

Visual Rx Faces 8.3 NNT for five year (high risk woman) and lifetime risk of fracture with HRT compared to no

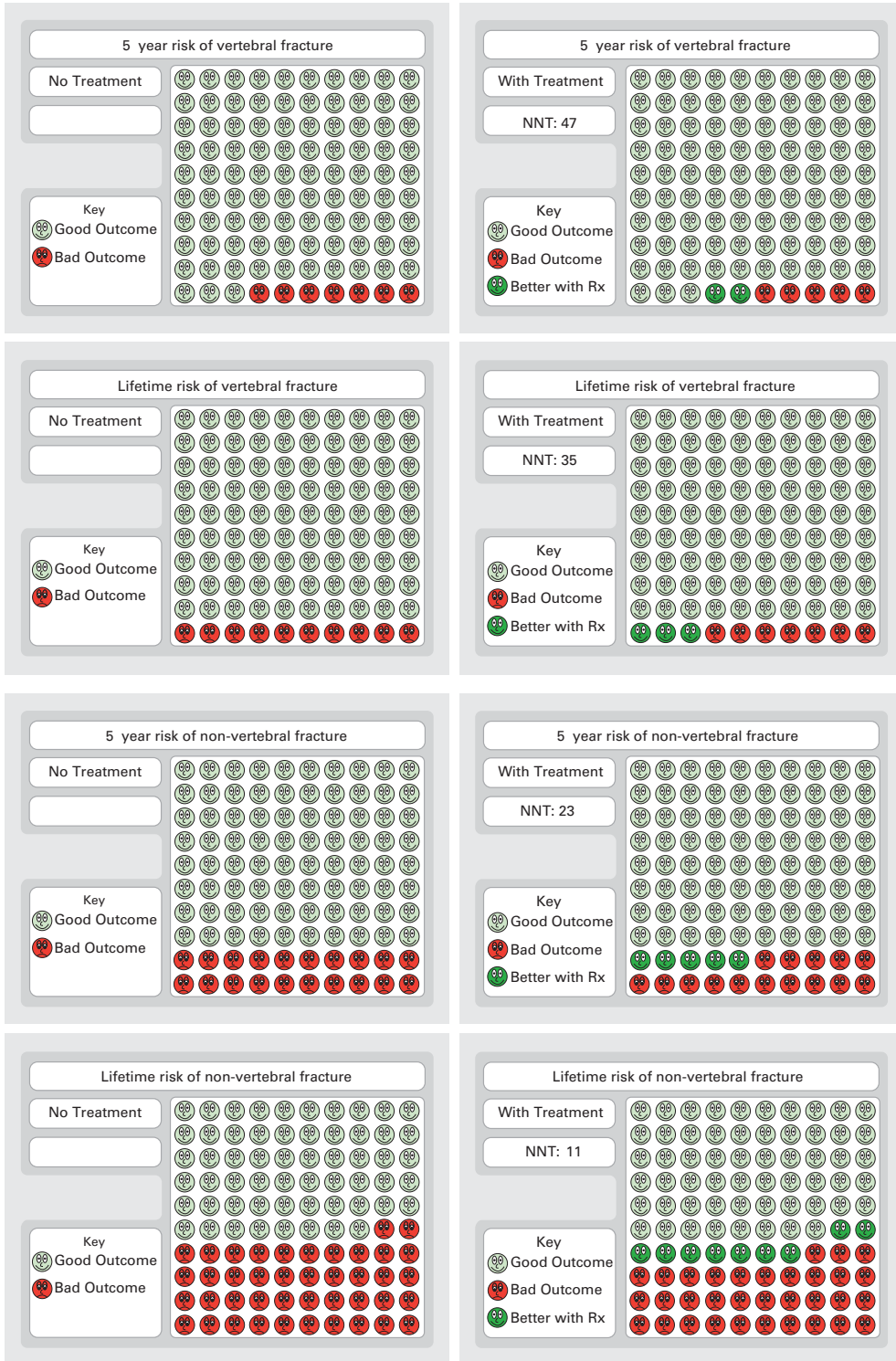
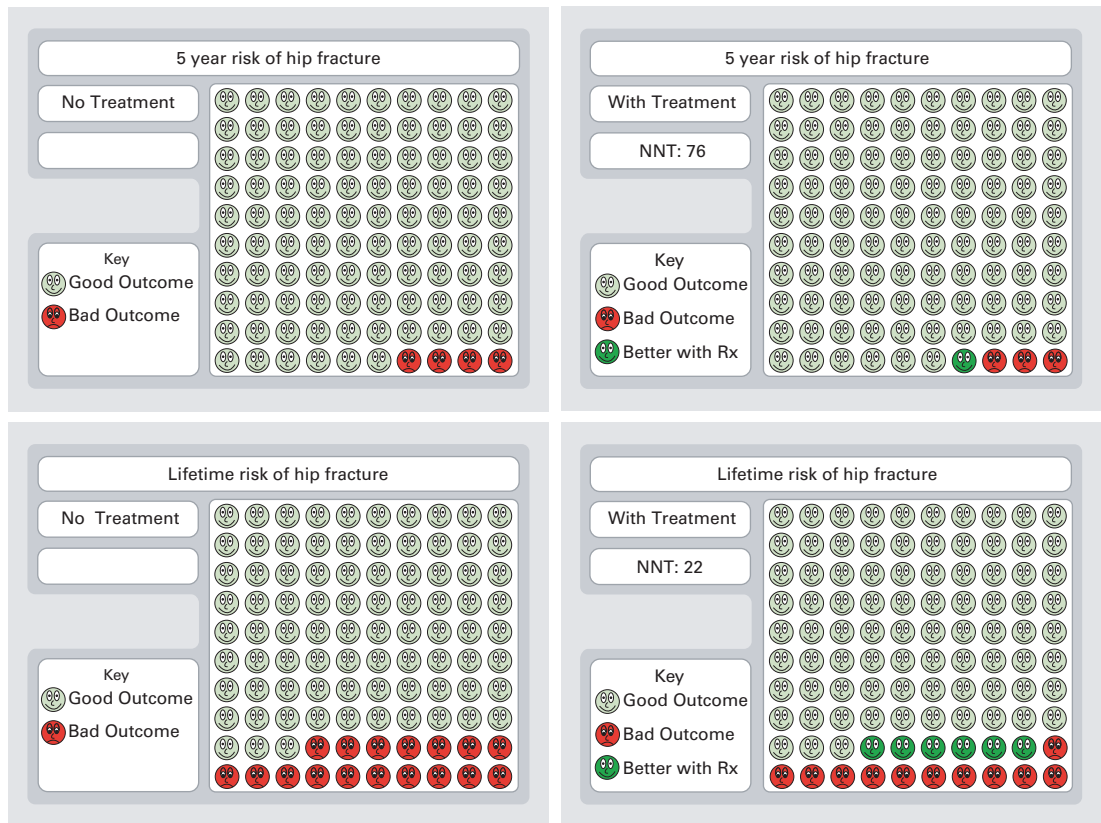


Table 8.5 NNT for five year (high risk woman) and lifetime risk of fracture with HRT compared to no treatment

Outcome	5 year and lifetime risk of fracture in untreated population	5 year and lifetime risk in a treated population	Relative risk with treatment (95% CI)	NNT
Vertebral fracture	5 year: 7.1%	5 year: 5.0%	0.70 (0.52–0.94)	5 year: 47
	Lifetime: 9.6%	Lifetime: 6.7%		Lifetime: 35
Non-vertebral fracture (including hip)	5 year: 19.8%	5 year: 15.4%	0.78 (0.64–0.96)	5 year: 23
	Lifetime: 42.1%	Lifetime: 32.8%		Lifetime: 11
Hip (1 trial, Women's Health Initiative 2002 CEE 0.625 mg + MPA 2.5 mg daily) ⁶⁰	5 year: 3.9%	5 year: 2.6%	0.66 (0.45, 0.98)	5 year: 75
	Lifetime 17.0%	Lifetime: 11.2%		Lifetime: 17

Visual Rx Faces 8.4 NNT for hip fracture with HRT compared to no treatment



Osteoporosis and hormone replacement therapy (HRT) Summaries and decision aid

How well does hormone replacement therapy (HRT) work to treat and prevent osteoporosis in women after menopause?

To answer this question, scientists found and analysed 2 reviews of the literature and 1 large study (Women's Health Initiative study) testing HRT in over 25 000 women after menopause. Women received HRT, placebo or vitamin D and calcium. These studies provide the best evidence today.

What is osteoporosis and how can HRT help?

Osteoporosis is a condition of weak brittle bones that break easily. In osteoporosis, breaks or fractures of the spine and hip, wrist or forearm (non-spinal fractures) may occur and often without a fall. After menopause, women make less sex hormones, such as oestrogen and progesterin, that help keep bones strong. HRT provides extra oestrogen and/or progesterin to the body to slow down bone loss.

How well did HRT decrease fractures and increase bone density?

One review and the Women's Health Initiative study showed that the chances of having **spine fractures** are less when taking HRT than when taking a placebo or calcium and vitamin D. Two reviews and the Women's Health Initiative study showed that the chances of having **non-spinal fractures (wrist, hip, etc.)** are less when taking HRT than when taking a placebo.

Bone mineral density increased about the same in the spine, forearm and hip when taking HRT for 2 years.

Were there any side effects?

Side effects such as depression, headaches, breast tenderness, premenstrual syndrome, skin irritation, and weight gain can occur with HRT. The Women's Health Initiative study showed that HRT may increase the chances of developing breast cancer, heart disease, stroke, and blood clots, but decrease the chances of developing colorectal cancer (bowel cancer).

What is the bottom line?

There is "Gold" level evidence that hormone replacement therapy increases bone density more than a placebo or no treatment in the lower spine, forearm, and hip. Hormone replacement therapy also decreases the chances of spine fractures and non-spinal fractures.

Hormone replacement therapy may increase the chances of developing breast cancer, heart disease, stroke, and blood clots but decreases the chances of bowel cancer. But taking hormone replacement therapy for a short period of time may be helpful to decrease symptoms of menopause and decrease the risk of fractures.

How well does hormone replacement therapy (HRT) work to treat and prevent osteoporosis in women after menopause?

What is osteoporosis and how can hormone replacement therapy help?

Osteoporosis is a condition of weak, brittle bones that break easily. In osteoporosis, breaks or fractures of the spine and hip, wrist or forearm (non-spinal fractures) may occur and often without a fall. Osteoporosis is detected using a bone density test that measures the amount of bone loss. A result that is at least 2.5 “standard deviations” below normal confirms the diagnosis. This means people have lost at least 25 per cent of their bone mass or density. Treatments have been developed to slow the bone loss and try to promote bone building.

After menopause, women make less sex hormones, such as oestrogen and progesterin, that help keep bones strong. Hormone replacement therapy provides extra oestrogen and/or progesterin to the body to slow down bone loss.

How did the scientists find the information and analyse it?

To find out just how well hormone replacement therapy works, the scientists searched for studies testing hormone replacement therapy. Unfortunately, not all studies found were of a high quality and so only those studies that met high standards were examined in this summary.

- Studies had to be randomised controlled trials – where a group of women after menopause (postmenopausal) received hormone replacement therapy and was compared to postmenopausal women who received a placebo (or sugar pill) or calcium and vitamin D, for at least one year.
- Studies had to show how well hormone replacement therapy works by measuring bone mineral density (BMD) and the number of fractures (or breaks).

Which high quality studies were examined in the summary?

Two reviews and 1 additional study were included in this summary.

- One review of the medical literature examined 57 high quality studies. The studies included over 9900 women after menopause (postmenopausal women) receiving different types of hormone replacement therapy including oestrogen and/or progesterin for, on average, 1 to 2 years. Forty-seven studies provided hormone replacement therapy to women with normal to near normal bone density to prevent bone loss and fractures and 10 studies provided hormone replacement therapy to treat women who already had bone losses (or low bone mineral density – BMD).
- Another review examined 22 studies.
- The additional study called the Women’s Health Initiative was just recently completed and tested one type of hormone replacement therapy in over 16 600 postmenopausal women.

How well did hormone replacement therapy decrease fractures and increase bone density?

Spine fractures: Results from five studies in the first review that tested over 3000 women and the additional recent Women’s Health Initiative study showed that the chances of having spine fractures over a lifetime are less when taking hormone replacement therapy than when taking a placebo or calcium and vitamin D:

- 7 out of 100 women receiving hormone replacement therapy will have a spine fracture over their lifetime
- 10 out of 100 women receiving no treatment or a placebo (sugar pill) will have a spine fracture over their lifetime.

This means that 3 out of 100 more women benefited from taking hormone replacement than a placebo

Hip and non-spinal fractures (wrist, etc.): Results from six studies in the first review that tested 3986 women combined with the Women's Health Initiative study, and results from another review showed that the chances of having non-spinal fractures over a lifetime are less when taking hormone replacement therapy than when taking no treatment or a placebo:

- 33 out of 100 women receiving hormone replacement therapy will have a non-spinal fracture over their lifetime
- 42 out of 100 women receiving no treatment or a placebo (sugar pill) will have a non-spinal fracture over their lifetime.

This means that 9 out of 100 more women benefited from taking hormone replacement therapy than a placebo

For hip fractures specifically, the Women's Health Initiative study showed that the chances of having a hip fracture over a lifetime are less when taking hormone replacement therapy than when taking a placebo:

- 11 out of 100 women receiving hormone replacement therapy will have a hip fracture over their lifetime
- 17 out of 100 women receiving no treatment or placebo (sugar pill) will have a spine fracture over their lifetime.

This means that 8 out of 100 women benefited from taking hormone replacement therapy than a placebo

Bone mineral density (BMD): Bone mineral density increased by about the same amount in the lower spine, forearm, and hip when taking hormone replacement therapy after 2 years. This increase in bone density was larger with higher doses of hormone replacement therapy.

Were there any side effects?

Side effects such as depression, headaches, breast tenderness, premenstrual syndrome, skin irritation, and weight gain can occur with hormone replacement therapy.

The Women's Health Initiative study showed that hormone replacement therapy may increase the chances of developing breast cancer, heart disease, stroke, and blood clots.

Breast cancer:

- 20 out of 1000 women with hormone replacement therapy developed breast cancer:
- 15 out of 1000 women with a placebo or sugar pill developed breast cancer.

Heart disease:

- 19 out of 1000 women developed heart disease with hormone replacement therapy
- 15 out of 1000 women developed heart disease with a placebo or sugar pill.

Stroke:

- 15 out of 1000 women had a stroke with hormone replacement therapy
- 10 out of 1000 women had a stroke with a placebo or sugar pill.

Blood clots:

- 18 out of 1000 women had blood clots with hormone replacement therapy
- 8 out of 1000 women had blood clots with a placebo or sugar pill.

But the Women's health Initiative study showed that hormone replacement therapy may decrease the chances of developing colorectal cancer (cancer of the bowels).

Bowel cancer:

- 5 out of 1000 women had cancer of the bowels with a hormone replacement therapy
- 8 out of 1000 women had cancer of the bowels with a placebo or sugar pill.

What is the bottom line?

There is "Gold" level evidence that hormone replacement therapy increases bone density more than a placebo or no treatment in the lower spine, forearm and hip.

There is "Gold" level evidence that hormone replacement therapy also decreases the chances of spine fractures and hip fracture and other non-spinal fractures.

Hormone replacement therapy increases the chances of developing breast cancer, heart disease, stroke, and blood clots but decreases the chances of bowel cancer.

The cons outweigh the pros of hormone replacement therapy in the long term. But taking hormone replacement therapy for a short period of time may be helpful to decrease symptoms of menopause and decrease the risk of fractures.

From Cranney A, Simon LS, Tugwell P, Adachi R, Ottawa Methods Group. Osteoporosis. In: *Evidence-based Rheumatology*. London: BMJ Books, 2003.

Information about osteoporosis and treatment

What is osteoporosis?

Osteoporosis is a condition of weak, brittle bones that break easily. The most common breaks or fractures are in the spine, hip, wrist or forearm, and these may occur without a fall. Osteoporosis is detected using a bone density test that measures the amount of bone loss. A result that is at least 2.5 “standard deviations” below normal confirms the diagnosis. This means people have lost at least 25 per cent of their bone mass or density.

Hip fractures can cause severe disability or death.

- Among 100 women with normal bone density, about **15** may break a hip in their lifetime.
- Among 100 women with low bone density, about **35 to 75** may break a hip in their lifetime.

This number depends on *amount of bone loss*, *age*, and other risk factors, such as:

- *major bone-related risks*: previous broken bones since age 50 (not from trauma); family history of fracture (e.g. mother who broke a hip, wrist, spine)
- *major fall-related risks*: poor health; unable to rise from a chair without help; use of sleeping pills.

Spine fractures are more common, disabling, and painful. They can cause stooped posture and loss of height of up to 6 inches.

To find out your personal risk of broken bones, ask your doctor.

What can I do on my own to manage my disease?

- ✓ Calcium and vitamin D
- ✓ Regular impact exercises (e.g. walking)

What treatments are used for osteoporosis?

Three kinds of treatment may be used alone or together. The common (generic) names of treatment are shown below.

1. *Bone-specific drugs*
 - Alendronate
 - Calcitonin
 - Etidronate
 - Risedronate
2. *Hormones that affect bones and other organs*
 - Parathyroid hormone
 - Raloxifene
 - Hormone replacement therapy (oestrogen and progestin)
3. *Other*
 - Hip protector pads

What about other treatments I have heard about?

There is not enough evidence about the effects of some treatments. Other treatments do not work. For example:

- Calcitonin for non-spinal fractures
- Etidronate for non-spinal fractures
- Raloxifene for non-spinal fractures

What are my choices? How can I decide?

Treatment for your disease will depend on your condition. You need to know the good points (pros) and bad points (cons) about each treatment before you can decide.

Osteoporosis decision aid

Should I take hormone replacement therapy (HRT)?

This guide can help you make decisions about the treatment your doctor is asking you to consider.

It will help you to:

1. Clarify what you need to decide.
2. Consider the pros and cons of different choices.
3. Decide what role you want to have in choosing your treatment.
4. Identify what you need to help you make the decision.
5. Plan the next steps.
6. Share your thinking with your doctor.

Step 1: Clarify what you need to decide

What is the decision?

Should I take hormone replacement therapy (HRT) to slow bone loss or prevent breaks?

Hormone replacement therapy (HRT) may be a combination of oestrogen and/or progestin and may be taken as pills, creams, injections or patches.

When does this decision have to be made? Check one

- within days within weeks within months

How far along are you with this decision? Check one

- I have not thought about it yet
- I am considering the choices
- I am close to making a choice
- I have already made a choice

Step 2: Consider the pros and cons of different choices

What does the research show?

Hormone replacement therapy (HRT) is classified as: **Trade-off between benefits and harms**

There is “Gold” level evidence from 1 large study and 2 reviews with over 25 000 women after menopause that tested hormone replacement therapy (HRT) and lasted up to 4 years. The women had osteoporosis (low bone density) or normal to near normal bone density. These studies found pros and cons that are listed in the chart below.

What do I think of the pros and cons of hormone replacement therapy (HRT)?

1. Review the common pros and cons that are shown below.
2. Add any other pros and cons that are important to you.
3. Show how important each pro and con is to you by circling from one (*) star if it is a little important to you, to up to five (*****) stars if it is very important to you.

PROS AND CONS OF HORMONE REPLACEMENT THERAPY (HRT)	
PROS (number of people affected)	How important is it to you?
Fewer broken bones in the spine 3 less women out of 100 have a break in the spine over their lifetime by taking HRT compared to no treatment	* * * * *
Fewer broken bones in the hip or wrist 9 less women out of 100 have a break in the hip or wrist over their lifetime when taking HRT compared to no treatment	* * * * *
Increases bone density	* * * * *
May decrease the changes of bowel cancer (colorectal cancer) 3 out of 1000 less women with HRT compared to placebo	* * * * *
Other pros:	* * * * *
CONS (number of people affected)	How important is it to you?
Side effects: depression, headaches, breast tenderness, premenstrual syndrome, skin irritation, and weight gain	* * * * *
Long term harms with hormone replacement therapy: Breast cancer (in 5 out of 1000 more women) Heart disease (in 4 out of 1000 more women) Stroke (in 5 out of 1000 more women) Blood clots (in 10 out of 1000 more women)	* * * * *
Personal cost of medicine	* * * * *
Regular menstrual periods	* * * * *
Other cons:	* * * * *

What do you think of hormone replacement therapy (HRT)? Check one

Willing to consider this treatment
Pros are more important to me than the Cons

Unsure

Not willing to consider this treatment
Cons are more important to me than the Pros

Step 3: Choose the role you want to have in choosing your treatment. Check one

- I prefer to decide on my own after listening to the opinions of others
- I prefer to share the decision with: _____
- I prefer someone else to decide for me, namely: _____

Step 4: Identify what you need to help you make the decision

What I know	Do you know enough about your condition to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know which options are available to you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know the good points (pros) of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know the bad points (cons) of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
What's important	Are you clear about which pros are most <i>important to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Are you clear about which cons are most <i>important to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
How others help	Do you have enough support from others to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Are you choosing without pressure from others?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you have enough advice to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
How sure I feel	Are you clear about the best choice for you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you feel sure about what to choose?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure

If you answered No or Unsure to many of these questions, you should talk to your doctor.

Step 5: Plan the next steps

What do you need to do before you make this decision?

For example: talk to your doctor, read more about this treatment or other treatments for osteoporosis.

Step 6: Share the information on this form with your doctor

It will help your doctor understand what you think about this treatment.

Decisional Conflict Scale © A. O'Connor 1993, Revised 1999.

Format based on the Ottawa Personal Decision Guide © 2000, A O'Connor, D Stacey, University of Ottawa, Ottawa Health Research Institute.