KING'S College LONDON

Woundcare for Epidermolysis bullosa

WEB Report

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Skinnies
Soft and Seamless Skinwear

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WEB (Woundcare for Epidermolysis Bullosa) Project
Executive Summary

Background

Epidermolysis Bullosa (EB) is an inherited chronic and lifelong condition, which affects the health of the skin and other organs. It is rare and reported as occurring in approximately 1 in 17,000 live births. It is estimated that there are currently 5,000 people with EB in the UK (www.debra.org.uk). At present there is no cure, therefore the care of people with EB is aimed at minimising the impact of the condition and preventing deterioration in physical and psychosocial functioning of individuals with EB.

An audit was undertaken of current wound care practice and costs (time and materials), with approval granted by Guy's and St Thomas' NHS Foundation Trust (Clinical audit ID [1457]: Enhancing current skin and wound care patient outcomes for Epidermolysis bullosa).
The audit study focused on patient outcomes for wound care, as opposed to auditing the overall service provided for EB. The methodology was based on the classic structure, process, and outcome cycle and the TELER method of clinical outcomes measurement was adopted.

TELER indicators define a hierarchy of lost function as a result of a clinical problem. They also record outcomes as a result of current interventions to recover lost function. A key finding from the audit study is the variability in recovery and loss of recovery on the 13 indicators used, reflecting unstable clinical outcomes from the local wound care interventions. The TELER indicators define realistic and achievable goals, which the participants identified as being important to them. This lack of stable goal achievement is therefore a significant finding, compounded by the fact that the participants and carers spent a significant proportion of their time in dressing changes and patch-ups in between

dressing changes. The amount of products used is also significant, as is the cost, including prescribing and logistics.

In addition to the TELER indicators an EB Deficit Index was developed to monitor the loss of function incurred because of the underlying EB.

The audit findings comprise a 'snapshot' of the participants' experiences of lifelong wound care. EB is an inherently unstable and potentially progressive condition. The wound dressing systems the participants use are also unstable because they made up of patch-worked dressings layered with padding and secured with flat and tubular bandages. The audit data give an overall picture of a resource intensive activity to achieve participant goals, and within and between participant variability in sustaining these goals.

The audit study findings justified the move to design and develop a range of novel garments to meet EB wound care needs in terms of reducing the instability of current dressings. The novel dressing retention garments were subjected to 'proof of concept' testing. The findings from this study are presented in detail in this Report. Detail of the audit study and findings are published in a separate report.

Aim of the Dressing Retention Garment 'Proof of Concept' Study

To test the hypothesis that certain novel dressing retention garments improve patient wound care experience and reduce costs, while inhibiting deterioration in a patient's clinical problems in relation to repeat blistering of the skin and wounds.

Ethical and Research and Development Approvals and Permissions

Ethical approval for the study was granted by the National Research Ethics Service (11/LO/0873) and local National Health Service research governance procedures were overseen and granted (RJ111/N243).

Study Design

A non randomised n-of-1 cross over design was adopted to evaluate individual and group level responses to the introduction of the novel garment, and to investigate the predicted mode of action of those responses.

Study Samples and Inclusion Criteria

The sample comprised a purposeful sample of 15 adults with EB recruited from the population of 160 adults with EB registered with the UK EB specialist centre.

Inclusion criteria included informed consent from participants over 18 years old who experience areas of broken skin and wounds that are difficult to manage with conventional wound dressings.

Methods

The TELER methodology with clinical outcome indicators was used in the audit and evaluations studies. The TELER indicators provide a measure of the quality of treatment and care against pre-defined goals. The time taken for dressing changes and the people involved were recorded at each data point, together with the monthly usage of dressing products. The 13 indicators used in the audit study were revised to 11 for the proof of concept study, following feedback from the audit study participants.

Data Analysis

Clinical outcomes were measured at the individual and group level using three indices: Disparity Index (deterioration, or loss of function), Improvement Index (recovery of lost goals) and Variability Index (patient experience of the variability of intervention effects).

Qualitative data comprising the participants' feedback on their experiences of the garments as well as the impact of participating in the research were analysed thematically and used to explain the findings from the quantitative analysis in terms of benefits, lack of benefits and outcomes that exceeded expectations, for example healing of longstanding wounds .

Key Findings

An overview of the findings is presented in four parts and includes an interpretation of the findings at an individual level in terms of improvement, or lack of improvement, on the outcomes of using the garments together with the clinical and personal significance of the outcomes to the individual concerned.

Four sections of findings are presented. The first section comprises a summary of the findings for the cost of treatment in terms of wound care products dispensed on a monthly basis, and the hours spent on dressing changes presented. The data have been arranged into a 'High Rate of Change Group (costs/hours)' and a 'Low Rate of Change Group (costs/hours)'. All the participants experienced savings in terms of dressing usage and time spent on dressing changes. The cost data are considered less robust than the time for dressing changes data. For the latter, in the High Rate of Change Group, the time savings are statistically significant at the 95% confidence interval ($p < 0.05$)

The second section is a summary of the findings for changes in participants' wound care problems, defined by the TELER indicators. These data have also been arranged into a 'High Rate of Change Group (wound care)' and a 'Low Rate of Change Group (wound care)'. The analysis indicates that the garment had two beneficial treatment effects. One was a reduction in the number of problems which deteriorated. The other was an increase in the number of problems which improved.

The third section is a summary of the findings for changes in the participants' wound care experiences. These findings are based on the number of treatment goals gained or lost by the

participants, before and after the introduction of the garment, on all eleven of the indicators. The findings indicate that the garment had two beneficial treatment experience effects in terms of the variability of outcomes. They demonstrate a reduction in the number of problems with increased variability of outcomes. They also demonstrate an increase in the number of problems with decreased variability of outcomes. In the High Rate of Change Group these findings are statistically significant at the 95% confidence interval ($p < 0.05$).

The fourth section provides a summary of the effectiveness of the garments. This was measured in terms of the rate of recovery of lost treatment goals during the intervention period. The association between the effectiveness of the garment and goal attainment was measured by ranking participants on the number of goals lost up to the start of the intervention period and on the number of goals recovered during the intervention period. The rank correlation coefficient is 0.63 for the 8 participants in the Low Rate of Change Group and 0.69 for the 7 participants in the High Rate of Change Group.

The positive responses, in terms of impact of the garments on individual participant experiences, are wide ranging from improved sleeping and comfort, and healing of wounds that had not healed in years because of a reduction in movement and friction from dressings. A sense of freedom and lack of restriction from layers of bandages was noted. In addition the ability to wear clothing and footwear and not stand out because of the appearance of white bandages was reported, together with increased confidence. The less positive responses included feeling restricted in the garments, and too warm in relation to a high neck style top. In addition the need for adjustments in depth of cuffs for example was reported and these have been included in the finalised garment range.

After the formal data period ended the supply of garments was continued by the manufacturer to participants who wanted them. A black range was developed in response to participants' requests and a stain resistant agent was added. Certain styles were modified to improve the fit. The participants spontaneously offered further qualitative feedback on the performance of the garments. Participants reported healing of their skin and wounds in places that had not healed for years. Participants who had not appeared to benefit greatly from the garments requested further supplies

indicating that they could not face reverting to standard tubular and flat bandages. For some the issue was a lack of familiarisation and a reluctance to attempt something new. This latent response is significant as it indicates that the beneficial effects of the garments are greater than indicated in the quantitative data presented on this Report.

The data collection phase should therefore have allowed a period of accommodation of new ways of applying and changing dressings and a longer post intervention phase together with a post test surveillance phase. The latter was built in to the original study protocol; however shortage of research resources forced a short pre and post data collection series.

Conclusions

Overall the garments exceeded the predicted mode of action in terms of wound healing. This was not anticipated given the underlying cause of the participants' skin problems, Epidermolysis bullosa, and the continued need to patch-work dressings under the garments. Some of the participants commented that the data collection phase should have given them time to get used to putting the garments on, and that the benefits they experienced became evident after the data collection phase had finished. Nevertheless the High Rate of Change Group demonstrate clinically and statistically significant reductions in the cost of wound care in terms of product use and time spent on dressing changes, and the variability of outcomes that impact their daily lives. Refinements made to the garments in response to the findings from this study should improve the outcomes for the Low Rate of Change Group. The participants have continued to use the garments, some reporting that they cannot go back to living in bandages. The garments have proved to be durable, in spite of their fine texture, remaining functional but showing signs of wear and tear after 40 washes at 60 ^{o}C. Current flat and tubular bandages are in the main disposed of after single use. The manufacturer is costing the garments to reflect the cost savings that accompany repeat use of a retention system.

The findings support the need for the development of the primary wound contact dressing to work with the garments as a two-layer dressing system for extensive and whole body wounds. In the meantime these findings indicate the immediate benefits accruing to people with EB and extensive and whole body wounds through the use of the dressing retention garment.

In terms of the research design, the data collection series in particular, the participants should have been given time to become accustomed to using the garments before commencing the 'after' data

collection phase. In addition, the ‘after’ phase should have been longer and included a post intervention surveillance phase. The latter was included in the original proposal but due to time and financial constraints the data collection phase was considerably shortened. The participants, in their enthusiasm, spontaneously emailed their post data collection feedback to the researchers direct, or via the clinical nurse specialists, pointing out the weakness of the study design.

WEB (Woundcare for Epidermolysis Bullosa)
Dressing Retention Garment 'Proof of Concept' Project

Purpose and Background

The project tested the hypothesis that certain bespoke garments improve patient wound care experience and reduce time spent on dressing changes, while inhibiting deterioration in a patient's clinical problems in relation to repeat blistering of the skin and wounds.

Epidermolysis Bullosa (EB) is a chronic and lifelong condition, which affects the health of the skin and other organs. At present there is no cure, therefore the care of people with EB is aimed at minimising the impact of the condition and preventing deterioration in physical and psychosocial functioning of individuals with EB. Care extends to their family and social group as the impact of a family member with EB has long term effects, including financial ones (1, 2), (http:www.debra.uk).

EB wound care is resource intensive, not least because of the time taken to cover large areas of broken skin with patch worked dressings. To keep them in place dressings need to be taped together and reinforced with additional layers of dressings and padding to prevent slippage and leakage of exudate. Significant amounts of different dressing products and creams are used at a single dressing change, repeated daily or alternate days. Patients are left exhausted by the process of a dressing change. During wear-time (day and night) dressing slip, drop off, and need replacing(3).

The WEB garments are one part of a two layer dressing system (reusable dressing retention garment and primary dressings) designed to hold dressings in place, without the need for patch-worked dressings and additional padding and bandaging. The primary wound contact layer has yet to be fully developed and validated. There are therefore limits to what the garment can do in terms of improving the current performance of dressings. The premise is that the garments will reduce the need to re-position and replace dressings during wear-time. The application of the patch-worked dressings may also be eased by preventing the dressings from rucking up as retention garments and bandages are applied. In addition, the time taken for dressing changes may also be reduced, thereby alleviating the exhaustion induced by dressing changes (4).

Ethical and Research and Development Approvals and Permissions

Ethical approval for the study was granted by the National Research Ethics Service (11/LO/0873) and local National Health Service research governance procedures were overseen and granted (RJ111/N243). Additional approval on two occasions was given; first to contact the participants for feedback on the black version of the garments, which was introduced as a result of their requests after the trial period; secondly to ask permission to use the spontaneous feedback, from the participants and clinical nurse specialists to the Principal Investigator, on the latent effects of the garments as qualitative, explanatory data.

Study Sample

Adults with Epidermolysis Bullosa and extensive areas of broken skin and wounds were invited to participate. A convenience sample of 15 participants was recruited. This number was reached on the basis that the population of adults with EB at the UK specialist centre is small (160), not all adults have extensive skin and wound problems, and those who do also participate in other research studies. The number of potential participants for the study was therefore small. The garments comprise a range of individual pieces to cover various parts of the body. The designer met each of the participants to understand their individual requirements and set up orders with the manufacturer. With very limited project resources, the logistics of fitting, individually, the garments and generating the trial sets, together with the resource requirement and costs to the manufacturer also limited the sample size. However the sample of 15 is considered sufficient for a 'proof of concept' study.

The sample profile in terms of diagnoses, age, gender, EB Deficit Index and data sets is displayed at Table 1. The EB Deficit Index measures the loss of function experienced by patients as a result of their EB in 10 domains. The Index follows the TELER format, which is described below, and a simple calculation provides the patient with an objective measure of the deficits they are experiencing as a result of their condition (Appendix 1 p 30)

Table 1 WEB Garment Proof of Concept Study Sample

Pt ID	Diagnosis	EB Deficit Index	Age	Gender	Data Set
WEB-01	Generalised Dystrophic EB Pruriginosa	30	31	F	13
WEB-02	Severe Generalised Recessive Dystrophic EB	42	41	M	12
WEB-03	Severe Generalised Recessive Dystrophic EB	67	28	F	12
WEB-04	Junctional EB Non Herlitz Generalised	62	57	M	11
WEB-05	Recessive Dystrophic EB Inversa	62	28	M	11
WEB-06	Severe Generalised Recessive Dystrophic EB	53	23	M	12
WEB-07	Severe Generalised Recessive Dystrophic EB	50	26	F	13
WEB-08	Generalised Dominant EB	73	30	M	9
WEB-09	Generalised Dominant EB	43	21	F	14

WEB-10	Recessive Dystrophic EB Pruriginosa	72	31	M	12
WEB-11	Severe Generalised Recessive Dystrophic EB	25	29	F	12
WEB-12	Severe Generalised Recessive Dystrophic EB	43	24	F	12
WEB-13	Severe Generalised Recessive Dystrophic EB	47	30	M	12
WEB-14	Severe Generalised Recessive Dystrophic EB	41	18	F	12
WEB-15	Severe Generalised Recessive Dystrophic EB	43	25	F	12

Methodology and Measures

The study is informed by the stages of health technology assessment from the UK Medical Research Council (MRC) framework (5, 6). In particular a non randomised n-of-1 cross over design was adopted to evaluate individual and group level responses to the introduction of the novel garment, and to investigate the predicted mode of action of those responses (7). This study was a 'proof of concept' study. The intervention was not randomised because the EB patients' unmet needs in relation to wound dressings is the driver for new product development, and the study participants contributed to designing the novel garments. There was uncertainty surrounding the performance of the novel garments. However equipoise between standard flat and tubular bandages and the novel retention garments was considered lacking in the sense that the study participants had a strong preference to test the garments they co-designed to overcome the limitations of standard products (8).

Study Aim

To test the hypothesis that certain bespoke garments improve patient wound care experience and reduce time spent on dressing changes, while inhibiting deterioration in a patient's clinical problems in relation to repeat blistering of the skin and wounds.

Study Objectives

To determine at the individual and group level the following measures of garment performance and response to the garments by the study participants:

- The cost of treatment in terms of wound care products dispensed on a monthly basis
- The hours spent on dressing changes, including patch ups
- The changes in the participants' wound care problems, defined by the TELER indicators
- The changes in the participants wound care experience
- The effectiveness of the garments

The methodology for testing the hypothesis and measuring outcomes is the TELER methodology. Clinical goals are set by the TELER indicators on a scale of 5 to 0, where 5 is the management goal and 4, 3, 2, 1, 0 are clinically significant deteriorations away from the goal(9). Table 2 provides a conceptual framework for the clinical indicators measuring the participants' clinical problems and their experiences.

Table 2 Conceptual Framework for TELER Indicators for Epidermolysis bullosa wound care and TELER Indicator Titles

Concept	Indicator Title
Psychosocial impact of wounds symptoms and wound care	• **Disruption to sleep** • **Recovery from pain induced at dressing changes** • **Recovery from exhaustion induced at dressing changes** • **Impact of odour**
Physical appearance of wound and peri-wound skin	• **Condition of the skin covered with dressings** • **Cleaning dead tissue from the wound**
Performance of wound dressings	• **Dressing sticking** • **Your experience of exudate leakage through dressings** • **Adapting dressings to make them EB 'friendly'** • **Interventions required between routine/planned dressing change**

Eleven TELER indicators were used to measure participant outcomes following the application of the garments. Two of the indicators are most closely related to the outcomes hypothesised above, and are highlighted in the List below (NEB009; NEB010). However improved dressing retention may also exert an improvement on the other named problems, such as exhaustion induced by dressing changes, disturbed nights, skin appearance, exudate leakage and odour, and therefore the outcomes on these indicators and others listed below were also measured.

Table 2 TELER Indicator List (Appendix 1 TELER Indicators p 36-38)

WEB Indicator Code	Indicator Title	TELER Library Code
1	Recovery from pain induced at dressing changes	NEB001
2	Recovery from exhaustion induced at dressing changes	NEB002
3	Dressing sticking	NEB003
4	Dressing trauma and bleeding	NEB004
5	Your experience of exudate leakage through dressings	NEB005
6	Cleaning dead tissue from the wound	NEB006
7	Skin appearance	NEB007
8	Disruption to sleep	NEB008

9	**Adapting dressings to make then EB 'friendly'**	**NEB009**
10	**Interventions required between routine/planned dressing change**	**NEB010**
11	Odour	NEB011

The time taken for dressing changes was recorded (minutes) at each data point and the type and number of dressings used at each dressing change counted and costed on the basis of monthly dressing usage and supplies as reported by the participants.

Data Analysis

In clinical intervention and outcome measurement terms the management of a chronic, unstable and potentially deteriorating condition indicates that the management focus is prevention of deterioration and loss of function. Clinical goals need to be realistic and wanted by the individuals affected.

Deterioration, or loss of function, was measured with the TELER Disparity Index, at the individual and group level. Deterioration occurs when the value after wound care interventions is less than the value before the interventions. The Disparity Index measures loss of physical, psychological or other clinically significant function presented by a patient, and permits valid between patient comparisons. The Disparity Index also permits valid comparisons between two runs of TELER indicator codes when the runs are 'before' and 'after' runs over the same number of data points on the same group of TELER indicators, thereby permitting data analysis within an n-of-1 research design. The values of the Disparity Index are percentages in the range 0 to 100 where 0 denotes 'total loss of function' and 100 denotes 'no loss of function'.

Improvements, or recovery of lost goals, are also measured. Recovery, measured by the TELER Improvement Index, is recovery while receiving an intervention but is not necessarily due to the intervention. The Improvement Index is a patient specific measure of all the lost function recovered while the patient was under intervention. The measure is based on the assumption that a clinically significant change occurs over a clinically significant period. The values of the Improvement Index are percentages in the range 0 to 100 where 0 denotes 'no recovery' and 100 denotes 'full recovery'. In WEB the explanations for improvement are reasoned from the qualitative data provided by the participants.

Patient experience was measured with the Variability Index, which measures the variability of intervention effects. In the clinical management of chronic conditions, it can be assumed that high variability measures a lack of control over clinical interventions, including the costs. The values of the Variability Index are percentages in the range 0 to 100 where 0 denotes 'no variability' and 100 denote 'maximum variability'. Additionally 0 can denote 'control over the clinical interventions and the costs', whereas 100 can denotes 'no control over the clinical interventions or the costs'.

For the purposes of data analysis the 'intervention phase' is defined as the data points following the introduction of the garment, and includes the last five data points in the analysis. The first data point and the last data point in the base phase were discarded to allow for the participants to become accustomed to using the new garments, and maximise data reliability. In addition some participants provided data for 12 data points, some for 14 data points and one for 13 data points. The base period was defined in the study protocol as six data points, after which the garments were introduced. However the data points which mark the end of the base period and the start of the treatment period were not specifically marked on the TELER forms, although the participants knew they should collect data for six dressing changes before using the garments, and data collection started before the delivery of their customized order of garments. Overall, to minimise bias, the analysis was restricted to the data from 10 data points. The first five provide the base period data and the last five provide the intervention period data.

Study Findings

An overview of the findings is presented in four parts and includes an interpretation of the findings at an individual level in terms of improvement, or lack of improvement, on the outcomes of using the garments together with the clinical and personal significance of the outcomes to the individual concerned.

The first part is a summary of the findings for the cost of treatment in terms of wound care products dispensed on a monthly basis, and the hours spent on dressing changes presented in Tables 1.1 to 1.2.2. The data have been arranged into a 'High Rate of Change Group (costs/hours)' and a 'Low Rate of Change Group (costs/hours)'. The second part is a summary of the findings for changes in participants' wound care problems, defined by the TELER indicators. Given that the TELER indicators measure change in a participant's condition in response to treatment and care, the TELER data have been arranged into a 'High Rate of Change Group (wound care)' and a 'Low Rate of Change Group (wound care)'. Tables 2.1 and 2.2 present the Chi Square analysis of the change in the participants' clinical

problems over the intervention period for Low and High and Rate of Change Groups and comments in Table 2. The findings for changes in the participants' wound care experience are summarised in the third part, and consist of Tables 3.1 and 3.2 and comments in Table 3. The fourth part gives a summary of the effectiveness of the garments, and consists of Tables 4.1 and 4.2 and comments in Table 4.

Findings: Part 1

The data analysis indicated that the outcomes data for wound care products dispensed and time taken for dressing changes fall into two groups (see Tables 1.1 and 1.2), which required two versions of the outcome analysis to avoid masking effects.

Table 1.1 displays of cost of the dressings per month for all the participants, comparing the base and the intervention periods. Although the measurement period was 10 days, the participants reported the products and the quantities they receive on a monthly basis. The change in product use between the base and the intervention period was therefore calculated on a monthly basis.

Table 1.1 Change in the cost of dressings during the intervention period

WEB ID	Rank	Cost of Dressings* (£ per month)		Saving	
		Base Period	Intervention Period	Amount (£ per month)	Rate (%)
WEB 10	1	35,865	32,973	2,892	8
WEB 13	2	12,633	12,555	78	1
WEB 02	3	11,645	10,889	756	6
WEB 15	4	7,963	7,482	481	6
WEB 01	5	3,222	2,254	968	30
WEB 08	6	2,720	2,079	641	24
WEB 06	7	2,443	2,129	314	13
WEB 07	8	1,829	1,614	215	12
WEB 04	9	1,723	1,19	4	0
WEB 12	10	1,694	1,630	63	4
WEB 05	11	1,022	721	301	29
WEB 09	12	775	709	66	9
WEB 11	13	411	362	49	12
WEB 14	14	386	293	93	24
WEB 03	15	346	214	132	38

	Total	84,677	77,623	7,058	8
	Average	5,645	5,175	471	8.3

* Estimated from monthly orders for dressings

Two groups of participants emerge from these data. The groups are defined in terms of the hours spent on dressings, and are labelled the Low Rate of Change Group (costs) and the High Rate of Change Group (costs).

The base period cost of dressings for the Low Rate of Change Group (costs) range from £411 to £35,865 per month and a saving rate during the intervention period ranging from 0% to 13% (shaded blue).

Those with base period cost of dressings for the High Rate of Change Group (costs) range from £346 to £3,222 per month and a saving rate during the intervention period ranging from 24% to 38% (shaded grey). The two groups appear to respond differently to the intervention, which is difficult to explain. With regard to the dressing products recorded for each participant, these comprised the products dispensed to them, which were significant in terms of variety and volume. However it is impossible to know which products were applied at a given dressing change. In addition, apart from a reduction in the use of bandages, no reduction in the use and cost of dressings might be expected as the participants still had to cover extensive areas of broken skin. The garments did however have an effect on reducing the need for patch ups between dressing changes and this may be where the savings have arisen. There was considerable variation in the need for patch ups amongst the participants; for example three required no patch ups before or after, three required between seven and four and this pattern did not change, two required between two and three before and none after, one required 14 before reduced to nine after, another two required seven reduced to none, one required 25 reduced to none, another ten reduced to five with the garment (see Appendix 2).

The costs do not include the cost of the garments as these had not been defined by the manufacturer. On the basis of these data, together with the report from the participants that the garments can be washed at 60^{o}C for 40 washes before showing signs of wear and tear and loss of function, the garments are being costed at a price that comes below the cost of flat and tubular bandages. Bandages tend to be disposed of at each dressing change. The reuse of the garments therefore constitutes not only a cost saving, but also has an environmental impact in terms of a reduction in waste, though this does need to be balanced against the laundry required.

Participants in both groups experienced a reduction in the hours spent on dressings. These data are considered more robust than the cost of dressings data. The time taken for dressing changes was recorded in terms of the start and finish time for the whole process of a dressing change, together with an estimation of the number of patch ups required between dressing changes and the time taken.

In the Low Rate of Change Group (hours), the time reduction was from an average of 91.25 to 84.63 hours per participant per month. The reduction of 6.63 hours per participant per month gives a savings rate of 7.27% per participant per month. This is not attributable to the garment at the 95% confidence interval ($p < 0.05$).

In the High Rate of Change Group (hours), the reduction was from an average of 74.29 to 44.43 hours per participant per month. The reduction of 29.86 hours per participant per month gives a savings rate of 40.19% per participant per month. This is attributable to the garment at the 95% confidence interval ($p < 0.05$). Table 1.2 displays the change in hours taken for dressing changes between the base and the intervention period for the individual participants, calculated on a monthly total.

Table 1.2 Change in the hours on dressings during the intervention period

WEB ID	Rank	Hours on Dressings* (per month)		Saving	
		Base Period	Intervention Period	Hours (per month)	Rate (%)
WEB 10	1	165	125	40	24
WEB 05	2	159	84	75	47
WEB 11	3	140	130	10	14
WEB 06	4	117	112	5	4
WEB 12	5	112	112	0	0
WEB 02	6	101	87	14	14
WEB 08	7	97	88	9	9
WEB 15	8	84	44	40	48
WEB 04	9	70	69	1	1
WEB 09	10	56	49	7	13
WEB 07	11	44	30	14	32
WEB 13	12	37	30	7	19
WEB 03	13	24	7	17	71
WEB 14	14	23	15	8	35
WEB 01	15	21	6	15	71
	Total	1,250	988	262	21

	Average	83.33	65.87	17.47	20.96

* Recorded

The Low Rate of Change Group (hours) base period hours on dressings range from 37 to 140 per month and a saving rate during the intervention period ranging from 0% to 19% (shaded blue). The High Rate of Change Group (hours) base period hours on dressings range from 21 to 165 per month and a saving rate during the intervention period ranging from 24% to 71%. (shaded grey). Table 1.2.1 displays the changes in hours spent on dressing changes by the Low Rate of Change Group (hours).

Table 1.2.1 Changes in the hours spent on dressings during the intervention period in the Low Rate of Change Group (hours)

WEB ID	Rank	Hours on Dressings (per month)		Saving	
		Base Period	Intervention Period	Hours (per month)	Rate (%)
WEB 11	3	140	130	10	14
WEB 06	4	117	112	5	4
WEB 12	5	112	112	0	0
WEB 02	6	101	87	14	14
WEB 08	7	97	88	9	9
WEB 04	9	70	69	1	1
WEB 09	10	56	49	7	13
WEB 13	12	37	30	7	19
	Total	730	677	53	7
	Average	91.25	84.63	6.63	7.27

In the Low Rate of Change Group (hours), the base period hours on dressings ranges from 37 to 140 per month. The saving rate during the intervention period ranges from 0 to 19%. The saving rate is highly variable. The average savings rate is not statistically significant at the 95% confidence interval ($p < 0.05$).

In the High Rate of Change Group (hours) the base period for hours spent on dressing changes range from 21 to 165 per month and the hours saved range from eight to 75. The saving rate during the intervention period ranges from 24 to 71%. It is however highly variable, but the average savings rate is statistically significant at the 95% confidence interval ($p < 0.05$), as is the difference between the

two rates of change ($p < 0.05$). Table 1.2.2 displays the changes in the hours spent on dressings during the intervention period in the High Rate of Change Group (hours).

Table 1.2.2 Changes in the hours spent on dressings during the intervention period in the High Rate of Change Group (hours)

WEB ID	Rank	Hours on Dressings (per month)		Saving	
		Base Period	Intervention Period	Hours (per month)	Rate (%)
WEB 10	1	165	125	40	24
WEB 05	2	159	84	75	47
WEB 15	8	84	44	40	48
WEB 07	11	44	30	14	32
WEB 03	13	24	7	17	71
WEB 14	14	23	15	8	35
WEB 01	15	21	6	15	71
	Total	520	311	209	40
	Average	74.29	44.43	29.86	40.19

Compared to the Lower Rate of Change (hours) average the Higher Rate of Change (hours) average for the base period is smaller by a fifth; the intervention period is smaller by a half; the savings are three and a half times larger; and the savings rate is four and a half times larger.

The potential for saving time on dressing changes is dependent on the effectiveness of the dressings and garments as well as the way they are applied. In this respect the two groups responded differently to the intervention with the Higher Rate of Change Group apparently gaining more from the garments than the Lower Rate of Change Group. This has been judged in terms of the reduction in the deficit as defined by the TELER indicators.

These differences between the participants may be explained by the variation in the extent of skin damage experienced. Tables 1.3 and 1.4 show the differences between their loss of function relative to skin and wounds, categorised by the EB Deficit Index. That said low skin and wounds codes on the EB Deficit Index did not necessarily relate to high or low rates of change. For example WEB10 had an EB Deficit Index of 72, skin code 1 (skin damage over trunk and buttocks, isolated patches on arms and legs), chronic wounds code 5; the highest cost of dressings of the sample at £35,865 before the

intervention and £32,973 after the intervention; and the highest number of hours spent of dressing changes at 165 before the intervention and 125 after the intervention.

Table 1.3 Low Rate of Change Group, EB Deficit Index and Codes for skin, wounds and related symptoms

WEB ID	EB Deficit Index	Skin Code	Chronic wounds Code	Pain Code	Pruritus Code
WEB 03	67	1	2	4	3
WEB 04	62	2	2	3	3
WEB 05	62	1	5	2	2
WEB 06	53	0	1	4	3
WEB 07	50	0	1	3	1
WEB 09	52	2	2	1	3
WEB 10	72	1	5	1	0
WEB 12	43	2	2	4	2

Table 1.4 High Rate of Change Group, EB Deficit Index and Codes for skin, wounds and related symptoms

WEB ID	EB Deficit Index	Skin Code	Chronic wounds Code	Pain Code	Pruritus Code
WEB 01	30	0	5	3	3
WEB 02	56	0	0	2	2
WEB 08	73	0	0	4	2
WEB 11	25	0	1	1	0
WEB 13	47	1	2	5	2
WEB 14	57	1	1	2	3
WEB 15	43	1	2	1	2

These data demonstrate variations in the extent of loss of function, which logically accounts for variations between individuals in terms of the dressings required and time needed for dressing changes, particularly as people with EB continue to patch-work dressings until the planned novel dressings have been developed. There is a also likely to be an element of custom and practice around dressing changes given the length of time (years) that these participants have been living in dressings and their need to 'tailor' pre-shaped and sized dressings to their individual needs(Table 1).

Findings Part 2: Changes in the participants' clinical problems

The data which inform the chi square analysis in Tables 2.1 and 2.2 comprise the number of problems per indicator aggregated over all participants. The analysis indicates that the garment had two beneficial treatment effects. One was a reduction in the number of problems which deteriorated.

The other was an increase in the number of problems which improved. Deterioration and improvement are defined by the TELER indicator codes.

The reduction in the number of problems which deteriorated was

a. 86%, from 44 to 6, in the Low Rate of Change Group (see Table 2.1)
b. 94%, from 35 to 2, in the High Rate of Change Group (see Table 2.2)

The increase in the number of problems which improved was

a. 10%, from 20 to 22, in the Low Rate of Change Group (see Table 2.1)
b. 48%, from 21 to 31, in the High Rate of Change Group (see Table 2.2)

The overall incidence of improvement in the clinical problems presented was

a. 45% for the Low Rate of Change Group
b. 56% for the High Rate of Change Group

Tables 2.1 and 2.2 display the findings from a Chi-square analysis of the change in the participants' clinical problems over the intervention period; the null hypothesis is that there is no evidence of an intervention effect.

Table 2.1

Low Rate of Change Group (wound care)

Chi-square analysis of the change in participants' clinical problems over the intervention period

Type of Change	Observed Number (O)	Expected Number [E = (p × b)]	$\chi^2 = \frac{(O-E)^2}{E}$
Improvement	22	20	0.20
None	60	24	54.00
Deterioration	6	44	32.82
Total	88	88	$\Sigma\chi^2$ = 87.02
Tabulated χ^2 (2 df and p < 0.05) = 5.991			

Table 2.2

High Rate of Change Group (wound care)

Chi-square analysis of the change in participants' clinical problems over the intervention period

Type of Change	Observed Number (O)	Expected Number [E = (p × b)]	$\chi^2 = \frac{(O-E)^2}{E}$
Improvement	31	21	4.76
None	44	21	25.19
Deterioration	2	35	2.83
Total	77	77	$\Sigma\chi^2$ = 32.78
Tabulated χ^2 (2 df and p < 0.05) = 5.991			

A comparison of the findings from the Chi-square analysis between the Low and High Rate of Change Groups indicates that there is evidence of a beneficial effect following the introduction of the garment in both the Low and High Rate of Change Groups (Table 2.3.)

Table 2.3 Comparison of the Chi-square analysis of the change in the participants' clinical problems over the intervention period

	Table 2.1 **Low Rate of Change Group (wound care)**		**Table 2.2** **High Rate of Change Group (wound care)**
1.	**Reject the null hypothesis and accept the alternate hypothesis that there is evidence of an intervention effect**	1.	Reject the null hypothesis and accept the alternate hypothesis that there is evidence of an intervention effect
2.	**Only six of the expected 44 deteriorations occurred**	2.	Only two of the expected 35 deteriorations occurred
3.	**Of the 38 expected deteriorations which did not occur, two became improvements and 36 became 'no changes'**	3.	Of the 33 expected deteriorations which did not occur, 10 became improvements and 23 became 'no changes'
4.	**The total number of 'no changes' is 60, consisting of the unexpected 36 and the expected 24 (68% of the 88 problems treated)**	4.	The total number of 'no changes' is 44, consisting of the unexpected 23 and the expected 21 (57% of the 77 problems treated)
5.	**That the observed number of improvements is only two (10%) larger than the expected 20 shows the intervention inhibited deterioration**	5.	That the observed number of improvements is 10 (48%) larger than the expected 21 shows the intervention inhibited deterioration and facilitating improvement
6.	**This conclusion may be unsafe as changes in the 11 problems treated per participant are not necessarily statistically independent**	6.	This conclusion may be unsafe as changes in the 11 problems treated per participant are not necessarily statistically independent

There are a number of contributing factors to account for differences in response and the limits to improvement. One key reason is the previously mentioned continued need to patch-work dressings under the garments. Another is the latent period before some of the participants experienced improvements such as wound healing. Wound healing was not anticipated, given the effects of EB and the continued need to patch-work dressings. The appearance of the skin was predicted to improve if exudate management improved with more stable dressings. In addition the potential for less moisture conservation and skin maceration was thought possible because of reductions in padding and the heat and moisture wicking properties of the garments (Appendix 1 TELER Indicator 7 p 37). However post the data collection period some of the participants reported healing of longstanding wounds, which is logically linked to a reduction in friction where dressing stability has improved.

> WEB02: *"…some minor improvements - Sleeping better, more comfortable etc - didn't happen until after about four or five days of the six day trial. These improvements then took a couple of days to be noticeable. ..The wounds on my shoulder only started to show an improvement when the dressing was able to be kept on for a couple of days without being disturbed. This sort of issue was very difficult to*

reflect in the forms as there was no immediate change in pain or appearance of any wounds on my back…"

Another participant asked his mother to give the following feedback indicating the need for a longer period of post intervention data capture to demonstrate a range of improvements.

WEB08 Feedback via his mother in a telephone call to Lead Investigator who took notes: *"…Six days post introduction of the garments was too short to show what is happening now in terms of healing. The indicators do not tap into comfort and ability to do things he has not been able to do before…*

- *Apply dressings under his arms. He is doing this now, they are staying in place and the wounds are beginning to heal when they have not done this for more than 20 years*
- *Wear a Manchester United white T shirt – he has not done this due to rapid soiling from exudate, described this as 'massive'*
- *The indicators measure the whole body and it is difficult to avoid a touch of sticking or soiling here and there. But the scale of the problem is much diminished.*
- *Tubular bandage has been too difficult to apply, even by carers. Now he is able to dress his torso, which his mother said is 'massive'*
- *Sizing and fit. His leg garment is a bit too tight, he would like to go up one size*
- *The socks are wonderful and the first his mother has ever been able to buy that have been any good at all. He can wear shoes with the socks, he cannot with the bandages…"*

One participant was very reluctant to try the garments as he felt he has grown up in bandages. This however was his post trial feedback via the clinical nurse specialist regarding wound healing and use of the garments

WEB08 post trial: *"…Desperate to have the web garments, preferably in black, as with only 3 tops and a recently broken down washing machine, he doesn't always wear one. He notices an immediate deterioration in his skin…"*

WEB01 took to the garments immediately and the beneficial effects have increased and been maintained beyond the trial period

WEB01 *"…I have just finished with the district nurses and they put the garment on for the first time today, normally it would take them about an hour with putting the mepilex and then the bandages on, but with the garments it only took them 20 minutes, so they have dramatically cut the time already …The most important thing is i feel FFFRRREEEE!!!! It feels like I dont have any dressings on whatsoever, its wonderful…*

…The garments are still continuing to do its job and I drove in them for the first time since having them yesterday. It was brilliant not to have the restriction in my knee like i did with the bandaging making it less painful and stiff to swap between accelerator to brake and vice versa…"

WEB13 feedback from a clinical nurse specialist: *"…He is really pleased with the top, he said it is making his skin heal and wanted to know if he could have some more asap. He said he wants to carry on using them and doesn't want to go back to old dressings as it would be like taking " Two steps forward and ten steps backwards" because of how he is healing…"*

With regard to heat and moisture, which also affect EB related pruritus, the garments are made of COOLMAX®, which is a fibre-based moisture management system. The system can move perspiration away from the body through the fabric, where it can evaporate, allowing the wearer to feel cooler and more comfortable. Until the secondary dressing layer is developed we did not anticipate that this function of the garment would be fully evident because of the patch-worked and multilayered dressings. However, as indicated above a reduction in padding together with the heat and moisture wicking properties of the garments reduced the sensation of heat and moisture under dressings. The effect has been variable. WEB01 offered the following positive impact of not wearing bandages.

WEB01: *"…I see what you meant by them being designed to repel heat and moisture which it did. It made a change to enjoy this warm spell without getting too hot under bandages. Normally I hate the warm weather for obvious reasons but now I can enjoy it so much now…"*

"…am continuing to see improvement in my skin due to the air being able to get through to my skin more than the bandages..."

WEB09 however found the high neck top too warm to wear, especially at night.

WEB09: *"…I felt too hot and restricted at night around the neck…"*

WEB12 found them restricting, warm, aggravating an existing itch problem.

WEB12: "…*I felt stiffer upon moving about and also much warmer, which made me itch more than usual so I don't think I'll be changing anytime soon…"*

The design consultant and manufacturer have addressed these issues in terms of style adjustments and recommendations from the style range as to which ones might be more suitable on an individual basis.

Findings Part 3: Changes in the participants' experiences

These findings are based on the number of treatment goals gained or lost by the participants, before and after the introduction of the garment, on all eleven of the indicators. The findings indicate that the garment had two beneficial treatment experience effects in terms of the variability of outcomes. Outcomes vary in two ways. The number of problems with variable outcomes can increase or

decrease and the variability itself can increase or decrease. The findings demonstrate a reduction in the number of problems with increased variability of outcomes.

a. 56%, from 45 to 20, in the Low Rate of Change Group (see Table 3.1)
b. 56%, from 36 to 16, in the High Rate of Change Group (see Table 3.2)

They also demonstrate an increase in the number of problems with decreased variability of outcomes.

a. 37%, from 19 to 26, in the Low Rate of Change Group (see Table 3.1)
b. 75%, from 20 to 35, in the High Rate of Change Group (see Table 3.2)

The overall incidence of improvement in treatment experience by reducing the variability of outcomes was

a. 36% for the Low Rate of Change Group
b. 45% for the High Rate of Change Group

Tables 3.1 and 3.2 present the Chi-square analysis of the change in the variability in the outcome of clinical problems over the intervention period. The null hypothesis is that there is no evidence of an intervention effect. The analysis shows that the expected increase in variability of the treatment outcomes of the clinical problems was less in the Lower and Higher rate of Change Groups.

Table 3.1

Low Rate of Change Group (wound care)

Chi-square analysis of the change in the variability in the treatment outcome of clinical problems over the intervention period

Type of Change	Observed Number (O)	Expected Number [E = (p × b)]	$\chi^2 = \frac{(O-E)^2}{E}$
Decrease	26	19	2.58
None	42	24	13.50
Increase	20	45	13.89
Total	88	88	$\Sigma\chi^2 = 29.88$
Tabulated χ^2 (2 df and $p < 0.05$) = 5.991			

Table 3.2

High Rate of Change Group (wound care)

Chi-square analysis of the change in the variability in the treatment outcome of clinical problems over the intervention period

Type of Change	Observed Number (O)	Expected Number [E = (p × b)]	$\chi^2 = \frac{(O-E)^2}{E}$
Decrease	35	20	11.25
None	26	21	1.19
Increase	16	36	11.11
Total	77	77	$\Sigma\chi^2 = 23.55$
Tabulated χ^2 (2 df and $p < 0.05$) = 5.991			

The change to the variability of the clinical problems over the intervention period is statistically significant in the Higher Rate of Change Group (Table 3.3).

Table 3.3 Chi-square analysis of the change to the variability in the outcome of clinical problems over the intervention period

Table 3.1 **Low Rate of Change Group (wound care)**	**Table 3.2** **High Rate of Change Group (wound care)**
1. Reject the null hypothesis and accept the alternate hypothesis that there is evidence of an intervention effect	1. Reject the null hypothesis and accept the alternate hypothesis that there is evidence of an intervention effect
2. The intervention effect reduced by nearly a half (56%) from 45 to 20 the expected number of problems for which the variability in outcomes increased	2. The intervention effect reduced by nearly a half (56%) from 36 to 16 the expected number of problems for which the variability in outcomes increased
3. The target number of problems with a Variability Index larger than 0 is the number, which differs from 0 by an amount that is not statistically significant ($p < 0.05$), namely, 0 or 1	3. The target number of problems with a Variability Index larger than 0 is the number, which differs from 0 by an amount that is not statistically significant ($p < 0.05$), namely, 0 or 1
4. The target number of problems with a Variability Index larger than 0 was not achieved	4. The target number of problems with a Variability Index larger than 0 was not achieved

Overall the garments appeared to deliver the intended and predicted stability to the dressings. In tangible ways the garments performed better than expected as the continued need to patch work dressing was stated as a limitation to achieving optimal performance.

> WEB02: *"…comfortable, easy to change and hold all 'wound contact' layers firmly, yet gently in place…"*
>
> WEB04 *"…My initial reaction is that it is not going to change my life but there are some distinct advantages over tubular bandage... The sock piece is easier to use and the toe area does not ruck up when putting my socks on. The garments are easier to remove when changing dressings as they don't stick. They feel nice and smooth…"*

At the end of the trial period WEB04 confirmed that his initial experience was sustained.

> WEB04 In conversation with the design consultant: *"He said that the tube (LEG) was very comfortable and soft and importantly had done exactly what it was supposed to do that is to keep the dressings in place without extra bandages. He said that the socks also worked very well, he was able to put his own socks over the top and did not have the usual problem of dressings falling apart or moving out of place…"*

Other participants gave additional advice on improving fit and also the feel of fabric. This issue has been addressed with the introduction of black garments – see below under Garment Colours.

> WEB05: *"…Vests hold dressings in place firmly. Gloves prevent nails from scratching. Gloves to be a bit bigger as difficult/fiddly to put on and ripped slightly when put on first time; comfortable when on. Garments could do with being a little more softer/silkier feel as they snag a little with rough skin."*

Some participants made modifications to the designs, which the design consultant interpreted into changes in the manufacture of the garments, which was part of the remit of this proof of concept study.

Findings Part 4: Effectiveness of the garments

The effectiveness of the garment is dependent on

a. The capacity of the dressings and garments to meet the defined goals (Code 5 on the TELER indicators)
b. The variability of outcomes

The effectiveness of the garment was measured in terms of the rate of recovery of lost treatment goals during the intervention period.

The Deficit Index at the start and end of the intervention period was calculated, together with the improvement on the deficit, calculated by the Improvement Index.

a. For the eight participants in the Low Rate of Change Group (see Table 4.1) the Improvement Index is 21
b. For the seven participants in the High Rate of Change Group (see Table 4.2) the Improvement Index is 50

Table 4.1 Improvement Indices for Low Rate of Change Group (wound care)

	Recovery of lost treatment goals						
Participant	Number of treatment goals				Deficit Index		Improvement
	At Start	At End	Recovered	Lost	Start	End	Index
WEB03	44	48	4		11	7	36
WEB04	46	47	1		9	8	11
WEB05	26	33	7		29	22	24
WEB06	44	48	4		11	7	36
WEB07	36	33	0	3	19	22	0
WEB09	49	49	0		6	6	0
WEB10	32	45	10		23	13	43

WEB12	50	51	1		5	4	20
Total	327	354	27	3	113	89	21

Table 4.2 Improvement Indices for High Rate of Change Group (wound care)

Recovery of lost treatment goals							
Participant	Number of treatment goals				Deficit Index		Improvement
	At Start	At End	Recovered	Lost	Start	End	Index
WEB01	37	54	17		18	1	94
WEB02	43	44	1		12	11	8
WEB08	40	39	0	1	15	16	0
WEB11	39	42	3		16	13	19
WEB13	43	52	9		12	3	75
WEB14	45	46	1		10	9	10
WEB15	32	55	23		23	0	100
Total	279	332	53	1	106	53	50

In both groups there are 'outliers' who at face value appear not to have needed or benefitted from the garments. Referring back to the data spreadsheets certain patterns are evident in the data which do not support this interpretation (see Appendix 3). In the Low Rate of Change Group WEB03 treatment codes improve and stabilise for two key indicators; interventions between dressing changes (Codes 2 before and codes 4 after) and adapting dressings (Codes 3 before and Codes 4 after). She requested more garments and is still using them. WEB04 also improved on a key indicator of garment effect, interventions between dressing changes (Codes 4, 3, 4, 4, before and all Codes 5 after).

WEB07 did not benefit from the garments because they did not fit her. The design consultant made a recommendation for the top she might wear, however she elected a different style and found it too short in the body. This required her to add a layer of tubular bandage and the system was not stable, therefore unsatisfactory. These findings indicate just how crucial the selection and fit of the garments are if they are to work optimally.

WEB07 *"…As you can see the garment has risen up and she has had to resort to using tubular bandage to keep her dressings in place on the lower part of her back and lower abdomen…"*

WEB09 codes for impact of pain and exhaustion induced by dressing changes were consistently Codes 5 before and after the intervention. Dressing sticking and trauma were occasional problems at codes 4, and these appear to resolve at Codes 5 after the intervention. The codes for the indicator recording the need to adapt dressings did not change from Code 2, and this can be explained by the continued need to patch-work dressings. Her requirement for interventions between dressing changes stabilised at Codes 5 after the intervention when before she had two data points of Code 4. An explanation of theses findings is that the multilayered dressings secured with flat and tubular bandages performed as a relatively stable system; she did not need patch ups for example. The garment also performed to an enhanced level of stability, two clinical significant data points. In terms of time taken for dressing changes she saved 14 hours a month with the use of the garments rather than the bandages.

The patterns for WEB12 are similar in terms of relatively high codes before the intervention. However she appeared to gain with less pain induced at dressing changes, though no impact was made on exhaustion. She experienced less leakage of exudate (Codes 5, 4, 4, 5, 3 before and Codes 4, 4, and stable Codes 5 after). This participant has requested more garments as she has noted an improvement in the condition of her legs, indicating a latent treatment effect.

In the High Rate of Change Group WEB02 apparently has a low deficit on the indicators as his codes are uniformly Code 4 with an occasional Code 3. The explanation for this is similar to above whereby multilayered dressings and bandages held dressings in place, but were onerous to wear. The garments achieved the same level of dressing stability with greater comfort. In addition a latent effect was healing. As reported below, WEB02 does not feel able to tolerate a return to bandages.

WEB08 lost treatment goals in terms of dressing trauma and bleeding (Codes 5 and one Code 2 before, Codes 3 and 4 after). There was improvement of leakage of exudate (Codes 4, 3, 2 before to Codes 4 after). After the end of the trial period he requested more supplies and also reported a significant boost to his personal confidence related to the non clinical appearance of the garments, as reported above.

WEB11 improved on the number of interventions between dressing changes from Codes 2 to Codes 3 in a stable pattern. Pain and exhaustion induced by dressing changes also improved by one clinically significant code to stable Codes 4 after the intervention, as did adapting dressings. The latter is indicative of a more stable dressing system than experienced with bandages. However she did report difficulties keeping the patch worked dressings in place as she applied to the garments. This situation should improve with the novel dressing layer. This participant stopped wearing the top, unless she was going out, the reason for this is unclear. However she has since placed orders for her complete set of garments.

> WEB11 "…*Has stopped wearing top (except when she goes out. Initially she wore it without Surgifix but dressing change was very difficult. Then she wore the top over the Surgifix and experienced fewer patch ups. She admits she does not bother to wear the top and the dressings fall off more easily at night without the top on. She is wearing the bottoms but cut the 'elastic' at the waist as it was too tight and marking the skin.."*

WEB14 appeared to experience more pain and exhaustion from dressing changes by one clinically significant data point (Code 4 to 3). However trauma and bleeding reduced by one clinically significant data point and was stable at Code 4. For interventions between dressing changes, she recovered one clinically significant code on one data point with stable codes 5.

As an example of a high rate of change from high deficits, WEB15 recovered these deficits on key indicators such as interventions between dressing changes (Codes 1 before to Codes 5 after), adapting dressings (codes 0 before to Codes 5 after) the latter is surprising as she still has to patch-work dressings; impact of odour has also been reduced (Codes 2 before to Codes 5 and 4 after). A possible explanation for this is that the dressings she used, which included antimicrobial products, were held against the skin. Other participants did not experience this level of improvement in odour management. Table 4.3 provides a summary of the recovery of lost treatment goals between the two groups.

Table 4.3 Summary of the comparisons of outcomes between the two groups in terms of recovery of lost treatment goals during the intervention period.

Table 4.1 **Low Rate of Change Group (wound care)**	**Table 4.2** **High Rate of Change Group (wound care)**
1. All 8 participants lost treatment goals up to the start of the intervention period	1. All 7 participants lost treatment goals up to the start of the intervention period
2. The number of goals lost by the start of the intervention period ranged from 5 to 29 per participant with an average of 14 per participant	2. The number of goals lost by the start of the intervention period ranged from 10 to 23 per participant with an average of 15 per participant
3. During the intervention period 6 of the 8 participants recovered lost treatment goals	3. During the intervention period 6 of the 7 participants recovered lost treatment goals
4. The number of goals recovered ranged from 0 to 10 per participant with an average of 3 to 4 per participant	4. The number of goals recovered ranged from 0 to 23 per participant with an average of 7 to 8 per participant
5. None of the 6 goals lost by one participant were recovered during the intervention period	5. None of the 15 goals lost by one participant were recovered during the intervention period
6. The participant who had lost 19 goals by the start of the intervention period lost another 3 goals during the intervention period	6. The participant who had lost 15 goals by the start of the intervention period lost another goal during the intervention period
7. The effect of the intervention on the goals of the 8 participants was an overall recovery of 24% with an overall loss of 2.73%	7. The effect of the intervention on the goals of the 7 participants was an overall recovery of 50% with an overall loss of 0.95%

The association between the effectiveness of the garment and goal attainment was measured by ranking participants on the number of goals lost up to the start of the intervention period and on the number of goals recovered during the intervention period. The rank correlation coefficient is

a. 0.63 for the 8 participants in the Low Rate of Change Group
b. 0.69 for the 7 participants in the High Rate of Change Group

Perhaps the most compelling indication of effectiveness is the participants continued use of the garments. As reported previously WEB06 for example, was suspicious that the garments would not

stretch enough to fit him, but is now asking for the garments. WEB 10 has been selective of the garments he wants to use:

> WEB10 *"…the main reason I stopped using the T-shirt is that I didn't feel comfortable - specifically I didn't feel clean and hygienic wearing it, especially after re-using them. Part of it is probably psychological in that I would take off my top to go to bed and there would be another T-shirt underneath it and that somehow caused me discomfort… I've stuck with the shorts because they're much better than the disposable net pants - more comfortable, longer legs keep the thigh dressings in place and the elasticated waist works well…"*

WEB02 reported an incident when he had run out of clean garments, leading him to propose an interrupted cross over design for future studies.

> WEB02: *"…a week ago I forgot to wash the garments …While I was waiting for them to dry, my regular Carer put bandages on my back - just like I used to use. I soon discovered how uncomfortable it was going back to 'the old fashioned way' and couldn't wait to get my garments dry. ..Only once I had the garments on my back again did I think, "oh my god! I don't want to go back to that again." The point I'm making is maybe - for future trials - there could be a follow up study that involves swapping the new method for the old, even if only for a short time - in my case, it was about 45mins…"*

Discussion and Conclusions

In terms of the findings there were differences in outcomes between Low Rate of Change Group and the High Rate of Change Group. Variations between the participants, in the extent of their skin problems and the location of the wounds, may contribute to differences in response to the garments. It is well known, for example, that some areas of the body are more difficult to dress than others with current wound dressing designs. Overall the garments exceeded the predicted mode of action in terms of wound healing. This was not anticipated given the underlying cause of the participants' skin problems, Epidermolysis bullosa, and the continued need to patch-work dressings under the garments. Some of the participants commented that the data collection phase should have given them time to get used to putting the garments on, and that the benefits they experienced became evident after the data collection phase had finished. Nevertheless the High Rate of Change Group demonstrate clinically and statistically significant reductions in the cost of wound care in terms of product use and time spent on dressing changes, and the variability of outcomes that impact their daily lives. Refinements made to the garments in response to the findings from this study should improve the outcomes for the Low Rate of Change Group. The participants have continued to use the garments, some reporting that they cannot go back to living in bandages. The garments have proved to be durable, in spite of their fine texture, remaining functional but showing signs of wear and tear

after 40 washes at 60 ^{o}C. Current flat and tubular bandages are in the main disposed of after single use. The manufacturer is costing the garments to reflect the cost savings that accompany repeat use of a retention system.

The findings support the need for the development of the primary wound contact dressing to work with the garments as a two-layer dressing system for extensive and whole body wounds. In the meantime these findings indicate the immediate benefits accruing to people with EB and extensive and whole body wounds through the use of the dressing retention garment.

In terms of the research design, the data collection series in particular, the participants should have been given time to become accustomed to using the garments before commencing the 'after' data collection phase. In addition, the 'after' phase should have been longer and included a post intervention surveillance phase. The latter was included in the original proposal but due to time and financial constraints the data collection phase was considerably shortened. The participants, in their enthusiasm, spontaneously emailed their post data collection feedback to the researchers direct, or via the clinical nurse specialists, pointing out the weakness of the study design.

References

1. Abercrombie EM, Mather CA, Hon J, Graham-King P, Pillay E. Recessive dystrophic epidermolysis bullosa. Part 2: care of the adult patient. British journal of nursing (Mark Allen Publishing). 2008;17(6).

2. Pillay E. Epidermolysis bullosa. Part 1: causes, presentation and complications. British Journal of Nursing. 2008;17(5):292-6.

3. Grocott P, Blackwell R, Weir H, Pillay E. Living in dressings and bandages: findings from workshops with people with Epidermolysis bullosa. 2012. D.O.I 10.1111_j.1742-481X.2012.00973.x[1].

4. Grocott P, Blackwell R, Currie C, Pillay E, Robert G. Co-producing novel wound care products for Epidermolysis bullosa; an empirical case study of the use of surrogates in the design and prototype development process. 2012 D.O.I. 10.1111_j.1742-481X.2012.00972.x[1].

5. MRC. A framework for development and evaluation of RCTs for complex interventions to improve health: Medical Research Council 2000. http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871

6. MRC. Developing and evaluating complex interventions: new guidance: Medical Research Council.2008 Contract No.: 10/10/2010. http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372

7. Grocott P, Campling N. A methodology for evaluating wound care products in complex chronic wounds. Wounds UK. 2009;5(4):28-34.

8. Lilford R, Jackson J. Equipoise and the ethics of randomisation. Journal of the Royal Society of Medicine. 1995;88(10):552-9.

9. Grocott P, Blackwell R, Pillay E, Young R. Digital TELER: Clinical Note-Making and Patient Outcome Measures.2011; 2(3): Available from: http://woundsinternational.com/ http://woundsinternational.com/article.php?issueid=336&contentid=122&articleid=10058&page=1.