


Physiotherapy for Joint Hypermobility

Patient Information Booklet

Helping you decide whether or not
to join our study

You are being invited to take part in a research study which is being conducted by the University of the West of England, University of Bristol and Kings College London.

Before you decide to take part, it is important you understand why the research is being done and what it will involve. Please read this leaflet carefully and discuss it with other people such as family, friends or your GP if you wish.

If there is anything you don't understand or if you would like more information, please contact


Part 1 tells you the purpose of the study and what will happen if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Part 1

1. What is the purpose of the study?

- Joint hypermobility (often known as being 'double-jointed') is quite common and may cause pain and disability. It is often treated by physiotherapists but we actually don't know if physiotherapy works or not.
- This study aims to test whether a course of physiotherapy is any better than giving detailed advice about managing joint hypermobility.
- The results will tell us whether it is worth doing a much larger study in the future.

2. Why have I been chosen?

- We are asking patients with joint hypermobility who have been referred for physiotherapy whether they can help.
- If you have never had physiotherapy for joint hypermobility, or your last treatment was longer than 12 months ago, then you may be able to take part.
- Unfortunately, we will not be able to include you if you have received another course of physiotherapy for joint hypermobility within the last 12 months; have other diagnosed conditions causing pain or stopping you exercising; have severe mental health issues; or if you are younger than 16 years of age. The researcher will ask you about these things before confirming that you can take part.

3. Do I have to take part?

- It is up to you to decide whether or not to take part in this study. Taking part is voluntary and will not affect, in any way, the current care you are receiving or any care you may have in the future.

4. What happens if I agree to take part?

- If you are interested in discussing whether you would like to take part in this study, please return the reply slip to the physiotherapy department in the pre-paid envelope.
- You may telephone the researcher to discuss what the study is about and you may ask any questions you wish. You will have further time to think about whether you would like to take part or not.
- If you decide you would like to take part you will attend your physiotherapy appointment as normal. The specifically trained physiotherapist will examine you as normal and will confirm whether or not you are eligible to take part. You can ask further questions about the research at that point and if you are happy to take part the physiotherapist will ask for your written consent. A copy of this will be given to you to keep, and the physiotherapist will keep a copy.
- You will then receive detailed advice about managing joint hypermobility, along with advice booklets about your condition. The advice will include information about things such as joint protection, dealing with flare ups and exercise. You will also be able to ask the physiotherapist any specific questions that you might have.
- Half of the people taking part will be advised to follow the detailed advice given by the physiotherapist at the initial appointment and will not be offered additional physiotherapy treatment. Whether or not you receive this will be decided completely at random (you have a 50:50 chance of receiving this alternative) and we will let you know shortly after your initial appointment with the physiotherapist.
- The other half of the people taking part will receive an additional course of 6 physiotherapy appointments. Each will last for half an hour and will involve further education, advice and exercise. You would normally receive up to 6 appointments so this is no different to usual. You will receive a patient handbook which contains useful information to help you manage your condition and to be more active. You will be expected to read a little bit of information

before each session and to do some exercises at home. Whether or not you receive these appointments will be decided completely at random (you have a 50:50 chance of getting them) and we will let you know shortly after your initial appointment with the physiotherapist.

- Randomly allocating people to receive advice or advice plus physiotherapy is needed so that we can see any additional benefit of physiotherapy over and above advice alone.

5. What will I have to do?

- If you agree to take part, you will be asked to attend your initial physiotherapy assessment as normal. At this appointment you will have a full assessment as you would normally receive. The physiotherapist will ask you to describe your symptoms and any specific problems that you have. They will also look closely at how you move your joints and how you walk. You will also receive detailed advice about managing joint hypermobility, some advice booklets and an opportunity to discuss your condition in detail with the physiotherapist and to ask any specific questions that you might have.
- The initial appointment will last a maximum of 1 hour 20 minutes.
- You will also be asked to complete some questionnaires about yourself and your general health. This will be sent to you in advance so that you can fill it out before your appointment and bring it with you. Otherwise you can complete it on the day.
- You may also be asked to take part in an interview about your experience of taking part in the study and the treatment you have received. We will not interview everybody but will try to interview a range of people based on the treatment they had, where they had treatment, and whether they seemed to get better or not. If you agree, the interview will take place with a researcher at a time and location which is convenient for you and in addition to what you would normally receive.
- You will also be sent questionnaires to complete at 4 months and 7 months after your initial physiotherapy appointment.
- Up to 60 people will take part in this part of the study which will last for approximately 18 months. Your involvement in the study will be approximately 7 months.
- If you have any concerns about your treatment or any aspect of your care please contact the [REDACTED]

6. What are the possible disadvantages of taking part?

- One disadvantage is the time it takes to complete the questionnaires and, if you are asked, to discuss your experience with a researcher.
- If physiotherapy is later shown not to be effective, those who receive it will have had the added inconvenience of attending appointments and engaging with treatment at home.
- If it is shown later that physiotherapy is effective, those who did not receive it will have missed out on that benefit. You can, of course, be re-referred for physiotherapy.
- If you receive the course of physiotherapy there may be a temporary increase in pain during or following exercise. This is likely to be similar to the normal muscle ache that people often get the day following activity that they are not used to. It is likely to go away after a few days and will improve over time as you get used to exercising. The choice of exercises and advice on progressing them will be specific to you to minimise any risk of causing pain. None of the exercises are likely to cause long-term pain.
- Taking part in this study will not affect, in any way, your medical care now or in the future.

7. What are the possible benefits of taking part?

- Everybody is likely to benefit from condition-specific advice and an opportunity to ask the physiotherapist questions.

- If physiotherapy is effective, those who receive it may gain additional benefit. Although it is important to remember that we actually don't know if it works or not and that is why this study is important.
- Taking part will help us to better understand the effects of physiotherapy for joint hypermobility and to decide whether it is worth doing a much larger study in the future.

8. Will my taking part in this study be kept confidential?

- Yes, all the information you give us will be kept strictly confidential and will be used only for the purposes of this study. It will be stored securely at the University, as well as on the University's secure (password protected, firewalled) database. Data will be anonymised and identifiable only to researchers by codes.
- Your name and personal details will not be reported in any reports about the study, or to anyone outside the study team. The study's written reports may include some quotations from the interviews with the researcher. These will be anonymous, and will not include anyone's names or have anything in them which will allow you or any other person taking part to be identified.
- I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- In the interview you will not be expected to talk about anything that you are not comfortable with.
- With your consent, your GP will be the only person informed about your involvement in this study.

9. Expenses and payment

- We will refund your travel expenses if you have to make a special trip to attend an interview with a researcher.
- Unfortunately we will not be able to reimburse you for your time, should you wish to take part.

This completes Part 1 of the Information Booklet. If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in Part 2 before making any decisions.

Part 2

10. What will happen if I don't want to carry on with the study?

- Your participation is voluntary and if you decide to take part you are still free to withdraw at any time, without giving a reason, and without your care or legal rights being affected.

11. What will happen to the results of the study?

- The results of this study will be published in reports, scientific journals and presented at scientific conferences so that other health care professionals can learn from your experiences. If the results look positive, they will also help us to design a much larger study of physiotherapy for people with hypermobility.
- A lay summary of the findings will be sent to all participants on completion of the study.

12. Who is organising and funding this study?

- The study is being conducted by researchers at the University of the West of England, University of Bristol and Kings College London.

- The study is funded by the NHS National Institute for Health Research, Health Technology Assessment Programme.
- The funding includes payment for the time that the researchers spend on the study.

13. How to make a complaint:

- If you have a concern about any aspect of this study, please contact [REDACTED]
- If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from Advice & Complaints Team [REDACTED]

14. Who has reviewed this study?

- All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by NRES Committee South West – Exeter.

15. What happens next?

- If you wish to take part in the study, please fill in the reply slip and return it in the pre-paid envelope provided. You will then be contacted by the physiotherapy department to arrange an appointment.
- If you have any questions about the study, please feel free to contact [REDACTED]
- Alternatively, advice on deciding whether or not to take part can be received from the Research & Innovation Department at North Bristol NHS Trust (details below). Although R&I staff are employed by NBT, this advice will be completely independent from the researchers.
- **Research & Innovation Department:** [REDACTED]
[REDACTED] Tel: [REDACTED]

Thank you very much for taking the time to read this information leaflet. Please keep a copy of this information leaflet.

