

Appendix 1. Free text comments

FORCE PIS FREE TEXT

10b. Was there anything you wanted to know about FORCE study but which wasn't included in the information you saw? If yes, please write them here.
The question that would be asked. Allowance for deviation -eg-have splint but child feeling ok - could it come off early. Soft bandage -how long ?? Return if child still uncomfortable
About the disadvantages of taking part in study.
What the hospitals current practice was- I asked this question whilst in A+E
The length of the follow on questionnaires we would be sent on day1 , day 3 etc.
I WANTED MORE INFO ON TREATMENT RISKS BUT PURPOSE OF STUDY IS TO ASSESS THEM! MY SON IS 14 AND I WANTED HIM TO BE DECISION MAKER HAVING HEARD+CONSIDERED INFO.
There should be a child friendly leaflet included, I had to ask my son whether he is happy with answering questions on the i-pad, as well as the computer selecting the treatment bandage or splint.
I wasn't completely sure if my child would get the best treatment if we took the study but the Dr said normally there would be no treatment so something felt better than nothing at all.
It was not mentioned if the splint gets dirty from perspiration due to change of weather or what to do in these circumstances.
I may have missed it but I felt the need to seek clarification from the staff member about whether we could change the treatment part-way through the study.
Good description of possible risks of taking part. I didn't properly read the explanation whilst in hospital as I had two young children with me but it was well explained when I read it at home. A bit more explanation of what buckle fracture are and maybe a picture/photo/diagram would have been helpful. I found this later on NH's website.
11. Can you tell us which aspect(s) about FORCE study was explained well in the information you saw? Please write them here:
All of them
Everything was explained really well. And the consultant was really helpful.
About my daughter's fracture
Reason for doing study
All aspects were explained well.
Treatment plan, Reason why
Not really
Benefits of potentially improving care for others as a result of finding out more about which treatment option is best to promote speedy recovery.
How to help the children Nationwide for better treatment.

All of it.
Section 5
Why the study was important.
No1- important things you need to know and no2. what treatment will my child receive. That helped me make my decision about taking part.
The two types of treatment possible in the study.
I THOUGHT IT WAS WELL WORDED AND DIDN'T NEED TO CLARIFY ANYTHING.
All of it.
That it will help others in the same situation as us.
Everything was covered just a lot of info to read.
Why it was being conducted. That we could change our mind at any time and opt for a different treatment.
That if we wasn't happy at all with anything we could change our minds.
The reasons for doing the study and how the study would happen/involvement/expectation
Why my child was chosen. How the study would benefit treatment in the future. How much correspondence I would receive. That my child would receive a voucher for taking part. That we could leave the study at any time. Essentially all was well explained.
Information sheet and Patient Information Leaflet
The introductory section 'What is Force'? Was precise and clear and gave an informative snapshot of the research. (age 10)my daughter information sheet was excellent. She understood exactly and could discuss the information with clarity.
I liked the idea of my child wearing a stretchy bandage! As I am legal guardian of my nephew, he has Foetal Alcohol Syndrome and would have been very distressed wearing a splint bandage. So, him being part of this study gave him another option.
I am very happy about everything and also my son. Very nice explanation, approach, empathy. Very positive.
SELECTION PROCESS. ONE AREA NOT COVERED IS PERCEPTION.PEOPLE UNDERSTAND CASTS/SPLINTS. THEY RECOGNISE THE NEED TO EXERCISE CARE TOWARDS AND FOR THEMSELVES. MY CONCERN IS PEOPLE (PARTICULARLY OTHER STUDENTS) WILL NOT PERCEIVE THE NEED FOR CARE BECAUSES INJURY TREATMENT PLAN IS LESS OBVIOUS.
The nurse we saw took time to explain which treatment my child could have, she broke it down in to easy language for my child who has Asperger's. We understood that this study was to determine what treatment is more successful in children.
POSSIBLE BENEFITS OF BANDAGE VS SPLINT IN RANGE OF MOTION IN WRIST. IF MY CHILD CHANGES HIS MIND ABOUT TAKING PART IN THE STUDY IT IS OK. THERE ARE NO RISKS TO TAKING PART. IT WILL HEAL WHETHER BANDAGE OR SPLINT USED.
No, all of it.
The reasons for the study.
Treatment, when we would be contacted, that it was our choice whether to take part.

It was made clear that my Daughter didn't have to take part if she didn't want to and that this study will help others in the future.
The difference in treatment options
What the intention of the study was and how it may help future treatment decisions for buckle fractures.
EVERYTHING. THANK YOU.
What the study covers and how it will be use for future treatment or care.
Purpose, potential outcomes+reasons for study.
THE NEED FOR BETTER EVIDENCE ON THE PREFERRED TREATMENT ROUTE. THE NEGATIVE ASPECT OF THE SPLINT (REDUCED MOBILITY FOR A PERIOD AFTER/STIFFNESS)
Why there is no risk to the healing of the injury based on taking part in the study
All of it.
Two different causes of treatment depending on answers from initial questionnaire on ipad. How this study could help future treatment for children.
You can withdraw at any time. What the study was trying to achieve.
All aspects.
How long it takes
I am happy with all aspects
The purpose of the study was explained well.
The reason of the study.
The doctor's explanation persuaded me to take part. NOT the printed material.
We can withdraw at any time during the study.
If we were to change our mind, we can pull out of the study at any point.
Information about how the procedure would be done, how long it would take.
The reason for the study. What they were hoping to achieve.
The fact that my child would be given a bandage or a splint to support their healing.
How the study could reduce the need for X-rays for children.
How it may help future diagnosis
It was all explained well.
About things to look out for and how to deal with them.
The reason for doing the study
It was clear and the information given to my daughter explained it well.

Available options
Everything really but In particular:- When + how we will be contacted over the next few weeks.
All aspects
the reasons why the study was undertaken i.e improve management of buckle fractures, making it better for the child. The option to opt out at anytime/ not taking part at all was fully explained, felt no pressure to undertake the study. Decision was solely based on improving care and in my child's case, he 50/50 option of having 'bandage' really appealed.
I thought the information regarding children maybe not needing a brace in future with this injury and the reasons behind was interesting.
The reason why the study is taking place and how the study is being conducted.
All of it.
All aspects.
The study would help understanding of pain management.
Aim of the study. Comparison of the 2 treatments.
Clear instructions. Colourful.

12. If you have any other comments about the information you were given about the FORCE study, please write them here:
None
None
Person was very informative, but decision was based on how active my child is
We decided not to take part in the study because we were concerned about our daughter and her healing. She is quite a clumsy girl and we were worried if she only had a bandage, and fell again, she would cause more damage. More information about this to ease our concerns would of been helpful.
The study was explained well by the nurse in charge.
THERE COULD BE MORE INFORMATION UP IN THE WAITING ROOM SO IF YOUR GIVEN THE OPTION YOU'VE ALREADY NOTICED INFROMATION. WE DID SEE A SIGN ON THE WALL SAYING FORCE STUDY+MY SON ASKED WHAT IT WAS BUT I COULDN'T TELL HIM.
N/A
The next day the hospital rang us to have a follow up appointment at the fracture clinic. We therefore attended straight away. My daughter was examined by a doctor and asked questions. She then said she would get a soft cast applied to my daughter's arm. I was somewhat confused as at A&E we were told the treatment for this injury was usually a splint or as part of the study it would be a splint or the soft bandage. I then mentioned the study to which she said to not worry about what she had said but this has left me questioning what the usual treatment procedure is and the decision I had made. I therefore hope there is no detrimental effect to the health and wellbeing of my daughter.
The last question referring to health/wellbeing wasn't specific enough - was it referring to general health before injury or after injury??

Detailed and clear
Very informative doctor and study coordinator through paperwork, no queries whatsoever. Good Luck!
Good clear choice! Not clear about second paragraph- what is an optional bandage? Or a hard splint? - Perhaps a small picture to show what those are.
None
I WAS PARTICULARLY IMPRESSED WITH THE NURSE WHO EXPLAINING THE STUDY TO US. HE TOOK THE TIME TO ENSURE MY SON KNOW WHAT WAS INVOLVED AND THAT HE WAS HAPPY TO TAKE PART. ALSO HAVING THE CHILD SEEN THE SCREEN WAS A NICE TOUCH TO MAKE MY SON FEEL INVOLVED.
No
I like it that the computer choose to randomise which trial a patient will be group.
As soon as I saw the information sheet and was asked I said yes. My company is all about innovation/NPD/insight and this research is vital. All I would say is having gone through (and sort of been sold) the ipad induction we felt disappointed to be allocated the traditional method. Needs slightly different intro to the study.
I decided on a splint due to the doctor advising this and my son holding his arm up to support it as it's causing him a lot of pain.
Yes, the question to asked of the children were not applicable e.g. can you brush your teeth - the accident had only just happened.
Staff explained enough to understand
What to do if the children tells you if the splint is causing an itch or other discomfort which cannot avoided.
N/A
N/A
The researcher was very clear about the study and said early on that it was a random allocation between soft bandage/splint. As I have an active child I didn't feel confident with a soft bandage. My daughter fractured her other wrist 2 years ago and had a splint then. She wanted a splint again as she felt it was helpful. So, in short, I stopped the researcher before she could offer us written information.

FORCE MMI FREE TEXT

10b. Was there anything you wanted to know about FORCE study but which wasn't included in the information you saw? If yes, please write them here.
But the team who dealt with my son were fantastic and very informative
Our treatment was opted as 'bandage'. I would like to have known how long the bandage have to stay on for. I would like to have known what the current treatment option nationally is recommended for a compound fracture.
No, everything I needed to know was explained in full by the doctor carrying out the study and the short film.
If my son had not taken part would his treatment be any different as he got a bandage for a fracture but would he have had something different?

No, very useful.
How many surveys these would be to complete and on what frequency.
It would have been good to have more written information rather than the videos as they didn't have subtitles and it was hard to hear in the hospital.
Yes it was fully explained by the ENP e.g whether she would have any problems with either course of action.
Evidence for and against each type of support/bandage.
cost of replying to text messages, If over 12 ?card text go to child, It wasn't really clear what advantages/disadvantages were, lots of questions were n/a such as how it feels to brush teeth, put on clothing, n/a in ED setting.
The benefits and disadvantages for my child.
I didn't ask if my son would be in more pain not having a splint and that it's purely a recovery study and not about pain management.
I am not sure I understand whether there are any disadvantages of not taking part in the FORCE study?
Why the reason for the study? I understand that we aren't certain on the best treatment for this injury but what is the research and science behind undertaking the trials? Do we have evidence that this trial is trying to prove?
The disadvantages it could cause comparing pro's and con's to each treatment.
I WAS NOT MADE AWARE OF ANY DISADVANTAGES TO THE STUDY? WOULD BE INTERESTED TO KNOW WHAT THEY ARE.
NO, IT WAS ALL EXPLAINED REALLY WELL.
Whether you can opt out of FORCE after you answered questions
THE FORCE THEY ARE DOING EXCELLENT JOB I AM VERY PLEASE WITH THEM. THEY ARE HARD WORKING STAFF I AM VERY PLEASE WITH THEM.
Will this study be published/when? Why are children with minor fractures being used for a research? (especially when they are still growing up and so are their bones). After long waits in A&E is difficult to spend even more time answering questions for a study.
1. How often do I change bandage? 2. How long should the bandage be left on? 3. Where do I obtain clean bandages from?
Would the study differ on the healing of each child? E.g some children heal faster than others.

11. Can you tell us which aspect(s) about FORCE study was explained well in the information you saw? Please write them here:

I thought it was all explained well. I don't remember seeing any disadvantages.

Everything from why it was being ?called out, to how my child would take part to how I can find out results

The questions were age appropriate for my son. Ultimately, I would want the best treatment for my son. I like the way you can change treatment if necessary and taking part will help treatment in the future for children with the same sort of injury.

All explained well.
The rationale behind the study was well explained.
All of it was explained in detail to both me and (<i>child's name</i>).
All of it.
Everything was explained well.
All information was clearly explained in regards to the main reasons for the study and why the research was being undertaken.
The study design was straight forward and the information provided explained this clearly.
What the study was for and why they were doing it.
All aspects explained in detail, especially about the different healing ways/ (splint) or (bandage).
How my child's wrist injury would be managed weekly by text and if any issues came up I could always return to the hospital for support.
IT WAS ALL EXPLAINED WELL.
The fact that it is not clear whether splint or bandage works better.
The importance of research into dealing with fractures treatment.
The research nurse made the whole study very clear. The videos on the website were harder to access due to slow wifi and no service at (<i>hospital name</i>) so maybe more written information with video's would be helpful on the website.
The doctor was fantastic and delivered all information, the above question was just something I thought afterwards.
Type of fracture and different course of treatment
It was all good and well explained.
Everything about what's been doing and how it will help people/children in the future.
IT WAS ALL EXPLAINED WELL.
THE REASON'S FOR THE STUDY. THE TREATMENT
All aspects were explained well including the reasons for the research.
It was all explained well and showed very good.
The overall aim.
Information on the injury and how the child felt.
The goals of the study and the different treatment types
The reason behind the study and how you may get a splint or not to help work out which treatment is best.
Everything was explained very well. Both my son and I knew what to expect and was happy to take part.
The doctor explained clearly.

the study between the different types of methods used for the repair of bones and the difference between a splint and bandage and if there are different benefits/results. That we would be asked questions as a patient and carer about the pain etc and this would be used as part of the trial and we would monitor progress. That if we were unhappy at any stage during the study we could withdraw participation.
How the ability to move the limb was particularly better for the child.
Can't remember the info really.
Why you were doing the study, options we had, what you will do with info collected. How the study was implemented.
Video was a good visual tool, but very minimalistic and not a great deal of detail or content.
How it worked and what was going to happen.
It helped to determine what will be the best treatment. Also, it gave my little daughter the ability to know about her treatment.
A&E my daughter broke her arm.
What will happen and why study taking place.
the comparison of outcome before splint vs bandage . -the outcome. -the random selection.
2 different support options
Felt happy with how the whole FORCE study has explained.
The treatment options and how what treatment my son would get was decided. Why this study being carried out.
Presentation style easy to understand for all age groups.
The benefit to future patients and the impact on the ~500K similar fractures per annum treated by the NHS
The medical practitioner was so kind and explained the different types of fractures and difference between young and old bones.
Why the study was being done. How it is decided.
Everything was explained very well to me and my son, so we could make an informative decision.
How you were selected to determine which treatment option you had. Overall all aspects were clear for children to understand.
How times have changed and no longer need a cast as only a bump in bone on wrist
Why the study was being done was explained clearly.
THAT THERE WOULD BE NO ADVERSE EFFECTS FROM NOT HAVING A BRACE/SPLINT IF THAT WAS THE OPTION CHOSEN.
The reasoning behind the study was explained well.
The random selection of either a splint or a sling and that this study will help provide more information on how best to treat buckle fractures or not at all. (In children)
I found it difficult to answer questions for my 4 years old that are not age appropriate eg, can he do his zip up? -he can't do that yet anyway. There were lots of things like that e.g pour from a jug, tie shoes laces etc etc. I suggest having

an option for 'not learnt yet' or make the example something a younger child can do. this questionnaire sound like you want to know about information given before choosing to participate in the study than the study itself?
Treatment was very clear.
All of it- simple and clear. Direct
Where it clearly talked about the random selection of treatments.
The advantages of choosing the right treatment.
The positives and negatives of the study were all explained very well and to our son
The information about how they wanted to know what was better use for a fractured wrist (a splint or bandage)
I was all explained well, from the doctor to the researcher.
How the trial will be carried out and why it is being carried out to a point.
How the data collected could help to better decide the treatment given for the type of injury to the age group.
All aspects were well explained
How it will help treatment for fractures in the future.
Everything
All aspects explained well including reasons why the study was being conducted, how, the various conditions of the study and the proposed findings.
Missing data
All of it. Helpful video and explanation.
The benefits of the study, how it will help future patients and how new methods can be tested.
Why it is needed. How the study works.
All the info displayed and shown on the tablet was clear.
About the research
The outline of the study was clear and the fact we would be contacted during the study for updates etc.
Why they are carrying out the research what the research was and what they are hoping to achieve.
I HAD NO IDEA IT EXISTED, BUT WAS FILLED IN REALLY WELL.
The differences between the different types of treatment and what they meant.
It was good that if you didn't want to take part you don't have to??? It a choice
liked the video for children
THEY EXPALINED SO CLEARLY AND POLITE WAY. THEY ARE DOING WELL DONE JOB AND HONESTLY THE JOB STATISFACTORY. GREAT.
National study/research. Ways of treating a buckle fracture: with or without splint.

I like the fact there's a video showing what RCTs are.
That it would help in future treatment of similar injuries.
How it's going to help to decide what best action to use in treatment
1. What is a clinical trial and why we have them. 2. Consent-What is consent/informed decision making
How the treatment my son would receive would be down to the computer but still help his recovery. If the treatment didn't work we could withdraw anytime.
N/A as my son opted for a splint rather than taking part and watching on video
Very well presented. Clear and quite easy to understand.
Using the splint to a bandage I personally would choose splint for protection but make parents aware or coach them to help their child to do physio.
The video we saw explained what the study was looking for very well. It was clear about the different types of treatment we would receive depending on what was randomly allocated.
I had never heard of a buckle fracture before but the nurse explained everything I needed to know in detail and answered all my questions.
It was clear+colourful+engaged adult + child. Suitable for age of my child (10 yrs) to understand.
All aspects
All aspects of the Force study was told to me correctly and as my daughter has autism, this way of doing things has enabled my child to be less stressed about her accidents
The purpose for the study in gathering information on the best way to treat children for a quick/best recovery.

12. If you have any other comments about the information you were given about the FORCE study, please write them here:

It would be interesting to know the outcome once complete.
Very informative
I think it is a good idea my daughter has her 2nd buckle fracture and says the splint feels like a hug on her wrist
We elected not to participate as I felt that the study design was not appropriate for us. We attended due to my child's pain after good simple analgesic at home and if we had been allocated to the study arm she would have received only a bandage which would have been unlikely to have alleviated her pain as effectively as the splint. Given that the aim of the study was to avoid consequences of longer term use of the splint, but that patients presenting are in acute pain due to the fracture. I was not clear why the study design had not been to allow short term use of a splint for pain management on the study arm. If this had been the design, we would have participated. I am happy with the decision not to participate as the splint was very effective in alleviating my child's pain. Thankfully, my child has not had any pain, stiffness or difficulty since removal of the splint.
At first I was slightly worried about taking part in the study allowing my child's wrist to heal without help but I am extremely happy so far with progress at the end of week 2 although she is still in a little pain at times. She is improving.
We got lots of information about the study but that got in the way slightly of information about what my son should or shouldn't do with his injured wrist whilst it heals.

THE CONSULTANT WAS CLEAR AND CONCISE.
ALL STAFF WERE VERY HELPFUL AND INFORMATIVE. GREAT TO BE DOING RESEARCH.
It was good, it was all electronic, so quick and easy for us and staff.
I think it is a very good research programme and if it works hopefully the findings will help children and help save the NHS money.
Question seem to lack purpose when being asked in on ED setting. I hadn't waited long to be seen, but if I had been there a long time, I would find these question inappropriate and a waste of time.
I think involving kids in watching the videos makes them feel more involved and plays on important role in helping them to feel better physiologically.
All the information given was fine. Being in A+E is stressful as my daughter was in a lot of pain and I was naturally protective. If the trial had suggested that she would not wear a splint I think this would have caused me and my daughter a lot more anxiety.
VERY GOOD ONLINE FOLLOW-UP/QUESTIONNAIRE
Again just to reiterate question 10. I am a little worried as a mum that am I causing him more pain choosing this as his treatment was a bandage , not a splint.
Information given at the hospital about taking part was very clear but the study itself wasn't easy to do because it wasn't age appropriate and the wording of some questions was confusing eg 'since the accident can your child do x---- rather than making it clear you mean at a specified point in time.
The film we watched on an ipad in the hospital has much too fast moving for us to be able to follow.
had a small child with me and therefore needed to leave quickly
Firstly diagnosed as sprain, 2nd X-ray review next day spotted fracture, had call re: trial but not qualify as delay in diagnosis
As our son is exceptionally active and sports orientated both of us as parents and our son preferred the splint option on this occasion
No
The video could include what paperwork and questionnaire will need to be undertaken whilst participating in the trial. More guidance on if your child needs alter their treatment and where to go? Hospital or GP?
Friendly staff and help was good.
N/A
I AM GLAD WE TOOK PART AS MY SON WOULD HAVE JUST HAD A CAST BUT HE ACTUALLY DOES NOT NEED ONE.
I did not 'view' the information about the study at the hospital. I spoke with the research nurse and she gave me clear, comprehensive information. I am a nurse, so I was automatically interested in taking part. I have since looked at the website at home. I thought it was beautifully designed. The graphics were very engaging and the clear information made it very effective. It was great to have the section for kids specifically.
I AM HAPPY AND PLEASED WITH THEIR SERVICES. THE FORCE THEIR WORK IS EXCELLENT
We should (as a country) do way more of these - hopefully the site, videos and tools can be rolled out to trial everything

I was relieved when we got the 'splint' so not sure if I could have continued without any support for my son's arm. Perhaps reassurance that there wouldn't be any negative outcomes if you did end up with 'nothing' would have made me feel less nervous about agreeing to the trial.