Participant Information Sheet

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Early motion and directed exercise (EMADE) post ankle fracture fixation.

A pragmatic randomised controlled trial

Principal Investigator: Mr. Benjamin Ollivere

EMADE Ankle study

PART 1

1. Invitation

You are being invited to take part in a study to see if additional and early physiotherapy provides faster and more complete recovery from your ankle fracture.

Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

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

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

2. What is the purpose of the study?

This study is designed to help us understand what rehabilitation method is better for your ankle fracture. The study is looking at two rehabilitation strategies either keeping the ankle immobilized in a cast (usual or normal practice) or supplying a removable cast which will allow you to perform exercises under the direction of a physiotherapist (EMADE or early mobilization and directed exercise). In both groups, patients **do not walk** on that leg until at least 6 weeks after their operation.

3. Why have I been chosen?

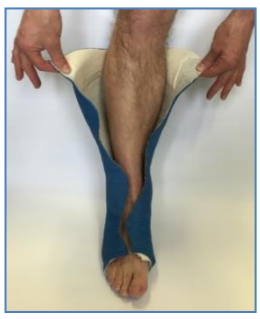
You have been chosen because you are of the right age (18 and over) and have had an ankle fracture that required surgery to get the bones in the right place and keep them there.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

5. What will happen to me if I take part?

As part of the study you will continue to follow the standard treatment plan as prescribed by your hospital, including your out-patient visits at around 2-weeks and 6-weeks after your surgery. The study will be explained to you in person by a member of the research team and if you agree to participate you will be asked to sign a consent form. During your 2-week visit a questionnaire will be completed and we will take some simple measurement of your ankle.



The decision about which treatment you receive will be decided by a process called randomisation and neither you, nor your doctor or the researcher will be able to choose which treatment you receive. You will have an equal chance of receiving either treatment.

If assigned to the usual-care group, you will remain in a standard plaster cast.

If assigned to the EMADE group you will receive a removable cast and invited to attend your hospital once a week until your NHS 6-week review with the Consultant's team. During each of these visits there may be some hands-on physio and you will be taught exercises to repeat several times each day at home. You will also be shown how to take the cast on and off, to allow you to do these exercises.

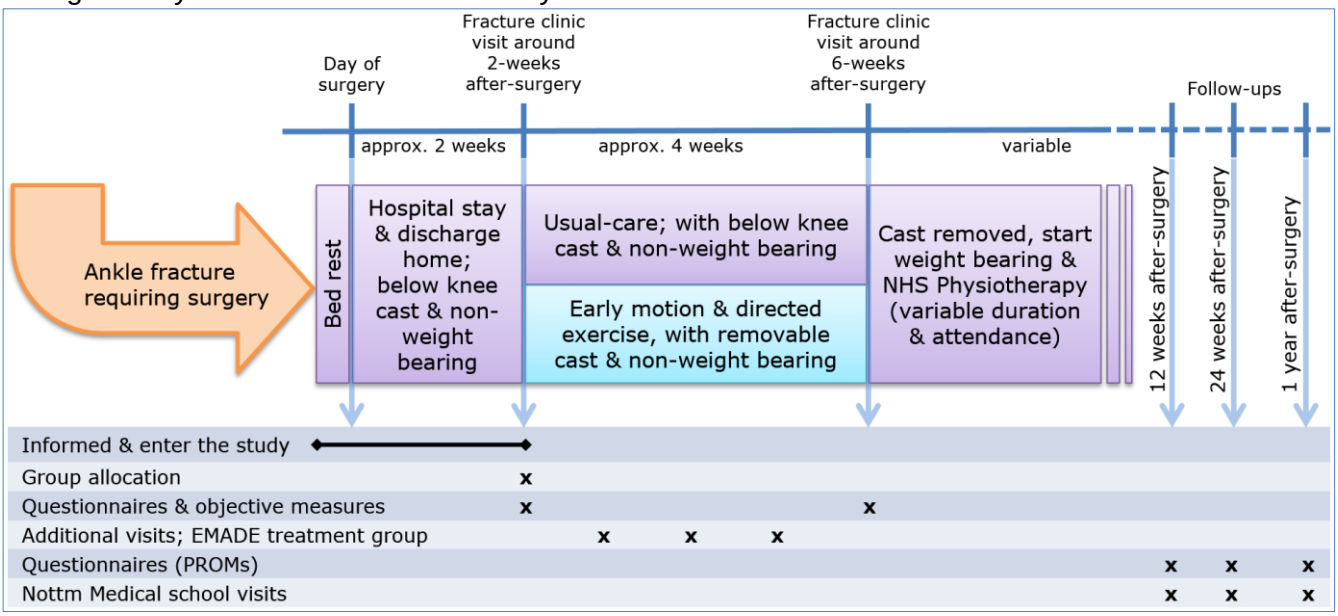
In which ever group are assigned to, you will not walk on the leg until the NHS 6-week review with the Consultant's team. During this review the cast is removed, a further X-ray taken, and the questionnaire and measurements are repeated. If the Consultant is happy with the scan, you may start taking weight on that leg immediately. You may also be referred to see the NHS Physiotherapists according to the standard procedures of your hospital. The need for further hospital visits and scans will be based on your clinical need.

You will be asked to repeat the same questionnaires at 12-weeks, 24-weeks and finally at one-year after your surgery, and invited to attend sessions at the Medical School where we measure your walking speed, ankle movements and size, balance, and calf strength. If you prefer not to come in for these measures, we would be grateful if you could answer the questionnaires by traditional post or email, or by telephone.

6 What do I have to do?

All patients involved in the study will be asked to complete a questionnaire either by post or at their clinic appointments. Patients assigned to the EMADE will be asked to perform the exercises several times daily as instructed.

A diagram of your involvement in the study is shown below:



7. What is the treatment that is being tested?

The study has been designed to establish if Usual-care or EMADE with a removable cast, provides faster and more complete recovery from your type of ankle fracture.

8. What are the alternatives for diagnosis or treatment?

These are two treatment protocols used following operative ankle fixation.

9. What are the side effects of any treatment received when taking part?

If you do decide to take part in the study, you must report any problems you have to the researchers using the contact number given on this information sheet. Also use this number if you should you require medical information during the study. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

10. What are other possible disadvantages and risks of taking part?

We do not expect there to be any disadvantages for taking part in the EMADE ankle study.

11. What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get might help improve the treatment of people who have had operative fixation of their ankle fracture.

12. What happens when the research study stops?
The last piece of information we need from you will be around a year after your ankle surgery. If you have problems after this date your GP can arrange for you to see an Orthopaedic Consultant once more.

13. What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

14. Will my taking part in this study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential. Details are included in Part 2.

15. Contact Details

Doctor	Mr. Benjamin Ollivere (Consultant)	Tel: 0115 924 9924 (via secretary)
Research team	EMADE	Tel: 0115 823 1412 (Incl's out of office hours No.)
Research coordinator	Miss. Jessica Nightingale	Tel: 0115 924 9924 ext 67502

Independent Advice or Complaints
If you wish to receive independent advice or to make a complaint this can be done through the Patient Advice and Liaison Service. Their contact details are given below.

By telephone:	Freephone: 0800 183 0204 (free from a UK landline)
	From a mobile or abroad: 0115 924 9924 ext 65412 or 62301
By e-mail:	pals@nuh.nhs.uk

This completes Part 1 of the Information Sheet. If this information has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

16. What if new information becomes available?
If you do not wish to continue with the study you will be withdrawn immediately and no further action on your part will be required. You will be asked if you are happy for any data already collected to be retained. If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

17. What will happen if I don't want to carry on with the study?
If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

18. Will my part in this study be kept confidential?
If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital under the provisions of the Data Protection Act 1998. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

If you withdraw consent from further study treatment, unless you object, your data and samples will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study.

19. Informing your General Practitioner (GP)

With your permission, we will write to your GP informing them of your participation in the study. They will also receive routine letters from your fracture clinic appointments to update them about your progress.

20. What will happen to any samples I give? No samples will be collected in this research.

21. Will any Genetic testing be done? No.

22. What will happen to the results of this clinical trial?

The results of the study will be available after it finishes and will usually be published in a medical journal and/or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask your study doctor.

23. Who is organising and funding this clinical trial?

The Nottingham University Hospitals NHS Trust will act as a sponsor for the research. Arthritis Research UK will fund the research along with the AO UK orthopaedic association.

24. Who has reviewed the 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, well-being and dignity. This study has been reviewed and given a favorable opinion by the NHS by the NUH Research Ethics Committee. The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust.

25. Expenses and inconvenience allowance

Travel expenses will be offered for any visits incurred that are in addition to NHS visit.

26. Contact for further information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people either of the contacts named above.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.