

# Development of the Bone Treatment Questionnaire: Patient Experience of Receiving Pharmacotherapy to Prevent Skeletal-Related Events

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## BACKGROUND

Bone is the most common site of metastatic disease in patients with breast cancer (Hess et al., 2006). A number of different pharmacotherapies are used to reduce the occurrence of skeletal complications (skeletal-related events; SREs) and maintain quality of life (Leppert, 2007). The use of patient reported outcomes (PROs) is a valuable and efficient method of collecting data on patient experience and satisfaction with care and treatment (Salisbury, Wallace & Montgomery, 2010). This study was designed to better understand breast cancer patients' experience of receiving pharmacotherapies to prevent SREs in order to develop a PRO instrument for this patient population.

## METHODS

**Three staged approach:**

**Stage 1:** Literature review to identify PROs and relevant concepts for patients' experience of taking pharmacotherapies to prevent SREs.

**Stage 2:** Concept elicitation interviews with breast cancer patients (n=8) and health care professionals (n=4) with experience in receiving and administering these pharmacotherapies, respectively. Interviews recorded and transcribed; analysed using thematic analysis to generate items.

**Stage 3:** Cognitive interviews with breast cancer patients being treated with pharmacotherapies to prevent SREs (n=5) to assess the content validity and comprehensiveness of newly developed PRO instrument.

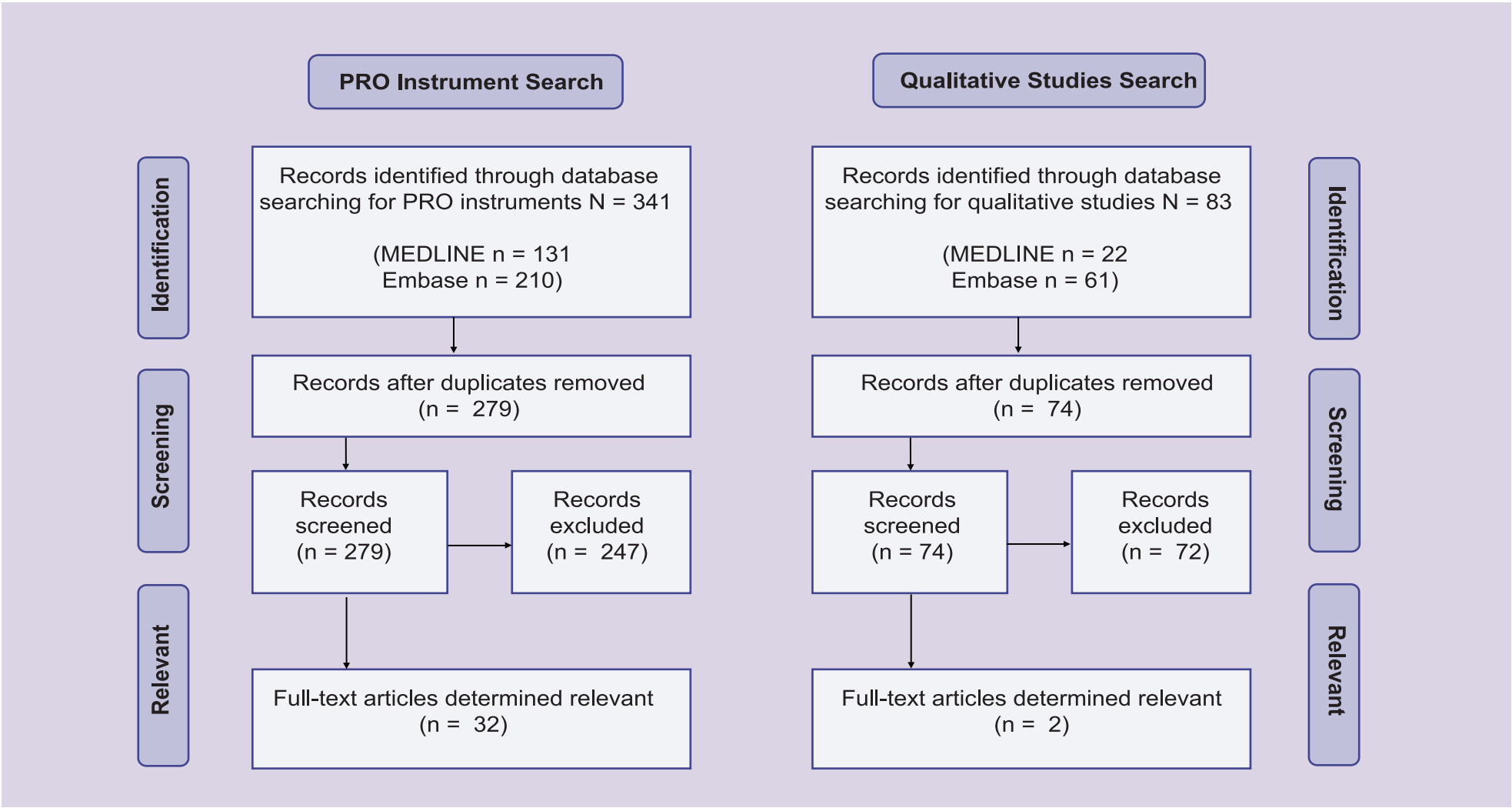
## RESULTS

**Stage 1:**

The literature review yielded 353 unique abstracts (see Figure 1). Thirty-two publications specified PRO instruments and two qualitative studies explored patient experiences.

The searches failed to identify a suitable PRO instrument for the target population.

**Figure 1. Literature search flow charts**



**Stage 2:**

Concept elicitation interviews were conducted with patients (n=8) and healthcare professionals (n=4). Inclusion and exclusion criteria are summarised in Table 1.

Patient Participants:

- All female
- Average age: 59 years (range 43-73 years)
- Average time since breast cancer diagnosis: 11 years (range 4 – 21 years)
- Average time since being prescribed pharmacotherapies to prevent SREs: 27 months (range 3 months – 4 years)
- Cycle of medication administration: monthly (4 patients), every three-weeks (3 patients), every six-weeks (1 patient)
- Medication: Zoledronic acid (6 patients), Pamidronate (1 patient), Ibandronate (1 patient)
- Three attended a clinic appointment purely to receive medication for SRE prevention
- Five had their clinic appointment to receive medication for SRE prevention combined with another medical appointment

**Table 1. Inclusion/exclusion criteria**

Inclusion criteria:
<i>Patient sample:</i> <ol style="list-style-type: none"><li>1. Be between 18 and 65 years of age.</li><li>2. Have a current diagnosis of advanced breast cancer.</li><li>3. Be receiving IV bisphosphonates for the prevention of SRE's.</li><li>4. Able to provide informed consent.</li></ol> <i>Health Care Professionals sample:</i> <ol style="list-style-type: none"><li>1. Regularly treat people with breast cancer and use IV bisphosphonates for the prevention of SRE's in their clinical role.</li></ol>
Exclusion criteria:
<i>Patient sample:</i> <ol style="list-style-type: none"><li>1. Newly diagnosed with breast cancer (e.g. within 6 months of diagnosis).</li><li>2. Breast cancer patients undergoing surgical intervention or receiving palliative care.</li><li>3. Lack of English language fluency.</li></ol>

## Healthcare Professionals

- Medical Oncologists with ten and 18 years' experience in breast cancer and IV bisphosphonate medication
- Specialist Oncology Nurses with five and ten years' experience in administering IV bisphosphonate medication

During the interviews several concepts of relevance were expressed by patients and healthcare professionals. Table 2 provides some verbatim examples related to the concepts identified in the interviews. Participants' responses related to 'before' and 'during' treatment. Item generation resulted in the 10-item Bone Treatment Questionnaire (BTQ; see Figure 2).

**Figure 2. Bone Treatment Questionnaire**

<i>Certain treatments can reduce the risk of bone injuries such as fractures in people receiving treatment for cancer. Some people may find these treatments to be inconvenient. We are interested in your experience of receiving treatment for your bones. (This is different to any chemotherapy treatment you may receive for your cancer). Please read each statement and tell us if you agree or disagree by ticking the box.</i>	Agree	Slightly agree	Neither agree nor disagree	Slightly disagree	Disagree	Not applicable
<b>Thinking about before you receive your bone treatment</b>						
1. Taking the time out of my daily activities for my bone treatment is inconvenient.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. My bone treatment stops me planning future holidays and other events.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Taking my bone treatment disrupts my day.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. It bothers me that someone has to attend my clinic appointments with me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I find travelling to receive my bone treatment is inconvenient.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Thinking about when you receive your bone treatment</b>						
1. I enjoy meeting other people when I go to receive my bone treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. For me, attending a clinic appointment is a reminder I am unwell.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Receiving my bone treatment is uncomfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. My appointments to receive my bone treatment take too long.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Given the choice, I would prefer to have my treatment closer to, or at home.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Table 2. Concept elicitation quotes**

	Concepts	Example Quotes
<b>Before (Q1 – Q5)</b>	Overall inconvenience	"Well, you're always stuck to it, you know. If you've got to, you know, plan a holiday or, you know, and I've got to have someone, you know, to take me all the time, you know, it's just an interruption. You know you're not normal."
	Travel considerations	"It's time-consuming, obviously, because I've got a half an hour journey to the hospital, and then there's the hanging around, which obviously would be better with tablets."
<b>During (Q6 – Q10)</b>	Social factors	"We get to see one another, so lots of us find it more like a social event, where we can get together, have coffee (...) and chat about things that have been going on and if anything's worrying you or sometimes, somebody just wants to chat to you, you know, and ask you about things."
	Social factors (impact on family and friends)	"Yeah, I normally take somebody with me, because they have said I shouldn't drive (...) That can be difficult, because I'm not running out of friends, but I feel it's quite a commitment, you know, sitting there, 'cause it's a long time."
	Psychological factors	"It's more of a psychological thing. I think any time you go into hospital, to have something intravenously, you're reminded that there is something wrong with you. And that can sometimes impact negatively on your self-esteem, and psychologically how you see yourself (...) because it's a reminder that you have a chronic illness and that can make you feel quite depressed."

**Stage 3:**

Cognitive interviews endorsed all items as being important and relevant. Patients were able to understand each item and complete the questionnaire with no difficulties. Table 3 provides some verbatim examples from the cognitive interviews.

Patient Participants:

- All female
- Average age: 53 years (range 43-62 years)
- Average time since breast cancer diagnosis: 9 years (range 4 – 12 years)
- Average time since being prescribed pharmacotherapies to prevent SREs: 29 months (range 4 months – 8 years)
- Cycle of medication administration: monthly (1 patient), every three weeks (3 patients), every six weeks (1 patient)
- Medication: Zoledronic acid (4 patients), Ibandronate (1 patient)
- Two attended a clinic appointment purely to receive medication for SRE prevention
- Three had their clinic appointment to receive medication for SRE prevention combined with another medical appointment

**Table 3. Cognitive debrief quotes**

	Concepts	Example Quotes
<b>Overall Impression</b>	Comprehension of introduction to questionnaire	"Very to the point... I understood it fully... I think it does what it says on the bottle sort of thing."
	Length	"It's not that long, so... I don't think it's too long and I don't think it's too short; it's just about right."
<b>Items Within the Questionnaire</b>	Relevancy	"I think you have covered everything, you know. I couldn't think of anything else that I would – that would be of concern or that I would want to, you know, be asked about. I think everything's covered."
	Item wording	"Oh yes, yes. Yes, it was very easy to understand."
	Response options	"I've completed a number of questionnaires along the same lines and this seems to be, you know, one of the better ones. The 'agree' to 'not applicable' seems to be a better spectrum than like – some of the questionnaires that I have had that's 'strongly agree', 'strongly' and I think that's overkill, if you like... So no, I wouldn't have thought that it needed any, you know, to make it better."

## CONCLUSION

The BTQ is designed to capture patient experience of receiving pharmacotherapies for the prevention of SREs. Initial research supports this newly developed PRO instrument demonstrates relevancy of content and comprehensiveness for breast cancer patients' experience of receiving pharmacotherapies to prevent SREs.

## REFERENCES

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