Welcome to the second issue of the PEGASUS Newsletter!

Welcome to the second PEGASUS Newsletter. There have been quite a few changes since the last issue; all seven sites are now open to recruitment and 21 patients have been randomised to the pilot trial so far. The staff attitude survey is almost at an end with over 230 completed surveys from staff at 28 burns services. The qualitative interviews (Phase 1) and the pilot trial process evaluation interviews (Phase 2) are well underway with two sites having almost reached their recruitment targets.
Message from the Chief Investigator

Dear Colleagues,

I am delighted that all centres are now open to recruitment and I thank you for all of your commitment and hard work. There are challenges but I am sure we can all work together to overcome these. The PEGASUS Study Team are always happy to assist with any issues (contact details can be found at the end of this newsletter) so please don’t hesitate to get in touch us.

Thank you for your continued support of this very important study.

Best wishes,
Mr Naiem Moiemen

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Trial Design

Open pilot 2-arm feasibility Randomised Controlled Trial

Aims

The overarching aim of the project is to define the design and assess the feasibility of a full-scale open trial of the effectiveness and cost-effectiveness of pressure garments. The aim is addressed through two interlinked Phases (P1 and P2) of feasibility work. Refer to the protocol for full aims.

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<tr>
<th>Inclusion Criteria</th>
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<tr>
<td>Adults and Children with burn injuries &gt; 1% Total Body Surface Area</td>
<td>Cannot read, write or understand English. Since the outcomes identified from P1 may not have data collection tools in translatable versions for the future RCT, patient’s understanding of English is essential.</td>
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<td>Those treated with split thickness skin grafts or conservatively managed burn wounds or donor sites which have taken &gt; 2 weeks to heal</td>
<td>Have pre-existing skin conditions affecting wound healing</td>
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<td>Those with potential for hypertrophic scarring</td>
<td>Have a history of keloid scarring</td>
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<td>Those considered suitable for Scar Management Therapy</td>
<td>Have a known allergy to Lycra or any other component of pressure garments</td>
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<tr>
<td>Are not, in the investigator’s opinion, suitable to participate in the trial due to clinically relevant past medical history or other pertinent factors.</td>
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Welcome to Hannah
A very warm welcome to the newest member of the PEGASUS Trial Team, Hannah Lack who joined us in early January as the PEGASUS Data Manager. Many of you will have already liaised with Hannah and over the coming months you will no doubt be in frequent contact with her as regarding data returns.

Website
We are very pleased to tell you that the PEGASUS website has now gone live and can be found by typing www.birmingham.ac.uk/pegasus into your search engine.

Screening Logs
With patient recruitment slipping behind target, we’re going to be monitoring screening closely to help identify any avoidable recruitment barriers. Please can you ensure that you continue send your completed, anonymised screening logs to the PEGASUS Trials Office at the end of each month?

Housekeeping – time for a Spring clean?
There have been many updates to trial documentation recently including the protocol, patient documentation and CRFs so can we ask that you take the time to ensure that all of your documents are up-to-date with previous versions marked as superseded and filed in your Investigator Site Files.

Likewise, please can you ensure that your delegation logs are kept up-to-date (this includes crossing out members of staff who no longer work on the trial).

Recruitment Countdown
Thank you to all of our recruiting sites, we are now a quarter of the way to hitting our recruitment target. Keep up the good work!

PEGASUS Newsletter, Issue 2, March 2015
Qualitative Work Updates
Phase 1: Staff Attitude Survey

This online staff attitude survey is for all burns service staff working with patients receiving pressure garment therapy in Burns Services across the England, Scotland and Wales. The aim is to understand their perspectives of pressure garment therapy and their views on a full scale randomised controlled trial.

233 surveys have been completed by staff from 28 of the 29 burns services. This is an excellent response rate and many thanks to all those who have completed the survey and a special thanks to the liaison at each service that disseminated the survey to burns service staff. These views will contribute to the pilot trial and will have a bearing on whether a full-scale randomised controlled trial can be undertaken in the future.

If you have not completed the survey there is still time! The deadline has been extended to the 14th March 2015 and you can access the survey via this link:

https://www.survey.bris.ac.uk/bham/pegasus_staff_attitude_survey_final

Who has completed the staff attitude survey so far?

- Consultants and Registrars: 38
- Nurses and Sisters: 35
- Occupational Therapist: 31
- Physiotherapist: 26
- Psychologist: 8
- Other roles: e.g. technicians, instructors, play therapists, counsellors, clinical scientists and support workers: 95

Consultants and Registrars
Nurses and Sisters
Occupational Therapist
Physiotherapist
Psychologist
Other roles: e.g. technicians, instructors, play therapists, counsellors, clinical scientists and support workers
What are patients saying?

“... my feeling was initially you go into hospital, you had an injury and it heals, ... you don’t have to wear anything after. But the pressure garment seems to me extend the healing process, you are not healed until if you like the pressure garments are off. But after a while you begin to realise that there is a purpose to wearing them, and I do notice the difference when I don’t wear them from when I do wear them. So I think it does make a difference really, and also it provides you with... I suppose I’m trying to come to terms with the fact, because you’ve got a scar, you don’t want to see it in your face every day. Initially you get used to the idea of a scar, so it gives you time to adjust by concealing the scar, do you see?” (QA07)

This is what one patient said about pressure garments (Phase 1).

“... my feeling was initially you go into hospital, you had an injury and it heals, ... you don’t have to wear anything after. But the pressure garment seems to me extend the healing process, you are not healed until if you like the pressure garments are off. But after a while you begin to realise that there is a purpose to wearing them, and I do notice the difference when I don’t wear them from when I do wear them. So I think it does make a difference really, and also it provides you with... I suppose I’m trying to come to terms with the fact, because you’ve got a scar, you don’t want to see it in your face every day. Initially you get used to the idea of a scar, so it gives you time to adjust by concealing the scar, do you see?” (QA07)

Parent with a child randomised to the no pressure garment arm in the pilot trial (Phase 2) said:

“... my feeling was initially you go into hospital, you had an injury and it heals, ... you don’t have to wear anything after. But the pressure garment seems to me extend the healing process, you are not healed until if you like the pressure garments are off. But after a while you begin to realise that there is a purpose to wearing them, and I do notice the difference when I don’t wear them from when I do wear them. So I think it does make a difference really, and also it provides you with... I suppose I’m trying to come to terms with the fact, because you’ve got a scar, you don’t want to see it in your face every day. Initially you get used to the idea of a scar, so it gives you time to adjust by concealing the scar, do you see?” (QA07)

And this is what one patient who had declined to take part in the pilot trial said.

“I felt like I’d go into a hat and be pulled out, and you either wore them or you didn’t, because they need to see people that have got them and to see which is working, and I just didn’t want the choice to be took away from me, I wanted to make it myself really that decision, and make it myself. That’s why I think I said no, because I wanted to be... and I said that to [research nurse] I want to be able to make the decision myself, and not be put into the trial...” (QAPD4)

* Analysis of the interviews is underway and there are still many more to do. These quotes are not representing the views of all the patients and parent/carers in the study.

What else has been happening?

The last Investigators’ meeting took place on the 20th January 2014.

The main focus was on issues relating to recruitment. Pictured are Mr Moiemen (Chief Investigator) fielding questions from the audience following a presentation from (left to right) Fay Gardiner (Occupational Therapist), Sara Payne (Research Nurse), Federica D’Asta (Research Fellow) and Amy Bamford (Research Nurse).
**PEGASUS Study Details**

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**The PEGASUS Study Team**

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<th>Queen Elizabeth Hospital Birmingham</th>
<th>Birmingham Clinical Trials Unit</th>
<th>Qualitative Team (UoB)</th>
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**Health Economics (UoB)**  

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<th>PPI (UoB)</th>
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<td>Karen Doyle</td>
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<td>Dr. Phil Kinghorn</td>
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**PEGASUS Trial Office (RCT):**

- **Website:** [www.birmingham.ac.uk/pegasus](http://www.birmingham.ac.uk/pegasus)
- **E-mail:** pegasus@trials.bham.ac.uk
- **Telephone:** (0121) 415 8445
- **Fax:** (0121) 415 9135

**Postal address:**

**PEGASUS Trial Office**  
**Birmingham Clinical Trials Unit (BCTU)**  
School of Health & Population Sciences  
College of Medical and Dental Sciences  
Public Health Building  
University of Birmingham  
Edgbaston  
Birmingham  
B15 2TT

**Randomisation (RCT):**

- **Telephone:** 0800 953 0274  
  (Available 9am-5pm, Monday – Friday)

**Upcoming Trial Office Closures**

BCTU will be closed for the Easter Break between Friday 3rd and Wednesday 8th April (inclusive) and for the May Bank Holidays (4th and 25th May).

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**Thank you for taking the time to read the PEGASUS Newsletter!**  
**Wishing you all a very Happy Easter!**