support the pre-existing beliefs while aspects that challenge the beliefs are downplayed or ignored.[17]

The majority of participants in the study considered that they were at lower risk of fracture than average, a consistent finding in many studies termed the "better than average effect". Providing comparisons of risk to the average person can change risk perception.[18] Individuals who believe they are at lower risk than average may consider they do not need to take treatment without actually considering the benefits of the treatment.

In summary, we found that patients referred for bone densitometry have a high threshold of fracture risk before they would consider taking treatment to prevent fractures, and this does not change after written information on fracture risk and treatment benefits is provided. These patients also substantially overestimate their risk of fracture, even after fracture risk estimates are provided to them explicitly in writing. We identified a number of logical contradictions in patients' views about fracture risk that present challenges for health care practitioners trying to accurately communicate fracture risk to patients as the first step in allowing informed, shared decision-making. It seems unwise to assume that simply providing absolute risks of fracture and treatment benefits to patients is adequate to allow this to occur. It is important to explore whether these findings are specific to fracture risk, or are a more general feature of conditions where absolute risk estimates of health events are a fundamental component, such as cardiovascular disease.

Acknowledgements:

Conflicts of Interest:

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: the study was funded by the Health Research Council (HRC) of New Zealand. Andrew Grey is a shareholder in Auckland Bone Density, an organisation that provides bone densitometry services. All other authors have no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work

Contributorship:

RK, KP, AG, GG, and MB designed the research. RK, ZN, AH, and MB ran the trial. MB and GG performed the analyses. MB drafted the paper. All authors critically reviewed and improved it. MB is the guarantor for the article. All authors had access to all the data and take responsibility for the integrity of the data and the accuracy of the data analysis.

Funding:

Funded by the Health Research Council (HRC) of New Zealand. The authors are independent of the HRC. The HRC had no role in study design, the collection, analysis, and interpretation of data, the writing of the article, or the decision to submit it for publication.

Transparency statement

MB affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

Data sharing: Patient level data available from the corresponding author upon reasonable request. Patient consent was not obtained but the presented data are anonymised and risk of identification is low.

References

1. Jackson R. Guidelines on preventing cardiovascular disease in clinical practice. *BMJ.* 2000;320(7236):659-661.
2. Dawson-Hughes B. A revised clinician's guide to the prevention and treatment of osteoporosis. *J Clin Endocrinol Metab.* 2008;93(7):2463-2465.
3. Compston J, Cooper A, Cooper C, et al. Guidelines for the diagnosis and management of osteoporosis in postmenopausal women and men from the age of 50 years in the UK. *Maturitas.* 2009;62(2):105-108.
4. McCartney M, Treadwell J, Maskrey N, Lehman R. Making evidence based medicine work for individual patients. *BMJ.* 2016;353:i2452.
5. Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. *BMJ.* 2003;327(7417):741-744.
6. Zipkin DA, Umscheid CA, Keating NL, et al. Evidence-based risk communication: a systematic review. *Ann Intern Med.* 2014;161(4):270-280.
7. Ancker JS, Senathirajah Y, Kukafka R, Starren JB. Design features of graphs in health risk communication: a systematic review. *J Am Med Inform Assoc.* 2006;13(6):608-618.
8. Akl EA, Oxman AD, Herrin J, et al. Using alternative statistical formats for presenting risks and risk reductions. *Cochrane Database Syst Rev.* 2011(3):CD006776.
9. Akl EA, Oxman AD, Herrin J, et al. Framing of health information messages. *Cochrane Database Syst Rev.* 2011(12):CD006777.
10. Ahmed H, Naik G, Willoughby H, Edwards AG. Communicating risk. *BMJ.* 2012;344:e3996.

11. Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2014;1:CD001431.

12. Douglas F, Petrie KJ, Cundy T, Horne A, Gamble G, Grey A. Differing perceptions of intervention thresholds for fracture risk: a survey of patients and doctors. *Osteoporos Int.* 2012;23(8):2135-2140.

13. Jones SM, Gell NM, Roth JA, Scholes D, LaCroix AZ. The Relationship of Perceived Risk and Biases in Perceived Risk to Fracture Prevention Behavior in Older Women. *Ann Behav Med.* 2015;49(5):696-703.

14. Rothmann MJ, Ammentorp J, Bech M, et al. Self-perceived facture risk: factors underlying women's perception of risk for osteoporotic fractures: the Risk-Stratified Osteoporosis Strategy Evaluation study (ROSE). *Osteoporos Int.* 2015;26(2):689-697.

15. Weinstein ND. Optimistic biases about personal risks. *Science.* 1989;246(4935):1232-1233.

16. Montori VM, Shah ND, Pencille LJ, et al. Use of a decision aid to improve treatment decisions in osteoporosis: the osteoporosis choice randomized trial. *Am J Med.* 2011;124(6):549-556.

17. Nickerson RS. Confirmation bias: A ubiquitous phenomenon in many guises. *Rev Gen Psychol.* 1998;2(2):175-220.

18. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. "If I'm better than average, then I'm ok?": Comparative information influences beliefs about risk and benefits. *Patient Educ Couns.* 2007;69(1-3):140-144.

Table 1: Text received by participants in each randomised group

Common text	• Based on the information in your questionnaire and your bone density: • Your estimated risk of osteoporotic fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next 5 years is: 20% • Your estimated risk of hip fracture in the next 5 years is: 5%
Group 1: Framed as chance of having an event and treatment benefits in natural frequencies	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 20 would have an osteoporotic fracture within the next 5 years, and 5 would have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that if all these 100 people took osteoporosis medication for 5 years, the number of people who would have an osteoporotic fracture within those 5 years would decrease from 20 to 13. The number who would have a hip fracture within those 5 years would decrease from 5 to 3.
Group 2: Framed as chance of not having an event and treatment benefits in natural frequencies	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 80 will **not** have an osteoporotic fracture within the next 5 years, and 95 will **not** have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that if all these 100 people took osteoporosis treatments for 5 years, the number of people who would **not** have an osteoporotic fracture within those 5 years would increase from 80 to 87. The number of people who would **not** have a hip fracture within those 5 years would increase from 95 to 97.

Group 3: Framed as chance of having an event and treatment benefits as number needed to treat	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 20 would have an osteoporotic fracture within the next 5 years, and 5 would have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that 15 people like you would need to be treated with osteoporosis medications for 5 years to prevent 1 osteoporotic fracture. 50 people like you would need to be treated for 5 years to prevent 1 hip fracture.
Group 4: Framed as chance of not having an event and treatment benefits as number needed to treat	• This means that in a group of 100 people of the same age and gender as you, who had similar risk factors for fracture as you, 80 will **not** have an osteoporotic fracture within the next 5 years, and 95 will **not** have a hip fracture within the next 5 years. • Osteoporosis medication reduces osteoporotic fractures by 33%, and hip fractures by 40%. • This means that if 15 people like you were treated with osteoporosis medications for 5 years, 14 would receive no benefit in terms of osteoporotic fracture prevention, and in 1 person a fracture would be prevented. If 50 people like you were treated for 5 years, 49 would receive no benefit in terms of hip fracture prevention, and in 1 person a hip fracture would be prevented.

For illustrative purposes, all options use a 5 year 20% risk of osteoporotic fracture and 5% risk of hip fracture.

Table 2: Baseline characteristics by randomised group

	Group 1	Group 2	Group 3	Group 4
n	51	49	51	49
Age (y)	69.1 (7.4)	68.3 (5.7)	70.3 (6.3)	68.9 (6.0)
Body mass index (kg/m^2)	26.7 (5.1)	27.1 (4.7)	26.4 (4.4)	26.5 (5.4)
Female (%)	86	71	75	90
European descent (%)	92	98	94	96
Fracture after 50 years (%)	41	31	35	22
Bone mineral density T-score				
Lumbar spine	-0.5 (1.6)	-0.3 (1.8)	-0.4 (2.0)	-0.1 (1.6)
Total hip	-1.2 (1.1)	-0.9 (1.3)	-1.1 (1.2)	-1.1 (2.3)
Femoral neck	-1.6 (0.9)	-1.3 (1.1)	-1.5 (1.0)	-1.3 (0.9)

Data are %, or mean (SD). Group 1: framed as chance of having an event and treatment benefits in natural frequencies; Group 2: framed as chance of not having an event and treatment benefits in natural frequencies; Group 3: framed as chance of having an event and treatment benefits as number needed to treat; Group 4: framed as chance of not having an event and treatment benefits as number needed to treat.

Table 3: Influence of providing information communicating risk of fracture and treatment benefits

	Group 1 (n=51)	Group 2 (n=49)	Group 3 (n=51)	Group 4 (n=49)	Entire cohort
Participant estimates at baseline					
5y fracture risk high enough to consider taking medications (tablet/intravenous) to prevent fracture (any/hip) (%)					
Any fracture/ tablets (%)	50 (23, 75)	50 (28, 60)	50 (35, 80)	50 (20, 60)	50 (25, 70)
Any fracture/ intravenous (%)	53 (40, 80)	55 (20, 72)	60 (50, 80)	60 (30, 80)	60 (30, 80)
Hip fracture/ tablets (%)	50 (30, 80)	50 (35, 73)	55 (50, 80)	48 (20, 60)	50 (30, 75)
Hip fracture/ intravenous (%)	60 (45, 80)	55 (30, 80)	60 (40, 80)	65 (30, 80)	60 (40, 80)
Risk of any fracture in next 5y (%)	25 (10, 50)	25 (10, 50)	20 (10, 50)	15 (10, 40)	20 (10, 50)
None/ very low risk	14	17	16	24	18
Low risk	44	38	45	47	43
Moderate risk	30	42	29	24	31
High risk	12	4	10	2	7
Very high risk	0	0	0	2	1
Risk of hip fracture in next 5y (%)	15 (10, 50)	20 (10, 45)	20 (10, 40)	10 (5, 30)	19 (10, 40)
Garvan fracture risk calculator estimates					
5y Osteoporotic fracture risk	7.9 (5.8, 12.3)	7.3 (4.4, 9.9)	8.5 (5.6, 14.6)	7.1 (5.0, 9.6)	7.4 (5.5, 12.0)
5y Hip fracture risk	1.6 (0.8, 3.4)	1.2 (0.7, 2.4)	1.8 (0.8, 4.1)	1.3 (0.6, 2.0)	1.4 (0.8, 3.0)
Participant estimates after information on fracture risk and treatment benefits provided					
Risk of any fracture in next 5y (%)	14 (9, 30)	19 (10, 27)	15 (7, 30)	10 (8, 20)	12 (8, 30)
None/ very low risk	20	29	27	33	27
Low risk	45	47	47	47	47
Moderate risk	31	18	20	10	20
High risk	4	6	4	8	6
Very high risk	0	0	2	2	1
Risk of hip fracture in next 5y (%)	8 (2, 20)	10 (2, 20)	10 (2, 20)	10 (2, 15)	10 (2, 20)

Data are percent or median (Q1,Q3). Group 1: framed as chance of having an event and treatment benefits in natural frequencies; Group 2: framed as chance of not having an event and treatment benefits in natural frequencies; Group 3: framed as chance of having an event

and treatment benefits with number needed to treat; Group 4: framed as chance of not having an event and treatment benefits with number needed to treat.

Table 4: Participant views about taking osteoporosis medicine grouped by their initial views

	Participants' initial view on whether they should take osteoporosis medication		
	Yes	**No**	**Don't know**
Prior to bone density scan			
n (%)	30 (15)	67 (34)	101 (51)
After information on fracture risk and treatment benefits provided			
Should you take osteoporosis medication?			
Yes (%)	20 (67)	3 (4)	14 (14)
No (%)	8 (27)	54 (81)	39 (39)
Don't know (%)	2 (7)	10 (15)	48 (48)
At 3m follow-up			
Started/intend to start osteoporosis medication			
Yes (%)	17 (65)	12 (19)	34 (35)
No (%)	9 (35)	51 (81)	62 (65)

Figure 1: Box and Whisker plots of the changes in the 5y risk thresholds participants considered high enough to take treatment, either by tablets or by intravenous infusion, to prevent any fracture or hip fracture after written information on fracture risk and treatment benefits was provided by treatment group. Group 1 (n=51): framed as chance of having an event and treatment benefits in natural frequencies; Group 2 (n=49): framed as chance of not having an event and treatment benefits in natural frequencies; Group 3 (n=51): framed as chance of having an event and treatment benefits as number needed to treat; Group 4 (n=49): framed as chance of not having an event and treatment benefits as number needed to treat.

Figure 2: Box and Whisker plots of the estimated 5y risk of osteoporotic and hip fracture before and after the provision of fracture risk estimates from the Garvan calculator. Group 1 (n=51): framed as chance of having an event and treatment benefits in natural frequencies; Group 2 (n=49): framed as chance of not having an event and treatment benefits in natural frequencies; Group 3 (n=51): framed as chance of having an event and treatment benefits as number needed to treat; Group 4 (n=49): framed as chance of not having an event and treatment benefits as number needed to treat.

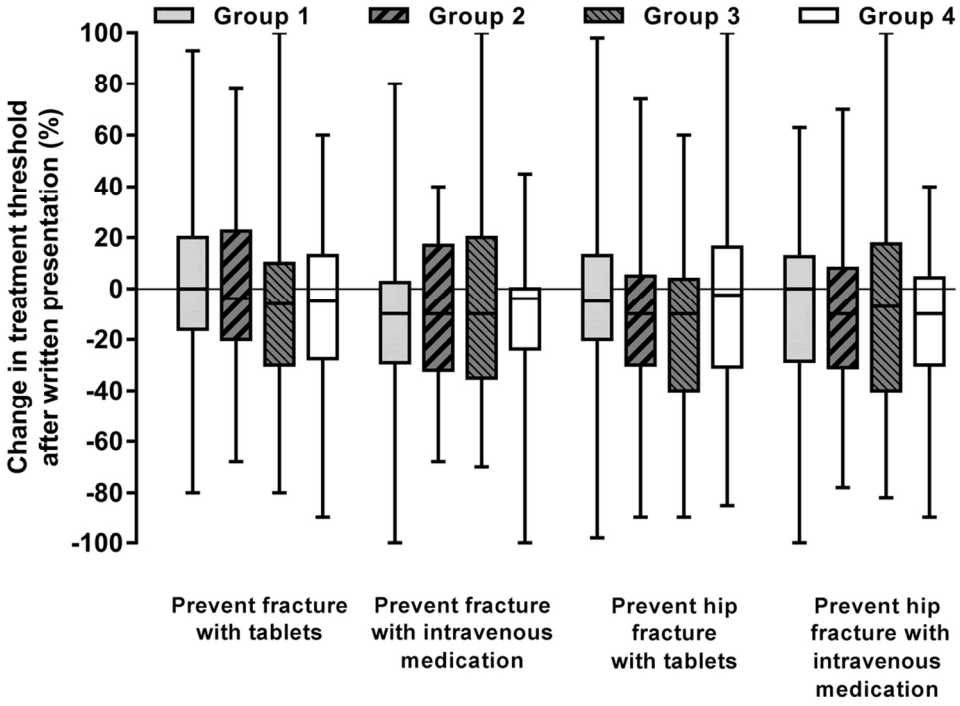


Figure 1: Box and Whisker plots of the changes in the 5y risk thresholds participants considered high enough to take treatment, either by tablets or by intravenous infusion, to prevent any fracture or hip fracture after written information on fracture risk and treatment benefits was provided by treatment group. Group 1 (n=51): framed as chance of having an event and treatment benefits in natural frequencies; Group 2 (n=49): framed as chance of not having an event and treatment benefits in natural frequencies; Group 3 (n=51): framed as chance of having an event and treatment benefits as number needed to treat; Group 4 (n=49): framed as chance of not having an event and treatment benefits as number needed to treat.
Figure 1
109x82mm (300 x 300 DPI)

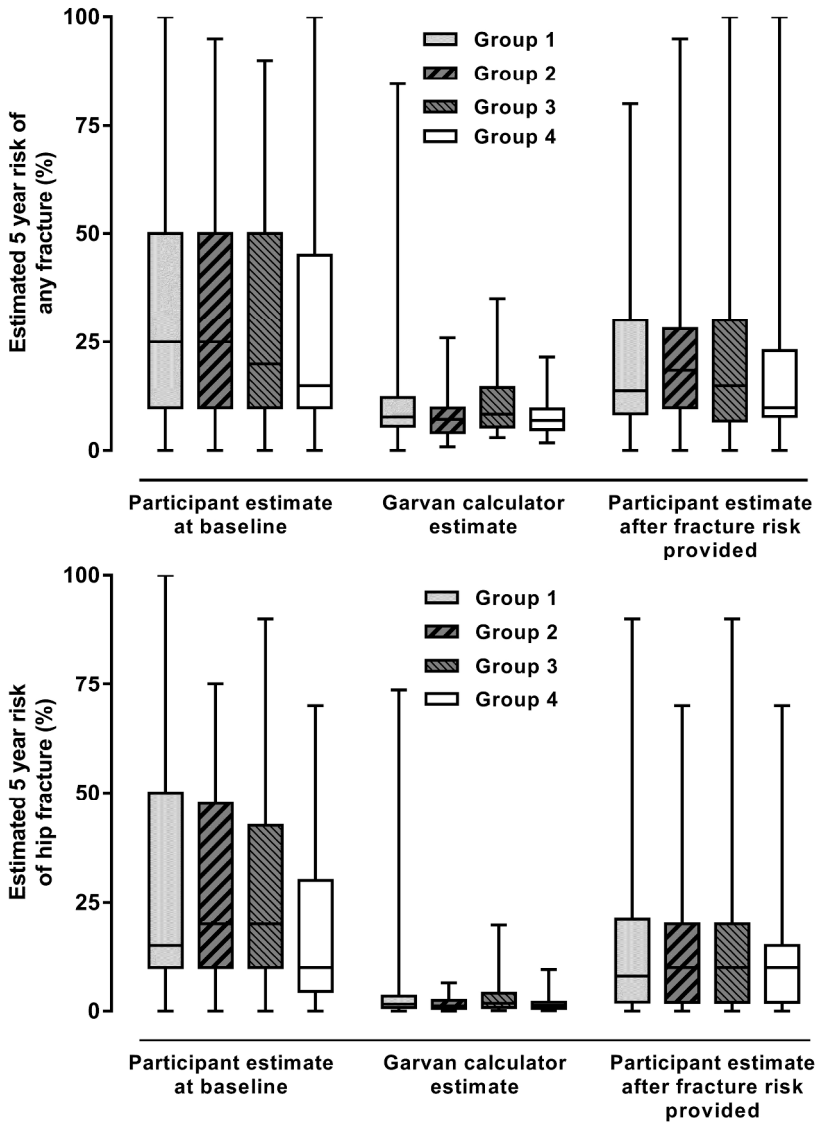


Figure 2: Box and Whisker plots of the estimated 5y risk of osteoporotic and hip fracture before and after the provision of fracture risk estimates from the Garvan calculator. Group 1 (n=51): framed as chance of having an event and treatment benefits in natural frequencies; Group 2 (n=49): framed as chance of not having an event and treatment benefits in natural frequencies; Group 3 (n=51): framed as chance of having an event and treatment benefits as number needed to treat; Group 4 (n=49): framed as chance of not having an event and treatment benefits as number needed to treat.

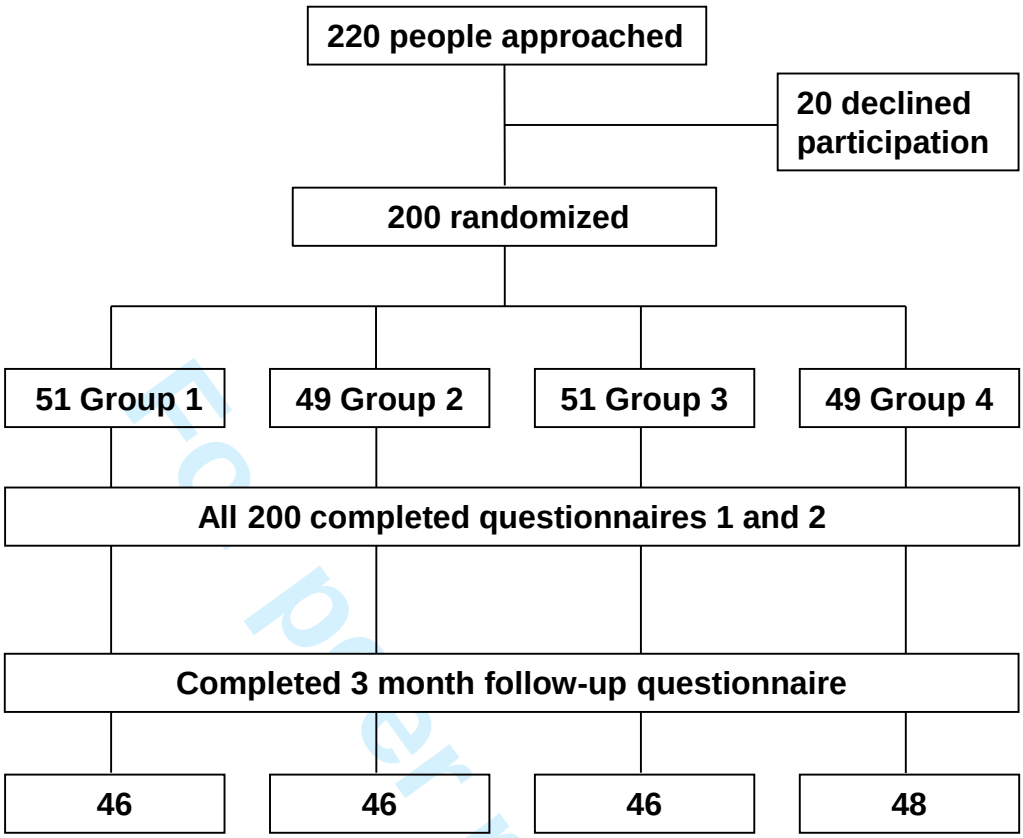
Figure 2
256x347mm (300 x 300 DPI)

Appendix:

Table 1: characteristics and results for participants grouped by their initial views about taking osteoporosis medicine

	Participant believed they should take osteoporosis medication prior to bone density measurement		
	Yes	**No**	**Don't know**
n (%)	30 (15)	67 (34)	101 (51)
Age (y)	69.6 (8.0)	68.2 (5.4)	69.8 (6.5)
Body mass index (kg/m^2)	25.9 (4.5)	26.5 (5.1)	26.9 (4.8)
Female (%)	77	87	78
European descent (%)	90	99	94
Fracture after 50y (%)	40	31	32
Bone mineral density T-score			
Lumbar spine	-0.2 (-1.6, 0.6)	-0.8 (-1.4, 0.6)	-0.6 (-1.5, 0.8)
Total hip	-1.4 (-2.6, -0.4)	-1.0 (-1.5, -0.3)	-1.1 (-2.0, -0.3)
Femoral neck	-1.8 (-2.5, -1.5)	-1.5 (-2.0, -0.8)	-1.6 (-2.1, -0.9)
Participant estimates at baseline			
5y risk high enough to consider taking medications (tablet/intravenous) to prevent fracture (any/hip) (%)			
Any fracture/ tablets (%)	50 (30, 70)	40 (15, 70)	50 (40, 70)
Any fracture/ intravenous (%)	64 (40, 80)	50 (20, 80)	60 (40, 80)
Hip fracture/ tablets (%)	35 (10, 60)	20 (10, 25)	30 (10, 50)
Hip fracture/ intravenous (%)	28 (10, 50)	10 (5, 25)	20 (10, 50)
Estimated risk ≥ treatment threshold (%)	47	43	48
Garvan fracture risk calculator estimates			
5y Osteoporotic fracture risk	8.8 (5.6, 14.9)	6.6 (5.3, 10.2)	7.7 (5.6, 11.9)
5y Hip fracture risk	2.1 (0.9, 4.1)	1.1 (0.7, 2.5)	1.5 (0.8, 3.0)
Participant estimates and views after information on fracture risk and treatment benefits provided			
5y risk high enough to consider taking medications (tablet/intravenous) to prevent fracture (any/hip) (%)			
Any fracture/ tablets (%)	50 (20, 80)	48 (20, 70)	50 (22, 60)
Any fracture/ intravenous (%)	45 (20, 80)	40 (20, 68)	50 (23, 70)
Hip fracture/ tablets (%)	14 (10, 35)	10 (8, 20)	15 (9, 30)
Hip fracture/ intravenous (%)	10 (4, 30)	10 (0, 15)	10 (3, 20)
Estimated risk ≥ treatment threshold (%)	33	30	43

Figure 1:



Flow of participants

Questionnaires 1-3

Written information sheets on fracture risk and treatment benefits provided to participants in each randomised group, with 20% 5y osteoporotic fracture and 5% 5y hip fracture risk used for illustrative purposes.

Questionnaire 1:

As explained in the information sheet, this study is designed to gather information about your perceptions of your bone health.

The questionnaire asks about your views of your bone health and your perceptions of treatments that influence bone health.

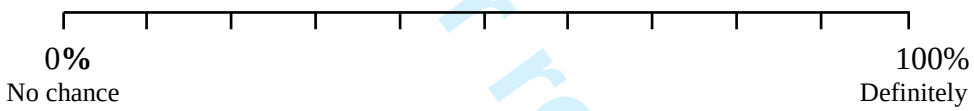
All of the information you provide is strictly *confidential* to the researchers, and will only be used for this study. This research will not affect your ongoing healthcare.

Please remember that there are no right or wrong answers to the questions – an answer is correct if it is true for you. We are interested in your experience and perception, as well as the way you evaluate risk. Please choose the responses that feel right for you.

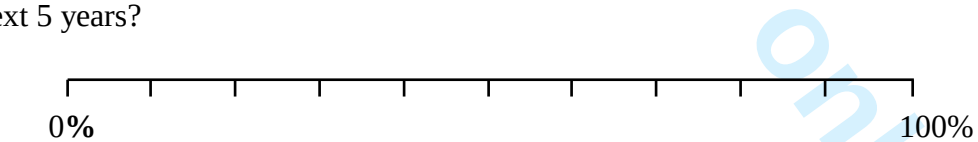
Your risk of fracture (breaking a bone):

1. How would you rate your risk of having any fracture in the next 5 years on a scale from 0% to 100%? (0% means no chance of fracture, 100% means you will definitely have a fracture)?

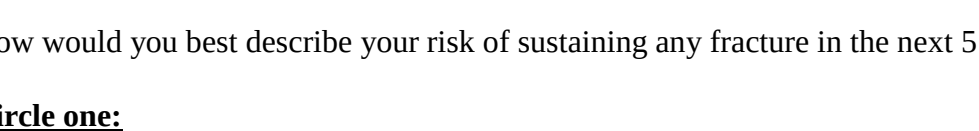
   Mark on the line to indicate your risk



2. How would you rate your risk of having a *hip* fracture in the next 5 years?



3. How would you rate the risk of the average woman/man your age of having any fracture in the next 5 years?



4. On the same scale, how would you rate the risk of the average woman/man your age having a *hip* fracture in the next 5 years?

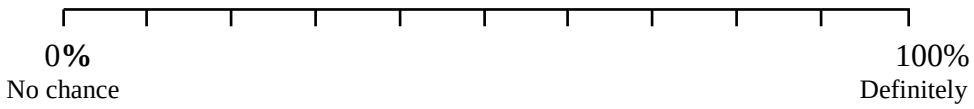
5. How would you best describe your risk of sustaining any fracture in the next 5 years?

   Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

How effective are osteoporosis treatments?

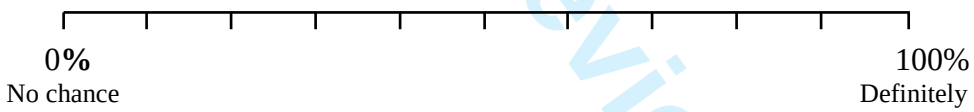
6. By how much do you think medications for osteoporosis are able to reduce the chance of fracture on a scale of 0% to 100%? (0% means not at all- the treatment prevents no fractures, 50% means that half of fractures would be prevented, and 100% means completely effective- all fractures are prevented)?



7. What risk of breaking a bone in the next 5 years, on a scale from 0% (no chance) to 100% (definitely will have a fracture), would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.

   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.

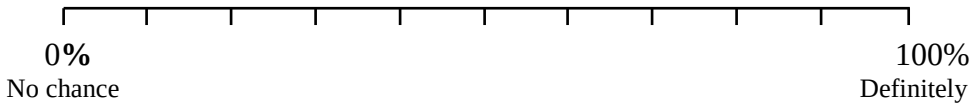


8. Hip fractures are the generally regarded as the most serious type of broken bone. They most commonly occur in older people. The average age someone sustains a hip fracture is 75-80 years. A person with a hip fracture almost always needs an operation, and many people will spend several weeks in hospital after a hip fracture. A substantial number of people will have ongoing pain, or difficulty walking for some time after a hip fracture.

   What risk of *hip* fracture in the next 5 years would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.

b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.



9. Do you think osteoporosis treatments are better at preventing hip fractures than other types of fractures?

Circle one:

Yes - osteoporosis medications are better at preventing hip fractures

No difference - osteoporosis medications prevent hip fractures as well as other types of fractures

No- osteoporosis medications are better at preventing fractures other than hip fractures

The National Osteoporosis Foundation in the United States recommends that individuals should take osteoporosis medications if their risk of a fracture over 5 years is greater than 10% (more than 10 people out of 100 will suffer a fracture in the next 5 years) **or** their risk of hip fracture over 5 years is greater than 2% (more than 2 people out of 100 will suffer a hip fracture in the next 5 years). We are interested in your views of these recommendations.

10. Do you think these thresholds (10% for osteoporotic fracture and 2% for hip fracture) are:

Circle one:

Too high (People at lower risk of fracture should be advised to take medication)

About right

Too low (People should not be treated until their risk of fracture is higher)

Please turn over the page for Question 11

Osteoporosis medications:

11. Do you think that **you** should take osteoporosis medication?

Circle one:

Yes **No** **Don't know**

12. What factors influenced your answer to question 11? Circle the number that best represents your views

My risk of breaking bones in the near future is:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

My bone density is probably

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

I don't think that I need to take osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am concerned about taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am worried about side-effects of taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications stop people breaking bones

1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications increase bone density

1	2	3	4	5
Strongly disagree				**Strongly agree**

13. Which statements do you think most accurately describes osteoporosis medications.

Circle one:

1. Osteoporosis medications are **highly** effective in preventing fractures

2. Osteoporosis medications are **moderately** effective in preventing fractures

3. Osteoporosis medications are **not very** effective in preventing fractures.

Circle one:

1. In New Zealand, osteoporosis medications are prescribed **too often**

2. In New Zealand, osteoporosis medications are prescribed **about right (not too much and not too little)**

3. In New Zealand, osteoporosis medications are **not prescribed often enough**

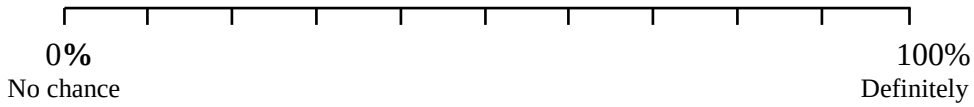
Questionnaire 2:

Option 1, 2, 3, or 4 for written information on fracture risk and treatment benefits and icon arrays.

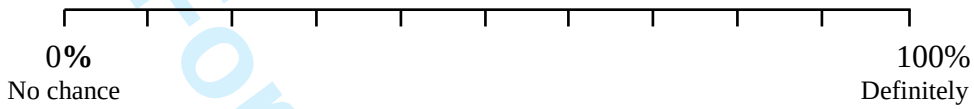
Based on this information:

Your risk of fracture (breaking a bone):

1. How would you rate your risk of having any fracture in the next 5 years on a scale from 0%- 100%? (0% means no chance of fracture, 100% means you will definitely have a fracture)?



2. How would you rate your risk of having a *hip* fracture in the next 5 years?



3. How would you best describe your risk of sustaining any fracture in the next 5 years?

Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

4. Do you think that you should take osteoporosis medication?

Circle one:

Yes	No	Don't know

5. What factors influenced your answer to question 4? Circle the number that best represents your views

My risk of breaking bones in the near future is:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

My bone density is probably

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

I don't think that I need to take osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am concerned about taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

I am worried about side-effects of taking long-term osteoporosis medications

1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications stop people breaking bones

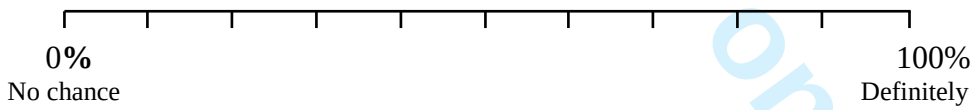
1	2	3	4	5
Strongly disagree				**Strongly agree**

Osteoporosis medications increase bone density

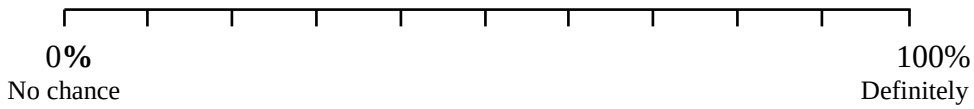
1	2	3	4	5
Strongly disagree				**Strongly agree**

6. What risk of breaking a bone in the next 5 years, on a scale from 0% (no chance) to 100% (definitely will have a fracture), would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.

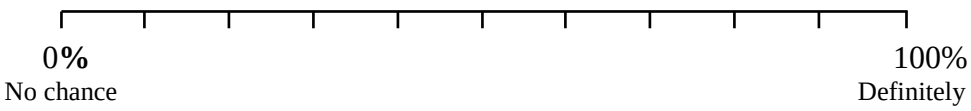


   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.

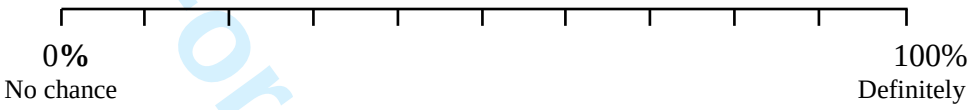


7. What risk of *hip* fracture in the next 5 years would you regard as high enough to consider taking a preventative medicine?

   a. If it was a tablet taken once per week, first thing in the morning, with a full glass of water, and after the tablet is taken, a person must remain upright for about 45 minutes and not eat during that time.



   b. If it was given by an intravenous infusion (drip) every one or two years at your local doctor's clinic.



The National Osteoporosis Foundation in the United States recommends that individuals should take osteoporosis medications if their risk of a fracture over 5 years is greater than 10% or their risk of hip fracture over 5 years is greater than 2%.

8. Do you think these thresholds (10% for osteoporotic fracture and 2% for hip fracture) are:

   Circle one:

   Too high (People at lower risk of fracture should be advised to take medication)

   About right

   Too low (People should not be treated until their risk of fracture is higher)

Questionnaire 3:

About 3 months ago you had a bone density scan and answered several questions about risk of fracture (breaking bones) and effectiveness of osteoporosis treatments. This is a short series of follow-up questions.

1. Have you discussed your bone density result with your GP/specialist?

   Circle one:

   Yes **No**

2. Have you started taking osteoporosis medication (or do you intend to start medication in the near future)?

   Circle one:

   Yes **No**

3. Who made the decision to start or not to start osteoporosis medication?

   Circle one:

   Myself

   My GP/Specialist

   Joint decision between myself and my GP/specialist

   Other- please explain _____

4. How would you best describe your risk of sustaining a fracture in the next 5 years?

   Circle one:

1	2	3	4	5
None/Very low	**Low**	**Moderate**	**High**	**Very High**

5. Which statements do you think most accurately describes osteoporosis medications.

   Circle one:

   Osteoporosis medications are **highly** effective in preventing fractures

   Osteoporosis medications are **moderately** effective in preventing fractures

   Osteoporosis medications are **not very** effective in preventing fractures.

   Circle one:

   In New Zealand, osteoporosis medications are prescribed **too often**

   In New Zealand, osteoporosis medications are prescribed **about right (not too much and not too little)**

   In New Zealand, osteoporosis medications are **not prescribed often enough**

Group 1

Based on the information in your questionnaire and your bone density: Participant Number 1

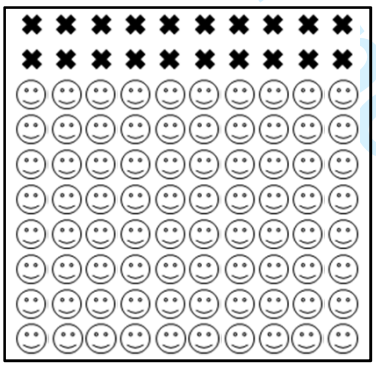
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

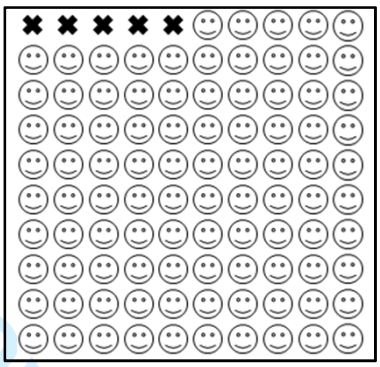
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **20** would have an **osteoporotic** fracture within the next **5** years, and **5** would have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the crosses indicate those who have a fracture within **5** years.
The smiley faces indicate those who do not have a fracture.

Osteoporotic fracture



Hip fracture

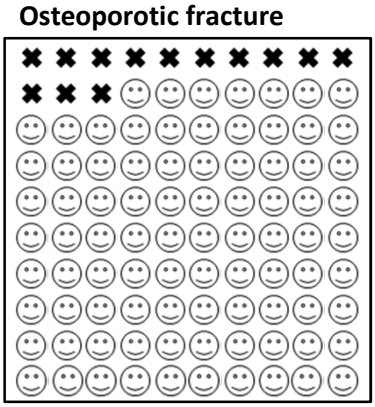


Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

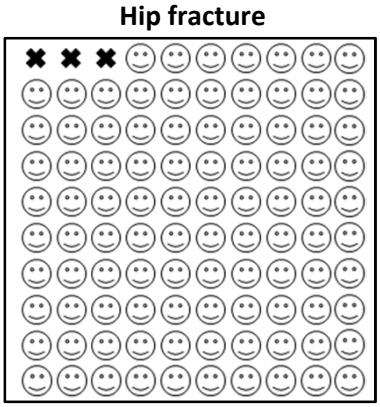
This means that if all these **100** people took osteoporosis medication for **5** years, the number of people who would have an **osteoporotic** fracture within those **5** years would decrease from **20** to **13**
The number who would have a **hip** fracture within those **5** years would decrease from **5** to **3**
(Note: sometimes these numbers are the same because of rounding.)

The crosses indicate those **with** a fracture, if **100** people took osteoporosis medication for **5** years

Osteoporotic fracture



Hip fracture



Group 2

Based on the information in your questionnaire and your bone density: Participant Number 1

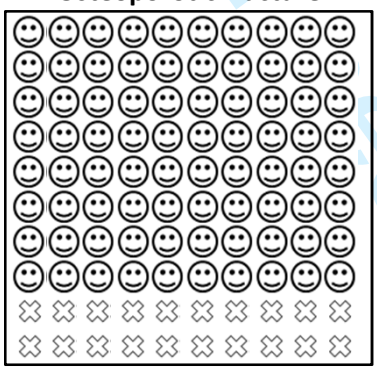
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

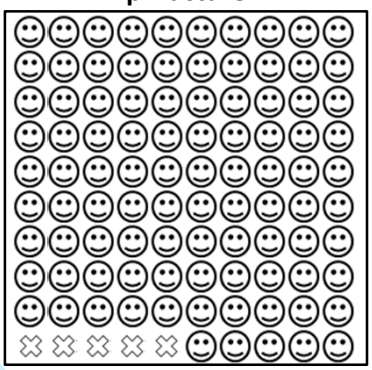
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **80** will **NOT** have an **osteoporotic** fracture within the next 5 years, and **95** will **NOT** have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the smiley faces indicate those who do **NOT** have a fracture within **5** years.
The crosses indicate those who have a fracture.

Osteoporotic fracture



Hip fracture

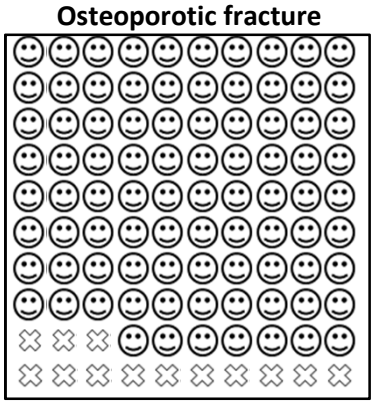


Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

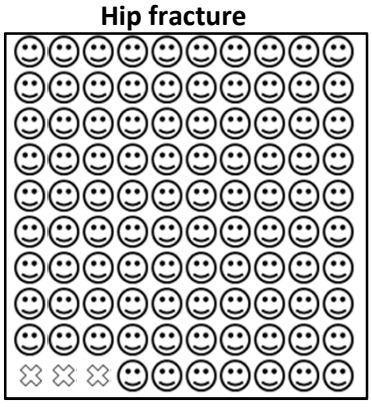
This means that if all these **100** people took osteoporosis medication for **5** years, the number of people who would **NOT** have an **osteoporotic** fracture within those **5** years would increase from **80** to **87**
The number who would **NOT** have a **hip** fracture within those **5** years would increase from **95** to **97**
(Note: sometimes these numbers are the same because of rounding.)

The smiley faces indicate those **without** a fracture, if **100** people took osteoporosis medication for **5** years

Osteoporotic fracture



Hip fracture



Group 3

Based on the information in your questionnaire and your bone density: Participant Number 1

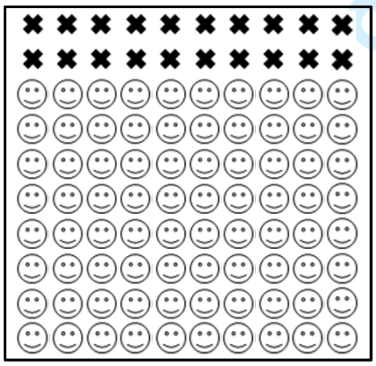
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

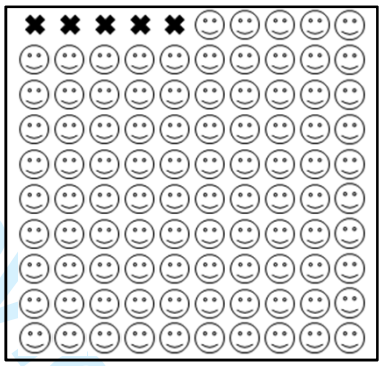
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **20** would have an **osteoporotic** fracture within the next **5** years, and **5** would have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the crosses indicate those who have a fracture within **5** years.
The smiley faces indicate those who do not have a fracture.

Osteoporotic fracture



Hip fracture



Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

This means that **15** people like you would need to be treated with osteoporosis medications for **5** years to prevent **1 osteoporotic** fracture.
50 people like you would need to be treated for 5 years to prevent 1 **hip** fracture.

These pictures show the benefits of treatment visually.
The smiley faces indicate those who benefited from treatment (by having an **osteoporotic** fracture prevented). The shaded faces indicate those who did not benefit from treatment.

The smiley faces indicate those who benefited from treatment (by having a **hip** fracture prevented). The shaded faces indicate those who did not benefit from treatment.

Group 4

Based on the information in your questionnaire and your bone density: Participant Number 1

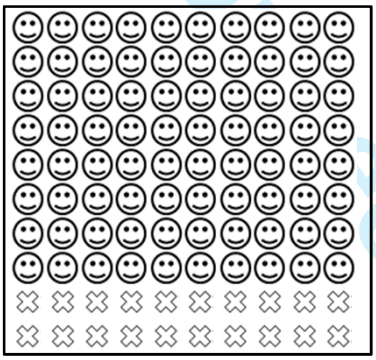
Your estimated risk of **osteoporotic** fracture (that is all fractures except fractures of the skull, face, hands and feet) in the next **5** years is: **20%**

Your estimated risk of **hip** fracture in the next **5** years is: **5%**

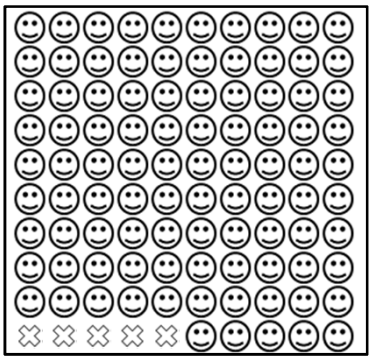
This means that in a group of **100** people of the same age and gender as you, who had similar risk factors for fracture as you, **80** will **NOT** have an **osteoporotic** fracture within the next 5 years, and **95** will **NOT** have a **hip** fracture within the next **5** years.

These pictures show your risk of fracture visually.
Out of **100** people, the smiley faces indicate those who do **NOT** have a fracture within **5** years.
The crosses indicate those who have a fracture.

Osteoporotic fracture



Hip fracture



Osteoporosis medication reduces osteoporotic fractures by **33%**, and hip fractures by **40%**.

This means that if **15** people like you were treated with osteoporosis medications for **5** years,
14 people would receive no benefit in terms of **osteoporotic** fracture prevention,
and in **1** person, a fracture would be prevented.

If **50** people like you were treated for 5 years, **49** would receive no benefit
in terms of **hip** fracture prevention, and in **1** person a **hip** fracture would be prevented.

These pictures show the benefits of treatment visually.
The shaded faces indicate those who did **NOT** benefit from treatment (ie. they did **NOT** have an **osteoporotic** fracture prevented). The smiley faces indicate those who benefited from treatment.

The shaded faces indicate those who did **NOT** benefit from treatment (ie. they did **NOT** have a **hip** fracture prevented). The smiley faces indicate those who benefited from treatment.

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

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6/7, Table 1, Appendix
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5-6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5-6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Not applicable

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Appendix Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Appendix Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1, 2 Table 3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Figure 1,2 Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Table 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-12
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	Supp file
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

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