



UK DCTN Annual Report 2015-16

A collaborative network of dermatology health professionals, health services researchers and patients conducting high quality, independent clinical trials for the treatment and prevention of skin disease



Letter from the Chair

What another fantastic year! New trials in development, newly funded trials, and existing trials achieving completion. Some of our studies show clear benefit, and some suggest that we should stop doing things – that is the nature of scientific and pragmatic independent research. As I write this, I have just received news that *The Lancet* has accepted our BLISTER study - what a wonderful way to end the year, thanks to all the hard work you have put into this practice-changing study. Funds and publishing are important markers of success, but I keep coming back to the same old thing when thinking about our Network, and that is the importance of people - Maggie and Carron who manage the Network, Shelley who supports the development of trial ideas, our kind colleagues who run the trial prioritisation and generation panel, and selflessly give up their time to give helpful feedback to those with new trial ideas. All those who contribute to our UK DCTN Steering Group and our decision-making Executive, especially our outgoing independent chair, Prof. Andrew Finlay. Then there are those who win our Fellowships - new dermatology trainees, nurses, GPs and SAS doctors who get a unique chance to develop their interest in clinical trials and critical appraisal. And let's give centre stage to all the dedicated patients and members of the public who help us to make sure that our study questions are relevant and important. Our research is pointless unless it results in patient benefit. Most of all, I would like to thank you, the members, as without your collective effort, however large or small, there would be no UK DCTN. We are a dispersed, democratic, independent, collaborative and inclusive network, and these attributes are the secret of our success. Your help has ensured that we are the WORLD LEADERS in independent pragmatic clinical trials that make a difference for all people with skin disease. Long may it continue.

Thank you UK DCTN

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Who are we?



The UK Dermatology Clinical Trials Network (UK DCTN) is a collaborative network of over 900 dermatologists, nurses, primary care staff, health care researchers and patients/carers.

Our co-ordinating centre is based at the Centre of Evidence Based Dermatology, University of Nottingham. We support and manage the development of dermatology clinical trials and provide training and support for Network members.

Membership of the Network is FREE and open to anyone with an interest in applied dermatology research.

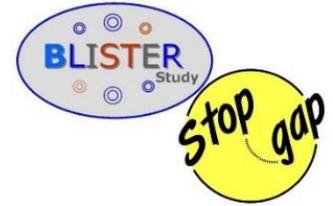
The Network is a registered charity (charity number: 1115745) and an affiliate group of the British Association of Dermatologists (BAD).



Events and highlights of the past year

BLISTER and STOP GAP Investigator Meeting

We held a joint BLISTER (bullous pemphigoid) and STOP-GAP (pyoderma gangrenosum) meeting to celebrate the achievements of the 50+ centres that had recruited into these rare disease studies. There was an exclusive preliminary presentation of the BLISTER study results, and investigators from across the country spoke about how their involvement in these trials contributed positively to their clinical practice.



CLOTHES Study recruits to time and target

This study looking at silk clothing for the treatment of eczema closed by the end of 2015 and succeeded in recruiting 300 participants to time and to target.



SWET study highlighted in HTA report

The SWET trial of water softeners for eczema was used as a case study in a major report assessing the impact of the NIHR Health Technology Assessment Programme.



BLISTER Study wins award at BAD 2016 meeting

The Blister study was awarded Best Scientific Session paper at the 96th annual meeting of the British Association of Dermatologists.



BEEP Study recruits ahead of target

The BEEP eczema prevention study reached its recruitment target of 1,350 participants before its closure date. This was a fantastic achievement for this large study.



Professor Andrew Finlay steps down as Chair of Executive Committee

We were sad to say goodbye to Professor Finlay this year, who has been our independent Chair on the UK DCTN Executive Committee since 2010. Dr Steven Jones will replace Andrew in this role from January 2017.



Funding confirmed for Trial Development Manager post

We are very grateful to the British Association of Dermatologists who confirmed this year that they will continue funding this essential post at the co-ordinating centre in Nottingham. Our current Trial Development Manager is Shelley Dowey (pictured).





“The development of the UK DCTN has transformed clinical dermatology research in the UK by providing a novel framework for widespread co-operation and joint ownership of studies, pooling resources and allowing high patient recruitment numbers to reach meaningful conclusions. This pioneering model has inspired imitators in other countries and in other UK specialties. The UK DCTN is providing sound clinical evidence that informs daily clinical decision taking in dermatology in a way unimaginable only a short time ago. Its presence inspires critical thinking in clinical dermatology because there is now a potential way to address key clinical questions.”

Professor Andrew Finlay,
Independent Chair of the UK
DCTN Executive Committee
2010-2016

What do we do?

The UK Dermatology Clinical Trials Network was established in 2002 in order to provide much needed evidence for dermatology clinical practice. The aim of the Network is simple - to develop independent, high quality randomised controlled clinical trials of interventions for the treatment or prevention of skin disease.

The Network is open to trial suggestions from any of its UK based members; if approved, these are then progressed through our trial development process. Funding for individual trials comes from external grant applications made to the National Institute of Health Research (NIHR) and charitable bodies.

Clinical Trial Development and Support

We provide practical help and advice towards for clinical trials in a variety of ways including protocol development, feasibility surveys, patient involvement, support with grant applications, site identification, publicity and dissemination of study results.

The Trial Development Manager, Shelley Dowey, works with study teams at all stages. Projects over the past 12 months have included:

- ❖ Psychological interventions for vitiligo – Support to the study team in developing protocols and funding applications.
- ❖ BLISTER study of doxycycline versus prednisolone for pemphigoid– Survey work to aid the uptake of the results of the study (once published) into clinical practice.
- ❖ HEALs cohort study - investigating the use of compression stockings in wound healing following lower leg surgery. Provided input to the 2014 UK DCTN themed call award winners to develop the protocol and trial set up in collaboration with Leeds Clinical Trials Unit.
- ❖ ALPHA Study - Provided input and support to help set up this large study on treatments for hand eczema.



The Trial Development Manager post is funded by the British Association of Dermatologists.



Research Prioritisation and Funding

Crucial to the continued success of the UK DCTN is a strong study pipeline. All research proposals submitted to the UK DCTN are reviewed by our Trial Generation & Prioritisation Panel. The following studies were reviewed in the past 12 months and approved for presentation to the Steering Committee, and are all now at different stages of our trial development process.

- Eczema Education Programme (EEP Study) - Assessing the impact of a structured nurse-led eczema education programme on eczema severity, quality of life and health care costs: a randomised controlled trial
- Managing acne in adult women - What is the effectiveness of spironolactone in the treatment of moderate-severe persistent acne in adult women?
- Emollients for the treatment of childhood eczema - Which of the four most commonly prescribed emollients is the best for the treatment of children with eczema?
- PAUSE study - Do peri-operative antibiotics reduce the risk of wound infection following excision of ulcerated skin cancers?

UK DCTN research prioritisation initiatives aim to address areas of particular research need, as shown in the table below. The focus of the 2015 Themed Call was rare skin diseases, and in 2016 hair and nails was the topic of interest. The 2015 competition has resulted in work beginning on the development of a patient-designed hidradenitis suppurativa quality of life scale and patient-reported outcomes measures for alopecia areata. We are keen to support James Lind Alliance Priority Setting Partnerships wherever possible. An initiative to identify research priorities in cellulitis is currently being undertaken.

Study title	Lead investigator	Award made
Development of a patient-designed Hidradenitis Suppurativa quality of life scale (PATHS) <i>(team pictured with Hywel Williams below left)</i>	Dr John Ingram Cardiff	Rare skin diseases themed call 2015
Cellulitis James Lind Alliance Priority Setting Partnership	Dr Sally Wilkes, Nottingham	Pump priming award
Refining Outcome Measures for trials in Alopecia areata - ROMA <i>(team pictured below right)</i>	Dr Abby Macbeth, Norwich	Hair & Nails themed call 2016





Current Trial Portfolio

	<p>RCT: TREAT - methotrexate versus ciclosporin in the treatment of severe atopic eczema in children</p> <p>Website: treat-trial.org.uk</p>	<p>Lead Investigator: Dr Carsten Flohr</p> <p>Email: treat.trial@liverpool.ac.uk</p>
	<p>RCT: ALPHA - comparing alitretinoin and PUVA for chronic hand eczema in adults</p> <p>Website: Medhealth.leeds.ac.uk/info/423/skin</p>	<p>Lead Investigator: Dr Miriam Wittmann</p> <p>Email: ctru-alpha@leeds.ac.uk</p>
	<p>Cohort study: HEALS - compression healing after excisional surgery for skin cancer on the lower leg</p>	<p>Lead Investigator: Dr Jane Nixon</p> <p>Email: ctru-heals@leeds.ac.uk</p>
	<p>RCT: HI-Light - Light therapy for vitiligo using hand held UVB devices at home</p> <p>Website: www.hilightstudy.com</p>	<p>Lead Investigator: Dr Jonathan Batchelor</p> <p>Email: hilight@nottingham.ac.uk</p>
	<p>RCT: BEEP - Barrier enhancement for the prevention of eczema - use of emollients for newborn babies</p> <p>Website: www.beepstudy.org</p>	<p>Lead Investigator: Professor Hywel Williams</p> <p>Email: beep@nottingham.ac.uk</p>
	<p>RCT: APRICOT - Treatment of pustular psoriasis with IL-1 receptor antagonist anakinra</p> <p>Website: apricot-trial.com</p>	<p>Lead Investigator: Professor Catherine Smith</p> <p>Email: dermatologytrials@gstt.nhs.uk</p>



Completed Studies

 <p>Clothing for the relief of Eczema Symptoms</p>	<p>RCT: CLOTHES - silk therapeutic clothing for the management of eczema in children</p> <p>Website: nottingham.ac.uk/clothes</p>	<p>Lead Investigator: Professor Kim Thomas</p> <p>Results: To be published 2017</p>
 <p>hELP systemic therapy for vulval Erosive Lichen Planus</p>	<p>RCT: hELP – systemic therapy for vulval erosive lichen planus</p> <p>Website: nottingham.ac.uk/helpstudy</p>	<p>Lead Investigator: Dr Ruth Murphy</p> <p>Results: To be published 2017</p>
 <p>BLISTER Study</p>	<p>RCT: BLISTER – comparing doxycycline with prednisolone for the treatment of bullous pemphigoid.</p> <p>Website: blistertrial.co.uk</p>	<p>Lead Investigator: Professor Fenella Wojnarowska</p> <p>Results: To be published in <i>The Lancet</i> in 2017</p>
	<p>RCT: SINS – Surgery vs imiquimod for nodular superficial basal cell carcinoma</p> <p>Results published in the <i>Lancet Oncology</i> January 2014</p>	<p>Lead Investigator: Professor Hywel Williams</p> <p>Follow up data (5 yrs) results: To be published in <i>Journal of Investigative Dermatology</i> 2017</p>
 <p>LIMIT 1</p>	<p>RCT: LIMIT – examining the effect of topical imiquimod on lentigo maligna</p>	<p>Lead Investigator: Dr Jerry Marsden</p> <p>Results published: <i>Marsden, J. R., Fox, R., Boota et al (2016) Br J Dermatol</i></p>
 <p>Stop gap</p>	<p>RCT: STOP GAP - prednisolone versus ciclosporin for the treatment of pyoderma gangrenosum</p> <p>Website: stopgaptrial.co.uk</p>	<p>Lead Investigator: Professor Anthony Ormerod</p> <p>Results published: <i>Ormerod AD, Thomas KS, Craig FE et al BMJ 2015;350</i></p>
 <p>PATCH Prophylactic Antibiotics for the Treatment of Cellulitis at Home</p>	<p>RCT: PATCH 1 & 2 – Does low dose penicillin prevent further episodes of cellulitis of the leg?</p> <p>Website: patchtrial.co.uk</p>	<p>Lead investigator: Professor Neil Cox</p> <p>Results published: <i>Kim S. Thomas, Angela M. Crook, Andrew J. Nunn et al N Engl J Med 2013;368</i> <i>Thomas K, Crook A, Foster K et al Br J Dermatol 2012;166</i></p>



Awards and Training

The UK DCTN recognises the importance of building research capacity across healthcare professionals and one of the ways it aims to address this is through a series of awards and training programmes.

UK DCTN Fellowship awards

These awards are made on an annual basis, encompassing a range of clinical staff groups as outlined in the table below and are undertaken for a period of two to three years. Established in 2007, the UK DCTN SpR Fellowships were the first such awards to be made and a cohort of 21 Fellows have now been trained through this scheme. The aim of the awards is to develop skills in clinical trials and clinical appraisal, to help cultivate the next generation of research-active and aware dermatologists, GPs and dermatology nurses. All the awards involve:

- ❖ Attending Getting to Grips Evidence Based Dermatology course
- ❖ Spending three days at the UK DCTN Co-ordinating Centre
- ❖ Developing critical appraisal skills by working closely with the Network Chair, Professor Hywel Williams on a series of papers
- ❖ Joining the UK DCTN Steering Committee
- ❖ Joining a clinical trial development team or a Cochrane systematic review team

The 2015 UK DCTN Fellowships were awarded as follows:

Neil Cox SpR Fellow	Alia Ahmed (London)
SpR Fellow	Lea Solmon (Harrogate)
SAS Award	Urvi Popli (Norwich)
GP Fellow	Emma LeRoux (Cheltenham)
Nursing Prize	Melanie Westmoreland (Oxford)

‘This Fellowship has really inspired me to continue contributing to clinical research throughout my career and has provided me with valuable skills I have been able to bring back to the dermatology department in Oxford. I am most grateful to the team at the UK DCTN for all their encouragement and support.’ Dr Antonia Lloyd-Lavery, UK DCTN SpR Fellow 2015-2016

‘I am so grateful that I was awarded the Fellowship. It has been an amazing experience for me and I have learnt so much over the last 2 years. I am looking forward to the HEALS cohort study and the future of this work.’ Dr Prativa Jayaskera, UK DCTN SpR Fellow 2014-2015

The UK DCTN GP Fellowship has enabled me to get formal and informal training in all aspects of research methods. I feel that research awareness is something that is valuable at all stages in a medical career, and offers a solution to mid-career stagnation.’ Dr Fiona Collier, UK DCTN GP Fellow 2014-2015



UK DCTN Trainee Groups

We have established a series of UK DCTN Trainee Groups to enable more dermatologists at the early stages of their career to become actively engaged in developing and running dermatology clinical studies. This activity is undertaken on a bi-annual basis, and the initial 2013 Trainee Groups have resulted in two studies which are currently on-going: the HEALS study (a cohort study investigating the use of compression stockings in wound healing following lower leg surgery) and a study investigating psychological interventions for vitiligo.

A one-day training course was held in September 2015 to help develop the clinical research skills of those getting involved in the second round of Trainee Groups. Prior to the event, delegates were allocated into small working groups based on their research interests, with each group being assigned two mentors. Before the course, these groups worked together (via teleconference and e-mail) to develop a research idea as outlined below for presentation and discussion on the day. We hope that a number of the groups will continue to work on their ideas to develop them into studies.

UK DCTN Trainee Groups 2015	
Eczema: Does the order of application, and time interval between applications, of topical corticosteroids and emollients make a difference to clinical outcomes in patients with eczema?	Mentors: Dr Jonathan Batchelor, Dr Susannah George and Dr Joanne Chalmers Group members: Dr Nisha Arujuna (Brighton), Dr Ravinder Atkar (Cambridge), Dr Parastoo Babekinejad (Durham), Dr Dawn M Caruana (Glasgow), Dr Seio Pei Tan (Kent), Dr Zoe Venables (Leicester)
Alopecia: Does iron replacement improve hair re-growth compared to placebo in patients receiving standard treatment for alopecia areata?	Mentors: Dr Abby Macbeth and Prof. Kim Thomas Group members: Dr Wehdad Abdelrahman (Belfast), Dr Ajoy Bardhan (Birmingham), Dr Kar-Hung Kuet (Sheffield), Dr Vincent Li (Cardiff), Dr Christos Tziotzios (London)
Urticaria: To compare the safety and effectiveness of ciclosporin versus omalizumab for the systemic treatment of recalcitrant chronic spontaneous urticaria (CSU)	Mentors: Dr John Ingram and Dr Carsten Flohr Group members: Dr Janet Dua (Oxford), Dr Kara Heelan (London), Dr Bernard Ho (London), Dr Ruth Jones (Edinburgh), Dr Lea Solmon Kosutic (Harrogate), Dr Justyn Thomas (Cambridge)
Surgery and non-melanoma skin cancer: Do prophylactic antibiotics reduce the risk of wound infection at 4 weeks following excision of ulcerated skin cancers?	Mentors: Dr Rubeta Matin and Dr Rachel Abbott Group members: Dr Sue Ann Chan (Birmingham), Dr Georgina Fremlin (Solihull), Dr Natasha Harper (Solihull), Dr Stamatina Verykiou (Newcastle), Dr Aaron Wernham (Worcester)



Evidence Based Update Meetings

Each spring we hold an Annual Evidence Based Update Meeting. The meeting summarises the most recent evidence in the form of systematic reviews and recently completed trials on the treatment and management of the chosen disease topic, which varies each year in response to delegate feedback.

The 2016 meeting on Cosmetic Dermatology was organised with support from the British Cosmetic Dermatology Group. This Royal College of Physicians accredited one day course included sessions on:

- Acne scarring (Dr Alison Layton, UK),
- IncobotulinumtoxinA for facial lines (Professor Berthold Rzany, Germany),
- Interventions for melasma (Dr Ratna Rajaratnam, Singapore),
- Interventions for hirsutism (Dr Esther van Zuuren, Netherlands)
- Satisfaction predictors for patients seeking facial cosmetic surgery (Dr Jasmijn Herruer, Netherlands)
- Cosmetic dermatology for skin of colour (Dr Sharon Aryiku, UK)
- The role of skin camouflage (Elizabeth Allen, British Association of Skin Camouflage, UK)



The programme includes a popular question & answer session, where delegates submit clinical questions to an expert panel composed of the speakers from the day. The 2016 panel, pictured above, included Dr Sean Lanigan, Dr Abhilash Jain, Dr Richard Barlow, Dr Tamara Griffiths and Dr Sharon Aryiku.

The 2017 meeting will be on **eczema and contact dermatitis**. The event will be run in association with the Centre of Evidence Based Dermatology (University of Nottingham) and the British Society of Cutaneous Allergy, and will be held on 17 May 2017 at East Midlands Conference Centre, Nottingham.

Cosmetic Dermatology (2016) - what the delegates said

- ❖ 'I will now have more confidence in recommending/refining cosmetic interventions supported by the right knowledge and evidence.'
- ❖ 'Excellent and practical course. Good balance of research and clinical experience from expert panel'
- ❖ 'Particularly enjoyed the Q&A session. Good informal learning environment'.



Publications 2015-2016

1. Batchelor, J. M., Tan, W., Tour, S., Yong, A., Montgomery, A. A. and Thomas, K. S. (2016). **Validation of the Vitiligo Noticeability Scale: a patient-reported outcome measure of vitiligo treatment success.** *Br J Dermatol*, **174**, 386-394.
2. Chalmers, J. R., Layfield, C. and Williams, H. C. (2015). **Developing a dermatology clinical trials network for improved therapeutics and clinical outcomes research.** *Current Dermatology Reports*, **4**, 90-95.
3. Chalmers, J. R., Wojnarowska, F., Kirtschig, G., Nunn, A. J., Bratton, D. J., Mason, J., Foster, K. A., Whitham, D., Williams, H. C. and group, B. s. (2015). **A randomized controlled trial to compare the safety and effectiveness of doxycycline (200 mg daily) with oral prednisolone (0.5 mg kg(-1) daily) for initial treatment of bullous pemphigoid: a protocol for the Bullous Pemphigoid Steroids and Tetracyclines (BLISTER) Trial.** *Br J Dermatol*, **173**, 227-234.
4. Eleftheriadou, V. and Ezzedine, K. (2016). **Portable home phototherapy for vitiligo.** *Clin Dermatol*, **34**, 603-606.
5. George, S. M. and Sherley-Dale, A. C. (2016). **Skin surgery, an evidence-based update: meeting report.** *Br J Dermatol*, **174**, 763-769.
6. Harrison, E. F., Haines, R. H., Cowdell, F., Sach, T. H., Dean, T., Pollock, I., Burrows, N. P., Buckley, H., Batchelor, J., Williams, H. C., Lawton, S., Brown, S. J., Bradshaw, L. E., Ahmed, A., Montgomery, A. A., Mitchell, E. J. and Thomas, K. S. (2015). **A multi-centre, parallel group superiority trial of silk therapeutic clothing compared to standard care for the management of eczema in children (CLOTHES Trial): study protocol for a randomised controlled trial.** *Trials*, **16**, 390.
7. Marsden, J. R., Fox, R., Boota, N. M., Cook, M., Wheatley, K., Billingham, L. and Steven, N. (2016). **Effect of topical imiquimod as primary treatment for lentigo maligna - the LIMIT-1 study.** *Br J Dermatol*.
8. Meijer, J. M., Jonkman, M. F., Wojnarowska, F., Williams, H. C. and Kirtschig, G. (2016). **Current practice in treatment approach for bullous pemphigoid: comparison between national surveys from the Netherlands and the UK.** *Clin Exp Dermatol*, **41**, 506-509.
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10. Simpson, R. C., Murphy, R., Bratton, D. J., Sydes, M. R., Wilkes, S., Nankervis, H., Dowey, S. and Thomas, K. S. (2016). **Systemic therapy for vulval Erosive Lichen Planus (the 'hELP' trial): study protocol for a randomised controlled trial.** *Trials*, **17**, 2.
11. Thomas, K. S., Ormerod, A. D., Craig, F. E., Greenlaw, N., Norrie, J., Mitchell, E., Mason, J. M., Johnston, G. A., Wahie, S., Williams, H. C. and U. K. Dermatology Clinical Trials Network's STOP GAP Team. (2016). **Clinical outcomes and response of patients applying topical therapy for pyoderma gangrenosum: A prospective cohort study.** *J Am Acad Dermatol*.
12. Thomas, K. S. and team, P. I. t. (2014). **Author response to van Zuuren et al., Penicillin to prevent recurrent cellulitis: a critical appraisal.** *Br J Dermatol*, **171**, 1303-1304.
13. Wilkes, S. R., Williams, H. C., Ormerod, A. D., Craig, F. E., Greenlaw, N., Norrie, J., Mitchell, E. J., Mason, J. M., Thomas, K. S. and United Kingdom Dermatology Clinical Trials Network, S. t. (2016). **Is speed of healing a good predictor of eventual healing of pyoderma gangrenosum?** *J Am Acad Dermatol*.



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