

NINJA PARTICIPANT INFORMATION SHEET (aged 11-16)

Nail bed INJury Analysis (NINJA):

Should the nail plate be replaced or discarded after nail bed repair in children?



Could you be a
NINJA?

WE WOULD LIKE TO INVITE YOU TO TAKE PART IN OUR
RESEARCH STUDY!

Before you decide if you would like to take part, we would like you to understand why the research is being done and what it would involve for you.

Please take time to read the following information and discuss it with family members, friends, and anyone else you would like to.

Local Research Team contact name

Local Research Team email and phone number

Local PI name

Document title	NINJA_PIS_11-15_V2.0_26Jan2018.docx	Version/date	V2.0. 26Jan2018
Study short title	NINJA	REC reference.	18/SC/0024
Chief Investigator	Prof Abhilash Jain	IRAS no.	219560
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Summary - A few important things you need to know:

- To make your fingernail better, you will need an operation - you will need this operation whether you are part of the study or not.
- There are different ways to treat your fingernail after the operation.
- We don't know which way will make your finger look nice again! That is why we are doing this study.
- We will collect information about your injury and the operation.
- We will ask you to come back 7-10 days after the operation so we can assess how your finger is doing and ask you some questions about the fingernail and give you and your grown up a questionnaire to fill in.
- We will then ask you to complete a short questionnaire after 4 months – this will be sent to you and your grown up at home via email or post – whichever you prefer.
- At 4 months we will ask you to send us a photo of your fingernail so we can see how it looks.
- This study is recruiting 416 patients from around 25 hospitals around the UK.

Nail bed injury information

- A nail bed injury affects the soft spongy tissue underneath the hard fingernail.
- It is often caused by jamming a finger in a door or getting a finger stuck in something.
- It needs surgery to repair the soft tissue nail bed underneath your fingernail because it will be cut and bleeding.
- To do this, your fingernail needs to be removed.
- The injured nail bed is cleaned up and fixed with tiny dissolving stitches.
- This is important to help your new fingernail grow out smoothly and look as normal as possible in the future.
- This is normally done while you're asleep under anaesthetic, and you won't feel a thing! Sometimes surgeons can do the operation by numbing your hand so you don't have to go to sleep. Your surgeon will tell you what they think will be best for you and your finger.
- Your finger is bandaged at the end of the operation and you can normally go home the same day.
- You will be asked to come back to a clinic in about a week for the doctors to see how the nail bed is healing.
- It usually takes about 4 months for a new nail to grow out from the base.

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Why does there need to be a study?

- Traditionally the nail was replaced after the nail bed is repaired. Recently surgeons are thinking that replacing the fingernail may not be essential.
- This old nail normally falls off within a week or two as the new fingernail grows out.
- Your fingernail will grow back!
- Both of these techniques (replacing the nail and discarding the nail) are routinely done in the NHS.
- We don't know whether replacing the nail or discarding it is better, so we are doing a research study to find out!

What is a research study and what is NINJA?

- Research is using a systematic method to investigate a question.
- For NINJA this question is: should the nail plate be replaced or discarded after nail bed repair in children?
- We are using the help of doctors and nurses in 25 hospitals in the UK to recruit patients to help us answer his question.

We've asked you to participate because you have a nailed injury and you need an operation to fix it



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What would taking part involve?



At the start



- We ask you and your grown up to complete some questionnaires about you and your injury
- We ask you to sign an assent form, which would allow us to collect information about your operation. Your parents will also need to sign a consent form on your behalf.
- We will ask you to come back to hospital to see your doctor in clinic about 7-10 days after your operation. If you choose not to take part in the study then you will still be invited back by your doctor to see how your finger is healing.



At the 7-10 day check-up

During your standard clinic visit:

- A doctor or nurse will change the finger dressings and assess your fingertip for any signs of infection.
- If an infection is identified they will treat it appropriately, usually with antibiotics.

As part of the NINJA study:

- We will ask you and your grown up to complete some questionnaires about the your general health, how the fingernail has been healing.
- Some of the questionnaire will be completed in the clinic and some will be sent to you and your grown up via email or post (whichever you prefer) so you can complete this in your own time.
- The questionnaires should take about 15-20 minutes to complete. And we will provide a postal envelope to return paper questionnaires.



After 4 months

- We will send you and your grown up some similar questionnaires via post or email again.
- The questions will be similar to the ones asked in the clinic visit and take 15-20 minutes to complete and we will provide a postal envelope to return paper questionnaires.
- Your grown up will be asked to take a photo of your injured finger and the same finger on the other hand, side by side, then send this in via a secure web link.
- We will send you a template and full instructions on how to do this.
- The photos will allow us to see how the new fingernail has grown and if it looks like your other finger nails

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Who will decide which treatment I have?

All patients will require surgery to repair their fingernail injury as part of their clinical care.

- If you participate in the study, whether your fingernail is replaced or discarded will be decided by a process called *randomisation*
- **Randomisation** means whether your finger nail replaced or discarded is decided *randomly* (like tossing a coin). This is done via a computer programme.
- We do this because it is the fairest way to decide between the 2 treatment options.
- When we split people into groups like this, it is called a “randomised clinical trial” and it is the best way to see how good a treatment is.
- We will split all the children in our study into teams: the **replaced** NINJA team or the **discarded** NINJA team



Please note – you will still receive the same care before, during and after your operation regardless of whether your fingernail is replaced or discarded.

What if I don't want to take part anymore?

Your participation in NINJA is entirely voluntary, and if you decide you don't want to be in the study anymore, that's perfectly ok! You don't even have to tell us why. Just let us know and we won't bother you anymore! Being in the study will not affect the treatment you have for your finger injury.

Who is running NINJA?

The central NINJA team is based in Oxford and all parts of the study have been checked over to make sure that we are asking the right questions and ensuring the wellbeing of our participants.

Will people know I'm taking part in NINJA?

No, taking part in NINJA is confidential. When you sign up you will be given a “NINJA number” and any information we have about you and your injury will be identifiable only by this number and all your information kept secure.

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The Fun Information!

- If your grown up agrees, you can be added to the *secret* NINJA Facebook group using their details, or your own, if you are old enough.
- The Facebook group will have competitions for all of the NINJA participants, including:
 - NINJA drawing competitions
 - Word jumbles & crosswords
 - Photo diaries
 - Finger trivia

THANK YOU FOR YOUR INTEREST IN

NINJA

Nail bed INJury Analysis

If you would like to know more your contact at your hospital is:

<NAME>

<TELEPHONE>

<ADDRESS>

<EMAIL>

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