Pressure garment to prevent abnormal scarring after burn injury in adults and children: the PEGASUS feasibility RCT and mixed-methods study

Naiem Moiemen,[1]* Jonathan Mathers,[2] Laura Jones,[2] Jonathan Bishop,[3] Philip Kinghorn,[4] Mark Monahan,[4] Melanie Calvert,[2] Gemma Slinn,[3] Fay Gardiner,[1] Amy Bamford,[1] Susan Wright,[2] Ian Litchfield,[2] Nicole Andrews,[2] Karen Turner,[5] Margaret Grant[3] and Jonathan Deeks[2,3] on behalf of the PEGASUS team

[1]University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK
[2]Institute of Applied Health Research, University of Birmingham, Birmingham, UK
[3]Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK
[4]Health Economics Unit, University of Birmingham, Birmingham, UK
[5]Cancer Research UK Clinical Trials Unit, University of Birmingham, Birmingham, UK

*Corresponding author naiem.moiemen@uhb.nhs.uk

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Scientific summary

The PEGASUS feasibility RCT and mixed-methods study

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Scientific summary

Background

Eleven million people suffer a fire-related injury worldwide every year. Seventy-one per cent of these will have significant scarring. Pressure garment therapy (PGT) has become a standard part of scar management across the globe; however, there is little evidence of its clinical effectiveness or cost-effectiveness. There is also anecdotal evidence of poor adherence with the treatment, inconvenience and occasional complications. Before the commissioning of a definitive randomised controlled trial (RCT) to assess the clinical effectiveness and cost-effectiveness of PGT, this study was completed to identify the barriers to, and facilitators of, conducting a full-scale trial and to assess whether or not such a trial is feasible at all.

Objectives

The objectives of this feasibility study were as follows:

- Investigate the current UK practice of PGT, including the number of children and adults receiving treatment who would be eligible for a RCT of PGT in UK NHS burns services, supply of the garment, costs and the recommended duration of PGT.
- Investigate attitudes to the participation in a RCT, perceived equipoise and barriers to, and facilitators of, consultants, nurses, physiotherapists and occupational therapists (OTs).
- Assess patients' and carers' experiences of PGT, including psychological and social functioning, body image, self-esteem, treatment burden, perceived benefits and adherence to PGT and their willingness to be randomised between PGT and no PGT.
- Identify patient-centred outcomes that specifically measure post-burn scarring, appropriate methods of evaluating these outcomes and methods for evaluating outcomes and resource use for a health economic analysis.
- Undertake a multicentre pilot RCT comparing scar management with and without PGT in paediatric and adult centres. In addition, recruitment rates; willingness to randomise; adherence with randomised allocation and PGT therapy; processes for achieving blinded assessment of outcomes; outcome distributions to inform a sample size calculation for a future trial; the perspectives and experiences of patients, carers and staff; and the feasibility and success of the health economic assessment were to be assessed.

Methods

Current UK practice

A web-based survey was sent to the lead OT or physiotherapist at each of the UK NHS burns services to obtain information on patient numbers and standard practice with PGT.

Staff attitudes to participating in a randomised controlled trial

A web-based survey of staff attitudes was sent to the lead therapist for circulation to all staff in 30 NHS burns services across the UK; the survey covered (1) respondent demographics, (2) experience with PGT, (3) views on PGT for children, young people and adults, (4) views on a full-scale RCT of PGT, (5) participation in a full-scale RCT of PGT, (6) patients' (children and young people, parents and adults) willingness to participate in a RCT and (7) clinical and non-clinical outcomes. Free-text responses were analysed using content analysis.

Semistructured individual interviews were undertaken with staff who were purposively sampled from the responses to the web-based survey to obtain variation across profession, attitudes towards support for a RCT and agreement with attitudinal survey questions. Interviews were undertaken by telephone, audio-recorded, transcribed and analysed using a thematic approach.

Patients' and carers' experiences of pressure garment therapy and patient-centred outcomes

Semistructured individual interviews were undertaken with patients or parents of paediatric (0–8 years) and adolescent (9–15 years) patients with at least 6 months' experience of PGT. Participants were recruited by staff working at four pilot trial sites and sampled to obtain variation according to sex, age, ethnicity, and type and severity of burn. Interviews were conducted in the patient's home, with some completed on university and hospital premises or via telephone. Interviews were audio-recorded, transcribed and analysed using a thematic approach.

Pilot randomised controlled trial

A pilot seven-centre, two-arm RCT was undertaken that compared scar management with and without PGT. Eighty-eight participants were recruited who were at risk of abnormal scarring following burn injury. Adults and children with burn injuries of > 1% of total body surface area (TBSA) were eligible if they had been treated with split-thickness skin grafts or had conservatively managed burn wounds or donor sites that (1) had taken > 2 weeks to heal, (2) had the potential for hypertrophic scarring and (3) were considered suitable for scar management therapy. All participants received standard education concerning scar management techniques involving demonstration and recommendations to undertake massage three or four times per day with moisturiser, stretching and other exercises. Patients allocated to the PGT arm also received pressure garments. Each centre used their standard supply route and the fit and wear of the garments were checked throughout the trial at the routine clinic visits. Garments were replaced as required.

Scar assessment was made at baseline, week 1 and months 1, 3, 6 and 12 using the Vancouver Scar Scale (VSS), the Patient and Observer Scar Assessment Scale (POSAS), range of movement (ROM) and Cutometer® (Courage+Khazaka electronic GmbH, Cologne, Germany) measurements (only at one site). Adherence and adverse events were also assessed.

The EuroQol-5 Dimensions, five-level version (EQ-5D-5L) was used to assess the quality of life (QoL) of those aged ≥ 16 years. The Child Health Utility Index 9D (CHU-9D) was completed by the children for those aged 7–16 years and by the parents for children aged 5–10 years; parents completed the Pediatric Quality of Life Inventory (PedsQL) for children aged 2–4 years. Patients and parents also completed a willingness-to-pay (WTP) exercise to measure the value of outcomes to a broader extent than those only for health. A NHS and societal perspective was adopted to capture and record cost data.

Semistructured individual interviews with a sample of adult patients and parents of paediatric patients recruited to the pilot trial occurred after treatment allocation and approximately 12 months after recruitment to the pilot. Patients who had declined to participate were also interviewed. Interviews were conducted face to face in the patient's home, or on hospital premises, or via telephone. Staff involved in the delivery of the pilot trial were also interviewed. Interviews were audio-recorded, transcribed and analysed using a thematic approach.

Results

Current UK practice

Twenty-six NHS burns services were identified that provided care to adults and 25 that provided care to children. Responses were received from 15 (58%) adult services and 15 (60%) paediatric services. We estimate that NHS burns services treat 2845 patients over a 12-month period, 1476 of whom are

aged < 16 years and 1369 of whom are ≥ 16 years old. Routinely, pressure garments are used for a 6- to 18-month time period. Between one-quarter and one-third of trusts employ in-house technicians to manufacture pressure garments; the majority choose to source externally. In-house manufactured garments are generally less expensive. It is estimated that pressure garments for burn patients cost the NHS £2,171,184 per annum.

Staff attitudes to participating in a randomised controlled trial

Responses were received from 245 staff from 28 out of 30 NHS burns services, 223 of whom provided usable data. Fifteen survey respondents from 13 NHS burns services participated in a semistructured telephone interview. The majority of staff perceived a need for a full-scale RCT of PGT; however, their rationale for this was complex. The core issue was an apparent lack of clinical equipoise around the research question and PGT as a treatment. A large proportion of staff stated that they wanted a full-scale RCT of PGT; however, the reasoning for this was not necessarily so that the trial would provide evidence of the best treatment for patients but rather that it would support current practice and the continued use of PGT for burns scar management. In general, staff and services were receptive to the idea of a UK trial and stated that they would probably participate, demonstrating 'buy-in'. However, it was clear that the strong views about the use of PGT have the potential to influence the conduct of a full-scale RCT. The exploration of the perceived barriers to, and facilitators of, a full-scale RCT of PGT highlighted that a future trial must take into account the following issues: the recruitment of parents and children; the definition of appropriate outcome measures and scar assessments; and the scope and definition of eligibility criteria for severity of burns.

Patients' and carers' experiences of pressure garment therapy and patient-centred outcomes

Forty interviews of adults ($n = 24$) and parents ($n = 16$) were undertaken across four NHS burns services; 33 were conducted face to face and seven were via telephone. The sample was approximately evenly split between males (53%) and females, across a range of ages. Most participants were white (78%), with the type of burn being predominantly reported as flame (45% total; 54% for adults and 31% for paediatric or adolescent patients) or scald (38% total; 29% for adults and 50% for paediatric or adolescent patients). The results demonstrate that a patient-centred assessment of the outcomes of PGT should be holistic in nature. The impact of scar management was noted to be complex and involved a range of outcome domains: perceptions of appearance, specific scar characteristics, function, pain and itch, broader psychosocial outcomes and treatment burden. Priorities for outcomes varied from patient to patient and over time. When asked hypothetically about participation in a RCT of PGT, most interviewees stated that they would be willing to take part.

Pilot randomised controlled trial

The trial recruited participants between 6 January 2015 and 19 August 2015, and recruitment of the sample size of 88 participants was achieved within the allotted 9 months. The eligibility rate among those screened was 88% [95% confidence interval (CI) 83% to 92%] and the consent rate among eligible participants was 47% (95% CI 40% to 55%). Five of the 88 (6%) participants were withdrawn, four of whom were initially allocated to no PGT and one to PGT treatment. Fourteen participants (16%) were lost to follow-up (LTFU): seven in each treatment arm. Correct trial procedures were not followed for some of the withdrawals and participants who were LTFU, as they should have continued in the study. Participants who were allocated to the PGT arm estimated that they wore their garments for an average of 21 hours per day. Eight participants crossed over to the other treatment arm and remained in the study: three participants in the no-PGT arm and five in the PGT arm. Some participants were inappropriately classified as crossing over from the PGT arm to the no-PGT arm when their scar was judged to no longer require treatment.

Blinded outcome assessment was judged as infeasible, as pressure garments leave indentations or markings on the skin and would need to be removed for a considerable length of time before any blinded assessment could be made.

The VSS was consistently well completed, but did not cover all the outcome domains identified as important by patients and staff. Separate POSASs were completed by staff members and participants; completion rates were higher for staff members. Completion rates were noted to be lower in paediatric participants. Moreover, the scale was noted not to cover all relevant outcome domains. There were low response rates for the ROM assessment and staff reported that they found ROM assessments challenging to complete. Up to one-third of participants reported adverse events at each time point, most frequently itch/pruritus, wound breakdown and blistering, underlining their importance in a holistic assessment of outcomes. A new patient-reported outcome measure scale, The Brisbane Burn Scar Impact Profile (BBSIP) was identified as highly likely to be suitable for a future trial, as it does provide coverage of all relevant patient domains and has multiple age-appropriate versions, but it is currently undergoing validation testing and was not available for use in the pilot trial.

The need to use three different age-appropriate QoL assessments across the broad age range was logistically challenging. There were high completion rates for the EQ-5D-5L and for CHU-9D, but completion of PedsQL was lower, as one section of the questionnaire was irrelevant for some participants. The WTP questionnaire proved problematic and the values measured may not be trustworthy, as participants and parents struggled to understand the underlying concept and to consider an appropriate monetary response. Many reported guessing or estimating the actual cost of the care received rather than valuing the outcomes that the care had created, with some being anxious not to undervalue the time and efforts of burn professionals. Measurement of resource use beyond the NHS perspective also proved problematic and it was unclear how the data obtained could be included in a meaningful analysis.

The process evaluation found that strong views in favour of PGT influenced perspectives in the trial and that there was subsequent recruitment, withdrawals and crossover between study arms. These views may be held by staff, including staff who are working in a burns service but who are not directly involved in the trial. Staff suggested that some participants LTFU may be those with less severe burns, as these patients are less likely to attend all follow-up visits. Staff suggested that more concentrated site initiation and rationalisation of outcome assessment were key concerns for a future trial.

Conclusions

The pilot trial demonstrated that staff members were willing to recruit to the RCT and 88 patients were willing to be randomised between scar management strategies with and without PGT. Completion of a definitive RCT appears feasible, given that the pilot trial recruited to time and target. Although 22% of participants were LTFU, this included participants who were mistakenly withdrawn from the trial because of early treatment success and, thus, the withdrawal rate in a definitive trial would be expected to be lower. Adherence to allocated therapy reflected adherence in standard care and appeared high enough to enable effects of PGT to be detected, should they exist.

However, we identified that current positive attitudes among staff to the use of pressure garments may lead to biases in recruitment and retention in treatment. Provision of training and support to sites and ongoing assessment of trial processes as part of a process evaluation are required.

The inclusion of children and infants in a future trial is desirable because of the high number and impact of burns injuries in these age groups. Identification of valid outcome assessments for use with children, particularly for cost-effectiveness analysis, remains challenging. Similarly, the recruitment of patients with both severe and less severe burns is essential to test the hypothesis that the benefits of PGT depend on the severity of the injury. A future trial should stratify participants by burn severity (i.e. TBSA percentage) and consider formally evaluating whether or not the benefits of PGT differ by severity.

The BBSIP tool that is currently in development and validation testing is likely to provide a suitable holistic outcome assessment tool for inclusion as a primary outcome in a future trial.

Recommendations for research

It is feasible that a definitive RCT of the value of PGT in the management of burn scars could be commissioned within the UK NHS context. Key aspects that need to be defined in such a study include the recruitment of infants and children, as well as adults; the specificity of the suitability for inclusion in a trial based on the degree of burn severity; whether or not the clinical effectiveness of PGT should be assessed according to burn severity; the selection of an appropriate outcome measure; and the choice of tools for the assessment of PGT cost-effectiveness in infants and children.

Although the BBSIP tool appears to be a suitable outcome measure, evaluations of the tool in a UK context are necessary to ensure that it has validity to obtain the estimates of measurement distributions and clinically important differences required to compute the sample size for a trial.

Trial registration

This trial is registered as ISRCTN34483199.

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