AIR

Ankle Injury Rehabilitation

Chief Investigator: Dr Rebecca Kearney

PATIENT INFORMATION SHEET

We would like to invite you to take part in our research study, investigating two different treatments for patients who have broken their ankle. This study will provide us with information which may help improve treatment of patients with similar injuries in the future.

Before you decide whether to take part we would like you to understand why the research is being done and what it would involve for you. A researcher from our team will go through this information sheet with you and answer any questions you have.

Background information

You have broken (fractured) your ankle, traditionally ankle fractures are placed in a plaster cast to keep the bones still whilst they heal. However keeping the ankle still can potentially cause complications such as joint stiffness and muscle weakness. An alternative way to treat this injury is to use functional bracing which can be removed regularly to perform exercises. However, it does not provide the same level of support for the healing ankle.

What is the purpose of this study?

Both the plaster cast and functional bracing are successfully used in hospitals throughout the UK for patients with injuries like yours. However, there is little evidence from research studies to say if one is better than the other.

This study is a local study to find out if a national study is possible. The national study will then be able to compare functional bracing versus plaster cast with regards to quality of life. It is important to perform a study in which the two methods are compared so in the future individuals with similar injuries will receive the best possible treatment

Why have I been chosen?

You have been chosen because you have had an ankle fracture. All patients at UHCW who sustain an ankle fracture will be approached to take part in this pilot study. We are aiming for 50 patients.

Do I have to take part?

It is up to you whether or not to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive.

Which treatment will I receive?

You will be allocated to either a functional brace or plaster cast. The allocation process will be performed purely by chance. There is an equal chance of you receiving either the functional brace or plaster cast. The researcher will tell you which treatment you have been allocated to if you decide to take part.

All patients will be asked to keep a daily diary whilst wearing the cast or brace to monitor how much weight is put through the healing ankle fracture. The amount of weight you are allowed to place through your healing ankle will be guided by your operating surgeon. In addition to this, all patients receiving a functional brace will be asked to remove the brace and perform daily exercises which will also be recorded in the diary. Six weeks following your injury all patients will receive the same physiotherapy advice.

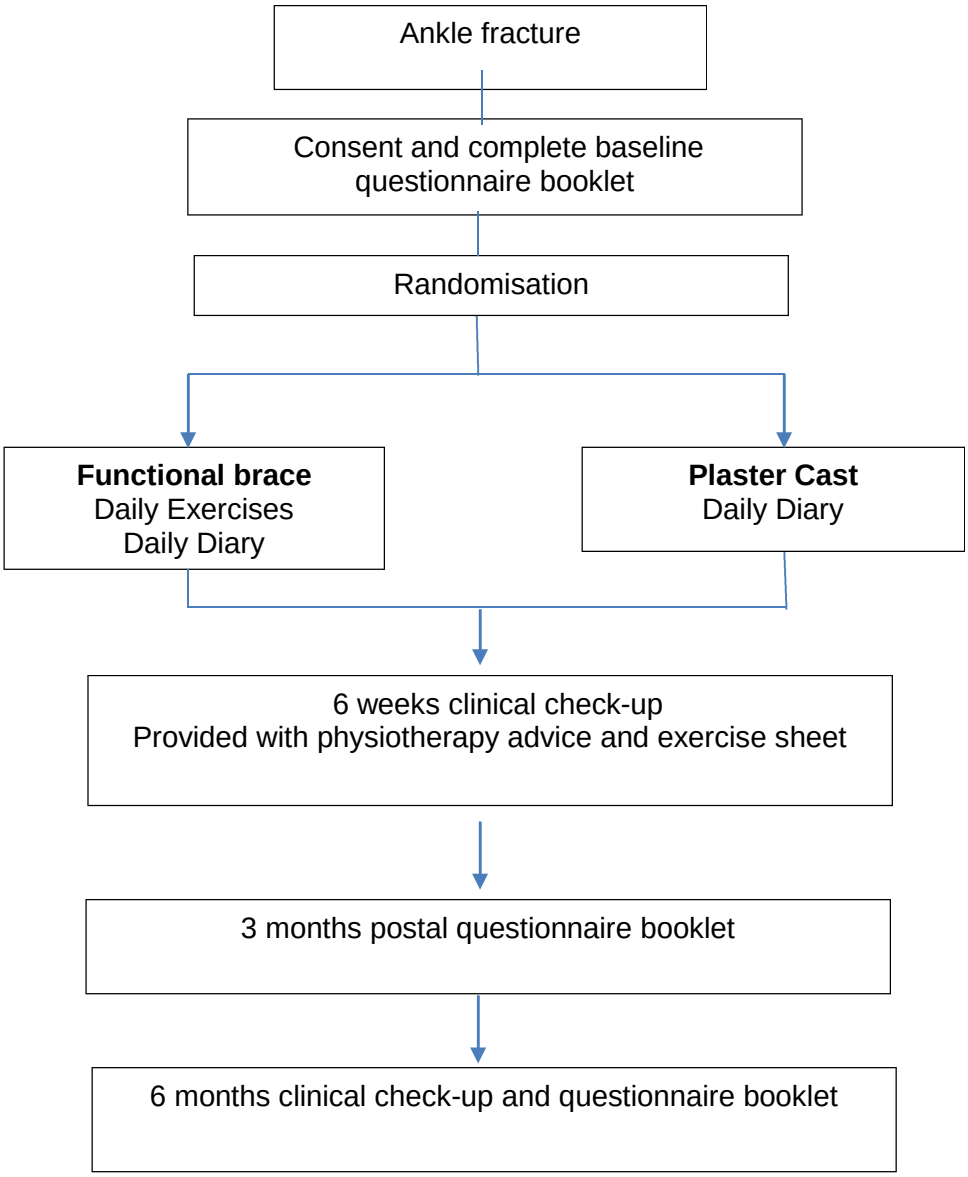
What will happen if I take part?

All patients with an ankle fracture are followed up carefully to make sure their fracture is healing during the first 6 months after their injury. You will be followed up in the usual way. For the purpose of the research we will ask you to complete a booklet of questionnaires on four occasions to tell us about your recovery and complete a daily diary.

Once you have signed the consent form we will ask you to fill out the first questionnaire booklet that will take approximately 10 minutes to complete. The questions will ask you about how well you were able to perform certain day-to-day activities and how you were feeling before your injury occurred. We will ask you to complete a similar questionnaire booklet approximately 6 weeks, 3 and 6 months after your injury. At 3 months we will send the questionnaire booklet to you in the post (with a free post return envelope), at 6 weeks and 6 months it will be completed during your routine clinic appointment. With your permission, we may occasionally phone or send you a mobile text message to inform you a questionnaire is due.

Appropriate personal identifying information will be collected, stored and used by the University of Warwick Clinical Trials Unit to enable the follow up of participants in the study. Any information will be treated with the strictest security and confidentiality.

In the flow chart below you can see a schedule of the visits / assessments and what would happen during your recovery.



What are the possible disadvantages and risks of taking part?

We do not know which of these treatments gives the best results; both treatments are already available and used widely within the NHS.

What are the possible benefits of taking part?

Both treatments are widely used for people with this injury. This study may improve the treatment of ankle fractures in the future there is no specific advantage to you for taking part in the study.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, a researcher from Warwick Clinical Trials Unit will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will encourage you to discuss your continued care with your doctor. If you decide to continue in the study you will be asked sign an updated consent form.

What happens when the research study ends?

You will be in the study for 6 months. If you are still having problems after this time, your surgeon will arrange for you to have an appointment with an appropriate specialist to continue your care.

What happens if there is a problem?

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for legal action for compensation against the University of Warwick. This study is covered by the University of Warwick’s insurance and indemnity cover. If you have an issue, please contact the Chief Investigator of the study: Dr Rebecca Kearney (02476 573 156).

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study:

Director of Delivery Assurance
Registrar's Office
University House
University of Warwick
Coventry
CV4 8UW
Complaints@Warwick.ac.uk
024 7657 4774

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves Warwick Clinical Trials Unit will have your name and address removed so that you cannot be recognised from it. Your GP and other doctors who may treat you but are not part of this study will be notified, with your consent, that you are taking part in this study.

What will happen to the results of the research study?

The study is expected to last for 22 months. At the end of this time we will publish the findings

in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please ask a member of the research team.

What will happen if I decide not to participate in the research study?

If you decide not to participate in the research study your care will not be affected and you will be followed up in the usual way.

Who has reviewed this study?

This study has been reviewed by the West Midlands – The Black Country Research Ethics Committee.

Contacts for further information

If, at any time, you would like further information about this research project you may contact your local Research Team on 02475 968734 or AIR@warwick.ac.uk

The study is funded by the Department of Health and coordinated by University of Warwick Clinical Trials Unit. Dr Rebecca Kearney, who is the overall lead for this study, may also be contacted on: 02476 573 156

For independent advice contact the PALS service (Patient Advice Liaison Service) on 0800 0284203.

Thank you for considering participation in this study and for taking time to read this information sheet