The case:
The patient is Roberta an 87-year-old female who is being treated for mild hypertension but is otherwise healthy, with no chronic diseases. She is a widow who lives at home with a young family that provides her with companionship. She has very little sensation in her lower legs, due to poor circulation and walks with a cane. She is very concerned about falling. Her son, the "health nut", just read an article about Vitamin D. He strongly urges her to start taking Vitamin D because the article said it can prevent accidental falls. However she finds it difficult to remember to take pills every day. After watching a commercial for an osteoporosis medication that is taken once a year, the son asks “what about taking a mega dose of Vitamin D once a year” would that help?

The question:

<table>
<thead>
<tr>
<th>Patient</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome</th>
<th>Type of Question</th>
<th>Type of Study</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

State the question:

The search:
Keywords/MeSH and filters to include in the search strategy:

The articles:
## Critical Appraisal Worksheet with Key Learning Points

<table>
<thead>
<tr>
<th>THERAPY STUDY</th>
<th>Key Learning Points</th>
</tr>
</thead>
</table>
| **Randomization**  
Was the allocation (assignment) of patients to treatment randomized?  
Was the allocation concealed? | Why is randomization important?  
Randomization guarantees that each subject has the same chance of entering any group. In this way, randomization aims to balance groups for known and unknown prognostic factors by allocating subjects to groups by chance alone, so that any observed group differences can be attributed to the effect of treatment.  
Allocation concealment assures that those assessing eligibility and assigning subjects to groups don’t have knowledge of the allocation sequence. |
| **Similar Baseline Characteristics of Patients**  
Were groups similar at the start of the trial? | Why should groups be similar at baseline?  
It is important to verify that those factors known to influence outcome are equally distributed. And to assess the potential effect on the study outcome of an imbalance that occurs by chance. |
| **Blinding**  
Were patients, health workers, and study personnel "blind" to treatment? | Why is blinding important?  
Blinding equalizes the effect of patient and therapist expectations on outcome across groups. For raters, blinding minimizes subjectivity in outcome measurement. For providers, blinding eliminates the possibility of either conscious/unconscious differential administration of effective intervention to either group, such as co-interventions (unintended additional care to either group) or contamination (provision of the intervention to the control group). |
| **Equal Treatment**  
Aside from the experimental intervention, were the groups treated equally? | Why should groups be treated equally?  
Equal treatment helps guarantee that the groups will remain prognostically balanced by avoiding systematic differences in the care provided other than the intervention. |
| **Patient Follow-Up**  
Were all patients who entered the trial properly accounted for and attributed at its conclusion?  
Was follow-up complete? | How do dropouts threaten validity?  
Dropouts or those lost to follow-up create missing data that may disrupt the balance in groups created by randomization, especially since those who discontinue a study often have a different prognosis than that of those who continue. In this way, a high ratio of dropouts to events may introduce systematic differences between groups in those lost to follow-up. |
| **Intention-to-Treat Analysis**  
Were patients analyzed in the groups to which they were randomized?  
Were all randomized patient data analyzed? | Why is intention-to-treat analysis important?  
ITT preserves the balance of prognostic factors in groups created by the original random group allocation. It provides the truest estimate of the effects of treatment allocation in real-world practice by including data from crossovers, nonadherents, dropouts and those lost to follow-up, plus estimates of missing data points. ITT thereby avoids overly optimistic estimates of treatment efficacy resulting from excluding non-compliers. |
Summary of article’s validity

How serious are the threats to validity and in what direction could they bias the study outcomes?

B. WHAT ARE THE RESULTS?
How large was the treatment effect?

How precise was the treatment effect?

Calculate and state the plain English meaning of summary statistics for dichotomous outcomes: Absolute Risk Increase (ARI), Relative Risk Increase (RRI), and Number Needed to Harm (NNH)

Response rates on dichotomous outcome measure:

<table>
<thead>
<tr>
<th></th>
<th>Outcome Present</th>
<th>Outcome NOT present</th>
</tr>
</thead>
<tbody>
<tr>
<td>experimental</td>
<td></td>
<td></td>
</tr>
<tr>
<td>control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Experimental Event rate:

Control event rate:

Absolute Risk Increase:

Relative Risk Increase:

Number Needed to Harm: