



In confidence

Potential participant study ID number

Back Skills Training (BeST) Trial

Nurse randomisation assessment form

The University of Warwick
Centre for Primary Health Care

THE UNIVERSITY OF
WARWICK



MRC General Practice Research
Framework

First, please check that the participant study number is correct. Then ask the potential participant all of the following questions.

Some of these questions are the same as those I asked you last time I saw you.
This is to make sure that you are still suitable for the study.

1. On what date are you completing this form?	<input type="text"/> <input type="text"/> <input type="text"/> day	<input type="text"/> <input type="text"/> <input type="text"/> month	<input type="text"/> <input type="text"/> <input type="text"/> year
2. What is your date of birth?	<input type="text"/> <input type="text"/> <input type="text"/> day	<input type="text"/> <input type="text"/> <input type="text"/> month	<input type="text"/> <input type="text"/> <input type="text"/> year
To enter the trial potential participants must be 18 years or older when they attend the randomisation assessment.			
<p>First I would like to ask you some questions about your back pain and symptoms.</p> <p>By back pain we mean pain in the back anywhere between the bottom of the chest and the top of the legs. This area includes the lower back and buttocks. (<i>Show patient laminated card</i>) This is the area marked on this card.</p> <p>An attack of back pain can last for just a few hours, or may be for much longer. Some people may also experience stiffness, discomfort, anxiety, fatigue, moodiness, numbness or tingling due to the back.</p>			
			Yes No
3. Are you still being troubled by your back pain?	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	
4. How often have you had back pain or symptoms in the last six weeks?	Everyday <input type="checkbox"/> ₁ Between everyday and three quarters of the days <input type="checkbox"/> ₂ Between three quarters of the days and half of the days <input type="checkbox"/> ₃ Between half of the days and a quarter of the days <input checked="" type="checkbox"/> ₄ Rarely <input type="checkbox"/> ₅		
5. How troublesome has your back pain or symptoms been during the past 6 weeks?	Not at all troublesome <input checked="" type="checkbox"/> ₁ Slightly troublesome <input type="checkbox"/> ₂ Moderately troublesome <input type="checkbox"/> ₃ Very troublesome <input type="checkbox"/> ₄ Extremely troublesome <input type="checkbox"/> ₅		

	Yes	No
6. Have you lost weight significantly over the last 6 months? By how much was this? <input type="text"/> Kg or St&lbs (please circle) Were you trying to lose weight?	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
7. Are you having any problems passing water or moving your bowels? <i>By this we mean symptoms related to their back pain, not long standing problems such as constipation or stress incontinence.</i> <i>If NO, please go to question 8.</i> <i>If YES, has the GP given consent to join the study?</i> <i>If GP is satisfied that there is not a serious cause for these symptoms, they can still join the study.</i>	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
If answered 'yes' to questions 6 and lost more than 10kg/1.7 stone or 'yes' to question 7, refer the patient to their GP for further screening.		
8. Are you currently being treated for back pain at a hospital or elsewhere by a consultant, physiotherapist, chiropractor or osteopath or are you about to start treatment for your back pain?	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
9. If you joined this trial and were randomised to the Back Skills Training would you be willing and able to attend for treatment? <i>You will need to explain the likely times, places and frequencies of the training. They need to be able and willing to attend to be eligible for the trial.</i>	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
10. In the past have you ever attended a specialised pain clinic or pain management programme for back pain or have you ever received prolonged psychological treatment for your back pain? <i>By pain clinic we do not mean an ordinary orthopaedic/neurosurgery/ rheumatology clinic but a clinic providing a multi-disciplinary approach to the management of back pain.</i>	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
11. Women only: Are you pregnant at the moment? If you join the trial and find out that you are pregnant during the first three months please let me know as soon as possible. <i>Although the back skills training is believed to be safe in early pregnancy we do not want pregnant women to have any trial treatments because a different treatment approach may be needed.</i>	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
12. Do you want to join this study of back pain treatments?	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁
Check from your records for the following information		
13. Has the GP signed consent for the patient to enter the trial?	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁

PTO

The patient is eligible if there are no responses to questions in a shaded box.

If the patient appears eligible but does not wish to take part, explain that this will not affect their care from the practice in any way. Please ask them their reasons and enter them in the comments section below.

If potential participants are temporarily not eligible for the trial give them a temporary exclusion letter and explain that if they become eligible and they wish to enter the trial then they can book a randomisation appointment with you.

If they are eligible for the trial:

- 1. ask them to sign the consent form*
- 2. ask them to complete the baseline questionnaire.*

After the baseline questionnaire has been completed:

- complete the randomisation form*
- randomise the patient*

Tell the participant their randomised treatment. If randomised to the Back Skills Training you need to send a notification letter to the therapist. Please advise the patient that the therapist will then contact the participants to arrange a time to start their treatments. Please ensure we have a contact number.

*Please give **all** randomised participants a copy of 'The Back Book'. Reinforce its message and tell them how important it is that they read it and follow its advice. Take time to answer their questions and refer them back to their GP if they still have any queries.*

Give the participant:

- An address change form and reply paid envelope to notify address and telephone number changes.*

Comments